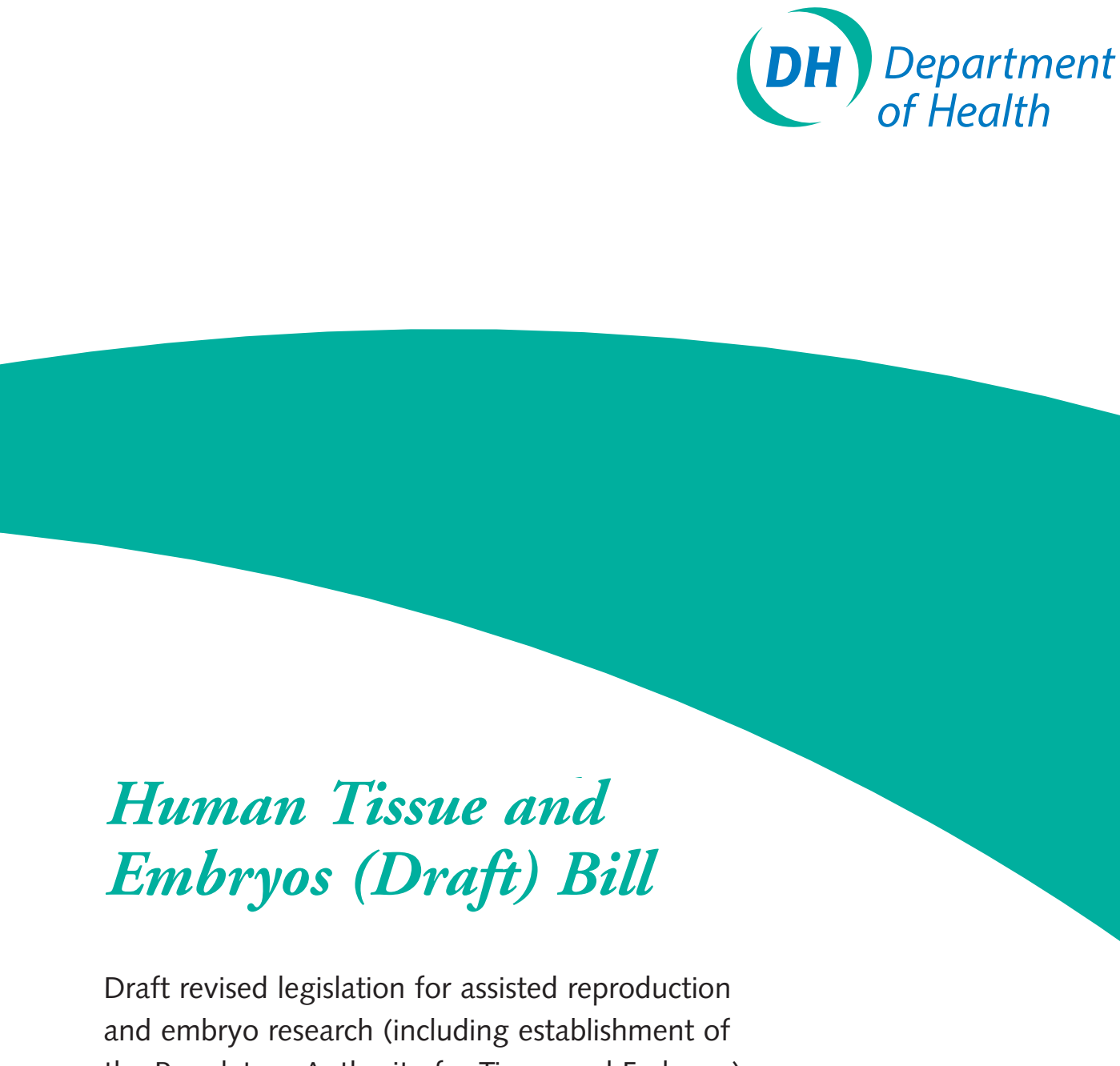

Human Tissue and Embryos (Draft) Bill

Draft revised legislation for assisted reproduction and embryo research (including establishment of the Regulatory Authority for Tissue and Embryos).

Presented to Parliament by the Secretary of State for Health by Command of Her Majesty

May 2007

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Draft revised legislation for assisted reproduction and embryo research (including establishment of the Regulatory Authority for Tissue and Embryos).

Department of Health 2007

Cm 7087 £32.50

Contents

Foreword

The birth of the first *in vitro* fertilisation baby in the world at Oldham and District General Hospital in 1978, the establishment of the Human Fertilisation and Embryology Authority in 1991, the screening of embryos for serious disease and the introduction of legislation in 2001 allowing the creation of "cloned" embryos for stem cell derivation are clear examples of why the United Kingdom has long been regarded as a leader in assisted reproduction technology and embryo research.

That reputation has been built on legislation and a regulatory system that has struck a fine balance between allowing developments in treatments, techniques and research whilst maintaining public confidence. The Human Fertilisation and Embryology Act has, over the past 16 years, been a model that many countries across the world have looked towards in determining their own approaches to assisted reproduction and embryo research.

However, time, particularly in this field, does not stand still. Technological advances, increased potential for research and changes in public perception have taken place since the introduction of the Act, and more developments can be expected over the forthcoming years.

In order to maintain the United Kingdom's leading position and ensure that the legislation is fit for the future, the Government announced in January 2004 a review of the Human Fertilisation and Embryology Act. In 2005, following an inquiry by the House of Commons Science and Technology Select Committee into the future of human reproductive technologies and the law, the Government published a consultation document and, in December 2006, a White Paper setting out the Government's proposals for legislation. This prompted a further inquiry by the Science and Technology Committee on the specific issue of the creation of human-animal hybrid embryos for research.

The Government also announced, in 2004, as part of the Department of Health's review of its arms-length bodies, that the Human Fertilisation and Embryology Authority and the Human Tissue Authority would be replaced by the Regulatory Authority for Tissue and Embryos. It was decided that this would be most appropriately achieved by the legislation that will introduce the proposed changes to the Human Fertilisation and Embryology Act.

We recognise fully that the Human Fertilisation and Embryology Act and regulation in this field cover a variety of contentious and complex issues, and we do not consider that the Government has a monopoly on identifying and producing the most effective and necessary

amendments needed to the Act. We are therefore publishing a draft Bill for pre-legislative scrutiny by a Parliamentary Committee.

The provisions in the draft Bill are fundamental to future regulation. They include welfare of the child, embryo screening and selection, sex selection, the definition of human embryos, sperm and eggs, legal parenthood, embryo research, surrogacy and the constitution and functions of the Regulatory Authority for Tissue and Embryos.

In order to help scrutiny of the draft Bill, we are publishing it with Explanatory Notes and a version of how the Human Fertilisation and Embryology Act would look if amended by the Bill.

We very much welcome the scrutiny process and look forward to receiving the Committee's comments and recommendations. Our announcement in 2004 to review the Human Fertilisation and Embryology Act was widely supported, as has been our decision to publish the Bill in draft. Our aim is that this will lead subsequently to a Bill introduced in Parliament which has been thoroughly tested and would be conducive to informed and pertinent debate. This, in turn, would help ensure an updated Human Fertilisation and Embryology Act and regulatory system that are well-placed to continue to provide clarity and assurance to patients, treatment providers, researchers and the public for years to come.

Caroline Flint MP
Minister of State for Public Health
May 2007

Introduction

1.1 This document presents a draft of the Human Tissue and Embryos Bill and supporting documents. The draft Bill follows an extensive review of the Human Fertilisation and Embryology Act 1990 ("the 1990 Act") and establishes a new regulatory body, the Regulatory Authority for Tissue and Embryos (RATE) taking up the functions of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA).

Review of the 1990 Act

1.2 The 1990 Act was developed, and the HFEA established, following a Committee of Inquiry chaired by Dame (now Baroness) Warnock. The Government recognise that the 1990 Act has worked well and has allowed developments in this area of medicine and research to progress. However, the Government decided a review was timely and desirable in light of:

- new procedures and technologies in assisted reproduction
- possible changes in public perceptions and attitudes on complex ethical issues
- the need to ensure the continued effectiveness of regulation, to reduce uncertainty and the scope for legal challenges.

1.3 Following a public consultation on the review of the 1990 Act,[1] the Government produced a White Paper,[2] in December 2006. The White Paper set out the policy proposals for revised legislation. The Government's principal aims for the revisions proposed in the White Paper and implemented by the draft Bill are:

- to ensure that legitimate medical and scientific applications of human reproductive technologies can continue to flourish
- to promote public confidence in the development and use of human reproductive technologies through efficient regulatory controls applicable to them
- to secure that regulatory controls accord with better regulation principles and encourage best regulatory practice.

1 *Review of the Human Fertilisation and Embryology Act* – A Public Consultation. Department of Health, 2005

2 *Review of the Human Fertilisation and Embryology Act* – Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos) December 2006 (Cm 6989)

1.4 The Government is committed to establishing RATE as part of its wider review of arms-length bodies.

Publication of the draft Bill

1.5 The Government is committed to publishing more Bills in draft. Accordingly, this draft Bill, has been published for the purpose of pre-legislative scrutiny by a Parliamentary Committee. Following this consideration, the Bill may be amended before the full Parliamentary process and consideration continues.

Documents within this paper

1.6 In addition to the draft Bill, other supporting documents are included in this paper. The purpose of these additional documents is to assist the reader in understanding the impact of the Bill and how it amends existing legislation. This document contains:

- the draft Bill
- the explanatory notes
- a Regulatory Impact Assessment (RIA)
- a version of the 1990 Act as it would appear if amended by the draft Bill and the EU Tissue Directive – see below.

The draft Human Tissue and Embryos Bill

1.7 The Bill consists of four parts and eight schedules. For detailed descriptions of the clauses in the Bill, please refer to the explanatory notes that accompany the Bill in this document. Briefly, the first Part of the Bill contains clauses relating to the establishment of RATE. Part 2 contains amendments to the 1990 Act. Part 3 contains clauses relating to parenthood where assisted reproduction has been used and Part 4 contains general and miscellaneous clauses.

The European Union Tissue Directive

1.8 The draft Bill amends the 1990 Act as amended by the requirement of the EU Tissue Directive.[3] Regulations transposing the Directive into the Act, the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007, were laid before Parliament in April and are due to come into force in June. RATE will be the single competent Authority under the Directive.

3 EU 2004/23/EC

The Human Fertilisation and Embryology Act if amended

1.9 In order to assist the reader and clarify the consequences of the Bill on the 1990 Act, a version of the 1990 Act as amended by both the regulations transposing the EU Tissue Directive and the draft Human Tissue and Embryos Bill has been produced. This shows what the 1990 Act would look like with these changes included. To demonstrate the origin of each of the amendments, they have been colour coded. Text that is added as a result of the EU Tissue Directive is green, amendments resulting from the draft Bill are in blue. This amended Act has been produced by the Department of Health. It is not an official legal document. It is intended to help the reader understand the changes proposed by the draft Bill and the changes made as a result of the EU Tissue Directive.

Inter-species embryos (hybrids and chimeras)

1.10 In the White Paper[2] setting out the proposals for revised legislation published prior to this draft Bill, the Government stated that the Bill would clarify the extent to which regulation would apply to embryos containing both human and animal material. The White Paper also proposed that the creation of hybrid and chimera embryos *in vitro* should not be permitted but that there should be a regulation-making power allowing exceptions to the prohibition. The Bill as currently drafted reflects this position (clause 17(2)).

1.11 Following the publication of the White Paper, the House of Commons Science and Technology Committee conducted an inquiry into the proposals around hybrids and chimeras. The report of the Committee[4] concluded that the creation of hybrid and chimera embryos is necessary for research.

1.12 Having regard to the scientific evidence produced during the Committee's inquiry, and that the recommendations are the consensus view of a Parliamentary Committee, we intend to accept the principle that legislation should provide for the following inter-species entities (hybrids and chimeras) listed in clause 17(2) of the draft Bill to be created for research purposes subject to the usual requirements for embryo research in the 1990 Act (i.e. that the research is necessary or desirable):

- cytoplasmic hybrid (cybrid) – an embryo created by replacing the nucleus of an animal egg or a cell derived from an animal embryo with a human cell or the nucleus of a human cell)

4 House of Commons Science and Technology Committee – Government proposals for the regulation of hybrid and chimera embryos. Fifth Report of Session 2006-07. April 2007 (HC 272-I)

- human transgenic embryos – a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal
- human-animal chimera – a human embryo that has been altered by the introduction of one or more animal cells.

1.13 This list includes the cytoplasmic hybrids that the Committee particularly wants to see allowed, and for which the HFEA has received two licence applications, but does not include 'true' hybrids created from mixing human and animal gametes[5]. In order to prevent regulation by two bodies, provision is made in the Bill (clause 17(2)) to exclude those inter-species embryos that are within the remit of the Home Office under the Animal (Scientific Procedures) Act 1986 (for further details see the explanatory notes).

1.14 We consider it important that we have the views of the pre-legislative scrutiny committee on this revised proposal. We will therefore ask the committee specifically to consider it, including, if they agree with it, whether it should be effected by a change to the draft clause in the Bill or through regulations.

Contact for enquiries

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5 Other than as currently permitted for the purpose of testing the fertility or normality of human sperm.

Human Tissue and Embryos Bill

CONTENTS

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TO

Establish a Regulatory Authority for Tissue and Embryos; to amend the Human Fertilisation and Embryology Act 1990 and the Surrogacy Arrangements Act 1985; to make provision about the persons who in certain circumstances are to be treated in law as the parents of a child; to make provision about licences under the Human Tissue Act 2004 and about fees in respect of such licences; to make provision about the fees that may be charged under subordinate legislation implementing Community legislation relating to human tissue; and for connected purposes.

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

PART 1

THE REGULATORY AUTHORITY FOR TISSUE AND EMBRYOS

1 Constitution

(1) There is to be a body known as the Regulatory Authority for Tissue and Embryos.

(2) The Authority is to have the functions conferred on it by or under this Act or any other enactment.

(3) The Human Fertilisation and Embryology Authority and the Human Tissue Authority are dissolved and their functions are (subject to the provisions of this Act) transferred to the Authority.

(4) Schedule 1 contains provision about the constitution of the Authority and related matters.

2 Designation as competent authority

The Authority is designated as the competent authority for the purposes of—

(a) Directive 2002/98/EC of the European Parliament and the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components,

(b) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells,

(c) Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council of 8 February 2006 as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, and

(d) Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and the Council of 24 October 2006 as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

3 General functions of Authority

(1) The Authority must—

(a) monitor developments relating to regulated activities,

(b) advise the Secretary of State on issues relating to such activities if requested to do so by the Secretary of State or if the Authority thinks fit,

(c) advise the Scottish Ministers, the Welsh Ministers or the relevant Northern Ireland Department on issues relating to regulated activities falling within subsection (2)(b) to (d) if requested to do so by the person to whom the advice is to be provided or if the Authority thinks fit,

(d) publicise the services provided to the public by the Authority,

(e) publicise the services provided in pursuance of licences under Schedule 2 to the 1990 Act, and

(f) provide to the public, and to persons carrying on regulated activities, such other information and advice as it considers appropriate in relation to regulated activities.

(2) The following are regulated activities for the purposes of this Part—

(a) activities governed by the 1990 Act,

(b) activities within the remit of the Authority under the 2004 Act,

(c) the activities listed in regulation 3(2) of the Blood Safety and Quality Regulations 2005 (S.I. 2005/50), and

(d) the activities to which regulation 7(1) or (2) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (S.I. 2007/....) apply.

(3) The Authority must also—

(a) maintain a statement of the general principles which it considers should be followed—

(i) in the carrying-on of regulated activities, and

(ii) in the carrying-out of its functions in relation to such activities,

(b) promote, in relation to activities governed by the 1990 Act, compliance with—

(i) requirements imposed by or under that Act, and

(ii) codes of practice under section 25 of that Act, and

(c) promote, in relation to activities within the remit of the Authority under the 2004 Act, compliance with—

(i) requirements imposed by or under Part 1 or 2 of that Act, and

(ii) codes of practice under that Act, and

(d) promote, in relation to activities falling within paragraph (c) or (d) of subsection (2), compliance with the regulations mentioned in that paragraph.

(4) The Authority is to perform such other functions as may be specified in regulations made by the Secretary of State.

(5) The Authority may, if it thinks fit, charge for any advice or assistance provided under subsection (1)(f) or for the provision of information.

(6) In this section—

(a) any reference to activities governed by the 1990 Act is to be read in accordance with section 4(5) of that Act, and

(b) any reference to activities within the remit of the Authority under the 2004 Act is to be read in accordance with section 14 of that Act.

4 Agency arrangements and provision of services

(1) Arrangements may be made between the Authority and a government department, a public authority or the holder of a public office ("the other authority") for—

(a) any functions of the Authority to be exercised by, or by members of the staff of, the other authority, or

(b) the provision by the other authority of administrative, professional or technical services to the Authority.

(2) Arrangements under subsection (1)(a) do not affect responsibility for the carrying-out of the Authority's functions.

(3) Subsection (1)(a) does not apply to any function of making subordinate legislation.

5 Contracting out of functions of Authority

(1) This section applies to any function of the Authority other than—

(a) any function which, by virtue of any enactment, may be exercised only by members of the Authority,

(b) a function excluded from this section by subsection (2), or

(c) a function excluded from this section by the Secretary of State by order.

(2) A function is excluded from this section if—

(a) it relates to the grant, revocation or variation of—

(i) any licence, or

(ii) an authorisation under Blood Safety and Quality Regulations 2005 (S.I. 2005/50),

(b) it is a power or right of entry, search or seizure into or of any property, or

(c) it is a function of making subordinate legislation.

(3) The Authority may make arrangements with any person ("the authorised person") for the exercise by that person, or by the employees of that person, of any function of the Authority to which this section applies.

(4) Any arrangements made by the Authority under this section—

(a) may be revoked at any time by the Authority, and

(b) do not prevent the Authority from exercising any function to which the arrangements relate.

(5) Subject to subsection (6), anything done or omitted to be done by or in relation to the authorised person (or an employee of the authorised person) in, or in connection with, the exercise or purported exercise of any function to which the arrangements relate is to be treated for all purposes as done or omitted to be done by or in relation to the Authority.

(6) Subsection (5) does not apply—

(a) for the purposes of so much of any contract between the authorised person and the Authority as relates to the exercise of the function, or

(b) for the purposes of any criminal proceedings brought in respect of anything done or omitted to be done by the authorised person (or any employee of the authorised person).

(7) Section 38A(2) of the 1990 Act (which relates to the keeping of embryos or gametes) applies in relation to the authorised person or any employee of the authorised person, when exercising functions of the Authority, as it applies in relation to any member or employee of the Authority exercising functions as member or employee.

6 Disclosure of information where functions of Authority exercised by others

(1) This section applies to—

(a) the Authority,

(b) any public authority or other person exercising functions of the Authority by virtue of section 4 or providing services to the Authority by virtue of that section,

(c) any member of staff of any person falling within paragraph (b),

(d) any person exercising functions of the Authority by virtue of section 5, or

(e) an employee of any person falling within paragraph (d).

(2) No obligation of confidence is to prevent the disclosure of information by a person to whom this section applies to another such person if the disclosure is necessary or expedient for the purposes of the exercise of any function of the Authority.

7 Power of Authority to assist other public authorities

(1) The Authority may if it thinks it appropriate to do so provide assistance to any other public authority in the United Kingdom for the purpose of the exercise by that authority of its functions.

(2) Assistance provided by the Authority under this section may be provided on such terms, including terms as to payment, as it thinks fit.

8 Provision of assistance to bodies outside the United Kingdom

(1) The Authority may provide assistance to any authority in any country or territory outside the United Kingdom if it appears to the Authority that that authority exercises functions similar to any of those of the Authority.

(2) Assistance provided by the Authority under this section may be provided on such terms, including terms as to payment, as it thinks fit.

9 Annual reports

(1) The Authority must prepare—
(a) a report for the initial period, and
(b) a report for each successive period of 12 months ending with 31 March.

(2) In subsection (1)(a) "the initial period" means the period beginning with the establishment of the Authority and ending with the next 31 March, except that if the Authority is established on a date falling within the first three months of a calendar year, it means the period beginning with the establishment of the Authority and ending with 31 March in the next calendar year.

(3) A report prepared under this section for any period must deal with the activities of the Authority in the period and the activities the Authority proposes to undertake in the succeeding period of 12 months.

(4) The Authority must send each report under this section—
(a) to the Secretary of State,
(b) to the Welsh Ministers,
(c) to the Scottish Ministers, and
(d) to the relevant Northern Ireland department,
as soon as practicable after the end of the period for which it is prepared.

(5) The Secretary of State must lay before each House of Parliament a copy of each report received by the Secretary of State under this section.

(6) The Welsh Ministers must lay before the National Assembly for Wales a copy of each report received by them under this section.

(7) The Scottish Ministers must lay before the Scottish Parliament a copy of each report received by them under this section.

(8) The relevant Northern Ireland department must lay before the Northern Ireland Assembly a copy of each report received by it under this section.

10 Duties in relation to carrying out of functions

(1) The Authority must carry out its functions effectively, efficiently and economically.

(2) In carrying out its functions, the Authority must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

11 Transfer of property, rights and liabilities from HFEA and HTA

On the coming into force of section 1(3), the property, rights and liabilities of the Human Fertilisation and Embryology Authority and the Human Tissue Authority become the property, rights and liabilities of the Authority.

12 Transfer of property, rights and liabilities from Secretary of State

(1) The Secretary of State may make one or more schemes ("transfer schemes") for the transfer to the Authority of such property, rights and liabilities of the Secretary of State as appear to the Secretary of State appropriate to be transferred having regard to the functions conferred on the Authority—

(a) by provision made by or under this Act, or

(b) by provision made under section 2(2) of the European Communities Act 1972 (c. 68).

(2) A transfer scheme—

(a) may provide for the transfer of property, rights and liabilities that would not otherwise be capable of being transferred or assigned,

(b) may define property, rights and liabilities by specifying or describing them or by referring to all of the property, rights and liabilities comprised in a specified part of the undertaking of the Secretary of State (or partly in one way and partly in the other),

(c) may provide for the creation—

(i) in favour of the Secretary of State, or of the Authority, of interests in, or rights over, property to be transferred or, as the case may be, retained by the Secretary of State, or

(ii) of new rights and liabilities as between the Secretary of State and the Authority,

(d) may require the Secretary of State or the Authority to take any steps necessary to secure that the transfer of any foreign property, rights or liabilities is effective under the relevant foreign law, and

(e) may make such incidental, supplemental and consequential provision as the Secretary of State considers appropriate.

(3) On the date appointed by a transfer scheme the property, rights and liabilities which are the subject of the scheme become, by virtue of this subsection, property, rights and liabilities of the Authority (and any other provisions of the scheme take effect).

(4) The Secretary of State may, at any time before the date appointed by a transfer scheme, modify the scheme.

13 Interpretation of Part 1

In this Part—

"regulated activity" is to be read in accordance with section 3(2);

"the relevant Northern Ireland department" means the Department of Health, Social Services and Public Safety.

PART 2

AMENDMENTS OF HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

14 Meaning of "embryo" and "gamete"

(1) Section 1 of the 1990 Act (meaning of "embryo", "gamete" and associated expressions) is amended as follows.

(2) For subsection (1) substitute—

"(1) In this Act (except in section 4A)—

(a) embryo means a live human embryo and does not include an inter-species embryo (as defined by section 4A(5)), and

(b) references to an embryo include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo."

(3) In subsection (2), for paragraph (a) substitute—

"(a) references to embryos the creation of which was brought about *in vitro* (in their application to those where fertilisation or any other process by which an embryo is created is complete) are to those where fertilisation or any other process by which the embryo was created began outside the human body whether or not it was completed there, and".

(4) For subsection (4) substitute—

"(4) In this Act (except in section 4A)—

(a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,

(b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and

(c) references to gametes are to be read accordingly."

(5) After subsection (5) insert—

"(6) If it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine, regulations may provide that in this Act (except in section 4A) "embryo", "eggs", "sperm" or "gametes" includes things specified in the regulations which would not otherwise fall within the definition.

(7) Regulations made by virtue of subsection (6)—

(a) may not provide for anything containing any nuclear or mitochondrial DNA that is not human to be treated as an embryo or as eggs, sperm or gametes, but

(b) may make any amendment of section 4A(7) or (8) that appears to the Secretary of State to be appropriate in consequence of the provision falling within subsection (6)."

15 Meaning of "nucleus" etc.

In section 2 of the 1990 Act (other terms), after the definition of "non-medical fertility services" insert—

" "nucleus", in relation to an embryo, includes pronucleus and, accordingly, "nuclear DNA", in relation to an embryo, includes DNA in the pronucleus of the embryo,".

16 Prohibitions in connection with embryos

(1) Section 3 of the 1990 Act (prohibitions in connection with embryos) is amended as follows.

(2) For subsection (2) substitute—

"(2) No person shall place in a woman—

(a) an embryo other than a permitted embryo (as defined by section 3ZA), or

(b) any gametes other than permitted eggs or permitted sperm (as so defined)."

(3) In subsection (3)—

(a) at the end of paragraph (b), insert "or", and

(b) omit paragraph (d) and the "or" immediately before it.

(4) In subsection (4), for "the day when the gametes are mixed" substitute "the day on which the process of creating the embryo began".

(5) After section 3 insert—

"3ZA Permitted eggs, permitted sperm and permitted embryos

(1) This section has effect for the interpretation of section 3(2).

(2) A permitted egg is one—

(a) which has been produced by or extracted from the ovaries of a woman, and

(b) whose nuclear or mitochondrial DNA has not been altered.

(3) Permitted sperm are sperm—

(a) which have been produced by or extracted from the testes of a man, and

(b) whose nuclear or mitochondrial DNA has not been altered.

(4) An embryo is a permitted embryo if—

(a) it has been created by the fertilisation of a permitted egg by permitted sperm, and

(b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered.

(5) Regulations may provide that—

(a) an egg can be a permitted egg, or

(b) an embryo can be a permitted embryo,

even though the egg or embryo has had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease.

(6) In this section—

(a) "woman" and "man" include respectively a girl and a boy (from birth), and

(b) "prescribed" means prescribed by regulations."

(6) The Human Reproductive Cloning Act 2001 (c. 23) (which is superseded by the preceding provisions of this section) ceases to have effect.

17 Prohibitions in connection with genetic material not of human origin

(1) In section 4 of the 1990 Act (prohibitions in connection with gametes)—

(a) in subsection (1), omit—

(i) paragraph (c), and

(ii) the word "or" immediately before it, and

(b) in subsection (5), after "section 3" insert "or 4A".

(2) After section 4 of the 1990 Act insert—

"4A Prohibitions in connection with genetic material not of human origin

(1) No person shall place in a woman—

(a) an embryo other than a human embryo,

(b) an inter-species embryo, or

(c) any gametes other than human gametes.

(2) No person shall—

(a) mix human gametes with the gametes of an animal,

(b) bring about the creation of an inter-species embryo, or

(c) keep or use an inter-species embryo,

except in pursuance of a licence.

(3) A licence cannot authorise the keeping or using of an inter-species embryo after the earliest of the following—

(a) the appearance of the primitive streak,

(b) the end of the period of 14 days beginning with the day on which the process of creating the inter-species embryo began, or

(c) the time when half the gestation or incubation period for any species whose nuclear or mitochondrial DNA is contained in the embryo has elapsed,

but any period during which the inter-species embryo is stored is not counted under paragraph (b) or (c).

(4) A licence cannot authorise placing an inter-species embryo in an animal.

(5) For the purpose of this Act an inter-species embryo is—

(a) an embryo created by using human gametes and the gametes of an animal,

(b) an embryo created by replacing the nucleus of an animal egg or a cell derived from an animal embryo with a human cell or the nucleus of a human cell,

(c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal,

(d) a human embryo that has been altered by the introduction of one or more animal cells, or

(e) any other embryo that contains both—

(i) any haploid set of human chromosomes, and

(ii) any haploid set of animal chromosomes or any other sequence of nuclear or mitochondrial DNA of an animal.

(6) For the purposes of this section an "animal" is an animal other than man.

(7) In this section "embryo" means a live embryo, including an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

(8) In this section—

(a) references to eggs are to live eggs, including cells of the female germ line at any stage of maturity, but not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,

(b) references to gametes are to eggs (as so defined) or to live sperm, including cells of the male germ line at any stage of maturity."

18 Activities that may be licensed

(1) Schedule 2 contains amendments of Schedule 2 to the 1990 Act (which relates to the activities for which licences may be granted under the Act).

(2) The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (S. I. 2001/188) (which are superseded by the amendments made by Schedule 2) cease to have effect.

19 Application of consent provisions to non-medical fertility services

In section 12 of the 1990 Act (general conditions of licences under that Act), in subsection (1)(c) (condition relating to compliance with Schedule 3 to the Act), omit "or non-medical fertility services".

20 Consent to storage or use of gametes or embryos

Schedule 3 contains amendments of Schedule 3 to the 1990 Act (which relates to consent to the storage or use of gametes or embryos).

21 Conditions of licences for treatment

(1) Section 13 of the 1990 Act (conditions of licences for treatment) is amended in accordance with subsections (2) to (4).

(2) In subsection (5), omit—

(a) ", other than basic partner treatment services,", and

(b) "(including the need of that child for a father)".

(3) For subsection (6) substitute—

"(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

(6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

(6B) The reference in subsection (6A) to the intended second parent is a reference to—

(a) any man as respects whom the agreed fatherhood conditions in section 43 of the Human Tissue and Embryos Act 2007 ("the 2007 Act") are for the time being satisfied in relation to treatment provided to the woman being treated, and

(b) any woman as respects whom the agreed female parenthood conditions in section 50 of the 2007 Act are for the time being satisfied in relation to treatment provided to the woman to be treated.

(6C) Where the person responsible receives from a person ("X") notice under section 43(1)(c) or 50(1)(c) of the 2007 Act of X's withdrawal of consent to X being treated as the parent of any child resulting from the provision of treatment services to a woman ("W"), the person responsible—

(a) must notify W in writing of the receipt of the notice from X, and

(b) no person to whom the licence applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified.

(6D) Where the person responsible receives from a woman ("W") who has previously given notice under section 43(1)(b) or 50(1)(b) of the 2007 Act that she consents to another person ("X") being treated as a parent of any child resulting from the provision of treatment services to W—

(a) notice under section 43(1)(c) or 50(1)(c) of the 2007 Act of the withdrawal of W's consent, or

(b) a notice under section 43(1)(b) or 50(1)(b) of the 2007 Act in respect of a person other than X,

the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b)."

(4) After subsection (7) insert—

"(8) In determining—

(a) the persons who are to provide gametes for use in pursuance of the licence in a case where consent is required under paragraph 5 of Schedule 3 for the use in question,

(b) the woman from whom an embryo is to be taken for use in pursuance of the licence, in a case where her consent is required under paragraph 7 of Schedule 3 for the use of the embryo, or

(c) which of two or more embryos to place in a woman,

persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition must not be preferred to those that are not known to have such an abnormality.

(9) No embryo appropriated for the purpose of training persons in the testing of embryos shall be kept or used for the provision of treatment services.

(10) The person responsible shall comply with any requirement imposed on that person by section 31ZC."

(5) After Schedule 3 to the 1990 Act insert the Schedule set out in Schedule 4 to this Act.

(6) In any licence under paragraph 1 of Schedule 2 to the 1990 Act (licences for treatment) that is in force immediately before the commencement of subsection (2)(b) of this section, the condition required by virtue of section 13(5) of that Act is to have effect as the condition required by that provision as amended by subsection (2)(b) of this section.

22 Conditions of storage licences

(1) Section 14 of the 1990 Act (conditions of storage licences) is amended as follows.

(2) In subsection (1), for paragraph (a) substitute—

"(a) that gametes of a person shall be placed in storage only if—

(i) received from that person,

(ii) acquired in circumstances in which by virtue of paragraph 9 or 10 of Schedule 3 that person's consent to the storage is not required, or

(iii) acquired from a person to whom a licence or third party agreement applies,

(aa) that an embryo taken from a woman shall be placed in storage only if—

(i) received from that woman, or

(ii) acquired from a person to whom a licence or third party agreement applies,

(ab) that an embryo the creation of which has been brought about *in vitro* otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence or third party agreement applies,".

(3) In subsection (4), for "five years" substitute "ten years".

(4) In subsection (5), omit "or, as the case may be, five years".

23 Conditions of licences relating to inter-species embryos etc.

After section 15 of the 1990 Act insert—

"15ZA Conditions of licences relating to inter-species embryos etc.

(1) If by virtue of regulations under sub-paragraph (3) of paragraph 3 of Schedule 2, any of the activities mentioned in that sub-paragraph can be authorised by a licence under that paragraph, regulations may provide for specified conditions to be conditions of—

(a) every licence under paragraph 3 of Schedule 2 authorising such activities, and

(b) every licence under paragraph 2 of that Schedule authorising the storage of inter-species embryos.

(2) Regulations made by virtue of this section may, in particular, exclude or modify—

(a) any of the provisions of section 12, except subsection (1)(c) of that section, and

(b) any of the provisions of sections 14 and 15,

in their application to a licence falling within subsection (1)(a) or (b)."

24 Grant of licences

(1) Section 16 of the 1990 Act (grant of licences) is amended as follows.

(2) For subsection (1) substitute—

"(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met."

(3) In subsection (2) for "licence committee" substitute "Authority" in each place it occurs.

(4) In subsection (4) for "licence committee" substitute "Authority".

(5) In subsection (5) for "licence committee" substitute "Authority".

(6) Omit subsections (6) and (7).

25 Repeal of definition of "nominal licensee"

In section 17 of the 1990 Act (the person responsible), omit subsection (3) (which defines "the nominal licensee").

26 Revocation and variation of licences

For section 18 of the 1990 Act substitute—

"18 Revocation of licence

(1) The Authority may revoke a licence on application by—

(a) the person responsible, or

(b) the holder of the licence (if different).

(2) The Authority may revoke a licence otherwise than on application under subsection (1) if—

(a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading,

(b) it is satisfied that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17,

(c) it is satisfied that the person responsible has failed to comply with directions given in connection with any licence,

(d) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,

(e) it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are suitable for the activities entrusted to the third party by the person who holds the licence,

(f) it ceases to be satisfied that the holder of the licence is a suitable person to hold the licence,

(g) it ceases to be satisfied that the person responsible is a suitable person to supervise the licensed activity,

(h) the person responsible dies or is convicted of an offence under this Act, or

(i) it is satisfied that there has been any other material change of circumstances since the licence was granted.

18A Variation of licence

(1) The Authority may on application by the holder of the licence vary the licence so as to substitute another person for the person responsible if—

(a) the application is made with the consent of that other person, and

(b) the Authority is satisfied that the other person is a suitable person to supervise the licensed activity.

(2) The Authority may vary a licence on application by—

(a) the person responsible, or

(b) the holder of the licence (if different).

(3) The Authority may vary a licence without an application under subsection (2) if it has the power to revoke the licence under section 18(2).

(4) The powers under subsections (2) and (3) do not extend to making the kind of variation mentioned in subsection (1).

(5) The Authority may vary a licence without an application under subsection (2) by—

(a) removing or varying a condition of the licence, or

(b) adding a condition to the licence.

(6) The powers conferred by this section do not extend to the conditions required by sections 12 to 15ZA of this Act."

27 Procedure for refusal, variation or revocation of licence

For section 19 of the 1990 Act substitute—

"19 Procedure in relation to licensing decisions

(1) Before making a decision—

(a) to refuse an application for the grant, revocation or variation of a licence, or

(b) to grant an application for a licence subject to a condition imposed under paragraph 1(2), 1A(2), 2(2) or 3(5) of Schedule 2,

the Authority shall give the applicant notice of the proposed decision and of the reasons for it.

(2) Before making a decision under section 18(2) or 18A(3) or (5) the Authority shall give notice of the proposed decision and of the reasons for it to—

(a) the person responsible, and

(b) the holder of the licence (if different).

(3) Where an application has been made under section 18A(2) to vary a licence, but the Authority considers it appropriate to vary the licence otherwise than in accordance with the application, before so varying the licence the Authority shall give notice of its proposed decision and of the reasons for it to—

(a) the person responsible, and

(b) the holder of the licence (if different).

(4) A person to whom notice is given under subsection (1), (2) or (3) has the right to require the Authority to give him an opportunity to make representations of one of the following kinds about the proposed decision, namely—

(a) oral representations by him, or a person acting on his behalf;

(b) written representations by him.

(5) The right under subsection (4) is exercisable by giving the Authority notice of the exercise of the right before the end of the period of 28 days beginning with the day on which the notice under subsection (1), (2) or (3) was given.

(6) The Authority may by regulations make such additional provision about procedure in relation to the carrying out of functions under sections 18 and 18A and this section as it thinks fit.

19A Notification of licensing decisions

(1) In the case of a decision to grant a licence, the Authority shall give notice of the decision to—

(a) the applicant, and

(b) the person who is to be the person responsible.

(2) In the case of a decision to revoke a licence, the Authority shall give notice of the decision to—

(a) the person responsible, and

(b) the holder of the licence (if different).

(3) In the case of a decision to vary a licence on application under section 18A(1), the Authority shall give notice of the decision to—

(a) the holder of the licence, and

(b) (if different) the person who is to be the person responsible.

(4) In the case of any other decision to vary a licence, the Authority shall give notice of the decision to—

(a) the person responsible, and

(b) the holder of the licence (if different).

(5) In the case of a decision to refuse an application for the grant, revocation or variation of a licence, the Authority shall give notice of the decision to the applicant.

(6) Subject to subsection (7), a notice under subsection (2), (4) or (5) shall include a statement of the reasons for the decision.

(7) In the case of a notice under subsection (2) or (4), the notice is not required to include a statement of the reasons for the decision if the decision is made on an application under section 18(1) or 18A(2).

19B Applications under this Act

The Authority may by regulations make provision about applications under this Act and may, in particular, make provision about—

(a) the form and content of such an application,

(b) the information to be supplied with such an application, and

(c) procedure in relation to the determination of such an application."

28 Reconsideration and appeals

For sections 20 and 21 of the 1990 Act substitute—

"20 Right to reconsideration of licensing decisions

(1) If an application for the grant, revocation or variation of a licence is refused, the applicant may require the Authority to reconsider the decision.

(2) Where the Authority decides to vary or revoke a licence, any person to whom notice of the decision was required to be given (other than a person who applied for the variation or revocation) may require the Authority to reconsider the decision.

(3) The right under subsections (1) and (2) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under section 19A.

(4) Subsections (1) and (2) do not apply to a decision on reconsideration.

20A Appeals committee

(1) The Authority shall maintain one or more committees to carry out its functions in pursuance of notices under section 20.

(2) A committee under subsection (1) is referred to in this Act as an appeals committee.

(3) An appeals committee shall consist of not less than five members of the Authority.

(4) The quorum for an appeals committee shall be three.

20B Procedure on reconsideration

(1) Reconsideration shall be by way of a fresh decision.

(2) On reconsideration—

(a) the person by whom reconsideration is required ("the appellant") shall be entitled to require that he or his representative be given an opportunity to appear before and be heard by the appeals committee dealing with the matter,

(b) at any meeting at which such an opportunity is given, the person who made the decision which is the subject of reconsideration shall be entitled to appear and be heard in person or by a representative, and

(c) the appeals committee dealing with the matter shall consider any written representations received from the appellant or the person who made the decision which is the subject of reconsideration.

(3) The appeals committee by which a decision is reconsidered in pursuance of a notice under section 20 shall give the appellant notice of its decision.

(4) If on reconsideration an appeals committee upholds the previous decision, the notice under subsection (3) shall include a statement of the reasons for the appeal committee's decision.

(5) The Authority may by regulations make such other provision about procedure in relation to reconsideration as it thinks fit.

(6) Where reconsideration of a decision is required under section 20(2) by only one of two persons by whom it could have been required it shall be treated for the purposes of this section as required by both of them.

(7) In this section "reconsideration" means reconsideration in pursuance of a notice under section 20.

21 Appeal on a point of law

A person aggrieved by a decision on reconsideration in pursuance of a notice under section 20 may appeal to the High Court or, in Scotland, the Court of Session on a point of law."

29 Power to suspend licence

For section 22 of the 1990 Act substitute—

"22 Power to suspend licence

(1) Where the Authority—

(a) has reasonable grounds to suspect that there are grounds for revoking a licence, and

(b) is of the opinion that the licence should immediately be suspended,

it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice.

(2) The Authority may continue suspension under subsection (1) by giving a further notice under that subsection.

(3) Notice under subsection (1) shall be given to the person responsible or where the person responsible has died or appears to be unable because of incapacity to discharge the duty under section 17—

(a) to the holder of the licence, or

(b) to some other person to whom the licence applies.

(4) Subject to subsection (5), a licence shall be of no effect while a notice under subsection (1) is in force.

(5) An application may be made under section 18(1) or section 18A(1) or (2) even though a notice under subsection (1) is in force."

30 Directions

(1) Section 24 of the 1990 Act (directions as to particular matters) is amended as follows.

(2) After subsection (4A) insert—

"(4B) If, by virtue of regulations under sub-paragraph (3) of paragraph 3 of Schedule 2, any of the activities mentioned in that sub-paragraph can be authorised by a licence under that paragraph, regulations may make provision requiring or authorising the giving of directions in relation to particular matters related to such activities and specified in the regulations.

(4C) Regulations made by virtue of subsection (4B) may, in particular, make provision in relation to inter-species embryos corresponding to that made by subsection (3) or (4) in relation to embryos."

(3) For subsections (5) to (10) substitute—

"(5A) Directions may make provision for the purpose of dealing with a situation arising in consequence of—

(a) the variation of a licence, or

(b) a licence ceasing to have effect.

(5B) Directions under subsection (5A)(a) may impose requirements—

(a) on the holder of the licence,

(b) on the person who is the person responsible immediately before or immediately after the variation, or

(c) on any other person, if that person consents.

(5C) Directions under subsection (5A)(b) may impose requirements—

(a) on the person who holds the licence immediately before the licence ceases to have effect,

(b) on the person who is the person responsible at that time, or

(c) on any other person, if that person consents.

(5D) Directions under subsection (5A) may, in particular, require anything kept, or information held in pursuance of the licence to be transferred in accordance with the directions.

(5E) Where a licence has ceased to have effect by reason of the death or dissolution of its holder, anything subsequently done by a person before directions are given under subsection (5A) shall, if the licence would have been authority for doing it, be treated as authorised by a licence."

(4) In subsection (11), for "3(5)" substitute "3(2)".

31 Code of practice

(1) Section 25 of the 1990 Act (code of practice) is amended as follows.

(2) In subsection (2), omit "(including a child's need for a father)".

(3) In subsection (6)(a) and (b), for "a licence committee" substitute "the Authority".

32 Register of information

(1) For section 31 of the 1990 Act substitute—

"31 Register of information

(1) The Authority shall keep a register which is to contain any information which falls within subsection (2) and which—

(a) is obtained by the Authority, or

(b) immediately before the coming into force of section 32 of the Human Tissue and Embryos Act 2007, was contained in the register kept under this section by the Human Fertilisation and Embryology Authority.

(2) Subject to subsection (3), information falls within this subsection if it relates to—

(a) the provision for any identifiable individual of treatment services other than basic partner treatment services,

(b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual,

(c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,

(d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services,

(e) the use of an embryo taken from any identifiable woman,

or if it shows that any identifiable individual is a relevant individual.

(3) Information does not fall within subsection (2) if it was provided to the Authority for the purposes of any voluntary contact register as defined by section 31ZE(1).

(4) In this section "relevant individual" means an individual who was or may have been born in consequence of—

(a) treatment services, other than basic partner treatment services, or

(b) the procurement or distribution of any sperm (other than partner-donated sperm which has not been stored) in the course of providing non-medical fertility services.

31ZA Request for information as to genetic parentage etc.

(1) A person who has attained the age of 18 ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2), and the Authority shall do so if—

(a) the information contained in the register shows that the applicant is a relevant individual, and

(b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person ("the donor") other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that—

(a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information),

(b) stating whether or not that information shows that, but for the relevant statutory provisions, the applicant and a person specified in the request as a person whom the applicant proposes to marry or with whom the applicant proposes to enter into a civil partnership, would or might be related, or

(c) stating whether or not the information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so—

(i) the number of those other persons,

(ii) the sex of each of them, and

(iii) the year of birth of each of them.

(3) The Authority need not comply with a request made under subsection (2)(c) by any applicant, if it considers that special circumstances exist which increase the likelihood that compliance with the request would enable the applicant—

(a) to identify the donor, in a case where the Authority is not required by regulations under subsection (2)(a) to give the applicant information which identifies the donor, or

(b) to identify any person about whom information is given under subsection (2)(c).

(4) Regulations cannot require the Authority to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Authority or, as the case may be, the Human Fertilisation and Embryology Authority could not have been required to give information of the kind in question.

(5) A person who has not attained the age of 18 ("the minor") may by notice to the Authority specifying another person ("the intended spouse or civil partner") as a person whom the minor proposes to marry or with whom the minor proposes to enter into a civil partnership, require the Authority to comply with a request under subsection (6) and the Authority shall do so, to the extent it is able, if—

(a) the information shows that the minor is a relevant individual,

(b) the minor has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(6) The minor may request the Authority to give the minor notice stating whether or not the information contained in the register shows that, but for the relevant statutory provisions, the minor and the intended spouse or civil partner would or might be related.

(7) In this section—

"relevant individual" has the same meaning as in section 31;

"the relevant statutory provisions" means sections 27 to 29 of this Act and Part 3 of the Human Tissue And Embryos Act 2007.

31ZB Power of Authority to inform donor of request for information

(1) Where—

(a) the Authority has received from a person ("the applicant") a notice containing a request under subsection (2) of section 31ZA, and

(b) compliance by the Authority with its duty under that section has involved or will involve giving the applicant information relating to a person other than the parent of the applicant who would or might, but for the relevant statutory provisions, be a parent of the applicant ("the donor"),

the Authority may notify the donor that a request under section 31ZA(2) has been made, but may not disclose the identity of the applicant or any information relating to the applicant.

(2) In this section "the relevant statutory provisions" has the same meaning as in section 31ZA.

31ZC Provision to donor of information about resulting children

(1) This section applies where a person ("the donor") has consented under Schedule 3 (whether before or after the coming into force of this section) to the use, for the purposes of treatment services provided under a licence, of—

(a) the donor's gametes, or

(b) an embryo the creation of which was brought about using the donor's gametes.

(2) In subsection (1) "treatment services" do not include treatment services provided to the donor, or to the donor and another person together.

(3) The donor may by notice request the appropriate person to give the donor notice stating—

(a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a

parent by virtue of the use of the gametes or embryos to which the consent relates,

(b) the sex of each of those persons, and

(c) the year of birth of each of those persons.

(4) Subject to subsections (5) and (6), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.

(5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify any of the persons falling within subsection (3)(a) to (c).

(6) Where the person who held the licence referred to in subsection (1) continues to hold a licence under paragraph 1 of Schedule 2, the Authority need not comply with a request under subsection (3) made to the Authority unless the donor has previously made a request under that subsection to the person responsible and the person responsible —

(a) has notified the donor that information concerned is not held, or

(b) has failed to comply with the request within a reasonable period.

(7) In this section—

"the appropriate person" means—

(a) in a case where the person who held the licence referred to in subsection (1) continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or

(b) the Authority;

"the relevant statutory provisions" has the same meaning as in section 31ZA.

31ZD Provision of information about donor-conceived genetic siblings

(1) For the purposes of this section two relevant individuals are donor-conceived genetic siblings of each other if a person ("the donor") who is not the parent of either of them would or might, but for the relevant statutory provisions, be the parent of both of them.

(2) Where—

(a) the information on the register shows that a relevant individual ("A") is the donor-conceived genetic sibling of another relevant individual ("B"),

(b) A has provided information ("the agreed information") to the Authority with the request that it should be disclosed to any donor-conceived genetic sibling of A, and

(c) the conditions in subsection (3) are satisfied,

the Authority shall disclose the agreed information to B.

(3) The conditions referred to in subsection (2)(c) are—

(a) that each of A and B has attained the age of 18,

(b) that B has requested the disclosure to B of information about any donor-conceived genetic sibling of B,

(c) that each of A and B has been given a suitable opportunity to receive proper counselling about the implications of disclosure under subsection (2), and

(d) that the disclosure of information under subsection (2) will not lead to A or B identifying the donor unless—

(i) the donor has consented to the donor's identity being disclosed to A or B, or

(ii) were A or B to make a request under section 31ZA(1), the Authority would be required by regulations under section 31ZA(2)(a) to give A or B information which would identify the donor.

(4) In this section—

(a) "the relevant individual" has the same meaning as in section 31; and

(b) "the relevant statutory provisions" has the same meaning as in section 31ZA.

31ZE Power of Authority to keep voluntary contact register

(1) In this section and section 31ZF a "voluntary contact register" means a register of persons who—

(a) have expressed their wish to receive information about any person to whom they are genetically related as a consequence of the provision to any person of treatment services in the United Kingdom before 1 August 1991, and

(b) have attained the age of 18.

(2) The Authority may—

(a) set up a voluntary contact register in such manner as it thinks fit,

(b) keep a voluntary contact register in such manner as it thinks fit,

(c) determine criteria for eligibility for inclusion on the register and the particulars that may be included,

(d) charge a fee to persons who wish their particulars to be entered on the register,

(e) arrange for samples of the DNA of such persons to be analysed at their request,

(f) make such arrangements as it thinks fit for the disclosure of information on the register between persons who appear to the Authority to be genetically related, and

(g) impose such conditions as it thinks fit to prevent a person ("A") from disclosing information to a person to whom A is genetically related ("B") where that information would identify any person who is genetically related to both A and B.

(3) The Authority may make arrangements with any person by whom a voluntary contact register is kept before the commencement of this section for the supply by that person to the Authority of the information contained in the register maintained by that person.

31ZF Financial assistance for person setting up or keeping voluntary contact register

(1) The Authority may, instead of keeping a voluntary contact register, give financial assistance to any person who sets up or keeps a voluntary contact register.

(2) Financial assistance under subsection (1) may be given in any form, and in particular, may be given by way of—

(a) grants,

(b) loans,

(c) guarantees, or

(d) incurring expenditure for the person assisted.

(3) Financial assistance under subsection (1) may be given on such terms and conditions as the Authority considers appropriate.

(4) A person receiving assistance under subsection (1) must comply with the terms and conditions on which it is given, and compliance may be enforced by the Authority."

33 Restrictions on disclosure of information

For section 33 of the 1990 Act substitute—

"33A Disclosure of information

(1) No person shall disclose any information falling within section 31(2) which the person obtained in the person's capacity as—

(a) a member or employee of the Authority,

(b) any person exercising functions of the Authority by virtue of section 4 or 5 of the Human Tissue and Embryos Act 2007 (including a person exercising such functions by virtue of either of those sections as a member of staff or as an employee),

(c) any person engaged by the Authority to provide services to the Authority,

(d) any person employed by, or engaged to provide services to, a person mentioned in paragraph (c),

(e) a member or employee of the Human Fertilisation and Embryology Authority,

(f) a person to whom a licence applies,

(g) a person to whom a third party agreement applies, or

(h) a person to whom directions have been given.

(2) Subsection (1) does not apply where—

(a) the disclosure is made to a person as a member or employee of the Authority or as a person exercising functions of the Authority as mentioned in subsection (1)(b),

(b) the disclosure is made to or by a person falling within subsection (1)(c) for the purpose of the provision of services which that person is engaged to provide to the Authority,

(c) the disclosure is made by a person mentioned in subsection (1)(d) for the purpose of enabling a person falling within subsection (1)(c) to provide services which that person is engaged to provide to the Authority,

(d) the disclosure is made to a person to whom a licence applies for the purpose of that person's functions as such,

(e) the disclosure is made to a person to whom a third party agreement applies for the purpose of that person's functions under that agreement,

(f) the disclosure is made in pursuance of directions given by virtue of section 24,

(g) the disclosure is made so that no individual to whom the information relates can be identified,

(h) the disclosure is of information falling within section 31(2)(a) and is made with the consent required by subsection (4),

(i) the disclosure is of information falling within section 31(2)(b) to (e) and is made—

(i) with the consent of the individual to whom it relates, and

(ii) with the consent of any other individual who may be identified from that information,

(j) the disclosure is of information which shows that an individual who has attained the age of 18 is a relevant individual and is made—

(i) with the consent of that individual,

(ii) in a case where the disclosure of that information would also disclose any information falling within section 31(2)(a), with the consent required by subsection (4), and

(iii) with the consent of any other individual who may be identified from that information,

(k) the disclosure is of information which has been lawfully made available to the public before the disclosure is made,

(l) the disclosure is made in accordance with sections 31ZA to 31ZD,

(m) the disclosure is required or authorised to be made—

(i) under regulations made under section 33C, or

(ii) in relation to any time before the coming into force of the first regulations under that section, regulations made under section 251 of the National Health Service Act 2006,

(n) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) for the purpose of carrying out the Authority's duties under section 8A,

(o) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) in pursuance of an order of a court under section 34 or 35,

(p) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to the Registrar General in pursuance of a request under section 32,

(q) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to any body or person discharging a regulatory function for the purpose of assisting that body or person to carry out that function,

(r) the disclosure is made for the purpose of establishing in any proceedings relating to an application for an order under

subsection (1) of section 60 of the Human Tissue and Embryos Act 2007 whether the condition specified in paragraph (a) or (b) of that subsection is met,

(s) the disclosure is made under section 3 of the Access to Health Records Act 1990,

(t) the disclosure is made under Article 5 of the Access to Health Records (Northern Ireland) Order 1993, or

(u) the disclosure is made necessarily for—

(i) the purpose of the investigation of any offence (or suspected offence), or

(ii) any purpose preliminary to proceedings, or for the purposes of, or in connection with, any proceedings.

(3) Subsection (1) does not apply to the disclosure of information in so far as—

(a) the information identifies a person who, but for sections 27 to 29 of this Act or Part 3 of the Human Tissue and Embryos Act 2007, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, and

(b) the disclosure is made for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent.

(4) For the purpose of subsection (2)(h) and (j)(ii), the consent required by this subsection is—

(a) where any person is identifiable from the information, the consent of that person, or

(b) where treatment services were provided to two persons together and both persons are identifiable, if disclosure is made for the purpose of disclosing information about the provision of treatment services to one of them, the consent of that person.

(5) For the purposes of subsection (2)(h), (i) and (j), consent to disclosure given at the request of another shall be disregarded unless, before it is given, the person requesting it takes reasonable steps to explain to the individual from whom it is requested the implications of compliance with the request.

(6) Information falling within section 31(2) cannot be disclosed by virtue of subsection (2)(h), (i) or (j) to a person who has not attained the age of 18.

(7) Paragraph (u) of subsection (2), so far as relating to disclosure for the purpose of the investigation of an offence or suspected offence, or for any purpose preliminary to, or in connection with proceedings, does not apply—

(a) to disclosure of information enabling a person to be identified as a person whose gametes were used in accordance with consent given under paragraph 5 of Schedule 3 for the purposes of treatment services or non-medical fertility services, in consequence of which an identifiable individual was, or may have been, born, or

(b) to disclosure, in circumstances in which subsection (1) of section 34 of this Act applies, of information relevant to the determination of the question mentioned in that subsection,

made by any person acting in a capacity mentioned in paragraphs (c) to (h) of subsection (1).

(8) In the case of information which relates to the provision of treatment services for any identifiable individual, subsection (1) does not apply to disclosure in an emergency, that is to say, disclosure made—

(a) by a person who is satisfied that it is necessary to make the disclosure to avert an imminent danger to the health of an individual with whose consent the information could be disclosed under subsection (2)(h), and

(b) in circumstances where it is not reasonably practicable to obtain that individual's consent.

(9) In the case of information which shows that any identifiable individual was, or may have been, born in consequence of treatment services, subsection (1) does not apply to any disclosure which is necessarily incidental to disclosure under subsection (2)(h) or (8).

(10) Subsection (1) does not apply to the disclosure to any individual of information which—

(a) falls within section 31(2) of this Act by virtue of any of paragraphs (a) to (e) of that section, and

(b) relates only to that individual or, in the case of an individual treated together with another, only to that individual and that other.

(11) In subsection (2)—

(a) in paragraph (j) "relevant individual" has the same meaning as in section 31,

(b) in paragraph (q) "regulatory function" has the same meaning as in section 32 of the Legislative and Regulatory Reform Act 2006 (c. 51), and

(c) in paragraph (u) references to "proceedings" include any formal procedure for dealing with a complaint.

33B Power to provide for additional exceptions from section 33A(1)

(1) Regulations may provide for additional exceptions from section 33A(1).

(2) No exception may be made under this section for—

(a) disclosure of a kind mentioned in paragraph (a) or (b) of section 33A(7), or

(b) disclosure in circumstances in which section 32 of this Act applies of information having the tendency mentioned in subsection (2) of that section, made by any person acting in a capacity mentioned in paragraphs (c) to (h) of section 33A(1).

33C Disclosure for the purposes of medical research

(1) Regulations may make such provision for and in connection with requiring or regulating the processing of protected information for the purposes of medical research as the Secretary of State considers necessary or expedient—

(a) in the interests of improving patient care, or

(b) in the public interest.

(2) Regulations under subsection (1) may, in particular, make provision—

(a) for requiring or authorising the disclosure or other processing of protected information to or by persons of any prescribed description subject to compliance with any prescribed conditions (including conditions requiring prescribed undertakings to be obtained from such persons as to the processing of such information),

(b) for securing that, where prescribed protected information is processed by a person in accordance with the regulations, anything done by that person in so processing the information must be taken to be lawfully done despite any obligation of confidence owed by the person in respect of it,

(c) for the establishment of one or more bodies to exercise prescribed functions in relation to the processing of protected information under those regulations,

(d) as to the membership and proceedings of any such body, and

(e) as to the payment of remuneration and allowances to any member of any such body and the reimbursement of expenses.

(3) Regulations under subsection (1) may enable any approval given under regulations made under section 251 of the National Health Service Act 2006 (control of patient information) to have effect for the purposes of the regulations under subsection (1) in their application to England and Wales.

(4) Subsections (1) to (3) are subject to subsections (5) to (7).

(5) Regulations under this section may not make provision for or in connection with the processing of protected information in a manner inconsistent with any provision made by or under the Data Protection Act 1998 (c. 29).

(6) Subsection (5) does not affect the operation of provisions made under subsection (2)(b).

(7) Before making any regulations under this section the Secretary of State shall consult such bodies appearing to the Secretary of State to represent the interests of those likely to be affected by the regulations as the Secretary of State considers appropriate.

(8) In this section—

"prescribed" means prescribed by regulations made by virtue of this section,

"processing", in relation to information, means the use, disclosure, or obtaining of the information or the doing of such other things in relation to it as may be prescribed for the purposes of this definition, and

"protected information" means information falling within section 31(2)."

34 Mitochondrial donation

After section 35 of the 1990 Act insert—

"Mitochondrial donation

35A Mitochondrial donation

(1) Regulations may provide for any of the relevant provisions to have effect subject to specified modifications in relation to cases where—

(a) an egg which is a permitted egg for the purposes of section 3(2) by virtue of regulations made under section 3ZA(5), or

(b) an embryo which is a permitted embryo for those purposes by virtue of such regulations,

has been created from material provided by two women.

(2) In this section "the relevant provisions" means—

(a) the following provisions of this Act—

(i) section 31 (register of information),

(ii) sections 31ZA to 31ZD (provision of information), and

(iii) Schedule 3 (consents to use of gametes or embryos), and

(b) section 60 of the Human Tissue and Embryos Act 2007 (parental orders)."

35 Fees under 1990 Act

After section 35A of the 1990 Act insert—

"Fees

35B Fees

(1) The Authority may charge a fee in respect of any of the following—

(a) an application for a licence,

(b) the grant or renewal of a licence,

(c) an application for the revocation or variation of a licence, or

(d) the exercise by the Authority of any other function under this Act—

(i) in relation to a licence,

(ii) in relation to premises which are or have been premises to which a licence relates,

(iii) in relation to premises which are or have been relevant third party premises in relation to a licence, or

(iv) in relation to premises which, if an application is granted, will be premises to which a licence relates or relevant third party premises.

(2) The amount of any fee charged by virtue of subsection (1) is to be fixed in accordance with a scheme made by the Authority with the approval of the Secretary of State and the Treasury.

(3) In fixing the amount of any fee to be charged by virtue of that subsection, the Authority may have regard to the costs incurred by it in

exercising its functions under this Act or under Part 1 of the Human Tissue and Embryos Act 2007.

(4) The Authority may also charge such fee as it thinks fit in respect of any of the following—

(a) the giving of notice under section 31ZA(1) or (5),

(b) the provision of information under section 31ZA(2) or (6), 31ZB(1) or 31ZD.

(5) In fixing the amount of any fee to be charged by virtue of subsection (4) the Authority may have regard to the costs incurred by it in exercising the function to which the fee relates.

(6) Different fees may be fixed under this section for different circumstances."

36 Powers of inspection, entry, search and seizure

(1) Before section 39 of the 1990 Act (but after the heading "Enforcement" immediately before that section) insert—

"38A Powers of members and employees of Authority

(1) Schedule 3B (which makes provisions about the powers of inspection, entry, search and seizure) has effect.

(2) Nothing in this Act makes it unlawful for a member or employee of the Authority to keep any embryo, inter-species embryo or gametes in pursuance of that person's functions as such."

(2) After Schedule 3A to the 1990 Act insert the Schedule set out in Schedule 5 to this Act.

(3) Section 39 of the 1990 Act (powers of members and employees of Authority) and section 40 of that Act (power to enter premises) (which are superseded by the amendments made by subsection (2)) cease to have effect.

37 Penalties for offences under 1990 Act

(1) Section 41 of the 1990 Act (offences) is amended as follows.

(2) In subsection (1)(a), for "4(1)(c)" substitute "4A(1) or (2)".

(3) In subsection (2)—

(a) after paragraph (a) insert—

"(aa) contravenes section 3(1B) of this Act,",

(b) after paragraph (ba) insert—

"(bb) contravenes section 4(1A) of this Act,", and

(c) in paragraph (d), for "section 24(7)(a)" substitute "section 24(5D)".

(4) In subsection (4), omit ", other than an offence to which subsection (4B) applies,".

(5) In subsection (5), for "section 33" substitute "section 33A".

(6) In subsection (8), for "or the nominal licensee" substitute "or the holder of the licence".

(7) In subsection (9), omit "(6), (7) or".

(8) For subsection (10) substitute—

"(10) It is a defence for a person ("the defendant") charged with an offence of doing anything which, under section 3(1) or (1A), 4(1) or 4A(2), cannot be done except in pursuance of a licence to prove—

(a) that the defendant was acting under the direction of another, and

(b) that the defendant believed on reasonable grounds—

(i) that the other person was at the material time the person responsible under a licence, a person designated by virtue of section 17(2)(b) of this Act as a person to whom a licence applied, or a person to whom directions had been given under section 24(5A) to (5D), and

(ii) that the defendant was authorised by virtue of the licence or directions to do the thing in question.

(10A) It is a defence for a person ("the defendant") charged with an offence of doing anything which, under section 3(1A) or (1B) or 4(1A), cannot be done except in pursuance of a licence or a third party agreement to prove—

(a) that the defendant was acting under the direction of another, and

(b) that the defendant believed on reasonable grounds—

(i) that the other person was at the material time the person responsible under a licence, a person designated by virtue of section 17(2)(b) of this Act as a person to whom a licence applied, a person to whom a third party agreement applied, or a person to whom directions had been given under section 24(5A) to (5D), and

(ii) that the defendant was authorised by virtue of the licence, third party agreement or directions to do the thing in question."

(9) Omit subsections (2A), (4A), (4B), (6) and (7).

(10) Section 41(2) of the 1990 Act as amended by subsection (3) is to be treated as a relevant enactment for the purposes of section 282 of the Criminal Justice Act 2003 (c. 44) (increase in maximum term that may be imposed on summary conviction of offence triable either way).

38 Regulations under 1990 Act

(1) Section 45 of the 1990 Act (regulations) is amended as follows.

(2) After subsection (1) insert—

"(1A) Subsection (1) does not enable the Secretary of State to make regulations by virtue of any of sections 19(6), 19B and 20B(5) (which confer regulation-making powers on the Authority)."

(3) In subsection (2), after "regulations" insert "under this Act".

(4) For subsection (3) substitute—

"(3) The power to make regulations under this Act may be exercised—

(a) either in relation to all cases to which the power extends, or in relation to those cases subject to specified exceptions, or in relation to any specified cases or classes of case, and

(b) so as to make, as respects the cases in relation to which it is exercised—

(i) the full provision to which the power extends or any less provision (whether by way of exception or otherwise);

(ii) the same provision for all cases in relation to which the power is exercised, or different provision as respects the same case or class of case for different purposes;

(iii) any such provision either unconditionally, or subject to any specified condition.

(3A) Any power of the Secretary of State or the Authority to make regulations under this Act includes power to make such transitional, incidental or supplemental provision as the Secretary of State or the Authority considers appropriate."

(5) For subsection (4) substitute—

"(4) The Secretary of State shall not make regulations by virtue of any of the provisions specified in subsection (4A) unless a draft has been laid before and approved by a resolution of each House of Parliament.

(4A) Those provisions are—

section 1(6);
section 3(3)(c);
section 3ZA(5);
section 4(2) or (3);
section 15ZA;
section 24(4B);
section 31ZA(2)(a);
section 33B;
section 33C;
section 35A;
section 43;
paragraph 1(1)(g), 1ZC, 2(1A), 3(3), 3A(1)(c) of Schedule 2;
paragraph 13 of Schedule 3."

(6) In subsection (5), after "regulations" insert "made by the Secretary of State".

PART 3

PARENTHOOD IN CASES INVOLVING ASSISTED REPRODUCTION

Meaning of "mother"

39 Meaning of "mother"

(1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.

(2) Subsection (1) does not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.

(3) Subsection (1) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

Application of sections 41 to 53

40 Application of sections 41 to 53

(1) Sections 41 to 53 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as "W") as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.

(2) Subsection (1) has effect subject to the provisions of sections 45, 46 and 52 limiting the purposes for which a person is treated as the child's other parent by virtue of those sections.

Meaning of "father"

41 Woman married at time of treatment

(1) If—

(a) at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination, W was a party to a marriage, and

(b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage,

then, subject to section 44(2) to (4), the other party to the marriage is to be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).

(2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1)(a).

42 Treatment provided to woman where agreed fatherhood conditions apply

If no man is treated, by virtue of section 41, as the father of the child and no woman is treated, by virtue of section 48, as a parent of the child but—

(a) the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,

(b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed fatherhood conditions (as set out in section 43) were satisfied in relation to a man, in relation to treatment provided to W under the licence,

(c) the man remained alive at that time, and

(d) the creation of the embryo carried by W was not brought about with the man's sperm,

then, subject to section 44(2) to (4), the man is to be treated as the father of the child.

43 The agreed fatherhood conditions

(1) The agreed fatherhood conditions referred to in section 42(b) are met in relation to a man ("M") in relation to treatment provided to W under a licence if, but only if,—

(a) M has given the person responsible a notice stating that he consents to being treated as the father of any child resulting from treatment provided to W under the licence,

(b) W has given the person responsible a notice stating that she consents to M being so treated,

(c) neither M nor W has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of M's or W's consent to M being so treated,

(d) W has not, since the giving of the notice under paragraph (b), given the person responsible—

(i) a further notice under that paragraph stating that she consents to another man being treated as the father of any resulting child, or

(ii) a notice under section 50(1)(b) stating that she consents to a woman being treated as a parent of any resulting child, and

(e) W and M are not within prohibited degrees of relationship in relation to each other.

(2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.

44 Further provision relating to sections 41 and 42

(1) Where a person is to be treated as the father of the child by virtue of section 41 or 42, no other person is to be treated as the father of the child.

(2) In England and Wales and Northern Ireland, sections 41 and 42 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.

(3) In Scotland, sections 41 and 42 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.

(4) Sections 41 and 42 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the man's child.

45 Use of sperm, or transfer of embryo, after death of man providing sperm

(1) If—

(a) the child has been carried by W as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,

(b) the creation of the embryo carried by W was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in W after his death,

(c) the man consented in writing (and did not withdraw the consent)—

(i) to the use of his sperm after his death which brought about the creation of the embryo carried by W or (as the case may be) to

the placing in W after his death of the embryo which was brought about using his sperm before his death, and

(ii) to being treated for the purpose mentioned in subsection (3) as the father of any resulting child,

(d) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (3) as the father of the child, and

(e) no-one else is to be treated—

(i) as the father of the child by virtue of section 41 or 42 or by virtue of section 44(2) or (3), or

(ii) as a parent of the child by virtue of section 48 or 49 or by virtue of adoption,

then the man is to be treated for the purposes mentioned in subsection (3) as the father of the child.

(2) Subsection (1) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.

(3) The purpose referred to in subsection (1) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.

(4) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

46 Embryo transferred after death of husband etc who did not provide sperm

(1) If—

(a) the child has been carried by W as a result of the placing in her of an embryo,

(b) the embryo was created at a time when W was a party to a marriage,

(c) the creation of the embryo was not brought about with the sperm of the other party to the marriage,

(d) the other party to the marriage died before the placing of the embryo in W,

(e) the other party to the marriage consented in writing (and did not withdraw the consent)—

(i) to the placing of the embryo in W after his death, and

(ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,

(f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and

(g) no-one else is to be treated—

(i) as the father of the child by virtue of section 41 or 42 or by virtue of section 44(2) or (3), or

(ii) as a parent of the child by virtue of section 48 or 49 or by virtue of adoption,

then the man is to be treated for the purposes mentioned in subsection (4) as the father of the child.

(2) If—

(a) the child has been carried by W as a result of the placing in her of an embryo,

(b) the embryo was not created at a time when W was a party to a marriage or a civil partnership but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,

(c) a man consented in writing (and did not withdraw the consent)—

(i) to the placing of the embryo in W after his death, and

(ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,

(d) the creation of the embryo was not brought about with the sperm of that man,

(e) the man died before the placing of the embryo in W,

(f) immediately before the man's death, the agreed fatherhood conditions set out in section 43 were met in relation to a man in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,

(g) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and

(h) no-one else is to be treated—

(i) as the father of the child by virtue of section 41 or 42 or by virtue of section 44(2) or (3), or

(ii) as a parent of the child by virtue of section 48 or 49 or by virtue of adoption,

then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.

(3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.

(4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.

(5) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

47 Persons not to be treated as father

(1) Where the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to the 1990 Act (consent to use of gametes for treatment of others) was used for a purpose for which such consent was required, he is not to be treated as the father of the child.

(2) Where the sperm of a man, or an embryo the creation of which was brought about with his sperm, was used after his death, he is not, subject to section 45, to be treated as the father of the child.

(3) Subsection (2) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.

Cases in which woman to be other parent

48 Woman in civil partnership at time of treatment

(1) If at the time of the placing in her of the embryo or the sperm and eggs or of her artificial insemination, W was a party to a civil partnership, then subject to section 51(2) to (4), the other party to the civil partnership is to be treated as a parent of the child unless it is shown that she did not consent to the placing in W of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).

(2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1).

49 Treatment provided to woman who agrees that second woman to be parent

If no man is treated, by virtue of section 41 as the father of the child and no woman is treated by virtue of section 48 as a parent of the child, but—

(a) the embryo or the sperm and eggs were placed in W or she was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,

(b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed female parenthood conditions (as set out in section 50) were met in relation to another woman, in relation to treatment provided to W under that licence, and

(c) the other woman remained alive at that time,

then, subject to section 51(2) to (4), the other woman is to be treated as a parent of the child.

50 The agreed female parenthood conditions

(1) The agreed female parenthood conditions referred to in section 49(b) are met in relation to another woman ("P") in relation to treatment provided to W under a licence if, but only if,—

(a) P has given the person responsible a notice stating that P consents to P being treated as a parent of any child resulting from treatment provided to W under the licence,

(b) W has given the person responsible a notice stating that W agrees to P being so treated,

(c) neither W nor P has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of P's or W's consent to P being so treated,

(d) W has not, since the giving of the notice under paragraph (b), given the person responsible—

(i) a further notice under that paragraph stating that W consents to a woman other than P being treated as a parent of any resulting child, or

(ii) a notice under section 43(b) stating that W consents to a man being treated as the father of any resulting child, and

(e) W and P are not within prohibited degrees of relationship in relation to each other.

(2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.

51 Further provision relating to sections 48 and 49

(1) Where a woman is treated by virtue of section 48 or 49 as a parent of the child, no man is to be treated as the father of the child.

(2) In England and Wales and Northern Ireland, sections 48 and 49 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.

(3) In Scotland, sections 48 and 49 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.

(4) Sections 48 and 49 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.

52 Embryo transferred after death of civil partner or intended female parent

(1) If—

(a) the child has been carried by W as the result of placing in her of an embryo,

(b) the embryo was created at a time when W was a party to a civil partnership,

(c) the other party to the civil partnership died before the placing of the embryo in the woman,

(d) the other party to the civil partnership consented in writing (and did not withdraw the consent)—

(i) to the placing of the embryo in W after the death of the other party, and

(ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,

(e) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other party to the civil partnership to be treated for the purpose mentioned in subsection (4) as the parent of the child, and

(f) no one else is to be treated—

(i) as the father of the child by virtue of section 41 or 42 or by virtue of section 51(2) or (3), or

(ii) as a parent of the child by virtue of section 48 or 49 or by virtue of adoption,

then the other party to the civil partnership is to be treated for the purpose mentioned in subsection (4) as a parent of the child.

(2) If—

(a) the child has been carried by W as the result of the placing in her of an embryo,

(b) the embryo was not created at a time when W was a party to a marriage or a civil partnership, but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,

(c) another woman consented in writing (and did not withdraw the consent)—

(i) to the placing of the embryo in W after the death of the other woman, and

(ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,

(d) the other woman died before the placing of the embryo in W,

(e) immediately before the other woman's death, the agreed female parenthood conditions set out in section 50 were met in relation to the other woman in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,

(f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other woman to be treated for the purpose mentioned in subsection (4) as the parent of the child, and

(g) no one else is to be treated—

(i) as the father of the child by virtue of section 41 or 42 or by virtue of section 51(2) or (3), or

(ii) as a parent of the child by virtue of section 48 or 49 or by virtue of adoption,

then the other woman is to be treated for the purpose mentioned in subsection (4) as a parent of the child.

(3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.

(4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the deceased woman's particulars to be entered as the particulars of the child's other parent in a relevant register of births.

(5) In the application of subsections (1) and (2) to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

53 Woman not to be other parent merely because of egg donation

A woman is not to be treated as the parent of a child whom she is not carrying and has not carried, except where she is so treated—

(a) by virtue of section 48 or 49, or

(b) by virtue of section 52 (for the purpose mentioned in subsection (4) of that section), or

(c) by virtue of adoption.

Effect of sections 39 to 52

54 Effect of sections 39 to 52

(1) Where by virtue of section 39, 41, 42, 48 or 49 a person is to be treated as the mother, father or parent of a child, that person is to be treated in law as the mother, father or parent (as the case may be) of the child for all purposes.

(2) Where by virtue of section 39, 44, 47, 51 or 53 a person is not to be treated as a parent of the child, that person is to be treated in law as not being a parent of the child for any purpose.

(3) Where section 45(1) or 46(1) or (2) applies, the deceased man—

(a) is to be treated in law as the father of the child for the purpose mentioned in section 45(3) or 46(4), but

(b) is to be treated in law as not being the father of the child for any other purpose.

(4) Where section 52(1) or (2) applies, the deceased woman—

(a) is to be treated in law as a parent of the child for the purpose mentioned in section 52(4), but

(b) is to be treated in law as not being a parent of the child for any other purpose.

(5) Where any of subsections (1) to (4) has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.

(6) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 39(1) or 41 to 53, read with this section—

(a) affects the succession to any dignity or title or renders any person capable of succeeding to or transmitting a right to succeed to any such dignity or title, or

(b) affects the devolution of any property limited (expressly or not) to devolve (as nearly as the law permits) along with any dignity or title of honour.

(7) In relation to Scotland—

(a) those provisions do not apply to any title, coat of arms, honour or dignity transmissible on the death of its holder or affect the succession to any such title, coat of arms or dignity of or its devolution, and

(b) where the terms of any deed provide that any property or interest in property is to devolve along with a title, coat of arms, honour or dignity, nothing in those provisions is to prevent that property or interest from so devolving.

References to parties to marriage or civil partnership

55 Meaning of references to parties to a marriage

(1) The references in sections 41 to 53 to the parties to a marriage at any time there referred to—

(a) are to the parties to a marriage subsisting at that time, unless a judicial separation was then in force, but

(b) include the parties to a void marriage if either or both of them reasonably believed at that time that the marriage was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the marriage was valid.

(2) In subsection (1)(a) "judicial separation" includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

56 Meaning of references to parties to a civil partnership

(1) The references in sections 41 to 53 to the parties to a civil partnership at the time there referred to—

(a) are to the parties to a civil partnership subsisting at that time, unless a separation order was then in force, but

(b) include the parties to a void civil partnership if either or both of them reasonably believed at that time that the civil partnership was valid; and for the purposes of those sections it is to be presumed that, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.

(2) In subsection (1)(a), "separation order" means—

(a) a separation order under section 37(1)(d) of the Civil Partnership Act 2004 (c. 33),

(b) a decree of separation under section 120(2) of that Act, or

(c) a legal separation obtained in a country outside the United Kingdom and recognised in the United Kingdom.

Further provision about registration by virtue of section 45, 46 or 52

57 Meaning of "relevant register of births"

For the purposes of this Part a "relevant register of births", in relation to a birth, is whichever of the following is relevant—

(a) a register of live-births or still-births kept under the Births and Deaths Registration Act 1953 (c. 20),

(b) a register of births or still-births kept under the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49), or

(c) a register of live-births or still-births kept under the Birth and Deaths Registration (Northern Ireland) Order 1976 (S. I. 1976/1041 (N. I. 14)).

58 Late election by mother with consent of Registrar General

(1) The requirement under section 45(1), 46(1) or (2) or 52(1) or (2) as to the making of an election (which requires an election to be made either on or before the day on which the child was born or within the period of 42 or, as the case may be, 21 days from that day) is nevertheless to be treated as satisfied if the required election is made after the end of that period but with the consent of the Registrar General under subsection (2).

(2) The Registrar General may at any time consent to the making of an election after the end of the period mentioned in subsection (1) if, on an application made to him in accordance with such requirements as he may specify, he is satisfied that there is a compelling reason for giving his consent to the making of such an election.

(3) In this section "the Registrar General" means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or (as the case may be) the Registrar General for Northern Ireland.

Interpretation of references to father etc. where woman is other parent

59 Interpretation of references to father etc.

(1) Subsections (2) and (3) have effect, subject to subsections (4) and (6), for the interpretation of any enactment, deed or any other instrument or document (whenever passed or made).

(2) Any reference (however expressed) to the father of a child who has a parent by virtue of section 48 or 49 is to be read as a reference to the woman who is by virtue of that section the child's parent.

(3) Any reference (however expressed) to evidence of paternity is, in relation to a person who is a parent by virtue of section 48 or 49, to be read as a reference to evidence of parentage.

(4) This section does not affect the interpretation of the enactments specified in subsection (5) (which make express provision for the case where a child has a parent by virtue of section 48 or 49).

(5) Those enactments are—

(a) the Births and Deaths Registration Act 1953 (c. 20),
(b) Part 2 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49),
(c) the Congenital Disabilities (Civil Liability) Act 1976 (c. 28),
(d) the Legitimacy Act 1976 (c. 31),
(e) the British Nationality Act 1981 (c. 61),
(f) the Family Law Reform Act 1987 (c. 42),
(g) Parts 1 and 2 of the Children Act 1989 (c. 41),
(h) section 32 of the 1990 Act, and
(i) Part 1 of the Children (Scotland) Act 1995 (c. 36).

(6) This section does not affect the interpretation of references falling within section 1(2)(a) or (b) of the Family Law Reform Act 1987 (references to a person whose father and mother were, or were not, married to each other at the time of the person's birth).

Parental orders

60 Parental orders in favour of gamete donors

(1) On an application made by two people ("the applicants"), the court may make an order providing for a child to be treated in law as the child of the applicants if—

(a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination,
(b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and
(c) the conditions in subsections (2) to (8) are satisfied.

(2) The applicants must be—

(a) husband and wife,
(b) civil partners of each other, or

(c) two persons who are living as partners in an enduring family relationship and are not within prohibited degrees of relationship in relation to each other.

(3) Except in a case falling within subsection (11), the applicants must apply for the order during the period of 6 months beginning with the day on which the child is born.

(4) At the time of the application and the making of the order—

(a) the child's home must be with the applicants, and

(b) either or both of the applicants must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.

(5) At the time of the making of the order both the applicants must have attained the age of 18.

(6) The court must be satisfied that both—

(a) the woman who carried the child, and

(b) any other person who is a parent of the child but is not one of the applicants (including any man who is the father by virtue of section 41 or 42 or any woman who is a parent by virtue of section 48 or 49),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(7) Subsection (6) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

(8) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by either of the applicants for or in consideration of—

(a) the making of the order,

(b) any agreement required by subsection (6),

(c) the handing over of the child to the applicants, or

(d) the making of arrangements with a view to the making of the order,

unless authorised by the court.

(9) For the purposes of an application under this section—

(a) in relation to England and Wales, section 92(7) to (10) of, and Part 1 of Schedule 11 to, the Children Act 1989 (c. 41) (jurisdiction of courts) apply for the purposes of this section to determine the meaning of "the court" as they apply for the purposes of that Act and proceedings on the application are to be "family proceedings" for the purposes of that Act,

(b) in relation to Scotland, "the court" means the Court of Session or the sheriff court of the sheriffdom within which the child is, and

(c) in relation to Northern Ireland, "the court" means the High Court or any county court within whose division the child is.

(10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(11) An application which—

(a) relates to a child born before the coming into force of this section, and

(b) is made by two persons who, throughout the period applicable under subsection (2) of section 30 of the 1990 Act, were not eligible to apply for an order under that section in relation to the child as husband and wife,

may be made within the period of six months beginning with the day on which this section comes into force.

61 Parental orders: supplementary provision

(1) Regulations may provide—

(a) for any provision of the enactments about adoption to have effect, with such modifications (if any) as may be specified in the regulations, in relation to orders under section 60, and applications for such orders, as it has effect in relation to adoption, and applications for adoption orders, and

(b) for references in any enactment to adoption, an adopted child or an adoptive relationship to be read (respectively) as references to the effect of an order under section 60, a child to whom such an order applies and a relationship arising by virtue of the enactments about adoption, as applied by the regulations, and for similar expressions in connection with adoption to be read accordingly.

(2) The regulations may include such incidental or supplemental provision as appears to the Secretary of State to be necessary or desirable in consequence of any provision made by virtue of subsection (1)(a) or (b).

(3) In this section "the enactments relating to adoption" means—

(a) the Adoption (Scotland) Act 1978 (c. 28),

(b) the Adoption and Children Act 2002 (c. 38),

(c) the Adoption and Children (Scotland) Act 2007 (asp 4), and

(d) the Adoption (Northern Ireland) Order 1987 (S. I. 1987/2203 (N. I. 22)).

Amendments of enactments

62 Amendments relating to parenthood in cases involving assisted reproduction

Schedule 6 contains amendments related to the provisions of this Part.

General

63 Repeals and transitional provision relating to Part 3

(1) Sections 39 to 54 have effect only in relation to children carried by women as a result of the placing in them of embryos or of sperm and eggs, or their artificial insemination (as the case may be), after the commencement of those sections.

(2) Sections 27 to 29 of the 1990 Act (which relate to status) do not have effect in relation to children carried by women as a result of the placing in them of embryos or of sperm and eggs, or their artificial insemination (as the case may be), after the commencement of sections 39 to 54.

(3) Section 30 of the 1990 Act (parental orders in favour of gamete donors) ceases to have effect.

(4) Subsection (3) does not affect the validity of any order made under section 30 of the 1990 Act before the coming into force of that subsection.

64 Interpretation of Part 3

(1) In this Part "enactment" includes an enactment comprised in, or in an instrument made under, an Act of the Scottish Parliament or Northern Ireland legislation.

(2) For the purposes of this Part, two persons are within prohibited degrees of relationship if one is the other's parent, grandparent, sister, brother, aunt or uncle; and in this subsection references to relationships—

(a) are to relationships of the full blood or half blood or, in the case of an adopted person, such of those relationships as would subsist but for adoption, and

(b) include the relationship of a child with his adoptive, or former adoptive, parents,

but do not include any other adoptive relationships.

(3) Other expressions used in this Part and in the 1990 Act have the same meaning in this Part as in that Act.

PART 4

MISCELLANEOUS AND GENERAL

Miscellaneous

65 Sperm sorting kits

(1) In this section "sperm sorting kit" means a kit the purpose of which is to apply to human sperm any process that is designed to secure that any resulting child will be of one sex rather than the other.

(2) The Secretary of State may by regulations provide that a person—

(a) who sells or supplies to another a sperm sorting kit or any component part of such a kit,

(b) who advertises such kits or component parts,

is guilty of an offence.

(3) A person who contravenes regulations under this section is liable—

(a) on summary conviction, to imprisonment for a term not exceeding 12 months or to a fine not exceeding the statutory maximum, or to both;

(b) on conviction on indictment, to a fine or to imprisonment for a term of not more than two years, or to both.

(4) Where an offence under this section which is committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in any such capacity, that director or other person as well as the body corporate is guilty of the offence and is liable to be proceeded against and punished accordingly.

(5) In the application of this section—

(a) in England and Wales, in relation to an offence committed before the commencement of section 154(1) of the Criminal Justice Act 2003 (c. 44),

(b) in Scotland, until the commencement of section 45(1) of the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), or

(c) in Northern Ireland,

the reference in subsection (3)(a) to 12 months is to be read as a reference to 6 months.

66 Surrogacy arrangements

(1) The Surrogacy Arrangements Act 1985 (c. 49) is amended as follows.

(2) In section 1 (meaning of various terms), after subsection (7) insert—

"(7A) "Non-profit making body" means a body of persons whose activities are not carried on for profit."

(3) In section 2 (negotiating surrogacy arrangements on a commercial basis), in subsection (1)—

(a) in paragraph (a) omit "or take part in", and

(b) after paragraph (a) insert—

"(aa) take part in any negotiations with a view to the making of a surrogacy arrangement,".

(4) After subsection (2) insert—

"(2A) A non-profit making body does not contravene subsection (1) merely because—

(a) the body does an act falling within subsection (1)(a) or (c) in respect of which any payment is at any time received by it or another, or

(b) it does an act falling within subsection (1)(a) or (c) with a view to any payment being received by it or another in respect of facilitating the making of any surrogacy arrangement.

(2B) A person who knowingly causes a non-profit making body to do an act falling within subsection (1)(a) or (c) does not contravene subsection (1) merely because—

(a) any payment is at any time received by the body or another in respect of the body doing the act, or

(b) the body does the act with a view to any payment being received by it or another person in respect of the body facilitating the making of any surrogacy arrangement."

(5) After subsection (5) of that section insert—

"(5A) A non-profit making body is not guilty of an offence under subsection (5), in respect of the receipt of any payment described in that subsection, merely because a person acting on behalf of the body takes part in facilitating the making of a surrogacy arrangement."

(6) After subsection (8) of that section insert—

"(8A) A person is not guilty of an offence under subsection (7) if—

(a) the body of persons referred to in that subsection is a non-profit making body, and

(b) the only activity of that body which falls within subsection (8) is facilitating the making of surrogacy arrangements in the United Kingdom.

(8B) In subsection (8A)(b) "facilitating the making of surrogacy arrangements" is to be construed in accordance with subsection (8)."

(7) In section 3 (advertisements about surrogacy), after subsection (1) insert—

"(1A) This section does not apply to any advertisement placed by, or on behalf of, a non-profit making body if the advertisement relates only to the doing by the body of acts that would not contravene section 2(1) even if done on a commercial basis (within the meaning of section 2)."

67 Grant, revocation or variation of licences under Human Tissue Act 2004

(1) The 2004 Act is amended as follows.

(2) In section 19 (right to reconsideration of licensing decisions) for subsection (2) substitute—

"(2) Where the Authority decides to revoke or vary a licence, any person to whom notice of the decision was required to be given (other than a person who applied for the variation or revocation) may require the Authority to reconsider the decision."

(3) Schedule 3 (licences) is amended as follows.

(4) In paragraph 6, after sub-paragraph (5) insert—

"(5A) Where the Authority is of the opinion that the information provided in the application is insufficient to enable it to determine the application, it need not consider the application until the applicant has provided it with such further information as it may require."

(5) In paragraph 7(2)—

(a) after paragraph (b), insert—

"(ba) it is satisfied that the designated individual has failed to comply with directions given in connection with any licence," and

(b) in paragraph (f), after "dies" insert "or is convicted of an offence under this Act".

(6) In paragraph 10—

(a) after sub-paragraph (2) insert—

"(2A) Where an application has been made under paragraph 8(2) to vary a licence, but the Authority considers it appropriate to vary the licence otherwise than in accordance with the application, before so varying the licence the Authority shall give notice of its proposed decision and of the reasons for it to—

(a) the holder of the licence, and

(b) where different, the designated individual.";

(b) in sub-paragraph (3), for "or (2)" substitute ",(2) or (2A)";

(c) in sub-paragraph (4), for "or (2)" substitute ", (2) or (2A)".

68 Fees in respect of licences under the 2004 Act

(1) After section 25 of the 2004 Act insert—

"Fees

25A Fees

(1) The Authority may charge a fee in respect of any of the following—
(a) an application for a licence,
(b) the grant or renewal of a licence,
(c) an application for the revocation or variation of a licence, or
(d) the exercise by the Authority of any other function under this Act—
(i) in relation to a licence,
(ii) in relation to premises which are or have been premises to which a licence relates, or
(iii) in relation to premises which, if an application is granted, will be premises to which a licence relates.

(2) The amount of any fee charged by virtue of this section is to be fixed in accordance with a scheme made by the Authority with the approval of the Secretary of State and the Treasury.

(3) Different fees may be fixed for different circumstances.

(4) In fixing the amount of any such fee, the Authority may have regard to the costs incurred by it in exercising its functions under this Act or Part 1 of the Human Tissue and Embryos Act 2007."

(2) In Schedule 3 to the 2004 Act (licences for purposes of section 13)—
(a) in paragraph 2(4)(f), for the words from "at such times" to the end substitute "fees charged under section 25A(1).", and
(b) omit paragraph 13(2).

69 Fees under instruments implementing Community legislation on tissue etc.

Any subordinate legislation made under section 2(2) of the European Communities Act 1972 for the purpose of implementing any of the Directives referred to in section 2 may—
(a) enable the Authority to charge a fee, of an amount fixed in accordance with a scheme made by the Authority with the approval of the Secretary of State and the Treasury, in respect of the exercise by the Authority of any function conferred or imposed by the order, rules, regulations or scheme, and
(b) enable the Authority, in fixing the amount of any such fee, to have regard to the costs incurred by it in exercising its functions under the subordinate legislation in question or under any other enactment.

General

70 Orders and regulations: general provisions

(1) Any power of the Secretary of State to make an order or regulations under this Act is exercisable by statutory instrument.

(2) The power to make an order or regulations under this Act may be exercised—
  (a) either in relation to all cases to which the power extends, or in relation to those cases subject to specified exceptions, or in relation to any specified cases or classes of case, and
  (b) so as to make, as respects the cases in relation to which it is exercised—
    (i) the full provision to which the power extends or any less provision (whether by way of exception or otherwise);
    (ii) the same provision for all cases in relation to which the power is exercised, or different provision as respects the same case or class of case for different purposes;
    (iii) any such provision either unconditionally, or subject to any specified condition.

(3) Any power of the Secretary of State to make an order or regulations under this Act includes power to make such transitional, incidental or supplemental provision as the Secretary of State considers appropriate.

71 Orders and regulations: parliamentary control

(1) Orders and regulations made by the Secretary of State under this Act are subject to annulment in pursuance of a resolution of either House of Parliament.

(2) Subsection (1) does not apply to—
  (a) regulations to which subsection (3) applies,
  (b) an order to which subsection (4) applies, or
  (c) an order under section 77 (commencement).

(3) No regulations under section 61 (parental orders: supplementary provision) may be made unless a draft of the regulations has been laid before, and approved by a resolution of, each House of Parliament.

(4) No order under section 73 (power to make consequential and transitional provision etc) which includes provision made by virtue of subsection (2)(a) or (b) of that section may be made unless a draft of the order has been laid before, and approved by a resolution of, each House of Parliament.

72 Interpretation

In this Act—

"the 1990 Act" means the Human Fertilisation and Embryology Act 1990 (c. 37);

"the 2004 Act" means the Human Tissue Act 2004 (c. 30);

"the Authority" means the Regulatory Authority for Tissue and Embryos;

"subordinate legislation" has the same meaning as in the Interpretation Act 1978 (c. 30).

73 Power to make consequential and transitional provision etc.

(1) The Secretary of State may by order make—

(a) any supplementary, incidental or consequential provision, and

(b) any transitional or saving provision,

that the Secretary of State considers necessary or expedient for the purposes of, in consequence of, or for giving full effect to, any provision of this Act.

(2) An order under this section may—

(a) amend or repeal any Act (including any Act passed in the same Session as this Act) or any Act of the Scottish Parliament;

(b) amend or repeal Northern Ireland legislation;

(c) amend or revoke any subordinate legislation made before the passing of this Act.

(3) An order under this section may provide for any provision of this Act which comes into force before any other provision comes into force to have effect, until that other provision has come into force, with specified modifications.

(4) Before making an order under this section containing provision which would, if included in an Act of the Scottish Parliament, be within the legislative competence of that Parliament, the Secretary of State must consult the Scottish Ministers.

(5) Nothing in this section limits the power under section 70 to include transitional or saving provision in a commencement order under section 77(2).

(6) The amendments that may be made by virtue of subsection (2) are in addition to those that are made by any other provision of this Act.

74 Minor and consequential amendments

Schedule 7 contains consequential amendments.

75 Repeals

Schedule 8 contains repeals.

76 Extent

(1) Subject to the following provisions, this Act extends to England and Wales, Scotland and Northern Ireland.

(2) Any amendment or repeal made by this Act has the same extent as the enactment to which it relates.

77 Commencement

(1) The following provisions of this Act come into force on the day on which this Act is passed—

sections 70 to 73;

section 76, this section and section 78.

(2) The remaining provisions of this Act come into force in accordance with provision made by the Secretary of State by order.

78 Short title

This Act may be cited as the Human Tissue and Embryos Act 2007.

SCHEDULES

SCHEDULE 1

Section 1

THE REGULATORY AUTHORITY FOR TISSUE AND EMBRYOS

Status and capacity

1 The Authority is to be a body corporate.

2 The Authority is not to be regarded as the servant or agent of the Crown, or as enjoying any status, privilege or immunity of the Crown; and its property is not to be regarded as property of, or property held on behalf of, the Crown.

3 The Authority has power to do anything which is calculated to facilitate, or is conducive or incidental to, the carrying-out of its functions, but may not borrow money.

Membership

4 (1) The Authority is to consist of—

(a) a Chair appointed by the Secretary of State,

(b) a member appointed by the Scottish Ministers,

(c) a member appointed by the Welsh Ministers,

(d) a member appointed by the relevant Northern Ireland department, and

(e) such number of other members appointed by the Secretary of State as the Secretary of State thinks fit.

(2) A person who has, or has had, a professional interest in any of the regulated activities is disqualified for appointment as Chair of the Authority.

(3) The Secretary of State must exercise the power to appoint members of the Authority under sub-paragraph (1)(e) so as to secure that at all times not less than half of the members of the Authority appointed under any of sub-paragraph (1)(b) to (e) are persons who do not have, and have not had, a professional interest in any of the regulated activities.

Disqualification on grounds of insolvency or criminal conviction

5 (1) A person ("P") is disqualified for being appointed as Chair or other member of the Authority if—

(a) P is the subject of a bankruptcy restrictions order or interim order,

(b) a bankruptcy order has been made against P by a court in Northern Ireland, P's estate has been sequestrated by a court in Scotland or, under the law of Northern Ireland or Scotland, P has made a

composition or arrangement with, or granted a trust deed for, P's creditors, or

(c) in the last five years P has been convicted in the United Kingdom, the Channel Islands or the Isle of Man of an offence and has had a qualifying sentence passed on P.

(2) Where P is disqualified under sub-paragraph (1)(b) because a bankruptcy order has been made against P or P's estate has been sequestrated, the disqualification ceases—

(a) on P obtaining a discharge, or

(b) if the bankruptcy order is annulled or the sequestration of P's estate is recalled or reduced, on the date of that event.

(3) Where P is disqualified under sub-paragraph (1)(b) because of P having made a composition or arrangement with, or granted a trust deed for, P's creditors, the disqualification ceases—

(a) at the end of the period of five years beginning with the date on which the terms of the deed of composition or arrangement or trust deed are fulfilled, or

(b) if, before then, P pays P's debts in full, on the date on which the payment is completed.

(4) For the purposes of sub-paragraph (1)(c), the date of conviction is to be taken to be the ordinary date on which the period allowed for making an appeal or application expires or, if an appeal or application is made, the date on which the appeal or application is finally disposed of or abandoned or fails by reason of its non-prosecution.

(5) In sub-paragraph (1)(c), the reference to a qualifying sentence is to a sentence of imprisonment for a period of not less than three months (whether suspended or not) without the option of a fine.

Tenure of office

6 Subject to paragraphs 7 to 11, the Chair and other members of the Authority hold and vacate office in accordance with the terms of their respective appointments.

7 A person may not be appointed as Chair or other member of the Authority for more than three years at a time.

8 Previous service as Chair or other member of the Authority does not affect a person's eligibility for appointment to either office.

9 (1) A person holding office as Chair or other member of the Authority may resign that office by giving notice in writing to the appointing authority.

(2) In this paragraph "the appointing authority", in relation to a member of the Authority, means the person who appointed the member.

10 A person holding office as Chair or other member of the Authority is to cease to hold that office if the person becomes disqualified for appointment to it.

11 (1) The appointing authority may remove a person from office as Chair or other member of the Authority if the appointing authority is satisfied that the person—

(a) has been absent from meetings of the Authority for 6 consecutive months, or longer, without the permission of the Authority, or

(b) is unable or unfit to carry out the person's functions as Chair or other member.

(2) In this paragraph "the appointing authority", in relation to a member of the Authority, means the person who appointed the member.

Staff

12 The Authority may appoint such staff as it considers appropriate, on such terms and conditions as the Authority may determine.

Proceedings

13 (1) Subject to any provision of this Act, the Authority may regulate its own procedure, and make such arrangements as it thinks appropriate for the discharge of its functions.

(2) The Authority must determine a quorum for its meetings.

(3) At least three-quarters of the members of the Authority must participate in the process by which any determination under sub-paragraph (2) is made.

14 The validity of any proceedings of the Authority is not affected by—

(a) any vacancy in the office of—

(i) Chair, or

(ii) member appointed under paragraph (b), (c) or (d) of paragraph 4(1),

(b) any defect in a person's appointment as Chair or other member, or

(c) the composition for the time being of the membership of the Authority.

Delegation

15 (1) The Authority may delegate a function to a committee, to a member or to staff.

(2) Sub-paragraph (1) has effect subject to any enactment requiring a decision to be taken by the members of the Authority or by a committee consisting of members of the Authority.

Expert advisory panels

16 (1) The Authority may establish expert advisory panels to advise the Authority on matters referred to the panel by the Authority.

(2) The Authority must establish separate expert advisory panels in relation to each of the following three areas—

(a) reproductive medicine and embryo research,

(b) anatomy and pathology, and

(c) blood and transplantation.

(3) The Chair of an expert advisory panel must be a member of the Authority.

(4) The other members of the panel need not be members of the Authority, but must not be staff of the Authority.

(5) The Authority may establish working groups or sub-groups of an expert advisory panel.

Committees

17 (1) The Authority may establish such committees or sub-committees as it thinks fit (whether to advise the Authority or to exercise a function delegated to it by the Authority).

(2) The members of the committees or sub-committees may include persons who are not members of the Authority.

Members' interests

18 (1) The Authority must establish and maintain a system for the declaration and registration of the private interests of its members.

(2) The Authority must publish entries recorded in the register of members' interests.

Remuneration, &c.

19 (1) The Authority may pay to the Chair or any of the other members of the Authority such remuneration as the Secretary of State may determine.

(2) The Authority may pay, or make provision for paying, to or in respect of the Chair or any of the other members of the Authority such pensions, allowances, fees, expenses or gratuities as the Secretary of State may determine.

(3) The Authority may make a payment to a person who ceases to hold office as Chair or other member of the Authority otherwise than on the expiry of the person's term of office if it appears to the Secretary of State that there are special circumstances which make it right for that person to receive compensation.

(4) A payment under sub-paragraph (3) is to be of such amount as the Secretary of State may determine.

20 (1) The Authority may pay to or in respect of any member of—

(a) a committee or sub-committee of the Authority, or

(b) an expert advisory panel established under paragraph 16 or a working group or sub-group of such a panel,

such allowances, fees or expenses as the Authority may, with the approval of the Secretary of State, determine.

(2) This paragraph so far as relating to the payment of fees does not apply in relation to a person who is a member of the staff of the Authority.

Finance

21 The Secretary of State may out of money provided by Parliament make payments to the Authority of such amounts, at such times and on such conditions (if any) as the Secretary of State considers appropriate.

Accounts and audit

22 (1) The Authority must keep proper accounts and proper records in relation to its accounts.

(2) The Authority must prepare a statement of its accounts in respect of each of its financial years.

(3) Any such statement of accounts must comply with any directions given by the Secretary of State with the approval of the Treasury as to—

(a) the information to be contained in it,

(b) the manner in which that information is to be presented, and

(c) the methods and principles according to which the statement is to be prepared.

(4) The Authority must send a copy of each statement of accounts required by sub-paragraph (2) to—

(a) the Secretary of State,

(b) the Welsh Ministers,

(c) the Scottish Ministers,

(d) the relevant Northern Ireland department, and

(e) the Comptroller and Auditor General,

before the end of such period after the end of the financial year to which the statement relates as the Secretary of State may specify by notice given to the Authority.

(5) The Welsh Ministers must lay before the National Assembly for Wales each statement of accounts received by them under sub-paragraph (4).

(6) The Scottish Ministers must lay before the Scottish Parliament each statement of accounts received by them under sub-paragraph (4).

(7) The relevant Northern Ireland department must lay before the Northern Ireland Assembly each statement of accounts received by it under sub-paragraph (4).

(8) The Comptroller and Auditor General ("the Comptroller") must—

(a) examine, certify and report on each statement of accounts received by the Comptroller under sub-paragraph (4), and

(b) lay a copy of each such statement of accounts, and of the Comptroller's report on it, before each House of Parliament.

(9) The power under sub-paragraph (3) to give directions includes power to vary or revoke directions given in the previous exercise of the power.

(10) In this paragraph "financial year" means—

(a) the initial period as defined by section 9(2), and

(b) each successive period of 12 months ending with 31 March.

Application of Statutory Instruments Act 1946

23 The Statutory Instruments Act 1946 (c. 36) applies to any power to make orders or regulations conferred by an Act on the Authority as if the Authority were a Minister of the Crown.

Superannuation

24 In Schedule 1 to the Superannuation Act 1972 (c. 11) (which lists the kinds of employment etc. referred to in section 1 of that Act), after the entry relating to employment by the Pensions Ombudsman insert—

"Employment by the Regulatory Authority for Tissue and Embryos."

Public records

25 In Schedule 1 to the Public Records Act 1958 (c. 51) (definition of public records), in Part 2 of the Table at the end of paragraph 3, insert at the appropriate place the following entry—

"Regulatory Authority for Tissue and Embryos, except in respect of the register kept by it under section 31 of the Human Fertilisation and Embryology Act 1990 and records containing information falling within subsection (2) of that section."

Investigation by Parliamentary Commissioner

26 In Schedule 2 to the Parliamentary Commissioner Act 1967 (c. 13) (departments and authorities subject to investigation), insert at the appropriate place the following entry—

"Regulatory Authority for Tissue and Embryos."

House of Commons disqualification

27 In Part 2 of Schedule 1 to the House of Commons Disqualification Act 1975 (c. 24) (bodies of which all members are disqualified), insert at the appropriate place the following entry—

"Regulatory Authority for Tissue and Embryos."

Northern Ireland Assembly disqualification

28 In Part 2 of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 (c. 25) (bodies of which all members are disqualified), insert at the appropriate place the following entry—

"Regulatory Authority for Tissue and Embryos."

National Assembly for Wales disqualification

29 In Part 1 of Schedule 1 to the National Assembly for Wales (Disqualification) Order 2003 (SI 2003/437) (bodies of which all members are disqualified), insert at the appropriate place the following entry—

"Regulatory Authority for Tissue and Embryos."

Freedom of information

30 In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (c. 36) (public authorities), insert at the appropriate place the following entry—

"Regulatory Authority for Tissue and Embryos."

SCHEDULE 2

Section 18

ACTIVITIES THAT MAY BE LICENSED UNDER 1990 ACT

Introductory

1 Schedule 2 to the 1990 Act (activities for which licences may be granted) is amended as follows.

Licences for treatment

2 (1) Paragraph 1 (licences for treatment) is amended as follows.

(2) In sub-paragraph (1)—

(a) after paragraph (c) insert—

"(ca) using embryos for the purpose of training persons in the testing of embryos,"

(b) in paragraph (d), omit the words from "or" onwards,

(c) in paragraph (e), for "embryo" substitute "permitted embryo",

(d) in paragraph (g), after "practices" insert ", apart from practices falling within section 4A(2),".

(3) For sub-paragraph (4) substitute—

"(4) A licence under this paragraph cannot authorise altering the nuclear or mitochondrial DNA of a cell while it forms part of an embryo, except for the purpose of creating something that will by virtue of regulations under section 3ZA(5) be a permitted embryo."

(4) After sub-paragraph (4) insert—

"(4A) A licence under this paragraph cannot authorise the use of embryos for the purpose mentioned in sub-paragraph (1)(ca) unless the Authority is satisfied that the proposed use of embryos is necessary for that purpose."

(5) At the end insert—

"(6) In this paragraph, references to a permitted embryo are to be read in accordance with section 3ZA."

Embryo testing and sex selection

3 After paragraph 1 insert—

"Embryo testing

1ZA (1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes—

(a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality

or any other gene, chromosome or mitochondrion abnormality,

(c) in a case where there is a particular risk that the embryo may have an abnormality affecting the X or Y chromosomes, establishing the sex of the embryo,

(d) in a case where a person ("the sibling") who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a life-threatening medical condition which could be treated by umbilical cord blood stem cells, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and

(e) in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.

(2) A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) or (c) unless the Authority is satisfied—

(a) in relation to the abnormality of which there is a particular risk, and

(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),

that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

(3) In considering under paragraph 1(3) whether the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) or (c) is necessary or desirable for the purpose of providing treatment services, the Authority must have regard to—

(a) the extent to which the disability, illness or other medical condition involves intellectual, physical, emotional or psychological impairment, having regard to the treatment available,

(b) where relevant, the likely age of onset of the disability, illness or other medical condition in question,

(c) where any illness or other medical condition is a progressive disorder, the likely rate of degeneration,

(d) the proportion of those having the abnormality in question who are likely to be affected, and

(e) the reliability of the test to be applied.

(4) In considering under paragraph 1(3) whether the testing of embryos for the purpose mentioned in subsection (1)(d) is necessary or desirable for the purpose of providing treatment services, the Authority must have regard to—

(a) any alternative sources of tissue which are or may become available for treating the sibling, and

(b) the likely long-term effect of awareness of the testing on any child who results from an embryo that was subject to testing.

Sex selection

1ZB (1) A licence under paragraph 1 cannot authorise any practice designed to secure that any resulting child will be of one sex rather than the other.

(2) Sub-paragraph (1) does not prevent the authorisation of any testing of embryos that is capable of being authorised under paragraph 1ZA.

(3) Sub-paragraph (1) does not prevent the authorisation of any other practices designed to secure that any resulting child will be of one sex rather than the other in a case where—

(a) there is a particular risk that a woman will give birth to a child with an abnormality affecting the X or Y chromosomes, and

(b) the Authority is satisfied that the abnormality involves a significant risk falling within paragraph 1ZA(2).

(4) In considering under paragraph 1(3) whether any practice designed to secure that result in a case falling within sub-paragraph (3) is necessary or desirable for the purpose of providing treatment services, the Authority must have regard to the matters specified in paragraph 1ZA(3)(a) to (e).

Power to amend paragraphs 1ZA and 1ZB

1ZC (1) Regulations may amend paragraph 1ZA (embryo testing).

(2) Regulations under this paragraph which amend paragraph 1ZA may make any amendment of sub-paragraphs (2) to (4) of paragraph 1ZB (sex selection) which appears to the Secretary of State to be necessary or expedient in consequence of the amendment of paragraph 1ZA.

(3) Regulations under this paragraph may not enable the authorisation of—

(a) the testing of embryos for the purpose of establishing their sex, or

(b) other practices falling within paragraph 1ZB(1),

except on grounds relating to the health of any resulting child."

Licences for non-medical fertility services

4 In paragraph 1A (licences for non-medical fertility services) after sub-paragraph (1) insert—

"(1A) A licence under this paragraph cannot authorise the procurement or distribution of sperm to which there has been applied any process designed to secure that any resulting child will be of one sex rather than the other."

Licences for storage

5 In paragraph 2 (licences for storage), after sub-paragraph (1) insert—

"(1A) If regulations so provide, a licence under this paragraph or paragraph 3 may authorise the storage of inter-species embryos (whether or not the licence also authorises the storage of gametes or embryos or both)."

Licences for research

6 For paragraph 3 substitute—

"Licences for research

3 (1) A licence under this paragraph may authorise any of the following—

(a) bringing about the creation of embryos *in vitro*, and

(b) keeping or using embryos,

for the purpose of a project of research specified in the licence.

(2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.

(3) If regulations so provide, a licence under this paragraph may authorise other activities which fall within section 4A(2) (activities involving genetic material of animal origin) for the purpose of a project of research specified in the licence.

(4) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or inter-species embryos is necessary for the purposes of the research.

(5) Subject to the provisions of this Act, a licence under this section may be granted subject to such conditions as may be specified in the licence.

(6) A licence under this section may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.

(7) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.

(8) This paragraph has effect subject to paragraph 3A.

Purposes for which activities may be licensed under paragraph 3

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority—

(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) ("the principal purposes"),

(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or

(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are—

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,

(f) developing more effective techniques of contraception,

(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or

(h) increasing knowledge about the development of embryos."

SCHEDULE 3

Section 20

CONSENT TO USE AND STORAGE OF GAMETES OR EMBRYOS

Introductory

1 Schedule 3 to the 1990 Act (giving of consent to use and storage of gametes or embryos) is amended as follows.

General requirements as to consent

2 For paragraph 1 substitute—

"1 (1) A consent under this Schedule, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing and, subject to sub-paragraph (2), must be signed by the person giving it.

(2) A consent under this Schedule by a person who is unable to sign because of illness, injury or physical disability ("the incapacitated person"), and any notice under paragraph 4 by such a person varying or withdrawing a consent under this Schedule, is to be taken to comply with the requirement of sub-paragraph (1) as to signature if it is signed at the direction of the incapacitated person, in the presence of the incapacitated person and in the presence of at least one witness who attests the signature.

(3) In this Schedule "effective consent" means a consent under this Schedule which has not been withdrawn."

Consent to use of embryo for training purposes

3 In paragraph 2, in sub-paragraph (1), for the "or" at the end of paragraph (b) substitute—

"(ba) use for the purpose of training persons in the testing of embryos, or".

Variation and withdrawal of consents

4 In paragraph 4 (variation and withdrawal of consent), in sub-paragraph (2), for the "or" at the end of paragraph (a) substitute—

"(aa) in training persons in the testing of embryos, or".

Withdrawal of consent to storage: notification of other gamete donor

5 After paragraph 4 insert—

"4A Where, while an embryo the creation of which was brought about *in vitro* is in storage but before it is used as mentioned in paragraph 4(2), one of the persons whose gametes were used to bring about the creation of the embryo ("the first gamete donor") gives the person keeping the embryo notice withdrawing the consent of the first gamete donor to the storage of the embryo—

(a) the person keeping the embryo must as soon as possible take all reasonable steps to notify the other person whose gametes were used to bring about the creation of the embryo ("the second gamete donor") of the withdrawal of consent by the first gamete donor, and

(b) storage of the embryo remains lawful until—

(i) the end of the period of 12 months beginning with the day on which notice was received from the first gamete donor, or

(ii) if, before the end of that period, the person keeping the embryo receives notice from the second gamete donor withdrawing the consent of the second gamete donor to the storage of the embryo, the time when that notice is received."

Application of consent provisions to non-medical fertility services

6 In paragraph 5 (use of gametes for treatment of others), in sub-paragraph (1), after "treatment services" insert "or non-medical fertility services".

No advance consent to use of embryo for training purposes under licence for treatment

7 In paragraph 6 (*in vitro* fertilisation and subsequent use of embryo) in sub-paragraph (1), for "paragraph 2(1)" substitute "paragraph 2(1)(a), (b) and (c)".

Cases where consent not required for storage

8 In paragraph 8 (storage of gametes and embryos) after sub-paragraph (3)

insert—

"(4) Sub-paragraph (1) has effect subject to paragraphs 9 and 10; and sub-paragraph (2) has effect subject to paragraph 4A(b)."

9 After paragraph 8 insert—

"Cases where consent not required for storage

9 (1) The gametes of a person ("the child donor") may be kept in storage without the child donor's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by the child donor before the child donor attains the age of 18 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the child donor is expected to undergo medical treatment and that in the opinion of the registered medical practitioner—

(a) the treatment is likely to cause a significant impairment of the fertility of the child donor, and

(b) the storage of the gametes is in the best interests of the child donor.

(4) Condition C is that, at the time when the gametes are first stored, either—

(a) the child donor has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) the child donor has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.

(5) Condition D is that the child donor has not, since becoming competent to deal with the issue of consent to the storage of the gametes—

(a) given consent under this Schedule to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that he does not wish them to continue to be stored.

10 (1) The gametes of a person ("the patient") may be kept in storage without the patient's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by the patient after the patient has attained the age of 16 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the patient is expected to undergo medical treatment and that in the opinion of the registered medical practitioner—

(a) the treatment is likely to cause a significant impairment of the patient's fertility,

(b) the patient lacks capacity to consent to the storage of the gametes,
(c) the patient is likely to regain that capacity, and
(d) the storage of the gametes is in the patient's best interests.

(4) Condition C is that, at the time when the gametes are first stored, the patient lacks capacity to consent to their storage.

(5) Condition D is that the patient has not, after regaining capacity to give a consent under this Schedule—
(a) given consent to the storage of the gametes, or
(b) given written notice to the person keeping the gametes that the patient does not wish them to continue to be stored.

11 References in paragraphs 9 and 10 to capacity to consent are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

12 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death."

Consent to use of gametes for creation of inter-species embryos

10 After paragraph 12 insert—

"Creation of inter-species embryo and subsequent use of embryo

13 (1) If by virtue of regulations under sub-paragraph (3) of paragraph 3 of Schedule 2 a licence under that paragraph authorises the carrying out of any activity falling within section 4A(2) but not within sub-paragraph (2) of that paragraph, a person's gametes must not be used for the purpose of that activity unless there is an effective consent by that person complying with any conditions prescribed by regulations.

(2) An inter-species embryo must not be used for the purposes of a project of research unless there is an effective consent by any person whose gametes were used to bring about the creation of the embryo to the use of the inter-species embryo for that purpose.

14 An inter-species embryo must not be kept in storage unless there is an effective consent by any person whose gametes were used to bring about the creation of the inter-species embryo and the inter-species embryo is stored in accordance with the consent."

SCHEDULE 4

Section 21

SCHEDULE INSERTED IN 1990 ACT AS SCHEDULE 3ZA

"SCHEDULE 3ZA

CIRCUMSTANCES IN WHICH OFFER OF COUNSELLING REQUIRED AS CONDITION OF LICENCE FOR TREATMENT

PART 1

KINDS OF TREATMENT IN RELATION TO WHICH COUNSELLING MUST BE OFFERED

1 The treatment services involve the use of the gametes of any person and that person's consent is required under paragraph 5 of Schedule 3 for the use in question.

2 The treatment services involve the use of any embryo the creation of which was brought about *in vitro*.

3 The treatment services involve the use of an embryo taken from a woman and the consent of the woman from whom the embryo was taken was required under paragraph 7 of Schedule 3 for the use in question.

PART 2

EVENTS IN CONNECTION WITH WHICH COUNSELLING MUST BE OFFERED

4 A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 43 of the Human Tissue and Embryos Act 2007 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.

5 The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

6 A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 50 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.

7 The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection."

SCHEDULE 5

Section 36

SCHEDULE INSERTED IN 1990 ACT AS SCHEDULE 3B

"SCHEDULE 3B

POWERS OF INSPECTION, ENTRY, SEARCH AND SEIZURE

Inspection of statutory records

1 (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.

(2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—

(a) in a visible and legible form, or

(b) in a form from which they can be readily produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

Entry and inspection of premises

2 (1) A duly authorised person may at any reasonable time enter and inspect any premises to which a licence relates or relevant third party premises.

(2) The power in sub-paragraph (1) is exercisable for purposes of the Authority's functions in relation to licences and third party agreements.

Entry and search in connection with suspected offence

3 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—

(a) that an offence under this Act is being, or has been committed on any premises, and

(b) that any of the conditions in sub-paragraph (2) is met in relation to the premises,

the justice of the peace may by signed warrant authorise a duly authorised person, together with any constables, to enter the premises, if need be by force, and search them.

(2) The conditions referred to are—

(a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;

(b) that the premises are unoccupied;

(c) that the occupier is temporarily absent;

(d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) In relation to Scotland, any reference in sub-paragraph (1) to a justice of the peace includes a reference to a sheriff.

Execution of warrants

4 (1) Entry and search under a warrant under paragraph 3 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.

(2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—

(a) produce the warrant to the occupier, and

(b) give the occupier—

(i) a copy of the warrant, and

(ii) an appropriate statement.

(4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—

(a) produce the warrant to that other person,

(b) give that other person—

(i) a copy of the warrant, and

(ii) an appropriate statement, and

(c) leave a copy of the warrant in a prominent place on the premises.

(5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.

(6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

(7) Where the premises in relation to which a warrant under paragraph 3 is executed are unoccupied or the occupier is temporarily absent, the person executing the warrant shall when leaving the premises, leave them as effectively secured as the person found them.

Seizure in the course of inspection or search

5 (1) A duly authorised person entering and inspecting premises under paragraph 2 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for—

(a) the purposes of the Authority's functions relating to the grant, revocation, variation or suspension of licences, or

(b) the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction.

(2) A duly authorised person entering or searching premises under a warrant under paragraph 3 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Act.

(3) Where a person has power under sub-paragraph (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving that thing or preventing interference with it.

(4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of sub-paragraph (1) or (2) a person ("P") seizes anything, P shall leave on the premises from which the thing was seized a statement giving particulars of what P has seized and stating that P has seized it.

Powers: supplementary

6 (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(2) Power under this Schedule to inspect or search any premises includes, in particular—

(a) power to inspect any equipment found on the premises,

(b) power to inspect and take copies of any records found on the premises, and

(c) in the case of premises to which a licence relates or premises which are relevant third party premises in relation to a licence, power to observe the carrying-on on the premises of the licensed activity.

(3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

7 (1) A person's right to exercise a power under this Schedule is subject to production of evidence of the person's entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall—

(a) prepare a written report of the inspection and search, and

(b) if requested to do so by the appropriate person, give the appropriate person a copy of the report.

(3) In sub-paragraph (2), the "appropriate person" means—

(a) in relation to premises to which a licence relates, the person responsible, or

(b) in relation to any other premises, the occupier.

Enforcement

8 A person who—

(a) fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 6(3), or

(b) intentionally obstructs the exercise of any right under this Schedule,

is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Interpretation

9 In this Schedule—

(a) "duly authorised person", in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision, and

(b) "licensed activity", in relation to a licence, means the activity which the licence authorises to be carried on."

SCHEDULE 6

Section 62

AMENDMENTS RELATING TO PARENTHOOD IN CASES INVOLVING ASSISTED REPRODUCTION

PART 1

GENERAL

Births and Deaths Registration Act 1953 (c. 20)

1 In section 1 of the Births and Deaths Registration Act 1953 (particulars of births to be registered) after subsection (2) insert—

"(3) In the case of a child who has a parent by virtue of section 48 or 49 of the Human Tissue and Embryos Act 2007, the reference in subsection (2)(a) to the father of the child is to be read as a reference to the woman who is the parent by virtue of that section."

2 In section 2 of the Births and Deaths Registration Act 1953 (information concerning birth to be given to registrar within 42 days), renumber the existing provision as subsection (1) of the section and at the end insert—

"(2) In the case of a child who has a parent by virtue of section 48 or 49 of the Human Tissue and Embryos Act 2007, the references in subsection (1) to the father of the child are to be read as references to the woman who is the parent by virtue of that section."

3 (1) Section 10 of the Births and Deaths Registration Act 1953 (registration of father where parents not married) is amended as follows.

(2) For the heading to the section substitute "Registration of father where parents not married or of female second parent where parents not civil partners".

(3) After subsection (1A) insert—

"(1B) Notwithstanding anything in the foregoing provisions of this Act and subject to section 10ZA of this Act, in relation to a child to whom section 1(3) of the Family Law Reform Act 1987 does not apply no woman shall as parent of the child by virtue of section 49 of the Human Tissue and Embryos Act 2007 be required to give information concerning the birth of the child, and the registrar shall not enter in the register the name of any woman as a parent of the child by virtue of that section except—

(a) at the joint request of the mother and the person stating herself to be the other parent (in which case that person shall sign the register together with the mother); or

(b) at the request of the mother on production of—

(i) a declaration in the prescribed form made by the mother stating that the person to be registered ("the woman concerned") is a parent of the child by virtue of section 49 of the Human Tissue and Embryos Act 2007; and

(ii) a statutory declaration made by the woman concerned stating herself to be a parent of the child by virtue of by virtue of section 49 of that Act;

(c) at the request of the woman concerned on production of—

(i) a declaration in the prescribed form made by the woman concerned stating herself to be a parent of the child by virtue of section 49 of the Human Tissue and Embryos Act 2007; and

(ii) a statutory declaration made by the mother stating that the woman concerned is a parent of the child by virtue of section 49 of that Act; or

(d) at the request of the mother or the woman concerned on production of—

(i) a copy of any agreement made between them under section 4ZA(1)(b) of the Children Act 1989 in relation to the child; and

(ii) a declaration in the prescribed form by the person making the request stating that the agreement was made in compliance with section 4ZA of that Act and

has not been brought to an end by an order of a court; or

(e) at the request of the mother or the woman concerned on production of—

(i) a certified copy of an order under section 4ZA of the Children Act 1989 giving the woman concerned parental responsibility for the child; and

(ii) a declaration in the prescribed form by the person making the request stating that the order has not been brought to an end by an order of a court; or

(f) at the request of the mother or the woman concerned on production of—

(i) a certified copy of an order under paragraph 1 of Schedule 1 to the Children Act 1989 which requires that person to make any financial provision for the child and which is not an order falling within paragraph 4(3) of that Schedule; and

(ii) a declaration in the prescribed form by the person making the request stating that the order has not been discharged by an order of a court."

(4) After subsection (2) insert—

"(2A) Where, in the case of a child to whom section 1(3) of the Family Law Reform Act 1987 does not apply, a person stating herself to be a parent of the child by virtue of section 49 of the Human Tissue and Embryos Act 2007 makes a request to the registrar in accordance with any of paragraphs (c) to (f) of subsection (1B)—

(a) she shall be treated as a qualified informant concerning the birth of the child for the purposes of this Act; and

(b) the giving of information concerning the birth of the child by that person and the signing of the register by her in the presence of the registrar shall act as a discharge of any duty of any other qualified informant under section 2."

4 For section 10ZA of the Births and Deaths Registration Act 1953 substitute—

"10ZA Registration of father or female second parent by virtue of certain provisions of Human Tissue and Embryos Act 2007

(1) Notwithstanding anything in the foregoing provisions of this Act, the registrar shall not enter in the register—

(a) as the father of a child, the name of a man who is to be treated for that purpose as the father of the child by virtue of section 45(1) or 46(1) or (2) of the Human Tissue and Embryos Act 2007 (circumstances in which man to be treated as father of child for purposes of registration of birth where fertility treatment undertaken after his death), or

(b) as a parent of the child, the name of a woman who is to be treated for that purpose as a parent of the child by virtue of section 52(1) or (2) of that Act (circumstances in which woman to be treated as parent of child for purposes of registration of birth where fertility treatment undertaken after her death),

unless the condition in subsection (2) below is satisfied.

(2) The condition in this subsection is satisfied if—

(a) the mother requests the registrar to make such an entry in the register and produces the relevant documents, and

(b) in the case of the death or inability of the mother, the relevant documents are produced by some other person who is a qualified informant.

(3) In this section "the relevant documents" means—

(a) the consent in writing and election mentioned in section 45(1), 46(1) or (2) or 52(1) or (2) (as the case requires) of the Human Tissue and Embryos Act 2007, and

(b) a certificate of a registered medical practitioner as to the medical facts concerned; and

(c) such other documentary evidence (if any) as the registrar considers appropriate."

5 (1) Section 10A of the Births and Deaths Registration Act 1953 is amended as follows.

(2) For the heading to the section substitute "Re-registration where parents neither married nor civil partners".

(3) In subsection (1)—

(a) after "as the father of the child" insert "(or as a parent of the child by virtue of section 48 or 49 of the Human Tissue and Embryos Act 2007)", and

(b) for paragraph (ff) substitute—

"(ff) in the case of a man who is to be treated as the father of the child by virtue of section 45(1) or 46(1) or (2) of the Human Tissue and Embryos Act 2007, if the condition in section 10ZA(2) of this Act is satisfied, or".

(4) After subsection (1A) insert—

"(1B) Where there has been registered under this Act the birth of a child to whom section 1(3) of the Family Law Reform Act 1987 does not apply, but no person has been registered as a parent of the child by virtue of section 48, 49 or 52(1) or (2) of the Human Tissue and Embryos Act 2007 (or as the father of the child), the registrar shall re-register the birth so as to show a woman ("the woman concerned") as a parent of the child by virtue of section 49 or 52(1) or (2) of that Act—

(a) at the joint request of the mother and the woman concerned; or

(b) at the request of the mother on production of—

(i) a declaration in the prescribed form made by the mother stating that the woman concerned is a parent of the child by virtue of section 49 of the Human Tissue and Embryos Act 2007; and

(ii) a statutory declaration made by the woman concerned stating herself to be a parent of the child by virtue of by virtue of section 49 of that Act;

(c) at the request of the woman concerned on production of—

(i) a declaration in the prescribed form made by the woman concerned stating herself to be a parent of the child by virtue of section 49 of the Human Tissue and Embryos Act 2007; and

(ii) a statutory declaration made by the mother stating that the woman concerned is a parent of the child by virtue of section 49 of that Act; or

(d) at the request of the mother or the woman concerned on production of—

(i) a copy of an agreement made between them under section 4ZA(1)(b) of the Children Act 1989 in relation to the child; and

(ii) a declaration in the prescribed form by the person making the request stating that the agreement was made in compliance with section 4ZA of that Act and has not been brought to an end by an order of a court; or

(e) at the request of the mother or the woman concerned on production of—

(i) a certified copy of an order under section 4ZA of the Children Act 1989 giving the woman concerned parental responsibility for the child; and

(ii) a declaration in the prescribed form by the person making the request stating that the order has not been brought to an end by an order of a court; or

(f) at the request of the mother or the woman concerned on production of—

(i) a certified copy of an order under paragraph 1 of Schedule 1 to the Children Act 1989 which requires that person to make any financial provision for the child and which is not an order falling within paragraph 4(3) of that Schedule; and

(ii) a declaration in the prescribed form by the person making the request stating that the order has not been discharged by an order of a court; or

(g) in the case of a woman who is to be treated as a parent of the child by virtue of section 52(1) or (2) of the Human Tissue and Embryos Act 2007, if the condition in section 10ZA(2) of this Act is satisfied."

(5) In subsection (2), for paragraphs (b) to (c) substitute—

"(b) in the case of any of the following requests—

(i) a request under subsection (1)(a) or (b) or subsection (1B)(a) or (b),

(ii) a request under subsection (1)(d), (e), (f) or (g) or subsection (1B)(d), (e) or (f) made by the mother of the child,

the mother shall also sign the register;

(bb) in a case within subsection (1)(ff) or (1B)(g), the mother or (as the case may be) the qualified informant shall also sign the register;

(c) in the case of a request made under subsection (1)(a) or (c) or a request made under subsection (1)(d), (e), (f) or (g) by the

person requesting to be registered as the father of the child, that person shall also sign the register;

(cc) in the case of a request made under subsection (1B)(a) or (c) or a request made under subsection (1B)(d), (e) or (f) by a woman requesting to be registered as a parent of the child by virtue of by virtue of section 49 of the Human Tissue and Embryos Act 2007, that woman shall also sign the register; and".

6 In section 13 of the Births and Deaths Registration Act 1953 (registration of name of child or alteration of name) after subsection (1) insert—

"(1ZA) In the case of a child who has a parent by virtue of section 48 or 49 of the Human Tissue and Embryos Act 2007, the reference in subsection (1)(b) to the father of the child is to be read as a reference to the woman who is a parent by virtue of that section."

7 (1) Section 14 of the Births and Deaths Registration Act 1953 (re-registration of births of legitimated persons) is amended as follows.

(2) In subsection (1), in the proviso—

(a) in paragraph (a), after "legitimated person" insert ", or to be the parent of the legitimated person by virtue of section 49 of the Human Tissue and Embryos Act 2007,", and

(b) in paragraph (b), after "the paternity of the legitimated person" insert "(or, as the case may be, the parentage of the legitimated person by virtue of section 49 of that Act),".

(3) In subsection (2)—

(a) after "the marriage of his parents" insert "or on their becoming civil partners of each other", and

(b) after "the date of the marriage" insert "or of the formation of the civil partnership".

Registration of Births, Deaths and Marriages (Special Provisions) Act 1957 (c. 58)

8 At the end of section 5 of the Registration of Births, Deaths and Marriages (Special Provisions) Act 1957 insert—

"(3) In relation to a person who has a parent by virtue of section 49 of the Human Tissue and Embryos Act 2007—

(a) any reference to the person's father is a reference to the woman who is a parent by virtue of that section,

(b) the reference in subsection (1) to the subsequent marriage of the person's parents is a reference to their subsequent formation of a civil partnership, and

(c) the reference in that subsection to paternity is a reference to parentage by virtue of section 49."

Congenital Disabilities (Civil Liability) Act 1976 (c. 28)

9 In section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled), after subsection (4) insert—

"(4A) In the case of a child who has a parent by virtue of section 48 or 49 of the Human Tissue and Embryos Act 2007, the reference in subsection

(4) to the father of the child includes a reference to the woman who is the parent by virtue of the section in question."

10 In section 4 of the Congenital Disabilities (Civil Liability) Act 1976 (interpretation and other supplementary provision) at the end of subsection (4A) insert "or sections 39 to 53 of the Human Tissue and Embryos Act 2007."

Legitimacy Act 1976 (c. 31)

11 After section 2 of the Legitimacy Act 1976 insert—

"2A Legitimation by subsequent civil partnership of parents

Subject to the following provisions of this Act, where—

(a) a person ("the child") has a parent ("the female parent") by virtue of section 49 of the Human Tissue and Embryos Act 2007 (treatment provided to woman who agrees that second woman to be parent),

(b) at the time of the person's birth, the female parent and the child's mother are not civil partners of each other,

(c) the female parent and the child's mother subsequently enter into a civil partnership,

(d) the female parent is at the date of the civil partnership domiciled in England and Wales,

the civil partnership shall render the child, if living, legitimate from the date of the civil partnership."

12 In section 9 of the Legitimacy Act 1976 (re-registration of birth of legitimated persons), in subsections (1) and (3), after "marriage" insert "or civil partnership".

13 In section 10 of the Legitimacy Act 1976 (interpretation), in the definition of "legitimated person", in paragraph (a), after "section 2" insert ", 2A".

Supreme Court Act 1981 (c. 54)

14 In Schedule 1 to the Supreme Court Act 1981 (distribution of business in High Court) in paragraph 3(f) for sub-paragraph (iv) substitute—

"(iv) section 60 of the Human Tissue and Embryos Act 2007;".

British Nationality Act 1981 (c. 61)

15 In section 50 of the British Nationality Act 1981 (interpretation) in subsection (9A) (a child's father) for paragraphs (b) and (c) substitute—

"(b) where a person is treated as the father of the child under section 28 of the Human Fertilisation and Embryology Act 1990 or section 41 or 42 of the Human Tissue and Embryos Act 2007, that person,

(ba) where a person is treated as a parent of the child under section 48 or 49 of the Human Tissue and Embryos Act 2007, that person, or

(c) where none of paragraphs (a) to (ba) applies, a person who satisfies prescribed requirements as to proof of paternity."

Family Law Act 1986 (c. 55)

16 In section 56 of the Family Law Act 1986 (declarations of parentage, legitimacy or legitimation), in subsection (5)(a), after "section 2" insert "or 2A".

Family Law Reform Act 1987 (c. 42)

17 (1) Section 1 of the Family Law Reform Act 1987 (general principle) is amended as follows.

(2) In subsection (3) (children whose father and mother are to be taken to have been married to each other at the time of the child's birth) after paragraph (b) insert—

"(ba) has a parent by virtue of section 48 of the Human Tissue and Embryos Act 2007 (which relates treatment provided to a woman who is at the time of treatment a party to a civil partnership or, in certain circumstances, a void civil partnership);

(bb) has a parent by virtue of section 49 of that Act (which relates to treatment provided to woman who agrees that second woman to be parent) who—

(i) is the civil partner of the child's mother at the time of the child's birth, or

(ii) was the civil partner of the child's mother at any time during the period beginning with the time mentioned in section 49(b) of that Act and ending with the child's birth;".

(3) After subsection (4) insert—

"(5) A child whose parents are parties to a void civil partnership shall, subject to subsection (6), be treated as falling within subsection (3)(bb) if at the time when the parties registered as civil partners of each other both or either of the parties reasonably believed that the civil partnership was valid.

(6) Subsection (5) applies only where the woman who is the parent by virtue of section 49 was domiciled in England and Wales at the time of the birth or, if she died before the birth, was so domiciled immediately before her death.

(7) Subsection (5) applies even though the belief that the civil partnership was valid was due to a mistake as to law.

(8) It shall be presumed for the purposes of subsection (5), unless the contrary is shown, that one of the parties to a void civil partnership reasonably believed at the time of the formation of the civil partnership that the civil partnership was valid."

18 In section 18 of the Family Law Reform Act 1987 (succession on intestacy) after subsection (2) insert—

"(2A) In the case of a person who has a parent by virtue of section 49 of the Human Tissue and Embryos Act 2007 (treatment provided to woman who agrees that second woman to be parent), the second and third references in subsection (2) to the person's father are to be read

as references to the woman who is the person's parent by virtue of that section."

Children Act 1989 (c. 41)

19 (1) Section 2 of the Children Act 1989 (parental responsibility for children) is amended as follows.

(2) After subsection (1) insert—

"(1A) Where a child—

(a) has a parent by virtue of section 48 of the Human Tissue and Embryos Act 2007, or

(b) has a parent by virtue of section 49 of that Act and is a person to whom section 1(3) of the Family Law Reform Act 1987 applies,

the child's mother and the other parent shall each have parental responsibility for the child."

(3) After subsection (2) insert—

"(2A) Where a child has a parent by virtue of section 49 of the Human Tissue and Embryos Act 2007 and is not a person to whom section 1(3) of the Family Law Reform Act 1987 applies—

(a) the mother shall have parental responsibility for the child;

(b) the other parent shall have parental responsibility for the child if she has acquired it (and has not ceased to have it) in accordance with the provisions of this Act."

20 After section 4 of the Children Act 1989 insert—

"4ZA Acquisition of parental responsibility by second female parent

(1) Where a child has a parent by virtue of section 49 of the Human Tissue and Embryos Act 2007 and is not a person to whom section 1(3) of the Family Law Reform Act 1987 applies, that parent shall acquire parental responsibility for the child if—

(a) she becomes registered as the child's parent under any of the enactments specified in subsection (2);

(b) she and the child's mother make an agreement providing for her to have parental responsibility for the child; or

(c) the court, on her application, orders that she shall have parental responsibility for the child.

(2) The enactments referred to in subsection (1)(a) are—

(a) paragraphs (a), (b) and (c) of section 10(1B) and of section 10A(1B) of the Births and Deaths Registration Act 1953,

(b) section 18B of the Registration of Births, Deaths and Marriages (Scotland) Act 1965, and

(c) [registration provisions for Northern Ireland].

(3) The Secretary of State may by order amend subsection (2) so as to add further enactments to the list in that subsection.

(4) An agreement under subsection (1)(b) is also a "parental responsibility agreement", and section 4(2) applies in relation to such

an agreement as it applies in relation to parental responsibility agreements under section 4.

(5) A person who has acquired parental responsibility under subsection (1) shall cease to have that responsibility only if the court so orders.

(6) The court may make an order under subsection (5) on the application—

(a) of any person who has parental responsibility for the child; or

(b) with the leave of the court, of the child himself,

subject in the case of parental responsibility acquired under subsection (1)(c), to section 12(4).

(7) The court may only grant leave under subsection (6)(b) if it is satisfied that the child has sufficient understanding to make the proposed application."

21 (1) Section 12 of the Children Act 1989 (residence orders and parental responsibility) is amended as follows.

(2) After subsection (1) insert—

"(1A) Where the court makes a residence order in favour of a person who is a parent of the child by virtue of section 49 of the Human Tissue and Embryos Act 2007 it shall, if that person would not otherwise have parental responsibility for the child, also make an order under section 4ZA giving her that responsibility."

(3) In subsection (4)—

(a) after "(1)" insert "or (1A)",

(b) after "4" insert "or 4ZA", and

(c) for "father" substitute "parent".

22 In section 105 of the Children Act 1989 (interpretation), in subsection (1), in the definition of "parental responsibility agreement", after "sections 4(1)" insert ", 4ZA(4)".

23 In Schedule 1 to the Children Act 1989 (financial provision for children) at the end of paragraph 4 insert—

"(5) In the case of a child who has a parent by virtue of section 48 or 49 of the Human Tissue and Embryos Act 2007, any reference in sub-paragraphs (2), (3) or (4) to the child's father is a reference to the woman who is the child's parent by virtue of that section."

Human Fertilisation and Embryology Act 1990 (c. 37)

24 (1) Section 32 of the 1990 Act (information to be provided to Registrar General) is amended as follows.

(2) In subsection (1)—

(a) for "man" substitute "person", and

(b) for "father" substitute "parent".

(3) In subsection (2), for the words from "that the man" to "section 28 of this Act" substitute "that the person may be the parent of the child by virtue of any of the relevant statutory provisions".

(4) After subsection (2) insert—

"(2A) In subsection (2) "the relevant statutory provisions" means—

(a) section 28 of this Act, and

(b) sections 41 to 53 of the Human Tissue and Embryos Act 2007."

(5) In subsection (3), for "section 33" substitute "section 33A".

25 (1) Section 35 of the 1990 Act (disclosure of information in the interests of justice: congenital disabilities etc.) is amended as follows.

(2) In subsections (1) and (2), for "sections 27 to 29 of this Act" substitute "the relevant statutory provisions".

(3) After subsection (2) insert—

"(2A) In subsections (1) and (2) "the relevant statutory provisions" means—

(a) sections 27 to 29 of this Act, and

(b) Part 3 of the Human Tissue and Embryos Act 2007."

Child Support Act 1991 (c. 48)

26 In section 26 of the Child Support Act 1991, for Cases B and B1 in subsection (2) substitute—

"CASE B

Where the alleged parent is a parent of the child in question by virtue of an order under section 30 of the Human Fertilisation and Embryology Act 1990 or section 60 of the Human Tissue and Embryos Act 2007 (parental orders in favour of gamete donors).

CASE B1

Where the Secretary of State is satisfied that the alleged parent is a parent of the child in question by virtue of section 27 or 28 of the Human Fertilisation and Embryology Act 1990 or any of sections 39 to 52 of the Human Tissue and Embryos Act 2007 (which relate to children resulting from assisted reproduction)."

PART 2

ENACTMENTS RELATING ONLY TO SCOTLAND

Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49)

27 (1) Section 14 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 is amended as follows.

(2) After subsection (4), insert—

"(4A) In the case of a child who has a parent by virtue of section 48 of the Human Tissue and Embryos Act 2007, the references in subsections (1) and (2) to the father of the child are to be read as references to the woman who is the parent by virtue of that section."

(3) In subsection (5), at the end insert "or a woman treated as a parent by virtue of section 49 of the Human Tissue and Embryos Act 2007".

28 For section 18ZA of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 substitute—

"18ZA Registration of father or female second parent by virtue of certain provisions of the Human Tissue and Embryos Act 2007

(1) The registrar shall not enter in the register—

(a) as the father of a child the name of a man who is to be treated for that purpose as the father of the child by virtue of section 45(1) or 46(1) or (2) of the Human Tissue and Embryos Act 2007 (circumstances in which man to be treated as father of child for purpose of registration of birth where fertility treatment undertaken after his death); or

(b) as a parent of the child, the name of a woman who is to be treated for that purpose as a parent of the child by virtue of section 52(1) or (2) of that Act (circumstances in which woman to be treated as parent of child for purposes of birth where fertility treatment undertaken after her death),

unless the condition in subsection (2) below is satisfied.

(2) The condition in this subsection is satisfied if—

(a) the mother requests the registrar to make such an entry in the register and produces the relevant documents; or

(b) in the case of the death or inability of the mother, the relevant documents are produced by some other person who is a qualified informant.

(3) In this section "the relevant documents" means—

(a) the consent in writing and election mentioned in section 45(1), 46(1) or (2) or 52(1) or (2) (as the case requires) of the Human Tissue and Embryos Act 2007;

(b) a certificate of a registered medical practitioner as to the medical facts concerned; and

(c) such other documentary evidence (if any) as the registrar considers appropriate."

29 After section 18A of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 insert—

"18B Births of children where second female parent by virtue of section 49 of the Human Tissue and Embryos Act 2007

(1) No woman shall as a parent of a child by virtue of section 49 of the Human Tissue and Embryos Act 2007 ("the woman concerned") be required, as a parent of the child, to give information concerning the birth of the child and, save as provided in section 20 of this Act, the district registrar for the registration district shall not enter in the birth registration form concerning the birth the name and surname of any woman as a parent of the child by virtue of section 49 of that Act of 2007 except—

(a) at the joint request of the mother and the person acknowledging herself to be the other parent of the child (in

which case that person shall attest, in the prescribed manner, the birth registration form together with the mother); or

(b) at the request of the mother on production of—

(i) a declaration in the prescribed form made by the mother stating that the person is a parent of the child by virtue of section 49 of the Human Tissue and Embryos Act 2007; and

(ii) a statutory declaration made by the woman concerned acknowledging herself to be a parent of the child by virtue of section 49 of that Act; or

(c) at the request of the mother on production of a decree by a competent court finding or declaring the woman concerned to be a parent of the child by virtue of section 49 of that Act; or

(d) at the request of the woman concerned on production of—

(i) a declaration in the prescribed form made by the woman concerned acknowledging herself to be a parent of the child by virtue of section 49 of that Act; and

(ii) a statutory declaration made by the mother stating that the woman concerned is a parent of the child by virtue of section 49 of that Act.

(2) Where a person acknowledging herself to be a parent of the child by virtue of section 49 of the Human Tissue and Embryos Act 2007 makes a request to the district registrar for the registration district in accordance with paragraph (d) of subsection (1) of this section, she shall be treated as a qualified informant concerning the birth of the child for the purposes of this Act; and the giving of information concerning the birth of the child by that person and the attesting of the birth registration form concerning the birth by her in the presence of the registrar shall act as a discharge of any duty of any other qualified informant under section 14 of this Act.

(3) In any case where the name and surname of a woman who is a parent of a child by virtue of section 49 of the Human Tissue and Embryos Act 2007 has not been entered in the birth registration form concerning the birth, the Registrar General may record that name and surname by causing an appropriate entry to be made in the Register of Corrections Etc.—

(a) if there is produced to him a declaration and a statutory declaration such as are mentioned in paragraph (b) or (d) of subsection (1) of this section; or

(b) if, where the mother is dead or cannot be found or is incapable of making a request under subsection (1)(b) or (c) of this section, or a declaration under subsection (1)(b)(i) or a statutory declaration under subsection (1)(d)(ii) of this section, the Registrar General is ordered so to do by the sheriff upon application made to the sheriff by the person acknowledging herself to be a parent of a child by virtue of section 49 of the Human Tissue and Embryos Act 2007."

Children (Scotland) Act 1995 (c. 36)

30 In section 1(1) of the Children (Scotland) Act 1995, after "3(1)(b)" insert ", (c) and (d)".

31 In section 2(1) of the Children (Scotland) Act 1995, after "3(1)(b)" insert ", (c) and (d)".

32 (1) Section 3 of the Children (Scotland) Act 1995 is amended as follows.

(2) After subsection (1)(b), insert—

"(c) without prejudice to any arrangements which may be made under subsection (5) below, where a child has a parent by virtue of section 48 of the Human Tissue and Embryos Act 2007, that parent has parental responsibilities and parental rights in relation to the child;

(d) without prejudice to any arrangements which may be made under subsection (5) below and subject to any agreement which may be made under section 4A(1) of this Act, where a child has a parent by virtue of section 49 of the Human Tissue and Embryos Act 2007, that parent has parental responsibilities and parental rights in relation to the child if she is registered as the child's parent under any of the enactments mentioned in subsection (3A)."

(3) After subsection (3), insert—

"(3A) Those enactments are—

(a) section 18B of the Registration of Births, Deaths and Marriages (Scotland) Act 1965;

(b) paragraphs (a), (b) and (c) of section 10(1B) and of section 10A(1B) of the Births and Deaths Registration Act 1953;

(c) [registration provisions for Northern Ireland.]"

(4) In subsection (5), for "section 4(1)" substitute "sections 4(1) and 4A(1)".

33 After section 4 of the Children (Scotland) Act 1995 insert—

"4A Acquisition of parental responsibilities and parental rights by second female parent by agreement with mother

(1) Where—

(a) a child's mother has not been deprived of some or all of the parental responsibilities and parental rights in relation to the child; and

(b) the child has a parent by virtue of section 49 of the Human Tissue and Embryos Act 2007 and that parent is not registered as such under any of the enactments mentioned in section 3(3A),

the mother and the other parent may by agreement provide that, as from the appropriate date, the other parent shall have the parental responsibilities and rights (in the absence of any order under section 11 of this Act affecting responsibilities and rights) as if the other parent were treated as a parent by virtue of section 48 of that Act of 2007.

(2) Section 4(2), (3) and (4) applies in relation to an agreement under subsection (1) of this section as it applies in relation to an agreement under subsection (1) of section 4."

34 (1) Section 11 of the Children (Scotland) Act 1995 is amended as follows.

(2) In subsection (4)(c)—

(a) for "subsection (9) of section 30 of the Human Fertilisation and Embryology Act 1990 (provision for enactments about adoption to have effect with modifications)" substitute "section 61(1) of the Human Tissue and Embryos Act 2007 (parental orders: supplementary provisions)";

(b) for "subsection (1) of that section" substitute "section 60 of that Act".

(3) In subsection (11), after "4(2)" insert "or 4A(2)".

35 In section 15 of the Children (Scotland) Act 1995, in the definition of "parent"—

(a) after "1990" insert "and Part 3 of the Human Tissue and Embryos Act 2007"; and

(b) for "subsection (9) of the said section 30" substitute "section 61(1) of that Act of 2007".

Adoption and Children (Scotland) Act 2007 (asp 4)

36 In section 30(7) of the Adoption and Children (Scotland) Act 2007, after paragraph (c) insert—

"(ca) by virtue of section 41, 42, 48 or 49 of the Human Tissue and Embryos Act 2007, there is no other parent."

SCHEDULE 7

Section 74

MINOR AND CONSEQUENTIAL AMENDMENTS

Congenital Disabilities (Civil Liability) Act 1976 (c. 28)

1 In section 4 of the Congenital Disabilities (Civil Liability) Act 1976 (interpretation), in subsection (2), for "section 1 of the Human Fertilisation and Embryology Act 1990" substitute "section 1(1) of the Human Fertilisation and Embryology Act 1990 and any regulations under section 1(6) of that Act".

Human Fertilisation and Embryology Act 1990 (c. 37)

2 In section 2 of the 1990 Act (which relates to interpretation), in subsection (1) for the definition of "the Authority" substitute—

" "the Authority" means the Regulatory Authority for Tissue and Embryos;".

3 Omit sections 5 to 8 and 9 and 10 of the 1990 Act (which relate to the Human Fertilisation and Embryology Authority and its functions and procedure).

4 In section 13A of the 1990 Act (conditions of licences for non-medical fertility services), omit subsection (4).

5 In section 23 of the 1990 Act (directions: general)—

(a) in subsection (5), for paragraph (a) substitute—

"(a) in respect of any licence (including a licence which has ceased to have effect), by serving notice of the directions on the person—

(i) who is the person responsible or the holder of the licence, if different, or

(ii) who was the person responsible or the holder of the licence, if different,", and

(b) omit subsection (6).

6 In section 34 of the 1990 Act (disclosure in the interests of justice), in subsection (1)—

(a) after "of this Act" insert "or Part 3 of the Human Tissue and Embryos Act 2007", and

(b) for section "31(2)(b)" substitute "section 31(2)(c) to (e)".

7 In section 47 of the 1990 Act (index)—

(a) in the first column, after "embryo" insert "(except in section 4A)",

(b) in the first column, after "gametes, eggs or sperm", insert "(except in section 4A)",

(c) at the appropriate places insert—

"appeals committee	section 20A(2)"
"inter-species embryo	section 4A(5)"
"nucleus and nuclear DNA (in relation to an embryo)	section 2(1)", and

(d) omit the entries relating to "licence committee" and "nominal licensee".

8 In section 48 of the 1990 Act (application to Northern Ireland) for "sections 33(6)(h)" substitute "sections 33A(2)(s)".

9 Omit Schedule 1 of the 1990 Act (which contains supplementary provisions relating to the Human Fertilisation and Embryology Authority).

Criminal Justice and Police Act 2001 (c. 16)

10 In section 57 of the Criminal Justice and Police Act 2001 (retention of seized items), in subsection (1)(k), for "section 40(4) of" substitute "paragraph 5(4) of Schedule 3B to".

11 In section 66 of the Criminal Justice and Police Act 2001 (general interpretation of Part 2)—

(a) in subsection (4), after paragraph (j) insert—

"(ja) paragraph 2 of Schedule 3B to the Human Fertilisation and Embryology Act 1990."

(b) in subsection (5), omit paragraph (g).

12 In Schedule 1 to the Criminal Justice and Police Act 2001 (powers of seizure)

for paragraph 52 substitute—

"52 Each of the powers of seizure conferred by the provisions of paragraph 5(1) and (2) of Schedule 3B to the Human Fertilisation and Embryology Act 1990."

Human Tissue Act 2004 (c. 30)

13 Omit section 13 of the 2004 Act (which establishes the Human Tissue Authority) and the italic heading immediately before it.

14 Before section 14 of the 2004 Act insert—

"Role of Regulatory Authority for Tissue and Embryos in relation to activities involving human tissue

13A Meaning of "the Authority"

In this Act "the Authority" means the Regulatory Authority for Tissue and Embryos,"

15 (1) Section 14 of the 2004 Act (remit of Human Tissue Authority) is amended as follows.

(2) In subsections (1), (2) and (4), after "the remit of the Authority" insert "under this Act".

(3) In subsection (3), after "from the remit of the Authority" insert "under this Act".

16 Omit section 15 of the 2004 Act.

17 Omit section 35 (agency arrangements and provision of services) and section 36 (annual report of Human Tissue Authority) of the 2004 Act.

18 Omit section 38 of the 2004 Act (duties of Human Tissue Authority in relation to the carrying out of its functions).

19 Omit 42 of the 2004 Act (power of Human Tissue Authority to assist other public authorities).

20 (1) Section 54 of the 2004 Act is amended as follows.

(2) In subsection (1), in the definition of "the Authority", for "13(1)" substitute "13A".

(3) For subsection (6) substitute—

"(6) In this Act "embryo" and "gametes" have the same meaning as they have by virtue of section 1(1), (4) and (6) of the Human Fertilisation and Embryology Act 1990 in the other provisions of that Act (apart from section 4A)."

21 Omit Schedule 2 to the 2004 Act (which relates to the Human Tissue Authority).

Human Tissue (Quality and Safety for Human Application) Regulations 2007

22 In regulation 8 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007—

(a) in paragraph (1), for "(7)" substitute "(8)";
(b) after paragraph (6) insert—

"(6A) In its application by virtue of paragraph (2)(e), paragraph 7(2)(ba) of Schedule 3 to the 2004 Act shall be read as if the reference to a licence were to a licence under Schedule 1 to these Regulations."; and

(c) after paragraph (7) insert—

"(8) In its application by virtue of paragraph (2)(e), paragraph 7(2)(f) of Schedule 3 to the 2004 Act shall be read as if the reference to an offence under the 2004 Act were to an offence under these Regulations."

SCHEDULE 8

Section 75

REPEALS

PART 1

REPEALS

Short title and chapter	*Extent of repeal*
Public Records Act 1958 (c. 51)	In Schedule 1, in Part 2 of the Table at the end of paragraph 3, the entry relating to the Human Tissue Authority.
Parliamentary Commissioner Act 1967 (c. 13)	In Schedule 2, the entries relating to the Human Fertilisation and Embryology Authority and the Human Tissue Authority.
House of Commons Disqualification Act 1975 (c. 24)	In Part 2 of Schedule 1, the entries relating to the Human Fertilisation and Embryology Authority and the Human Tissue Authority.
Northern Ireland Assembly Disqualification Act 1975 (c. 25)	In Part 2 of Schedule 1, the entries relating to the Human Fertilisation and Embryology Authority and the Human Tissue Authority.
Surrogacy Arrangements Act 1985 (c. 49)	In section 2(1)(a), the words "or take part in".
Human Fertilisation and Embryology Act 1990 (c. 37)	In section 3(3), paragraph (d) and the "or" immediately before it. In section 4(1), paragraph (c) and the "or" immediately before it. Sections 5 to 8. Sections 9 and 10. In section 12(1)(c), the words "or non-medical fertility services". Section 13A(4).

Short title and chapter	*Extent of repeal*
Human Fertilisation and Embryology Act 1990 (c. 37)—*cont.*	In section 13(5), the words ", other than basic partner treatment services," and "(including the need of that child for a father)". In section 14(5), the words "or, as the case may be, five years". Section 16(6) and (7). Section 17(3). Section 23(6). In section 25(2), the words "(including a child's need for a father)". Section 30. Sections 39 and 40. In section 41, subsection (2A), in subsection (4), the words ", other than an offence to which subsection (4B) applies," subsections (4A), (4B), (6) and (7), and in subsection (9) the words "(6), (7) or". In section 47, in the index, the entries relating to "licence committee" and "nominal licensee". Schedule 1. In Schedule 2, in paragraph 1(1)(d), the words from "or" onwards.
Human Fertilisation and Embryology (Disclosure of Information) Act 1992 (c. 54)	The whole Act.
Freedom of Information Act 2000 (c. 36)	In Part 6 of Schedule 1, the entries relating to the Human Fertilisation and Embryology Authority and the Human Tissue Authority.
Criminal Justice and Police Act 2001 (c. 16)	Section 66(5)(g). In Schedule 2, paragraph 16(2)(e).
Human Reproductive Cloning Act 2001 (c. 23)	The whole Act.
Human Tissue Act 2004 (c. 30)	Section 13 (with the italic heading immediately before it). Section 15. Sections 35 and 36. Section 38. Section 42. Schedule 2. In Schedule 3, paragraph 13(2).

PART 2

REVOCATIONS

Title	*Extent of revocation*
Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (S. I. 2001/188)	The whole instrument.

These notes refer to the Human Tissue and Embryos Bill as published in draft

HUMAN TISSUE AND EMBRYOS BILL

EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes relate to the Human Tissue and Embryos Bill as published in draft. They have been prepared by the Department of Health in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.

2. The notes need to be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a clause or part of a clause does not seem to require any explanation or comment, none is given.

LIST OF ABBREVIATIONS USED IN THE EXPLANATORY NOTES

3. The following terms are used throughout the Explanatory Notes:

DI -	Donor Insemination
DNA -	Deoxyribose Nucleic Acid (genetic material)
ECHR	European Convention on Human Rights
EU Directive	The European Union Tissue Directive
HFEA -	Human Fertilisation and Embryology Authority
HTA -	Human Tissue Authority
IVF -	*In vitro* fertilisation
MHRA -	Medicines and Healthcare products Regulatory Agency
RATE -	Regulatory Authority for Tissue and Embryos
RIA -	Regulatory Impact Assessment
SI -	Statutory Instrument
The 1990 Act -	The Human Fertilisation and Embryology Act 1990
The 2004 Act -	The Human Tissue Act 2004

SUMMARY AND BACKGROUND

4. The Bill has two principal purposes. It establishes a new regulatory authority replacing two existing authorities, and amends the law relating to assisted reproduction treatment and embryo research. It is intended to implement the policy proposals contained in the White Paper *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including establishment of the*

Regulatory Authority for Tissue and Embryos) published in December 2006 (Cm 6989).

The Regulatory Authority for Tissue and Embryos

5. The Government announced in July 2004 its intention to create the Regulatory Authority for Tissue and Embryos (RATE), as part of a wider review of the Department of Health's arm's length bodies (stand-alone national organisations sponsored by the Department, undertaking executive functions). RATE will replace both the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) - the statutory licensing authority established by the Human Tissue Act 2004 ("the 2004 Act"). The HTA currently oversees activities relating to whole body donation and the taking, storage and use of human organs and tissue.

6. RATE will also take over, from the Medicines and Healthcare Products Regulatory Agency (MHRA), the regulation of the quality and safety of the collection, testing, processing, storage and distribution of blood and blood components, which is required by European Union Directives relating to blood and blood products.

Review of the Human Fertilisation and Embryology Act

7. The Human Fertilisation and Embryology Act 1990 ("the 1990 Act") currently regulates the creation, keeping or use of embryos outside the human body, the use of eggs and sperm, and the storage or donation of eggs, sperm or embryos. The 1990 Act prohibits certain activities from being carried out except pursuant to a licence.

8. Licences can currently be granted for the purpose of fertility treatment, for storage and for research. Following amendments to be made to the 1990 Act by the the regulations implementing EU Directive 2004/23[1] ("the European Union Tissue Directive"), a licence will also be available under the 1990 Act in respect of non-medical fertility services. Non-medical fertility services are defined as any services that are provided, in the course of a business, for the purpose of assisting women to carry children, but are not medical, surgical or obstetric services. In particular, they include a very small number of internet-based businesses that arrange for donated sperm to be delivered to women at home for self-insemination.

9. The 1990 Act imposes mandatory conditions on each type of licence and enables other conditions to be imposed.

10. Currently activities under the 1990 Act are overseen by a statutory licensing authority, the HFEA.

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[1] Human Fertilisation and Embryology (Quality and Safety) Regulations laid before Parliament on 25 April 2007.

11. The provisions of the 1990 Act were enacted after consideration of the report from the Warnock Committee of Inquiry (the Warnock Committee), which was published in July 1984. The Warnock Report considered the social, ethical and legal implications of developments in the field of human reproduction, most notably the birth in 1978 of the first child conceived through *in vitro* fertilisation. In January 2004, the Government announced a review of the 1990 Act citing developments in reproductive medicine since the passage of the original legislation, and conducted a public consultation during the latter half of 2005.

12. The draft Bill amends many of the provisions of the 1990 Act, but the main features of the existing model of regulation are retained.

13. Amendments include:

- extension of the meaning of the terms "embryo" and "gamete" to include, for example, technologically new processes of creation;
- retention of the duty on assisted reproduction clinics to consider prior to treatment the welfare of the potential child, but removal of the reference to the "need of that child for a father";
- extension of the statutory period for which embryos may be stored;
- introduction of criteria for licensing of embryo preimplantation testing;
- a ban on sex selection of offspring for non-medical reasons;
- extension of legal parenthood to civil partners and other same-sex couples in relation to children born as a result of assisted reproduction.

TERRITORIAL EXTENT

14. Parts 1 and 3 of the Bill (and the free-standing provisions in Part 4 of the Bill) extend to England and Wales, Scotland and Northern Ireland.

15. The other provisions of the Bill amend existing legislation and have the same extent as the provisions being amended. This means, in particular, that the amendments of the 1990 Act in Part 2 of the Bill extend to England and Wales, Scotland and Northern Ireland, while the amendments of the 2004 Act in Part 4 extend only to England and Wales and Northern Ireland.

16. The subject-matter of the 1990 Act and the subject-matter of the Surrogacy Arrangements Act 1985 are reserved matters as respects Scotland and Northern Ireland. Part 3 of the Bill deals with a subject (the legal parenthood of children resulting from assisted reproduction) that is already dealt with by sections 27 to 30 of the 1990 Act. Part 3 therefore also relates to a reserved matter. Clauses 64 and 65 also relate entirely to reserved matters.

17. The Blood Safety and Quality Regulations 2005 (S.I. 2005/50) extend

throughout the UK. It is intended that RATE should exercise functions under these regulations throughout the UK.

18. RATE will have powers to assist any other public authority in the UK. It would therefore have power to enter into arrangements with Scottish bodies for the provision of assistance to them.

Wales

19. The Bill does not confer any functions on the National Assembly for Wales, and in general applies to Wales in the same way as it applies to England. Paragraph 4 of Schedule 1 provides for a member of RATE to be appointed by the Welsh Ministers, and provisions relating to the Welsh Ministers or the National Assembly for Wales appear in clauses 3 and 8 and in paragraphs 22 and 29 of Schedule 1.

Scotland

20. This draft Bill contains provisions which if included in a future Bill introduced to the UK Parliament, would fall within the scope of the Sewel Convention. The Sewel Convention states that Westminster will not normally legislate with regard to devolved matters in Scotland without the consent of the Scottish Parliament.

21. Elections were held in Scotland on 3 May 2007. The UK Government is committed to full consultation with the new devolved administration in relation to the potential implications for devolved interests of the provisions contained within this draft Bill.

22. The current draft of the Bill will be amended, before introduction to the UK Parliament, to reflect the policy and handling preferences of the new Scottish Ministers, who are expected to be appointed later in May. Retention of devolved provisions within the Bill will also remain subject to a legislative consent motion in the Scottish Parliament, in line with normal procedures. If such agreement is not obtained, it is the policy of the UK Government to ensure that the relevant provisions do not extend to Scotland.

23. Publication of this draft Bill does not in any way pre-empt decisions which fall to the Scottish Ministers and to the Scottish Parliament. The objective is simply to allow consultation and pre-legislative scrutiny to proceed as quickly and as efficiently as possible in relation to proposed future legislation covering policy matters which are reserved to the UK Parliament.

Northern Ireland

24. Consequential amendments for Northern Ireland will be included prior to introduction of the Bill to Parliament.

OVERVIEW OF STRUCTURE

25. The draft Bill comprises four Parts, (including Schedules). In amending the 1990 and 2004 Acts, the Bill takes account of the amendments made by regulations implementing the European Union Tissue Directive as laid before Parliament on 25 April 2007.

Part 1

26. Part 1 contains the main clauses concerned with the constitution, functions, powers and duties of the new regulatory authority, RATE. Schedule 1 details further provisions in regard to membership and related matters. This Part of the draft Bill is 'stand-alone' in the sense that its effect is not achieved by amendment of existing primary legislation. Schedule 8 contains repeals and revocations of existing legislation, including in consequence of the replacement of the HFEA and HTA by RATE. For example, section 15 of the 2004 Act, which set out the general functions of the HTA, is repealed. Clause 3 of the draft Bill sets out the general functions of RATE.

Part 2

27. Part 2 (including Schedules 2 to 5) comprises a range of amendments to the 1990 Act to take account of scientific developments, to reflect changes in society and to reflect the fact that the HFEA will be replaced by RATE which, as mentioned above, will also be the regulatory authority for the 2004 Act.

28. To assist the reader of the Bill, the Department of Health has produced an illustrative text of the Human Fertilisation and Embryology Act 1990 as amended. This anticipates the amendments being made by regulations implementing the EU Tissue Directive and shows the effect of the amendments made by the draft Bill. The text has no official status.

Part 3

29. Part 3 deals with legal parenthood in cases involving assisted reproduction. This Part of the Bill is concerned with determining who are to be the parents of a child born following assisted reproduction in a variety of circumstances. The 1990 Act currently provides that where an unmarried couple are 'treated together' using donated sperm, the male partner will be regarded as the father of any child born as a result. 'Treated together' in this context is a somewhat loose concept. Clauses within Part 3 replace it with a more precise provision that both partners must consent in writing, before the donated gametes or embryos are transferred to the woman, to the non-carrying partner being treated as the father or (in the case of a same sex female partnership) parent of any child born as a result.

Part 4

30. Part 4 of the draft Bill contains amendments to the Surrogacy Arrangements Act 1985, miscellaneous provisions and general provisions about order and regulation-making powers, powers to make consequential and transitional provisions, and commencement.

COMMENTARY ON CLAUSES

PART 1: THE REGULATORY AUTHORITY FOR TISSUE AND EMBRYOS

Clause 1: Constitution

31. This clause sets up RATE and dissolves the HFEA and the HTA. Schedule 1 deals with the constitution of RATE and other related matters.

32. Schedule 1 to the Bill sets out the details of the composition of RATE and how it will operate. Paragraph 4 makes provision about the membership of RATE requiring that the chairman and at least half of the other members must not have a professional interest in the work of the Authority. Paragraph 7 provides that any appointment cannot exceed 3 years at a time. The Schedule also provides at paragraph 5 that certain people, in particular those who have been the subject of a bankruptcy order or certain criminal convictions, cannot be a member of the Authority.

33. Paragraph 13 provides that RATE may regulate its own proceedings and, in accordance with Paragraph 15, it may delegate its functions to a committee or a member of the Authority, or to the Authority's staff. Paragraph 16 requires RATE to set up expert advisory panels, each chaired by a member of the Authority, in the three areas of its work; (i) reproductive medicine and embryo research (ii) anatomy and pathology, and (iii) blood and transplantation although RATE may also set up other expert advisory panels to provide advice on other matters. RATE may also establish other committees, to deal with other matters such as the Code of Practice, under the provisions in Paragraph 17.

34. Paragraph 18 provides that RATE must have a register of members' interests, which must be published. Paragraph 21 provides the Secretary of State with the power to make payment from public funds to RATE and Paragraph 22 requires RATE to account for those funds and other income received. Paragraphs 23 to 30 apply other provisions to the Authority, such as certain requirements in respect of public records and freedom of information.

Clause 2: Designation as competent authority

35. This clause provides that RATE will be the competent authority for the EU Directives in the following areas: (i) setting standards of quality and safety for the

collection, testing, processing, storage and distribution of human blood and blood components; (ii) setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells; (iii) certain technical requirements for the donation, procurement and testing of human tissues and cells, and (iv) traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

Clause 3: General functions of Authority

36. Clause 3 provides that RATE will be responsible for monitoring 'regulated activities' as defined by *subsection (2)*. These include licensing treatment services involving the use of human embryos outside the body or the use of donated gametes (sperm or eggs) IVF and DI. They also include licensing the storage of embryos and gametes; and research involving embryos. These activities were previously within the remit of the HFEA. RATE will also be responsible for those activities previously within the remit of the HTA which include licensing the removal, storage, use (including anatomical examinations and post-mortems) and disposal of human bodies and certain material obtained from bodies. RATE may undertake inspections of licensed premises. Regulated activities also include the processing, storage and distribution of blood and blood products intended to be used for transfusion.

37. *Subsection (1)* provides that RATE will also be responsible for advising Ministers as appropriate; publicising the services it provides to the public; and providing information and advice to the public and those carrying out regulated activities.

Clauses 4 and 5: Arrangements for exercise of RATE's functions by others

38. These clauses give RATE power to make arrangements with a government department, a public authority or the holder of a public office for the carrying out any function of the Authority, although RATE will retain responsibility for the carrying out of its functions.

39. Similarly, RATE will have a limited power to contract-out certain of its functions. The functions that may be contracted out do not include the licensing or authorisation function, the right of entry and power of search and seizure; or the power to make subordinate legislation. Functions that may be contracted out may be restricted by an order made by the Secretary of State.

Clause 6: Disclosure of information where functions of Authority exercised by others

40. Clause 6 of the Bill will enable the Authority and those who are exercising functions of the Authority under an agency arrangement or contract to disclose information between themselves where this is necessary or expedient for the purpose of exercising the relevant function.

Clauses 7 and 8: Powers to provide assistance

41. RATE may also provide assistance to any other public authority in the UK or to any authority in any country or territory outside the UK. RATE may charge a fee for these services.

Clause 9: Annual reports

42. This clause provides that RATE must prepare an annual report to be submitted to the Secretary of State, the Welsh Ministers, the Scottish Ministers and the relevant Northern Ireland department. Each is then required to lay the report before, respectively, Parliament, the National Assembly for Wales, the Scottish Parliament and the Northern Ireland Assembly.

Clause 10: Duties in relation to carrying out of functions

43. This clause requires RATE to carry out its functions effectively, efficiently and economically and addresses the principles to which it must have regard in doing so.

Clauses 11 and 12: Transfer of property, rights and liabilities

44. Clauses 11 and 12 provide that the property, rights and liabilities of the HFEA and HTA become the property, rights and liabilities of the Authority. The Secretary of State may also make a scheme to transfer to RATE such property, rights and liabilities of the Secretary of State as appropriate. This is intended to apply in respect of any liabilities etc transferred from the MHRA to RATE when the latter becomes the 'competent authority' in respect of blood.

PART 2: AMENDMENTS OF HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Clause 14: Meaning of "embryo" and "gamete"

45. This clause amends section 1 of the 1990 Act so as to ensure that the Act applies to all live human embryos regardless of the manner of their creation, and to all live human gametes i.e. eggs and sperm.

46. An embryo will continue to be defined under the new section 1(1) in broad terms as a "live human embryo" but the definition no longer assumes that an embryo can only be created by fertilisation. This brings the term "embryo" up to date with technologies that have been developed since the time of enactment of the 1990 Act, such as cell nuclear replacement, sometimes referred to as therapeutic cloning.

47. Cell nuclear replacement involves the manipulation of a human egg to introduce the nuclear material of an existing human cell, thus producing an embryo genetically identical to the individual from whom the cell was taken. By contrast, fertilisation occurs by the impregnation of an egg with a sperm, thereby creating an embryo using the DNA of two individuals, a man and a woman.

48. The definition of an "embryo" under the new section 1(1)(a) of the 1990 Act has been limited to exclude certain types of embryos created by combining together human and animal gametes, or human embryos altered using animal DNA or animal cells. Such entities are defined as "inter-species" embryos and are regulated under the new section 4A in the 1990 Act by clause 17.

49. The term "gametes" under section 1(4) of the 1990 Act has been amended to expressly encompass not only mature eggs and sperm, but also immature gametogenic cells such as primary oocytes, and spermatocytes.

50. A regulation-making power has been taken to expand the definitions of "embryo", "eggs", "sperm" or "gametes" where this is considered by the Secretary of State to be necessary or desirable in light of developments in science or medicine (see new section 1(6)).

Clause 15: Meaning of "nuclear DNA"

51. This clause inserts a new definition into section 2 of the 1990 Act to clarify that, while there are scientific differences between the nucleus of a cell and the pro-nuclei of a very early embryo, they will be treated the same for the purposes of this Act.

Clause 16: Prohibitions in connection with embryos

52. Clause 16 amends section 3 of the 1990 Act, which covers prohibitions connected with embryos.

53. Section 3(2)(a) of the 1990 Act is also amended to prevent the placing in a woman of any human embryo other than a "permitted embryo". A permitted embryo is defined as an embryo formed by the fertilisation of a permitted egg with a permitted sperm. Permitted eggs are defined by new section 3ZA as eggs produced or extracted from the ovaries of a woman and permitted sperm as sperm produced or extracted from the testes of a man. These eggs and sperm must not have been subject to any nuclear or mitochondrial alterations and similarly a permitted embryo must not be subject to such alterations. This clause therefore ensures that other forms of embryos or gametes including artificial gametes, genetically modified gametes, genetically modified embryos and embryos created by cloning cannot be placed in a woman.

54. A regulation-making power has been provided under new section 3ZA(5) of the 1990 Act to allow the meaning of permitted embryos and permitted eggs to be extended to include eggs or embryos that have been treated to prevent the transmission of serious mitochondrial disease. Mitochondria are involved in energy production and are present in every cell in the body. If a woman's egg is fertilised the mitochondria from her egg will become the mitochondria for every cell of the embryo formed. Therefore, if a woman has medical/genetic problems associated with her mitochondria, these will be inherited via her eggs. In the future, it may be possible to create embryos using healthy donated mitochondria.

55. This regulation-making power will enable such embryos and eggs to be implanted in a woman if this technology became available and was proven to be safe. Further provision is made regarding mitochondrial donation in clause 34 of the Bill, which inserts new section 35A into the 1990 Act.

Clause 17: Prohibitions in connection with genetic material not of human origin

56. This clause inserts new section 4A into the 1990 Act to provide that certain types of embryo, which contain both human and animal DNA, are subject to regulation under the 1990 Act[2]. These are defined as "inter-species embryos" and include:

- Human-animal hybrid embryos: These are embryos created by the fertilisation of a human egg by the sperm of an animal, or fertilisation of an animal egg by a human sperm (section 4A(5)(a)).

- Cytoplasmic hybrids (Cybrids): These are embryos created by techniques used in cloning, using human cells and animal eggs. The embryos would be mostly human except for the presence of animal mitochondria (see the notes on clause 15 for more information on mitochondria) (section 4A(5)(b)).

- Human transgenic embryos: These are embryos created by the genetic modification of a human embryo, specifically by the addition of animal DNA to the nucleus of any cell of the embryo (section 4A(5)(c)).

- Human-animal chimeras: These are human embryos, altered by the addition of one or more cells from an animal or animal embryo (section 4A(5)(d)).

- Embryos created using the DNA from a human gamete or gamete like cell, where that embryo also contains animal DNA (section 4A(5)(e)).

57. Section 4A(1) also prevents the placing in a woman of any non-human gametes or embryo. This is in addition to the restrictions under section 3 of the 1990 Act, as amended by clause 16, on what type of human embryo can be placed in a woman.

58. Section 4A(2) prohibits mixing human gametes with the gametes of an animal and creating, keeping or using an inter-species embryo without a licence.

59. Section 4A(3) provides that any inter-species embryo created under licence cannot be kept after:

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[2] In view of the Science and Technology Committee report published in April 2007, the Government intend to accept the principle that legislation should provide for the inter-species entities listed in clause 17(2)(b) to (d) of the draft Bill to be created for research purposes (see introduction).

- the appearance of the primitive streak (an indicator for the start of a process by which the cells of the embryo begin to separate into three distinct cells types which will go on to form different types of tissue in the body);
- 14 days from the day on which the process of creating the inter-species embryo began; or
- half the gestation or incubation period for any species contained in the embryo has elapsed;

whichever occurs earliest.

60. This Bill prohibits keeping a research embryo, including inter-species embryos, for more than 14 days in culture. Some inter-species embryos, if kept for a time period within this 14-day limit, may also fall within the Animal (Scientific Procedures) Act 1986, for example, a human-mouse hybrid (under this Act, an animal falls within the Act from half-way through the gestation period and the gestation period for a mouse is approximately 19 days). Provision in the draft Bill ensures that no inter-species embryo would be allowed to develop to a stage at which regulation under the Animal (Scientific Procedures) Act 1986 would begin. This avoids the risk of dual regulation of some forms of inter-species embryos by the Home Office and the Authority.

61. Further provisions about the licensing of activities involving inter-species embryos are made in paragraphs 2, 5 and 6 of Schedule 2 to the Bill.

Clause 18: Activities that may be licensed

62. This clause refers to Schedule 2 which contains amendments to Schedule 2 of the 1990 Act. These amendments relate to licensable activities, specifically embryo testing and purposes for which research licenses can be granted.

Embryo testing

63. The 1990 Act as it stands does not specifically mention embryo testing and currently confers a wide discretion on the HFEA to make licensing decisions on this issue. The Bill adds paragraphs 1ZA to 1ZC to Schedule 2 of the 1990 Act dealing with embryo testing (for example preimplantation genetic diagnosis of an hereditary disease), and practices designed to secure that a resulting child will be of one sex rather than the other.

64. The effect of these provisions is that testing of an embryo can only be authorised for the purposes in new paragraph 1ZA(1)(a) to (e). These purposes involve invasive procedures such as embryo biopsy, involving removal of a cell or cells from the embryo for subsequent analysis. For example, sub-paragraph (a) could authorise testing to establish whether an embryo contained an abnormal number of chromosomes likely to result in miscarriage. Sub-paragraph (b) could, for example, authorise testing to establish the presence or absence of a genetic disorder in a case where there was a particular risk of such an abnormality being present. A particular risk might be evidenced, for example, by a family history of the disease. Sub-

paragraph (c) refers to establishing the sex of an embryo where the abnormality relates to the sex chromosomes – thereby enabling "sex selection" on medical grounds.

65. Paragraphs 1ZA(1)(b) and (c) are both subject to the further provisions set out in sub-paragraphs (2) and (3). Sub-paragraph (2) provides that in order for testing to be authorised under sub-paragraph (1)(b) or (c) that RATE must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. Sub-paragraph (3) makes further provision explaining how the requirement set out in paragraph 1(3) of Schedule 2 is to be dealt with by RATE in the case of testing embryos.

66. A provision of clause 20 is closely related to the provisions on embryo testing discussed above. Clause 20(4) amends the 1990 Act to make it a condition of a treatment licence that, in the circumstances described, embryos that are known to have an abnormality as described are not to be preferred to embryos not known to have such an abnormality. The same restriction is also applied to the selection of persons as gamete or embryo donors. There have been reported cases, outside the UK, involving the positive selection of deaf donors in order deliberately to result in a deaf child. The new section 13(8) would prevent this.

Tissue typing

67. Paragraph 1ZA(1)(d) is concerned with "tissue typing" – establishing whether the embryo would result in a child whose tissue was compatible with that of an existing child (the sibling), where the sibling suffers from a life-threatening disease and could be treated by umbilical cord blood stem cells. Sub-paragraph (4) sets out factors to which RATE must have regard in deciding whether testing in this type of case is necessary or desirable for the purpose of paragraph 1(3). This has the effect that RATE will need to consider whether carrying out "tissue typing" is necessary or desirable on the merits of each particular case. By contrast, licences for testing under paragraphs 1ZA(a), (b), or (c) can be considered on a general basis.

Testing in the event of uncertainty

68. Paragraph 1ZA(1)(e) is intended to ensure that embryos can be tested in order to resolve any uncertainty that has arisen as to the identity of the persons who provided the gametes used to create the embryo.

Sex selection

69. Currently the HFEA does not allow sex selection except for medical reasons. This position is maintained in the Bill which also does not allow for sex selection except where there are medical reasons to do so. Paragraph 1ZB deals more generally with practices of sex selection, and precludes them from being authorised by a licence other than for sex-linked medical reasons as described above, (subject to paragraphs 1ZA(2) and (3)).

70. Paragraph 1ZC provides regulation-making powers to amend new paragraph 1ZA (embryo testing), and to make consequential amendments of the new paragraph 1ZB (sex selection). However, regulations may not authorise sex selection, except on grounds relating to the health of any resulting child.

71. Paragraph 4 of Schedule 2 is intended to prevent sex selection in the context of the provision of non-medical fertility services. A licence cannot authorise the procurement or distribution of sperm to which any process has been applied which is designed to result in a child of pre-determined sex.

Research licences

72. Under paragraph 3 of Schedule 2 to the 1990 Act, a research licence may authorise the creation, keeping and use of human embryos for the purposes of a project of research. Paragraph 6 of Schedule 2 to the Bill substitutes new paragraphs 3 and 3A for the existing provision.

Purposes for which embryo research may be undertaken

73. A research licence may not authorise any activity unless RATE considers it to be necessary or desirable for one of the specified "research purposes". The list of permitted research purposes in the 1990 Act has been extended by the Human Fertilisation and Embryology (Research Purposes) Regulations (S.I. 2001/188) ("the 2001 Regulations"), which allowed embryos to be created and used for the purposes of research into stem cell therapies for the treatment of serious disease. New paragraph 3A brings together all the research purposes currently listed in the 1990 Act and the 2001 regulations. It also makes three significant changes to the previous position on licensable research using embryos.

74. The list of purposes for which research may be licensed has been expanded in new paragraph 3A(2)(a) to include research which is undertaken for the purpose of increasing knowledge not only about serious diseases, but also about other serious medical conditions. This clarifies that licences may be granted for research into conditions such as neural trauma or other tissue damage, which are arguably not diseases.

75. New paragraph 3A(2)(b) provides a similar extension of the existing provision in allowing for research into the development of treatments for other serious medical conditions, as well as for serious disease. Embryonic stem cells have the potential to develop into any type of cell found in the body. Future research may lead to an understanding of how to change stem cells into particular tissues. This knowledge would have the potential to create treatments to regenerate or repair different types of tissue damage caused by disease or trauma.

76. Developing an understanding of medical conditions is important in developing treatments for them. Equally important, yet not specific to any condition or treatment, is an understanding of the cells of the body, or of any cells developed for use as cell-based therapies. Such fundamental research provides a platform of knowledge upon

which diseases can be better understood and allows cell-based therapies to be better developed and utilised.

77. New paragraph 3A(1)(b) also extends the existing provision, giving RATE power to issue licences for research which will provide knowledge which, in the view of the Authority, might be applied for the purpose of increasing knowledge about serious disease or other serious medical conditions, or developing treatments for them. RATE will therefore be able to licence research into the underlying principles of cell biology which requires the use of embryos, where such research is dedicated to the understanding or treatment of serious diseases and medical conditions.

78. The 2001 Regulations have been superseded by the new provision described above and are therefore revoked by Part 2 of Schedule 8 to the Bill.

Genetic modification of cells
79. Currently, paragraph 3(4) of the 1990 Act prohibits alteration of the genetic structure of the cell of an embryo, except in such circumstances as may be specified in regulations. No such regulations have, in fact been made. This prohibition is not included in the re-enacted paragraph 3, so research which involves the genetic modification of embryos may now be authorised under a research licence.

Inter-species embryos
80. Paragraph 3 (2) is inserted into Schedule 2 to the 1990 Act to continue to allow the mixing of sperm with the egg of a hamster, or other animal specified in directions, for the purposes of research into testing the normality or fertility of sperm. Any resulting entity must be destroyed as soon as the research is complete and no later than when it has reached the two-cell stage.

81. A new paragraph 3(3) is inserted into Schedule 2 to the 1990 Act to provide a regulation-making power to enable licences to be granted to create, keep and use inter-species embryos and to mix human and animal gametes (beyond what is allowed under paragraph 3(2) above) for the purpose of a project of research as set out in the licence.

82. New paragraph 3(4) is inserted into Schedule 2 to the 1990 Act to provide that no research licence is to be granted unless the proposed use of inter-species embryos is necessary for the purposes of the research.

83. New paragraphs 3(5), (6) and (7) of Schedule 2 to the 1990 Act deal with time limits and conditions applying to research licences and will also apply to any licence in connection with an inter-species embryo which is granted pursuant to regulations under paragraph 3(3).

Storage licences for inter-species embryos
84. Under paragraph 2 of Schedule 2 to the 1990 Act a storage licence may authorise the storage of gametes or embryos, or both. Paragraph 5 of Schedule 2 to the

Bill inserts new sub-paragraph (1A) into paragraph 2 of Schedule 2 to the 1990 Act. Sub-paragraph (1A) provides a regulation-making power which enables a storage licence to authorise the storage of inter-species embryos. Any such licence would be subject to the same conditions and time limits under paragraph 2(2) and (3) of Schedule 2 to the 1990 Act as licences to store embryos and gametes.

Clause 19: Consent provisions and non-medical fertility services

85. This clause applies the provisions of Schedule 3 to the 1990 Act (consent to use and storage of gametes or embryos) to non-medical fertility services.

86. Non-medical fertility services (see paragraph 8) will be brought within the HFEA's regulatory remit in 2007 as a result of the implementation of the Directive. This will be achieved by regulations (made under section 2(2) of the European Communities Act 1972) which will amend the 1990 Act. Responsibility for licensing will pass to RATE under the Bill.

87. Neither the remit of the Directive or the powers under which it is to be implemented allow for the provisions in Schedule 3 to the 1990 Act about consent to the use and storage of gametes and embryos to be applied in the case of persons providing gametes for the purpose of the provision of non-medical fertility services. This clause amends section 12 of the 1990 Act to rectify that situation.

Clause 20: Consent to use and storage of gametes and embryos

88. Clause 20 introduces Schedule 3 to the Bill which amends Schedule 3 to the 1990 Act.

89. Schedule 3 to the 1990 Act contains provision relating to consents to use gametes and embryos. Schedule 3 of the Bill has amended this Schedule to the 1990 Act which requires consent to the storage and use of gametes and embryos to be given in writing. This requirement is retained but the amendments made by the Bill will add a further requirement that it must be signed by the person giving the consent, something that is already standard practice in licensed establishments. However, in some cases, obtaining consent in writing may not be possible. In some cases, however, it will not be possible for a person to sign the written consent; in other cases it will not be possible for a person to give consent at all. This Schedule makes provision for persons who are unable to sign a written consent. It also makes provision for gametes to be stored where the gamete provider cannot give consent because of a lack of mental capacity or, in the case of a child, a lack of competence to consent.

90. The consent provided must specify the purposes which any gametes or embryos are to be used. In addition to the previous purposes for which a person could specify, concerning their use in treatment or research, a person may through an amendment made by Schedule 3 to the Bill also specify that their embryos can be used in the training of embryologists.

Physical incapacity

91. Existing provisions require a person to give consent in writing. New paragraph 1(2) of Schedule 3 to the 1990 Act will allow a physically incapacitated person, who is unable to write, to direct another to sign on their behalf, in the presence of a witness. People who have suffered an injury resulting in quadriplegia or another similar condition, although competent to give consent to the storage and use of their gametes in fertility treatment, lack the physical ability to sign the consent form. This option is likely to be needed by a male quadriplegic, who provides sperm by electro-ejaculation for the artificial insemination of his partner. He will be able to give an effective consent to the use of his sperm in the provision of treatment services to his partner.

Variation and withdrawal of consent

92. Existing provisions require that the person withdrawing their earlier consent to the storage and/or use of gametes or embryos gives notice of this to the establishment holding the gametes/embryos. New paragraph 1(1) of Schedule 3 will specify that this notice must be in writing and signed by the person withdrawing consent. This is already common practice. Once the notice of withdrawal is received by the establishment storing or keeping gametes, the gametes will be allowed to perish.

93. In the case of embryos, where only one of the persons who provided gametes that created the embryos withdraws their consent, a separate procedure will apply (see new paragraph 4A). On the day on which the written notice of withdrawal of consent is received by the establishment storing the embryos, the statutory storage period will cease to apply and a new one year storage period will take effect. The establishment will then notify the second gamete provider, as soon as possible, of the withdrawal of the first gamete provider's consent.

94. This provision will allow the embryos to remain lawfully stored while the parties, if they wish, attempt to reach a private resolution on the future of the embryos. If the second gamete provider does not agree to the embryos being removed from storage or simply does not respond to the notification, the embryos will remain in storage until the one year period expires.

Cases where consent not required for storage

95. Patients about to undergo chemotherapy or radiotherapy, such as in the treatment of cancer, can be rendered infertile by such treatment. If time allows, they would be able to preserve their fertility by placing their gametes in storage before treatment commenced. Similarly, people who suffer a serious physical injury, the treatment of which could again render them infertile, would also be able to preserve their fertility by this means. Under existing provisions storage is not permitted unless the gamete provider gives consent to storage in writing. However, in some cases, the patient might not be competent to give consent to storage. In the case of childhood cancer, a child may simply be too young to be considered competent to give consent to storage of their gametes. In another example, a severe injury may have rendered an adult unable, perhaps because of a coma, to give consent or direct another person to

do so on his or her behalf. New paragraphs 9 and 10 of Schedule 3 will allow the storage, without written consent, providing a clinician certifies that the conditions set out in those paragraphs have been met.

96. The gametes cannot be used for any purpose until the gamete provider him/herself gains competency and is able to give consent to use.

Creation of inter-species embryo and subsequent use of embryo
97. Paragraph 10 of Schedule 3 to the Bill inserts paragraph 13 into Schedule 3 to the 1990 Act. Paragraph 13 provides that if regulations are made allowing a research licence to be granted to create, keep or use an inter-species embryo or to mix human and animal gametes then a person's gametes cannot be used for the purposes of those activities unless they have given effective consent. A regulation-making power is provided to set out conditions that must be complied with in order for there to be effective consent. The requirement for an effective consent under the new paragraph 13 of Schedule 3 to the 1990 Act does not apply to sperm mixed with hamster eggs (or other animal specified in directions) for the purposes of determining sperm fertility or normality under new paragraph 3(2) of Schedule 2 to the 1990 Act.

98. New paragraph 13 also provides that an inter-species embryo cannot be used for the purposes of a project of research unless there is effective consent by the persons who provided the gametes used to create that embryo to its use for that purpose. New paragraph 14 of Schedule 3 provides that such an embryo cannot be stored without the consent of those persons.

Clause 21: Conditions of licence for treatment
99. This clause amends section 13 of the 1990 Act which relates to conditions of licences for treatment.

"Welfare of the child"
100. Currently, the section 13(5) of the 1990 Act requires that:

> "[a] woman shall not be provided with any treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth."

101. The HFEA is required by section 25(2) of the 1990 Act to provide guidance on this duty, and does so in its Code of Practice to licence holders. The relevant guidance[3] currently states:

> "[w]here the child will have no legal father the treatment centre is expected to assess the prospective mother's ability to meet the child's/ children's needs and the ability of other persons within the family or social circle willing to share responsibility for those needs."

[3] HFEA Code of Practice, 6th Edition, paragraph 3.14.

102. *Subsection (2)(b)* of the Bill removes the reference to a child's need for a father from the licence condition to be imposed under section 13(5) of the 1990 Act and the guidance to be given about that condition under section 25(2). Section 13(5) is otherwise unchanged by the Bill and consideration of the welfare of a child who may be born as a result of treatment (and any other child who may be affected) will therefore remain a duty imposed on treatment licence holders and a matter on which the Authority must provide guidance.

Welfare of the child where basic partner treatment services are provided
103. *Subsection (2)(a)* applies the requirement to take account of the welfare of the child in the same way that the requirement applies to other treatment services covered by the 1990 Act.

104. Basic partner treatment services are treatment services that are provided for a woman and a man together, without using the gametes of any other person, gametes that have been stored, or embryos created outside the woman's body. That is, artificial insemination using sperm that has been processed but not been donated or frozen. These services will be brought within the HFEA's regulatory remit in 2007 as a result of the transposition of the EU Tissue Directive into the 1990 Act. This will be achieved by regulations (made under section 2(2) of the European Communities Act 1972) which will amend the 1990 Act. Regulation will pass to RATE on enactment of the Bill.

105. The power under which regulations implementing the EU Tissue Directive are to be made (section 2(2) of the European Communities Act 1972) was not regarded as giving power to apply the welfare of the child provisions in section 13(5) of the 1990 Act to the provision of "basic partner treatment services" as defined in the 1990 Act as amended by the regulations. Clause 20(2)(a) amends section 13(5) so that it does apply to the provision of basic partner treatment services.

106. Subsection (6) makes transitional arrangements so that licences which are in force at the date of commencement of the Bill's provisions will have effect as if they include the condition relating to consideration of welfare, as amended by the Bill.

Requirement to offer counselling
107. *Subsection 3* and Schedule 4 extend the existing requirements under the 1990 Act as to the provision of counselling by fertility clinics. Currently, it is a requirement of all licences for treatment issued by the HFEA that a woman may not be provided with any treatment services involving donated gametes or embryos, or the use of an embryo which has been created *in vitro*, unless she and any man with whom she is being treated have been provided with relevant information and offered counselling (section 13(6) of the 1990 Act). The new provision will extend this requirement to same sex couples. In addition, it will ensure that, before proceeding with embryo transfer or donor insemination, clinics are required to offer counselling to couples who have given notice that they consent to the intended mother's partner being treated as the parent of a child who is conceived using donor sperm. Where

such notices have been given, but one of the partners subsequently withdraws their consent, clinics will be required to notify the other partner of this.

108. This subsection recognises that it is not only heterosexual couples that have assisted reproduction treatment. The current section 13(6) of the 1990 Act refers to a suitable opportunity to receive counselling to be provided to the woman being treated and to any man with whom she is being treated. This subsection replaces it with a new section 13(6) that refers instead to counselling being provided to the woman being treated and her partner (if any).

109. Subsection 3 also reflects the provision in clauses 42 and 49 of the Bill that introduces new concepts of "agreed fatherhood conditions" and "agreed female parenthood conditions".

110. The substituted section 13(6) is introduced to require that two women receiving treatment together must, as with a man and women or a single woman, be given a suitable opportunity to receive counselling *before* treatment is provided. The new section 13(6A) requires a suitable offer of counselling to be provided before two people being treated together consent to the parenthood of any child that may be born as a result of that treatment, consent for which can be provided (or withdrawn) *after* treatment begins up to the moment the embryo or sperm is transferred to the woman.

111. The new section 13(6C) and (6D) inserted by subsection (3) provide that where either partner withdraws consent to agreed parenthood the person responsible for the clinic must notify the other partner. This includes where the woman being treated withdraws her consent for the other partner to be the parent of any resulting child. Where the partner of the woman receiving treatment withdraws their consent, the person responsible shall not place any embryo, sperm or eggs in the woman until she has been notified of it.

112. Schedule 4 to the Bill inserts a new Schedule 3ZA into the 1990 Act. Part 1 specifies treatment involving the use of donated gametes or embryos and the use of embryos created *in vitro* as the kinds of treatment in relation to which clinics must offer counselling in accordance with licence conditions imposed under section 13(6). Part 2 defines the events after which counselling must be offered in accordance with licence conditions imposed under section 13(6A) - that is, the giving of notices of consent as to parenthood. The concept of two people (who are unmarried and are not civil partners) signing a parenthood agreement where donated embryos or gametes are used replaces the less certain 'treated together' provision in the 1990 Act.

Clause 22: Conditions of storage licences

113. This clause retains the statutory conditions that are attached to storage licences but amends the maximum statutory storage limit for embryos to bring it into line with the ten year limit applicable to the storage of gametes.

114. Couples that have embryos in storage may, over a period of years, reach the

decision not to continue with their own treatment but may wish to ensure that their spare embryos do not go to waste. Currently, once the statutory five-year storage period has expired, the 1996 Human Fertilisation and Embryology (Statutory Storage Periods for Embryos) Regulations allow embryos to be kept in storage, for an additional five years, only if the couple are still considered to be infertile and the embryos are to be kept solely for their own treatment. Removing both the five year break point and the restriction on storage for own use will allow couples to opt for a full ten year storage period at outset and give them the opportunity, if they no longer wish to use the embryos themselves, to donate them for the treatment of others or for research. Couples will be able to take up this option at any point during the ten year period.

Clause 23: Conditions of licences relating to inter-species embryos etc.

115. As explained above, paragraphs 5 and 6 of Schedule 2 to the Bill provide a regulation-making power to enable research or storage licences to be granted in relation to inter-species embryos.

116. Clause 23 inserts new section 15ZA into the 1990 Act. Section 15ZA provides a regulation-making power so that if research or storage licences are granted in relation to inter-species embryos these can be made subject to specified conditions, as set out in regulations. The regulations can exclude or modify any of the conditions for licences set out in sections 12, 14 and 15 of the 1990 Act. However section 12(1)(c) of the 1990 Act cannot be excluded to ensure that the provisions of Schedule 3 relating to consent will apply to any licences relating to inter-species embryos.

117. Further provision is made in paragraph 10 of Schedule 3 to the Bill regarding consent in relation to inter-species embryos.

Clause 24: Grant of licences

118. This clause brings the provisions in the 1990 Act into line with the provisions in the 2004 Act in relation to the grant of licences. It removes from section 16 of the 1990 Act the requirement for the application to be in a particular form and for an initial and an additional fee to be paid. Fees will be set in accordance with a scheme made by RATE under new provisions at section 35B of the 1990 Act set out at clause 34.

Clause 25: Repeal of definition of 'nominal licensee'

119. This clause repeals the definition of 'nominal licensee' from the 1990 Act. The defined term "nominal licensee" is no longer to be used in the 1990 Act. It was thought that the term did not adequately reflect the responsibilities of the licence holder who holds a licence under which a different person is designated as the person responsible. The Bill provides at new section 18(1)(b) for example, that where a person holds a licence other than the 'person responsible' then that person will be called the 'licence holder'.

Clause 26: Revocation and variation of licences
120. Clause 26 provides that RATE may revoke any licence or may vary a licence either on application by the licence holder, or the person responsible, or of its own volition. The power to vary a licence does not include the power to vary the mandatory conditions imposed by the 1990 Act on every licence.

Clause 27: Procedure for refusal, variation or revocation of licence
121. Clause 27 makes a number of small amendments to the procedures in the 1990 Act for notifying licensing decisions to interested parties. RATE will provide the applicant with notice of its proposed decision. The reasons for the decision must also be given. Once a person has been given notice they will then have the right to require RATE to reconsider the decision and make representations to an appeal committee set up by RATE for this purpose.

Clause 28: Reconsideration and appeals
122. Clause 28 substitutes in the 1990 Act new provisions relating to the right to reconsideration of licensing decisions, the establishment of appeals committees and the procedure to be followed on reconsideration. The new provisions largely follow the corresponding provisions in the 2004 Act.

123. RATE must maintain one or more appeals committees composed of not less than 5 (with a quorum of 3) members of the Authority. The appeals committee will be responsible for reconsideration of the Authority's decisions.

124. Where a request for reconsideration has been made, the clause sets out the procedure for reconsideration of licensing decisions, which will be by way of a fresh decision. This includes the right of the appellant to appear before the appeals committee and for reasons to be given where the decision being appealed against is upheld. *Subsection (5)* provides that RATE may by regulations make further provision about the procedure to be followed. The clause provides that a further appeal may be made by the appellant to the High Court, but only on a point of law.

Clause 29: Power to suspend licence
125. This clause substitutes section 22 of the 1990 Act with a new section 22 giving RATE power to suspend a licence. The new provision largely follows the corresponding provision in the 2004 Act. RATE may, where it has reasonable grounds to suspect that there are grounds for revoking a licence, suspend the licence for a period not exceeding three months and may continue suspension by giving further notice. In such cases the suspension can only last for a maximum of three months at a time and the decision to suspend, which must be supported by reasonable grounds to suspect that there are grounds to revoke the licence, may be challenged in the usual way in the courts, most usually by judicial review.

Clause 32: Register of information
126. Section 31 of the 1990 Act requires the HFEA to keep a register of information obtained by it which relates to the provision of treatment services to any

identifiable individual, or the keeping or use of any gametes of any identifiable individual or an embryo taken from an identifiable woman. It also requires the HFEA to keep a register of information obtained by it about people born as a result of treatment services.

127. Section 31 also makes provision for people conceived as a result of donated gametes since the 1990 Act came into effect to require the HFEA to provide them with certain information.

128. Donor-conceived people are able to find out whether they would be related, but for the provisions of the Act which determine parenthood in relation to people born as a result of certain treatment services (sections 27 to 29 of the Act), to the person they intend to marry and at age 18 they are able to find out whether the register shows that they were or may have been conceived using donor gametes. If so they are able to obtain such information which is held on the register as is specified in regulations made under section 31(4).

129. The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 (2004/1511) specify the information which RATE must provide if a request is made by a donor-conceived person. Where information was provided by a donor to a person to whom a licence applied (i.e. the 'person responsible' in a fertility centre) before 1 April 2005, specified non-identifying information must be provided to the donor conceived person. Where identifying information was provided by a donor after 31 March 2005 then specified identifying and non-identifying information must be provided.

130. Donors who made their donation before 31 March 2005 but after the 1990 Act came into force can opt to re-register as identifiable, and information would also be released about them if a request was made by a person conceived from their donation.

131. Those who ask for information from the register must be given an opportunity to receive counselling.

132. Section 31 of the Act is to be amended by the regulations implementing the EU Tissue Directive so that it is not necessary for the HFEA to record information about the provision of basic partner treatment services to one or more identifiable individuals or about the use of gametes from any identifiable individual for basic partner treatment services. The HFEA is therefore required to record the other information referred to in paragraph 129 above and information about the procurement or distribution of sperm in the course of providing non-medical fertility services to any identifiable individual, other than where the sperm has been provided by one of the people receiving the services and it has not been stored. It is also required to record information which it obtains about any identifiable individual who is born as a result of non-medical fertility services (other than where unstored partner sperm was used).

133. Clause 32 of the Bill replaces section 31 (as amended) with new sections 31 to 31ZF.

134. New section 31 re-enacts the parts of the amended section 31 which deal with the register so that the new regulatory authority (RATE) must continue to keep a register of the information referred to above which has been collected by the HFEA and must also record such information which it obtains after the Bill comes into effect.

135. New section 31ZA re-enacts the existing provisions of section 31 of the 1990 Act which enable a donor conceived person ("the applicant") to obtain information about their donor and about whether they are related to a person who they intend to marry. *Subsections* (2)(b) and (5) also enable the applicant to find out whether they are related to a person with whom they propose to enter a civil partnership.

136. In *subsection (2)(c)* there is a further new provision, that a donor-conceived person is entitled to information, at age 18, and on request, about the number, sex and year of birth of their donor-conceived half siblings who were conceived using gametes of the same donor but are not the donor's legal children (see paragraph 143).

137. RATE has a discretion not to comply with a request for information about the genetic half-siblings if it considers that special circumstances exist which make it more likely that the applicant would be able to identify the donor (in a case where the applicant does not have a right to obtain information about the donor's identity) or any such genetic half-sibling.

138. New section 31ZB gives RATE the power to inform a donor of the fact that a donor-conceived person has requested identifying information about him. This may happen from 2023 onwards, in relation to donors who donated identifiably from April 2005. It would also apply at an earlier date, if someone donating before April 2005 elected to re-register as identifiable, and a person conceived from their donation requested identifying information from RATE. In practice, RATE would try to forewarn the donor before the information is given to the donor-conceived applicant. RATE may not be able to do this in all cases, for example if the donor has moved and has not updated his address, and is not traceable by RATE. RATE may not disclose identifying information about the donor-conceived person to the donor.

139. New section 31ZC enables donors (including past donors) to be provided with information on request about the number, sex and year of birth of children born as a result of their donations. They may ask the clinic where they donated (i.e. ask the 'person responsible' at the clinic, who is the person under whose supervision licensed activities are carried out) or the regulatory authority (if the clinic has closed or the clinic is not able to, or fails to, provide the information). The information can be withheld from the donor if, unusually, it would identify a child born as a result of their donation.

140. New Section 31ZD enables donor conceived people to request and obtain identifying information about their genetic half-siblings who were conceived using gametes from the same donor, where neither is the donor's legal offspring. The half sibling whose information is being released must consent to the disclosure and both siblings must have had a suitable opportunity to receive counselling. There is also a proviso that the disclosure would not lead to the identification of an anonymous donor without the donor's consent unless regulations provide his or her identity may be disclosed.

141. New section 31ZE introduces a power for RATE to set-up, or keep, a voluntary contact register of people who would like to receive information about any person to whom they are genetically related as a consequence of the provision to any person of assisted conception treatment services in the United Kingdom involving donors before the HFEA's register began on 1 August 1991. RATE may also fund another person or body to set-up and keep a voluntary register on such terms and conditions as RATE considers appropriate.

142. The provider of the voluntary register may charge a fee to people wishing to join it. They may arrange for DNA samples of people who join to be analysed, with their consent, and matched with those of others on the register, and make arrangements for information to be disclosed between people who are genetically related.

143. Such a voluntary contact register, UK DonorLink, has been run as a national pilot project since 2004 by After Adoption Yorkshire, a voluntary organisation. After Adoption Yorkshire are funded to carry out the project by the Department of Health under the provisions of Section 64 of the Health Services and Public Health Act 1968 which empowers the Department to fund voluntary bodies. The links between the donor-conceived people, their half siblings and donors are made through DNA testing. At mid-2007 there are approximately 150-200 registrants with UK DonorLink, of whom about one third are donors. Currently there is no power for either HFEA or RATE to run or fund this voluntary register instead of the Department of Health, but new section 31ZF would provide that power for RATE. There is currently a charge to participants, and new section 31ZF allows this to continue.

Clause 33: Restriction on disclosure of information

144. This clause retains the prohibition on the disclosure of the information referred to in section 31(2) of the 1990 Act, which was contained in section 33 of the 1990 Act, as amended by the regulations implementing the EU Tissue Directive. The structure of the provision is amended however. Such information which has been obtained by any person as an employee of RATE, or of the HFEA, a person to whom a licence applies, including those covered by third party agreements, those to whom directions from RATE have been given, and authorised people who are carrying out functions which have been contracted out to them by RATE, cannot be disclosed except to the categories of person or in the circumstances specified in new section

33A(1).

145. The exceptions to the prohibitions on disclosure include those under section 33 of the 1990, as amended by the regulations. However additional exceptions have been included to permit disclosure with the consent of the person to whom the information relates more widely than under the 1990 Act and in more circumstances, to permit disclosure to other persons or bodies discharging a regulatory function and to permit disclosure to authorised people who are performing functions contracted out to them by RATE. There are also new provisions, in section 33C, about disclosure for medical research purposes. Apart from disclosure for medical research purposes, the common law of confidentiality and the Data Protection Act 1998 continue to apply where an exception lifts the prohibition.

146. New section 33C enables the Secretary of State to make provision, in regulations, requiring or regulating the disclosure of identifying information for medical research purposes, where she considers it necessary or expedient, in the interests of improving patient care or the public interest. The regulations may make provision for disclosure to be lawful despite any duty of confidentiality owed in relation to the information.

147. Before making the regulations, the Secretary of State must consult, to the extent that she considers appropriate, such bodies or persons who appear to represent the interest of those who are likely to be affected by the regulations.

148. The regulations may make provision for a body to be established which will have the function of considering whether disclosure should be authorised, should the Secretary of State consider this to be the appropriate way forward.

Clause 34: Mitochondrial donation

149. Clause 16 of the Bill inserts new section 3ZA(5) into the 1990 Act to provide a regulation-making power to enable eggs and/ or embryos with altered mitochondrial DNA to be classified as "permitted" eggs or embryos, and thus to be implanted in a woman.

150. This clause which inserts new section 35A in the 1990 Act, is needed because of the power in new section 3ZA(5) of that Act to allow embryos of eggs to be placed in a woman where they have been subjected to a process designed to prevent the transmission of serious mitochondrial disease (see clause 16). The other provisions of the Act assume that only one woman's egg is used to produce a child. Section 35A provides a further regulation-making power which could be used to amend the provisions referred to in subsection (2) in relation to cases involving mitochondrial donation. The provisions referred to relate to the following sections which can be modified in relation to cases where permitted eggs and/ or embryos have been created from material provided from two women:

- the registration of donor information (section 31),

- the ability of donor-conceived individuals to request information about their genetic parentage (new section 31ZA inserted by clause 32),
- the power to inform a donor that information has been requested (new section 31ZB inserted by clause 32),
- the provision of information to donors about donor-conceived children resulting from donation (new section 31ZC inserted by clause 32),
- the provision of information about donor-conceived genetic siblings (new section 31ZD inserted by clause 32),
- consent requirements to use of gametes and embryos (Schedule 3).
- provision of parental orders to gamete donors (clause 60 of the draft Bill).

Clause 35: Fees under the 1990 Act

151. This clause sets out the circumstances where RATE may charge a fee under the 1990 Act. Fees are to be determined by RATE with the scheme being subject to the approval of the Secretary of State and the Treasury. Different fees may be fixed for different circumstances and in fixing the fee, RATE must have regard to the costs incurred in exercising its functions under the 1990 Act under Part 1 of the Bill.

152. RATE is given a new power providing scope for it to charge fees to recoup the cost of meeting various statutory requests from donor-conceived people for information about their genetic relatives. In these cases the amount of the fee can only reflect the cost of dealing with applications under the provision concerned.

Clause 36: Powers of inspection, entry, search and seizure

153. This clause gives effect to Schedule 5 of this Bill. This inserts into the 1990 Act a new Schedule 3ZB which is largely based on the corresponding provision in Schedule 5 to the 2004 Act. Schedule 3ZB provides a power for persons authorised by RATE to inspect certain records, enter, search and inspect premises and seize things on the premises in connection with the Authority's regulatory functions. The clause also provides that it is not unlawful for a member or employee of RATE to be in possession of embryos, gametes or inter-species embryos in the course of their employment.

Clause 37: Penalties for offences under 1990

154. Clause 37 relates to offences and penalties described in the 1990 Act, as extended by the Bill and the requirement for consent of the Director of Public Prosecutions remain unchanged.

PART 3: PARENTHOOD IN CASES INVOLVING ASSISTED REPRODUCTION

Clause 39: Meaning of "mother"

155. Clause 39 re-enacts section 27 of the 1990 Act. It will remain the case that the woman who carries a child following assisted reproduction anywhere in the world is

the child's mother, unless the child is subsequently adopted or parenthood is transferred through a parental order (fast track adoption).

Clauses 42 and 43: Meaning of "father" and fatherhood conditions

156. There is also no change, in the provision made by clause 42, to the existing position in relation to a child conceived as result of treatment with donor sperm by a married woman. Her husband will be treated as the child's father, unless it is shown that he did not consent to his wife's treatment. This provision (and others which operate to determine legal parenthood) is subject to the common law presumption that a child is the legitimate child of a married couple, as to which see the note on clause 43(2) to (4), below. The provisions of the 1990 Act which enable an unmarried man to be the father of a donor-conceived child if he is 'treated together' with the mother in a licensed clinic are replaced by clauses 42 and 43. The new provisions require the couple to be treated in a UK licensed clinic, as before, to ensure there is clear evidence of the parents' intentions about fatherhood. However, for the man to be the father, the couple must each give notice of consent to him being treated as the father. Neither of them must have given notice withdrawing that consent and the woman to be treated must not have given notice of consent to another man or woman being treated as the child's parent at the time of the transfer of the sperm or embryo which results in conception. The notices of consent do not necessarily have to be drawn up in the clinic, but they must be provided to the "person responsible" at the clinic. This is the person under whose supervision licensed activities are carried out. If, for example, a woman were to give notice of consent to several people being the father of a child, and there are corresponding notices give by the other persons, the latest set provided to the clinic would apply.

157. After the transfer of the gametes or embryo, neither the man nor the woman can withdraw their consent to the man being treated as the child's father unless the woman does not conceive and a new cycle of treatment has to begin. Changes to the conditions which must be included in all treatment licences, which are made by clause 20(3), will require that, if the man withdraws his consent at an earlier stage, the woman must be told before the treatment proceeds. She will therefore have the opportunity to decide whether she wishes to go ahead in these circumstances. If the woman withdraws her agreement to the man being the father, he must be told as soon as possible but he would not, through these provisions, be able to stop her going ahead if she wished to do so. These provisions about notices of consent to fatherhood are intended to apply to couples and notices may not validly be given by two people who are within the prohibited degrees of relationship. This is defined in clause 64(2) to include parents and children, siblings and uncles / aunts and their nephews / nieces. Close relatives of this kind may not jointly be treated as a child's parents.

158. The Bill will maintain the situation that if an unmarried couple carry out self insemination with donor sperm at home or elsewhere, not as part of licensed treatment, the male partner would not be the legal parent. He would have to take steps to acquire formal parental responsibility, for example by adopting the child. A partner cannot become a parent where sperm is provided under a licence under paragraph 1A

of Schedule 2 to the 1990 Act (non-medical fertility services).

Clause 44: Further provisions relating to sections 40 and 41

159. Clause 44(1) clarifies that where a person is treated as a child's father under the preceding clauses, no other person is to be treated as the father. A sperm donor, for example, would not have this status. Clause 44(2) to (4) provides that clauses 42 and 43 do not affect the common law presumption that a child is the legitimate child of the parties to a marriage. If, for example, a woman marries between the conception of the donor-conceived child and its birth, it will be presumed that her new husband is the father of the child, even if the agreed fatherhood conditions were satisfied in relation to a different man at the time when the gametes or embryo were transferred. This presumption may, however, be rebutted by evidence (for example a DNA test) showing that the husband is not in fact the child's father. In that case, the provisions of clause 42 would apply and the man in respect of whom the agreed fatherhood conditions were satisfied would be the child's father. There is no parallel presumption at common law for people who enter a civil partnership. So the provisions which would otherwise apply to determine parenthood will not be affected by the mother entering into a civil partnership after the transfer of an embryo or gametes.

Clause 45: Use of sperm, or transfer of embryo, after death of man providing sperm

160. Clauses 45 and 46 replace provisions inserted into the 1990 Act by the Human Fertilisation and Embryology (Deceased Fathers) Act 2003. Clause 45 applies in the case where a man's sperm, or an embryo created with his sperm, is used after his death. The man may, in these circumstances, be treated as the child's father for the purposes of birth registration only, if various conditions are met. The man must have consented to the use of the sperm or embryo after his death and to being treated as the child's father for the purposes of birth registration. The woman must elect that he should be treated in this way within 42 days of the child's birth. This provision applies whether the embryo or gametes were transferred to the woman in the UK or elsewhere.

Clause 46: Embryo transferred after death of husband etc who did not provide sperm

161. Clause 46 makes similar provision for the case where donated sperm has been used. If the woman was married at the time of creation of an embryo using donor sperm and her husband dies before transfer of the embryo to her, she may elect that he should be treated as the child's father for the purposes of birth registration, subject to the consents described above. If the woman and man were not married at the time of creation of the embryo, there are additional requirements in that the agreed fatherhood conditions must have been met at the date of death and the embryo must have been created in the course of licensed treatment services in the UK.

Clause 47: Persons not to be treated as father

162. This clause clarifies who is not the father of a child, for example a man who

donates sperm for the treatment of another couple, or a man who has not consented to his sperm being used after his death.

Clause 48: Cases in which woman to be other parent

163. Clause 48 is new and brings the provision for female civil partners into line with that which applies to married couples. Where a female civil partner gives birth to a child conceived as a result of donor insemination (anywhere in the world), she is the mother of the child and her civil partner will automatically be the other parent, unless she did not consent to the mother's treatment. The terminology is different, but otherwise the legal provisions are the same as for married couples.

Clauses 49 and 50: Female same sex couples who are not civil partners

164. Where one of the women has a child as a result of donor insemination in a UK licensed clinic and the couple have in place, at the time of the transfer of the sperm or embryo which results in conception, current notices of consent to the other woman being treated as a parent, then she will be a legal parent. This will reflect the provisions for an unmarried heterosexual couple who have a child. The same provisions about withdrawing consent and providing information to the other party will apply. Like the provision for unmarried couples, these provisions will apply to couples, not two sisters or other categories of female relationships in families.

Clause 52: Embryo transferred after death of civil partner or intended female parent

165. This clause makes provision about registration of a deceased same sex partner as a child's parent in the register of births in certain circumstances. The provision for civil partners is comparable to that under clause 45 for married couples using donor sperm. The provision for other same sex couples is comparable to that for unmarried couples using donor sperm.

Clause 53: Woman not to be other parent merely because of egg donation

166. Clause 53 makes clear that a woman will only be treated as the parent of a child whom she has not carried if the provisions relating to parenthood of the mother's partner apply, or she has adopted the child. Being an egg donor will not therefore make a woman the parent of a child carried by another woman, although parenthood could be conferred by other legal provisions. For example, if a woman donated an egg to her female partner, and the agreed female parenthood conditions were met in relation to her.

Clauses 54 to 57 and 64: Further explanation

167. These clauses give further explanation of the effect of the preceding clauses on legal parenthood and define certain terms used in those clauses.

Clause 58: Late election by mother with consent of Registrar General

168. This clause allows for extension of the period during which a woman may elect for her deceased partner to be treated as her child's parent for the purposes of

birth registration, with the consent of the relevant Registrar General.

Clause 59: Interpretation of references to father etc.
169. Clause 59 provides for references to a child's father in legislation and in other documents to be read, in relevant cases, as references to a woman who is the child's parent by virtue of the Bill's provision for parenthood in same sex couples. Although some legislation is expressly amended by clause 60 and Schedule 6 to take account of the possibility that a child may have two female parents, this provision will reduce the need for additional consequential amendments.

Clause 60: Parental orders in favour of gamete donors
170. In clause 60 there are new provisions extending the categories of couples who can apply for a parental order (fast track adoption) where a child has been conceived using the genetic material of one of the couple, and has been carried by a surrogate mother, and where specified conditions apply. Currently, only married couples can apply for a parental order. Under the new provisions, civil partners would also be able to apply, as would unmarried opposite-sex couples or same-sex couples not in civil partnership. The other provisions relating to parental orders remain the same as the existing provisions of the 1990 Act. A single person remains unable to apply, but would be able to apply to adopt the child from the surrogate mother.

PART 4: MISCELLANEOUS AND GENERAL

Clause 65: Sperm sorting kits
171. Clause 65 provides a power to make regulations which would create offences in relation to selling, supplying or advertising kits (or their component parts) which may be used for the purpose of selecting the sex of a child. The Department of Health is not aware of the existence of such kits at present, but it is possible that 'DIY' means of sex selection – such as kits to sort sperm mechanically into those which would produce a boy and those which would produce a girl– may be developed for home use in future.

Clause 66: Surrogacy arrangements
172. Some women cannot carry a child, because they were born with no uterus, have had their uterus removed, have had repeated miscarriages or would suffer severe harm to their health. In a small number of cases, they ask another woman to be a surrogate mother and carry a child for them. Under the Surrogacy Arrangements Act 1985 ("the 1985 Act") surrogacy arrangements are not enforceable in law.

173. To avoid the 'commercialisation' of surrogacy, the 1985 Act prohibits organisations, or people other than intended parents or surrogate mothers themselves, from undertaking certain activities relating to surrogacy on a "commercial basis". This is defined to include receipt of any payment. In particular, no person may on a commercial basis initiate or take part in any negotiations for a surrogacy arrangement,

offer or agree to negotiate an arrangement of this kind, or compile information with a view to its use in making an arrangement.

174. Clause 66 allows bodies which operate on a not-for-profit basis to receive payment for providing some of those services. It does so by exempting them from the prohibition in the current law.

175. The clause separates out into four categories the activities which are prohibited if done on a commercial basis. Not-for-profit bodies are permitted to receive payment for carrying out activity in two of those categories. The first is initiating negotiations with a view to the making of a surrogacy arrangement. A non-profit making body might charge, for example, for enabling interested parties to meet each other to discuss the possibility of a surrogacy arrangement between them. The second is compiling information about surrogacy. Not-for-profit organisations would, for example, be able to charge for establishing and keeping lists of people willing to be a surrogate mother, or intended parents wishing to have discussions with a potential surrogate mother.

176. It will remain the case that not-for-profit bodies will not be permitted to receive payment for offering to negotiate a surrogacy arrangement or for taking part in negotiations about a surrogacy arrangement. These activities are not unlawful if there is no charge, however.

177. The Bill also makes changes in relation to advertising by non-profit making bodies. Currently, under the 1985 Act, it is an offence to publish or distribute an advertisement that someone may be willing to enter into a surrogacy arrangement, or that anyone is looking for a surrogate mother, or that anyone is willing to facilitate or negotiate such an arrangement. The clause provides that this prohibition does not apply to an advertisement placed by, or on behalf of, a non-profit making body, provided that the advertisement only refers to activities which may legally be undertaken on a commercial basis. This would mean that a not-for-profit body could advertise that it held a list of people seeking surrogate mothers and a list of people willing to be involved in surrogacy, and that it could bring them together for discussion. But it would remain illegal for anyone to advertise that they wanted a surrogate mother or to be a surrogate mother.

Clause 67: Grant, revocation or variation of licences under Human Tissue Act 2004

178. Clause 67 makes a number of small amendments to the 2004 Act in relation to the procedure where RATE proposes to grant, vary or revoke a licence. The Authority will provide the applicant with notice of its proposed decision and the applicant may require RATE to reconsider its decision. The appellant has the right to appeal the decision of RATE to the appeals committee. The clause also provides that where RATE takes the view that it does not have enough information to decide an application, then it does not need to consider the application further until the required

information is provided.

Clause 68: Fees in respect of licences under Human Tissue Act 2004

179. Clause 68 sets out the circumstances where RATE may charge a fee in respect of licences under the Human Tissue Act 2004. Fees are to be determined by RATE with the scheme being subject to the approval of the Secretary of State and the Treasury. Different fees may be fixed for different circumstances and in fixing the fee, RATE must have regard to the costs incurred in exercising its functions under the 2004 Act as well as those in Part 1 of the Bill.

Clause 69: Fees under instruments implementing Community legislation on blood or tissue

180. Clause 69 widens the provisions that may be made by regulations or scheme made under section 2(2) of the European Communities Act 1972 for the purposes of implementing any of the Directives and sets out the circumstances where RATE may charge a fee in respect of any order, rules. Fees are fixed by RATE in accordance with a scheme approved by the Secretary of State and the Treasury. In fixing the fee, RATE may have regard to all the costs incurred in exercising its functions under the order, rules, regulations or scheme or any other enactment.

FINANCIAL EFFECTS OF THE BILL & SUMMARY OF THE REGULATORY IMPACT ASSESSMENT

181. A separate draft full Regulatory Impact Assessment (RIA) has been produced to accompany the draft Bill, comparing the Government's proposals with "do nothing" and de-regulatory options.

182. The analysis concludes that, in terms of benefits:

> "[u]pdating, and future proofing the law to deal with new situations will help maintain the UK's position as a world leader in reproductive technologies. Savings (in the region of £700,000 per annum) are expected to accrue from the formation of RATE. The precise amount will depend on RATE's detailed working practices, which largely fall for RATE itself to determine".

183. In terms of costs:

> "[t]ransitional costs of the move to RATE are estimated in the region of £2m to £6m depending chiefly upon location. Estimated cost of all changes in relation to legal parenthood (e.g. modifications of birth registration) up to £0.8m".

EFFECTS OF THE BILL ON PUBLIC SERVICE MANPOWER

184. The Government's view is that the Bill would have no overall effect on public service manpower. As referred to in the section above, there will be financial implications arising in consequence of the proposed changes in relation to legal

parenthood (notably in regard to births registration). However, the Government expects any impact on manpower to be negligible.

EUROPEAN CONVENTION ON HUMAN RIGHTS

185. As this is a draft Bill, no statement as to compatibility with Convention rights is required at this stage. However, it is the Department's view that such a certificate could be given if the Bill were introduced to Parliament in its current form. In relation to licensing decisions to be made by RATE, the Bill's provisions are compliant with article 6 ECHR, which requires that, in the determination of civil rights and obligations, everyone is entitled to a fair and public hearing within a reasonable time by an independent tribunal established by law. The Bill provides for a two stage process of appeal, firstly to a committee of RATE itself, followed by a right of appeal to the High Court on a point of law.

186. The subject matter of the Bill also raises issues in relation to articles 8, 12 and 14 ECHR, which respectively guarantee rights to protection of private and family life, the right to marry and found a family and freedom from discrimination in the enjoyment of rights under the Convention. Case law of the European Court of Human Rights in Strasbourg has established that, because there is no international consensus with regard to the regulation of IVF treatment or the use of embryos created by such treatment, and because the use of IVF treatment gives rise to sensitive moral and ethical issues against a background of fast moving medical and scientific developments, states are to be accorded a wide margin of appreciation in this area. We take the view that provision made by the Bill falls within this margin of appreciation. In some cases (for example, the extension of legal parenthood to same sex couples and availability of parental orders to unmarried and same sex couples) the provision made by the Bill will enhance the existing protection of rights under the Convention.

187. Case law of the European Court has also established that states have a broad margin of appreciation in determining the point at which life should begin to benefit from the protection guaranteed by article 2 ECHR. The approach taken by the Bill, that embryos have no right to life which is protected by article 2, is therefore is compliance with Convention obligations.

COMMENCEMENT DATE

188. The draft Bill will initially be subject to pre-legislative scrutiny.

189. Clause 77 contains the relevant commencement power. Clause 73 includes power to make transitional provisions.

Draft Full Regulatory Impact Assessment (RIA)

Title of proposal

4.1 Human Tissue and Embryos Draft Bill.

Purpose and intended effect

Objectives

4.2 The (Draft) Bill is intended to update the law on assisted reproduction and embryo research to ensure that it remains fit for purpose in the 21st century, and to rationalise regulatory structures.

4.3 The Bill's provisions will implement the proposals contained in the White Paper *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos*) published in December 2006.[1]

Background

4.4 Current legislation – principally the Human Fertilisation and Embryology Act 1990 (the 1990 Act), and the Human Tissue Act 2004 – imposes a range of regulatory measures to activities involving human organs, tissue and cells, including gametes (sperm and eggs) and embryos. The 1990 Act was based on the conclusions of the Warnock Committee of Inquiry, published in 1984, and subsequent extensive public consultation, which followed the birth of the first child conceived through *in vitro* fertilisation in 1978. The UK is a world leader in the development and use of reproductive technologies, including leading-edge stem cell research. The Human Tissue Act followed a broad and fundamental review of the law on human organs and tissues in 2002, after public inquiries had established that organs and tissues from people who had died had often been removed, stored or used without proper consent.

4.5 The Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) are statutory licensing bodies. The remits of both organisations involve licensing and inspection, producing codes of practice for licence holders, and

1 Available in hard copy from The Stationery Office or online from the Department of Health's website.

providing advice to Ministers as required. Both organisations will be "competent authorities" responsible for overseeing the requirements of European Union Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.[2]

Rationale for Government intervention

4.6 The 1990 Act was drawn up on the basis that certain activities involving human embryos outside the body, or the use of stored or donated gametes, demanded active regulation and definite legal limits. Ultimately, the Government believes that the force of law remains justified in the distribution of permissions, rights, responsibilities and prohibitions for the development and use of human reproductive technologies. Law and active regulation are necessary to set out and monitor a system of public oversight and accountability, taking account of the principles of good regulation.

4.7 The Government announced in January 2004 that it would undertake a review of the 1990 Act, in particular to take account of factors such as the development of new technologies and procedures, international developments in standards, possible changes in public attitudes on complex ethical and sometimes controversial issues and the need to ensure the effectiveness of regulation and its continued "fitness for purpose". In undertaking its review, the Government also took account of the House of Commons Science and Technology Committee's extensive report and recommendations on human reproductive technologies and the law, published in March 2005.

4.8 The Department of Health also undertook a review of its "arm's length bodies" – stand-alone national organisations sponsored by the Department undertaking executive functions – as part of a wider programme of measures to improve efficiency and cut bureaucracy.

4.9 The Government's decision to establish RATE was announced in July 2004. Replacement of the HFEA and HTA with a single authority will help to reduce the burden on the frontline, provide the potential for cost savings or benefits to be passed to the regulated sector and free-up more resources for the delivery of services to patients. It is therefore part of a wider change programme designed to ensure that arm's length bodies are able to make the greatest possible contribution to health and social care priorities. The programme has reduced the number of ALBs and is bringing about major improvements in their efficiency, generating significant savings for frontline services. As part of that programme of work, we have already seen an improvement to ALB operating efficiency, which has helped deliver a reduction in 2006-07 recurrent Grant in Aid of over £125m compared to 2005-06. This comes on top of a reduction in 2005-06 of over £150m compared to 2003-04.

2 Referred to hereafter as the EU Tissue Directive.

4.10 However, it is important to recognise that the establishment of RATE goes beyond the context of the ALB review. It provides an opportunity for the creation of a single regulatory body responsible for the regulation and inspection of all functions relating to the whole range of human tissue – blood, organs, tissues, cells, gametes and embryos. As such, RATE will be able to ensure that common principles and standards are applied wherever that is appropriate; that the risk of overlap between these sectors is minimised; and that there is continuity at the interface between closely related areas.

4.11 RATE will take over, from the Medicines and Healthcare products Regulatory Agency (MHRA), the regulation required by the European Union Blood Directives, of the quality and safety of the collection, testing, processing, storage and distribution of blood and blood components.

4.12 There will be no direct transfer of funds from the MHRA to RATE and it will be for RATE to assess the costs of regulating the quality and safety of the collection, testing, processing, storage and distribution of blood and blood components, and to set its fees accordingly with the agreement of Secretary of State and Treasury. It is unlikely that the costs of regulating the quality and safety of the collection, testing, processing, storage and distribution of blood and blood components will change greatly with a change of regulator, but there may be potential for cost savings if blood establishments that also store tissue and inspection costs can be rationalised.

4.13 The Government does not propose to make any changes to the substantive provisions of the Human Tissue Act 2004 – such as the requirement for appropriate consent to the removal of organs and other tissue from the body of a deceased person – other than any changes consequential upon the replacement of the HTA by RATE. The provisions of the Human Tissue Act were conclusively debated in the previous Parliament.

Consultation

4.14 The Department of Health published a consultation paper on 16 August 2005. The closing date for responses was 25 November 2005. A total of 535 responses were received from a wide range of stakeholders including licence holders, patient's representatives, professional bodies and individual members of the public. A report summarising the landscape of arguments put forward in response to the consultation document was prepared by *People Science and Policy Ltd* and published on 30 March 2006.

4.15 The Government's proposals for revised legislation, including replacement of the HFEA and HTA with a single regulator, were detailed in a White Paper published on 14 December 2006.

Options

4.16 Four options have been identified:

Option 1 – Do nothing

4.17 This option means, essentially, retaining the current regulatory provisions and structures. This would risk the law becoming outmoded by, for example, new technological developments, or outdated in relation to the other factors mentioned above that led to the Government's decision to review the law in this area. This would threaten the UK's position at the forefront of development of reproductive technology which is, in part, attributed to robust and transparent regulatory controls. The establishment of RATE is a government commitment. To do nothing would miss the opportunity to streamline regulation by replacing two non-departmental public bodies with one.

Option 2 – De-regulation

4.18 This option means, essentially, removing the current regulatory requirements in whole or in part – for example it could mean retaining certain prohibitions, but removing some licensing requirements. The requirements of the EU Tissue Directive relating to quality and safety of blood and blood products, tissue and cells would still apply, however these do not extend to 'ethical' matters or to research *in vitro*. This would leave a range of activities involving, for example, the use of embryos for research *in vitro* including embryonic stem cell research, or donated gametes, without specific regulation beyond quality and safety aspects. Risks include the opening up of inconsistencies in the way in which specific and closely related cases are handled.

Option 3 – Revision of current regulation and regulatory structures

4.19 This option means reviewing current arrangements and structures and making changes where it is judged necessary taking account of a range of factors. It carries risks associated with change such as possible planning blight, uncertainty and transitional costs.

Option 4 – Update the 1990 Act but retain the HTA and HFEA

4.20 This option would update the law on assisted conception but leave the current regulatory authorities in place. This would not achieve the Government commitment

to combine the HTA and HFEA as part of the ALB Review and would reduce the potential for cost savings to be passed to the regulated sector.

Costs and benefits

Sectors and groups affected

4.21 Currently there are 84 HFEA-licensed treatment clinics, mainly providing privately-funded treatment, plus an additional 8 centres licensed to store gametes or embryos, and 34 licensed embryo research projects. Licensed centres, their patients, donors, and persons involved in licensable research, will be directly affected by the proposed measure.

4.22 Indicative costs of compliance with the HFEA's Code of Practice for licence holders, other than licence fees, have been estimated, as part of a cross-Whitehall project to calculate and reduce administrative burdens, to be in the region of £10 million.

4.23 In addition, this RIA presupposes implementation of the requirements of the aforementioned EU Tissue Directive, which will expand the scope of licensable activities to include, for example, processing of partner gametes within treatment services. This change will increase the number of licensed fertility centres to 124. Therefore centres licensed as a result of the Directive will also be directly affected by the proposed legislation (a separate RIA accompanies regulations transposing the requirements of the Directive into domestic law). In terms of indirect effect, regulation governing the use and development of assisted reproduction, and the use of human embryos in research aimed at the advance of assisted reproduction techniques or the discovery of treatments for serious disease, is clearly of wider interest to society as a whole.

4.24 There are approximately 600 licensed tissue establishments, plus 284 satellite sites within the remit of the Human Tissue Authority.

4.25 There are approximately 400 hospital blood banks in the UK, the majority are within the NHS, with about 40 in the private sector.

4.26 The legislation will apply to the whole of the United Kingdom as far as assisted reproduction and embryo research aspects are concerned (mirroring current extent of the 1990 Act), and will apply to England, Wales and Northern Ireland as far as human tissue is concerned (mirroring current extent of the Human Tissue Act 2004). The regulator will have powers to assist any other public authority in the UK, and will therefore be able to undertake functions in relation to human tissue in Scotland if commissioned to do so.

Benefits

Option 1: Do nothing

4.27 In maintaining the status quo, this option has the short term merit of temporary avoidance of costs and uncertainty/ disruption associated with change.

Option 2: De-regulation

4.28 This option has potential benefits in terms of the avoidance of the costs of regulation, which largely fall on licence-holders and generally are passed on to service users. Arguably, other benefits could accrue from fewer constraints on clinical and academic freedom from regulatory intervention.

4.29 *Prima facie*, this option would release the current direct costs of regulation (other than costs of, for example, licensing and inspection associated with the requirements of the EU Tissue Directive which would address quality and safety aspects).

4.30 The direct compliance costs of current regulation under the HFEA are as follows: initial treatment licence fees of £500 (£200 for storage only licences), then fees of £105.50 per cycle of *in vitro* fertilisation, and £52 per donor insemination cycle. A fee of £500 is charged to small embryo research projects, and £750 to larger projects.

4.31 The extent to which the estimated £10m "administrative burdens" costs would not apply in the absence of the current scheme of regulation would depend on the costs arising due to other statutory requirements (in particular the EU Tissue Directive) that would remain, and compliance with non-statutory regulation and other professional good practice.

4.32 The table below shows the current fee structure (annual payment) for the regulation of human tissue. These figures follow a recent consultation by the HTA, to ensure that fees continue to reflect the level of service required from the Authority.

Sector	Fee for main site (£)	Fee for satellite (£)
Research	5200	800
Public display	3600	500
Pathology	5300	2100
Anatomy	5200	700
Tissue banks	7600	1000

4.33 Currently MHRA inspections of third party laboratories carrying out testing on behalf of blood establishments (there are no more than 10) cost £2,000 to £4,000 per laboratory per inspection. The size of the fee varies with the range of testing activities undertaken. These fees are the same as those charged by the MHRA for similar

inspections of contract laboratories under The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2004 No. 666. The total inspection costs over a 2 year period are estimated to be in the range of £20,000 to £40,000.

4.34 Both the NHS and the private sector are charged an annual compliance fee of £775 per blood bank. This fee is calculated to cover the operational costs to the MHRA of the receipt and assessment of annual compliance reports from hospital blood banks and the operation of the haemovigilance system for the receipt and assessment of reports of serious adverse events and adverse reactions. The MHRA developed a *pro forma* compliance report for hospital blood banks to complete and return, which they were required to do in the first instance by 31 December 2005. The Agency has also developed an online system for the reporting of serious adverse events and serious adverse reaction to blood and blood components. The total cost to hospital blood banks of the compliance monitoring and haemovigilance services is estimated to be £310,000 PA.

4.35 There are currently 4 blood establishments which will be charged an annual fee of £375 for the operation of a haemovigilance system for reports of serious adverse events and serious adverse reactions. A blood establishment that is operating as blood bank will be charged an annual fee for the receipt and assessment of annual compliance reports. The total cost to these blood establishments for the haemovigilance service will be £1,500 PA.

4.36 Transplant centres that take preoperative autologous donations of blood or blood components and are not also a blood establishment will be subject to an annual fee of £375 for the operation of a haemovigilance system for reports of serious adverse events and serious adverse reactions. The majority of the 50 NHS transplant centres are already counted within the 400 hospital blood banks in the UK. If a transplant centre is in a hospital with a blood bank only one annual fee of £375 would chargeable.

Option 3: Revision of current regulation and regulatory structures

4.37 This option (as envisaged under the proposed RATE Bill) has benefits arising from the rationalisation of regulatory structures, increased clarity (and reduced scope for legal challenge) in the substantive legal provisions, and keeping pace with current and anticipated changes in technology and attitudes. Replacing two arm's length bodies with one will produce savings in operating costs (merging back office functions, streamlining licensing arrangements) and the fees that the new body will charge licence holders to cover the costs of regulation. The estimated saving is approximately £700,000 per annum. These savings represent around 10% of operating costs of the

HTA and HFEA, which is a useful guide in terms of merged organisations and potential savings.

Option 4: Update the 1990 Act but retain the HTA and HFEA

4.38 This option would allow the legislation to meet the necessary changes to reflect technological advances in fertility medicine but would not encompass the merging of the two organisations to form RATE, thereby retaining a regulatory 'status quo'. It would therefore have some of the benefits of option 3, insofar as these relate to the provisions of the 1990 Act, but not those associated with establishment of RATE.

Costs

Option 1: Do nothing

4.39 Costs (not including the current costs of regulation per se) associated with this option are difficult to quantify. They include both costs arising from, for example, legal challenges as technological advances overtake the wording of the Act, and 'opportunity costs' as a result of increasing legal uncertainty impacting on, for example, investment decisions in relation to stem cell research. Further this option would continue to incur the costs of running two separate regulatory authorities.

Option 2: De-regulation

4.40 It is difficult to quantify 'costs' arising from a perceived lack of adequate regulation of activities in this area. The current regulatory scheme arose from public concern that there was a need for active regulation and monitoring, recognised by those who are subject to regulation.

4.41 The point was made by the Better Regulation Task Force, in its 2003 report Scientific Research: Innovation with Controls, that "the UK is seen as a world leader in embryonic stem cell research, and this is largely due to the effective regulations that control it".

Option 3: Revision of current regulation and regulatory structures

4.42 It is proposed that the new regulatory authority (RATE) would be funded in part by grant-in-aid from the Department, with the bulk of the costs of regulation recovered via licence fees, as at present.

4.43 There will, however, be additional costs incurred during transition to the new arrangements, including the cost of setting up RATE (the location of RATE is yet to be determined). It is expected, however, that these will be minimised in the interim through close joint working and sharing of 'back office' functions of the HFEA and HTA. Current estimates of transitional costs are in the range £2m to £6m depending mainly upon issues of shared accommodation and ultimate location of RATE.

Such costs are likely to include fit out/ refurbishment costs, potential redundancy payments, potential relocation packages etc and expert consultancy support etc. The cost of blood regulation should largely be recouped from fees as for the MHRA. MHRA and RATE will, over time, recover inspection costs from the blood establishments and blood banks inspected. Should RATE occupy existing London office space, already on the civil estate, then there is scope for these costs to be less than £2 million. In all cases, one-off transitional funding will be required to be provided by Government in the first year and will not produce any burden on the regulated sectors.

Option 4 – Update the 1990 Act but retain the HTA and HFEA

4.44 Although this would retain the benefits of revising the 1990 Act, it would not enable the two regulators to merge or for the regulated sector to share the potential for better regulation, streamlining of functions and possibly a reduction in the costs of regulation.

Benefits and costs of specific proposals

4.45 For the vast bulk of the proposed changes to the 1990 Act, we envisage their effect being cost-neutral. Some are unquantifiable in monetary terms or in terms of direct effects. For example, it is intended that the definition of the term "embryo" be reviewed and more clearly defined to reflect new techniques of embryo creation that have arisen since the passage of the original legislation. This will, in effect, secure the status quo in regulatory terms, and provide future-proofing against subsequent developments. The benefits accruing from avenues of scientific research using new forms of embryo creation within a more certain (rather than a less certain) regulatory environment are, however, difficult to establish quantitatively. Similarly, other proposed changes seek to put into statute requirements which already apply in practice via the powers granted to the regulator. For example, there is already a *de facto* ban on the use of embryo testing other than for serious non-medical reasons through the HFEA's licensing criteria and code of practice for licence holders.

4.46 In some areas, however, there will be a clear gain for certain groups. Recognition of the advent of civil partnerships will bring benefits to those persons affected. For example, direct attribution of parental status will obviate the need to initiate adoption procedures and any associated costs. Extended storage limits can be expected to benefit persons choosing to store embryos and those who are responsible for their storage in terms of reduced paperwork. Less strict limits on access to information held on the HFEA's register of information about infertility treatments can be expected to be of general benefit, particularly by increasing opportunities for follow-up research and any subsequent improvements made to treatment regimes for the benefit of future patients.

4.47 The attached table gives more detail on individual proposals.

Small Firms Impact Test

4.48 Many licensed clinics (which are predominantly private sector based) and research centres can be considered to be small firms. Officials from the Department of Health visited at an early stage a sample of assisted conception clinics to discuss possible areas of the law and regulation to be covered by the review. The Department also has regular dialogue with bodies representing the sector. Representations received from the sector during the Government's consultation revealed a broad level of support for the Government's proposals. The Government believes that the proposed measure, by reducing direct costs of regulation, will have a positive effect on small firms. At the same time increased clarity in the law will also be of benefit in terms of investment decisions.

Competition assessment

4.49 The Government's proposals retain the overall structure of regulation (that is, a statutory licensing authority and fee-paying licence holders) and many of its current aspects. Therefore no effect is envisaged on the 'market' structure or on the ability of suppliers to enter or exit the market or to compete. Reduction in the costs of regulation can, however, be expected to have a positive impact on 'supply' and therefore have a knock-on impact for paying consumers.

Equality issues

4.50 Many of the topics within the scope of the proposals deal with fundamental matters associated with human reproduction and health. It is therefore the case that, whether or not assisted reproduction techniques are employed, there will necessarily be issues arising due to biological factors – including age, gender, and sexual orientation. Relevant genetic factors may sometimes be correlated to a greater or lesser extent with ethnicity, and be of particular interest to persons carrying heritable conditions leading to disability. Further, there can be strong religious beliefs associated with the development and use of reproductive technologies. Assessment of equality issues in this area is also complicated by the question of whose equality is under consideration – given that it is not a straightforward matter of there being simply one person involved.

4.51 The Government believes that the proposals for revised legislation will not have any adverse impact on equality, including with regard to race, and also would not have any adverse rural impact.

4.52 There are, however, proposals relating to the assessment of patients prior to treatment, and parental recognition following the use of donated sperm, eggs or embryos which can be expected to have a positive impact for certain groups. The Government proposes that whereas treatment providers will continue to be required to take account of the welfare of the prospective child, the current reference in law to the child's "need for a father" will be removed. Recognition of legal parenthood following assisted reproduction will be extended to cover civil partnerships and other same sex couples, broadly mirroring existing provisions relating to married and unmarried couples.

Enforcement, sanctions and monitoring

4.53 Existing law in this area is enforced through a range of sanctions including criminal penalties as well as measures attaching to licensing. The remits of both the HFEA and the HTA have inspection and monitoring functions. The Government proposes that a similar range of measures will continue with the advent of RATE, but this will be reviewed in light of the emerging issues following the Macrory review of penalties.[3]

Implementation and delivery plan

4.54 The Bill is intended to amend primary legislation, and also contains a range of secondary legislative powers in order to allow some flexibility to respond to developments in this fast-moving area of science and medicine. The Bill will be published initially in draft form for pre-legislative scrutiny in the 2006-07 parliamentary session, and introduced formally thereafter when parliamentary time allows.

4.55 In advance of the establishment of RATE, officials at the HTA and HFEA are already working closely to obtain a greater understanding of each other's organisations. In addition, one person now chairs both organisations. This also ensures that, where possible, any major projects, for example on procurement, are undertaken with RATE in mind. Such an approach reflects the need to consider the Government's wider plans at an early stage whilst not pre-empting Parliament's agreement to the establishment of RATE.

3 Regulatory Justice: Sanctioning in a post-Hampton World, Cabinet Office, May 2006.

Post-implementation review

4.56 The existing regulatory bodies have specific functions to monitor developments in their fields of interest and it is proposed that RATE will retain this function, including to advise Ministers as required. The effectiveness of RATE itself will be monitored primarily through the usual procedures for oversight of arm's length bodies, including clearance and monitoring of business plans and annual accountability reviews.

Summary and conclusion

4.57 The Government believes that primary legislation, and regulation by a dedicated authority remain necessary in response to public concerns about the development and use of reproductive technologies and human tissue, in order to meet international obligations such as relevant European Union directives, and to maintain the UK's position as a world leader.

4.58 Option 3 will meet the Government's stated objectives to provide a legislative framework that is fit for purpose into the future whilst rationalising regulatory structures. Options 1 and 2 would not meet those objectives, and option 4 would only meet those objectives in part. The present law on assisted reproduction and embryo research needs to be updated to take account of developments of new technologies, changes in public attitudes and to ensure that regulation remains effective, and continues to secure public confidence. Replacement of two existing regulatory bodies with a single authority will rationalise regulation and produce savings.

Summary costs and benefits

Option	Total benefit per annum	Total cost per annum
1 Do nothing	This option would leave in place the current regulatory controls and structures, without updating them in the light of relevant reviews.	Current regulatory costs are in the region of £8m in fees levied on establishments across the sectors of fertility/ embryology, tissue and blood. Indicative compliance costs of £10m were calculated for the fertility embryology sector. Approximately £2.65m is provided to the HFEA and HTA per year as grant in aid.
2 De-regulation	Avoidance of some of the costs of regulatory compliance. See for example the direct costs of compliance in paragraph 27, including £500 initial licence fee for assisted conception clinics.	Unknown consequences arising from lack of statutory regulation, such as increased adverse incidents and litigation.
3 Revision of law and structures	Updating, and future proofing of law to deal with new situations will help maintain the UK's position as a world leader in reproductive technologies. Recurrent savings (in the region of £700,000 per annum) are expected to accrue from the formation of RATE. The precise amount will depend on RATE's detailed working practices, which largely fall for RATE itself to determine.	Transitional one-off costs of the move to RATE are estimated in the region of £2m to £6m depending chiefly upon location. Estimated cost of all changes in relation to legal parenthood (e.g. modifications of birth registration) up to £0.8m.
4 Update 1990 Act, but do not create RATE.	Benefits are as per option 3 but without the estimated savings resulting from rationalisation of the regulatory bodies.	Costs are essentially as per option 1 with regard to regulatory structures.

Annex: Summary of revising legislation, regulatory impact and administrative burdens

Proposal		Current position	Regulatory impact
1	The current model of regulation, whereby Parliament sets the prohibitions and parameters within which a statutory authority licenses activities should continue.	The Human Fertilisation & Embryology Act sets out parameters within which the Human Fertilisation & Embryology Authority (HFEA) licenses activities.	These proposals will, in principle, retain similar regulatory arrangements as at present, based on a scheme of licensing with an appropriate range of enforcement options. Within that broad framework, the regulatory authority will have a range of functions and responsibilities to discharge, taking into account the principles of good regulation. See further under the heading "RATE" for details on the proposed new regulatory authority.
2	Activities involving the creation, keeping and use of embryos outside the body, or the use of donated gametes, should continue to be subject to licensing by an independent regulator.	The law requires that these activities may only be undertaken under the authority of a licence from the HFEA.	

Proposal		Current position	Regulatory impact
3	All human embryos outside the body, regardless of the manner of their creation, will be within the scope of regulation.	The current wording of the Act in relation to embryos has cast doubt on the application of the law to embryos created by novel processes.	Clarification of definitions and the framework surrounding them will reduce the risk legal challenge, including judicial review, over decisions made by the regulatory authority. Previously non-scientific, or inexplicit text within the Act has led to judicial review of decisions. By bringing the Act up to date and providing regulation-making powers, the Act is far more robust thereby reducing the burden brought on by legal challenges. In effect this maintains the status quo, but with a greater degree of future-proofing. The aim of the law is active monitoring and regulation of, *inter alia*, the creation and use of embryos, and therefore must have all human embryos clearly within its purview.
4	The law will continue to treat 'eggs in the process of fertilisation' in the same way as embryos, and this will also apply to eggs undergoing other processes of embryo creation.	The law currently includes 'eggs in the process of fertilisation' within the meaning of the term 'embryo', for the avoidance of doubt. It does not mention other processes of embryo creation.	

Proposal		Current position	Regulatory impact
5	Artificial gametes. The Government proposes a ban on the use of non-naturally occurring gametes (cells not originating in the testes or ovaries) in assisted reproduction treatment.	The law does not currently refer to artificial gametes.	Artificial gametes, while not a reality at the moment, research into them may in some years time come to fruition, potentially allowing the creation of gametes from any cell in the human body. Clarification of the distinction between natural and artificial gametes will remove any need for decision making over the legality of artificial gametes from the regulatory authority, thereby reducing the risk of burdens to the regulatory authority through judicial challenge. The development of artificial gametes, will bring with it many safety concerns, which would require resolution prior to their ever being used in treatment.
6	The Government proposes to retain a duty for treatment centres to consider the welfare of the child who may be born as a result of treatment (or any other child who may be affected).	The law requires that account is taken of the welfare of the child (including the need for a father) before providing treatment. The HFEA is obliged to provide practical guidance on this duty.	As at present, practical arrangements for fulfilling this duty will be a matter for guidance from the regulator. The current arrangements were recently and extensively reviewed by the HFEA including through consultation with treatment clinics, and changes were made. Guidance currently focuses on the likelihood of serious harm, and may therefore be considered to be more proportionate to the risks involved than previously. This is, arguably, also more akin to the "good medical practice" that would prevail in the absence of statutory regulatory controls. The regulatory burden is unlikely to increase or decrease significantly as a result of these proposals.
7	On balance, the Government has decided to propose that the reference to the need for a father (in consideration of the welfare of the child) should be removed from the Act.		

Proposal	Current position	Regulatory impact
8 The law will enable the *storage* of gametes from persons lacking capacity where the gametes have been lawfully removed in the best interests of that person, without written consent, where medical opinion indicates that the person is likely to gain/ regain capacity.	There is currently no provision to make exceptions to the rule requiring written consent for storage, even where this would be in the patient's best interests.	Fulfilling the necessary conditions in this case will, in itself, be a minor new regulatory burden. This is because it deals with a situation not currently addressed in law, which differs significantly from the norm. The current legal requirement for *written* consent to storage will be set aside in the case of non-competent adults and non-Gillick competent young people if a clinician certifies in the patient's health record that: • the gametes have been lawfully removed • in his opinion storage of gametes is in the patient's best interest • in the case of a non-competent adult, that person is expected to regain competence (a similar declaration will not be required for a young person because they will generally be expected to gain competence with age). It is likely that much of this information would routinely be recorded in health records as a matter of good practice, so this requirement is unlikely to present a significant administrative burden. As this is likely to be a rare occurrence, additional administrative costs cannot be accurately estimated. As a guide, indicative costs from the Department's administrative burdens project ascribed a unit cost of £1.95 for a number of different requirements that needed information to be recorded in the patient's health record. The unit cost of obtaining a written opinion that fertility is likely to remain impaired was estimated at £35.

Proposal		Current position	Regulatory impact
9	There should be a 'cooling off' period of up to one year following the withdrawal of consent to embryo storage by one of the persons whose gametes were used in the creation of the embryo.	Written withdrawal of consent from either party removes authority for continued storage.	In the relevant circumstances, this will create a minor new regulatory burden, against which must be offset the benefits of enabling scope for conflicts to be resolved –potentially without expensive litigation. If a licensed establishment receives written notice of withdrawal of consent from one of the parties whose gametes created the stored embryo(s), a one year storage period, starting on the day the notice was received, will take effect. The establishment will be required to take all reasonable steps to inform the second party that the first has withdrawn consent to allow the second party to: • agree to the removal of the embryo(s) from storage • reach a resolution with the other party, or • take legal advice/ action. If no agreement can be reached the embryos will remain in storage for the remainder of the one year "cooling off " period. If the second party does not respond to the licensed establishment's communication the embryos will still be held in storage until the one year period expires. This is likely to be a very rare occurrence. The administrative burdens project ascribed an indicative unit cost of £60.06.

Proposal	Current position	Regulatory impact
10 The Government proposes to extend the statutory storage period for embryos from five years to ten years, bringing embryos into line with gametes.	The current statutory storage period for embryos is five years subject to exceptions as set out in regulations.	This change will decrease a regulatory burden and provide a cost saving. Currently, patients wishing to extend storage of their embryos for a further 5 years can only do so for their own use and must complete a second prescribed consent form (ES form). The treating clinician must also state on the form his opinion that the patients' fertility is likely to remain impaired. The move to a statutory limit of 10 years will allow patients to consent to storage for the full 10 years at outset, without the need for a second consent form. It will also remove the requirement that the final 5 years storage should only be for patients' own use, allowing donation of the embryos for the treatment of others or for research should the patients later wish to do so. The indicative cost of obtaining completion of ES form was estimated in the administrative burdens project to have a unit cost of £16.19, equating to £405,000 across the assisted reproduction sector.

Proposal		Current position	Regulatory impact
11	The law will include explicit criteria for the testing of embryos. Legitimate purposes will be (i) screening out genetic or chromosomal abnormalities leading to serious medical conditions, disabilities, or miscarriage (ii) tissue typing to provide umbilical cord blood to treat a sibling suffering a life threatening illness. Deliberately screening-in a disease or disorder will be prohibited. The regulator will license these activities to ensure consistency, and will consider tissue-typing applications on a case by case basis.	The law does not refer explicitly to embryo testing. The HFEA is able to license this activity, although this has been subject to legal challenge.	The proposed legislative provisions will essentially have the effect of putting existing practices into statute. Therefore the regulatory impact, as compared to the status quo, will be negligible in terms of costs.
12	Sex selection for non-medical reasons within treatment services will be prohibited, including for 'family balancing'.	The law does not mention sex selection. It is banned for non-medical reasons in relation to embryos as a matter of HFEA policy, and in relation to gametes insofar as these fall within the HFEA's remit.	The revised legislation will enshrine restrictions that exist currently in the form of requirements placed on licence holders by the regulatory authority. The regulatory impact of putting these restrictions into statute is therefore, effectively, nil.
13	The Government proposes that the law will clearly ban genetic modification of the nuclear DNA of embryos and gametes for reproductive purposes.	Treatment licences cannot authorise "altering the genetic structure of a cell while it forms part of an embryo". Research licences have the same restriction, subject to a regulation-making power. The scientific meaning of "altering the genetic structure has proven difficult to interpret in practice.	The changes to the legislation clarify the restriction on altering the genetic structure in relation to reproductive purposes in light of up to date knowledge.

Proposal		Current position	Regulatory impact
14	For research purposes only, the restriction on altering the genetic structure of a cell while it forms part of an embryo will be removed.	See above.	This will allow a greater degree of research on the genetics of early embryonic development. This clause will lead to an increase of scope for researchers, and could therefore lead to an increase in research licence applications to the Authority, offset against any benefits accruing from research.
15	The Government proposes to revise the confidentiality restrictions in the HFE Act relating to the use of data on assisted reproduction treatments, so that it is possible to disclose information held by the HFEA (RATE) and clinics more widely.	The HFE Act contains very strict criteria on the disclosure of information from the HFEA's register of information about licensed treatment. Despite amendment in 1992, these are widely seen as impeding the effective use of the database for uses such as follow up research.	Transposition into domestic law of the EU Tissue Directive requires a higher level of confidentiality for records pertaining to gametes and embryos for use in treatment, than would be met by provisions regulating access to identifying information from other health records. For this reason, the majority of the existing restrictions will remain. However, provision will be made for RATE and licensed establishments to share identifying information with other statutory regulatory bodies, where this is necessary for the investigation of potential breaches of legislation or poor practice placing patients at risk. It is also proposed that RATE will expand the HFEA model and prescribed consent forms to allow patients an opportunity to consent to: • use of identifying information for health follow-up research • being contacted by researchers • to allow access to identifying information by contractors maintaining establishments' electronic records systems, or systems auditors (bound by confidentiality agreements)

Proposal	Current position	Regulatory impact
15 cont		• allowing RATE to use their NHS number for tracing/ verification purposes via the Connecting for Health NHS database. The cost of providing this additional consent would increase costs but not by a significant margin. For pre-2009 data, where it is not possible to obtain the consent of the person to whom the information relates. Regulations will be made to permit researchers to apply to the Secretary of State for permission to have access to this information. In making a decision the Secretary of State will consult relevant bodies, such as the Patient Information Advisory Group, for their views on the appropriateness of disclosing this information. Where it is known the person to whom the information relates has refused permission for it to be disclosed, an application to the Secretary of State cannot override this decision. It is not possible, at this time, to estimate how many applications might be made or the nature and amount of the information that might be sought. For this reason, administrative costs cannot be ascribed at this time. These would, however, need to be weighed against the benefits arising from, for example, follow up research.

Proposal		Current position	Regulatory impact
16	The law will make clear that gamete donors will be able to access limited, non-identifying information about children conceived as a result of their donation. Donors will be able to be informed when their identifying details have been requested by those children (from age 18).	The law does not currently contain any explicit recognition of a right of donors to be told when a child is born from their donation or to be informed when identifying information about the donor is divulged to them.	Not anticipated to impose significant additional costs, as intended to clarify current situation and practices.
17	Donor-conceived children will be able to find out if they have donor-conceived siblings, as part of the information accessible to them from age 18.	The law does not contain any reference to access to information about siblings.	Small addition to costs as part of a package of existing information that may be provided on request, using existing systems in place.
18	Persons intending to form civil partnerships will be able to find out whether they are related as a result of gamete donation.	The law currently enables persons wishing to marry to find out if they are related as a result of gamete donation.	Expands current responsibility to provide information treating civil partnerships on the same basis as married couples. Small increase in costs to service requests, depending on demand.
19	The extent to which not-for-profit organisations may undertake activities for the facilitation of surrogacy arrangements will be clarified.	The Surrogacy Arrangements Act 1985 imposes a range of restrictions on surrogacy, aimed at preventing commercial arrangements.	Expected to be cost neutral.
20	The status and legal parenthood provisions of the HFE Act will be revised to enable a greater range of persons to be recognised as parents following assisted reproduction.	The Act currently assigns parental status to married men, or men treated together with a woman, where donor sperm is used. It also provides a mechanism for reassigning parental status in surrogacy cases.	Changes will be required in relation to records (such as birth registration), systems and forms required to reflect the category "parent". Total costs of changes is estimated to be up to £0.8m.

Proposal		Current position	Regulatory impact
21	Legislation will make clear that basic (as well as applied) embryo research is permissible subject to the controls of the 1990 Act. Also, the law will be clear that research into serious injuries (such as spinal cord injuries) is permissible, as well as research into serious diseases as at present.	The Act refers to research into serious disease, but does not explicitly mention research that may be a necessary precursor to such projects. Similarly it does not explicitly mention damage or injury.	Explicitly bringing "basic" research upon embryos within the scope of the Act clarifies an established position for the avoidance of doubt. There are a limited number of purposes for which the 1990 Act allows research upon human embryos. Almost all research which scientists wish to do falls within these purposes, although research applications have in the past combined basic and applied research elements. This is so the entirety of the research is explicitly licensable by the regulatory authority.
22	The Government proposes to remove the restriction on replacing the nucleus of a cell of an embryo for research purposes only, subject to the controls of the 1990 Act.	The Act bans replacement of the nucleus of a cell of an embryo with another nucleus. This purpose of this provision was to preclude reproductive cloning – a role now fulfilled by the Human Reproductive Cloning Act 2001.	This change will allow a greater degree of research into the genetic influences of early embryonic development, and also removes a redundant provision restricting research activity. This clause will lead to an increase of scope for researchers, and could therefore lead to an increase in research licence applications to the Authority.
23	The Government proposes that the use of embryos for training in treatment and research techniques will clearly be permissible under the authority of a licence.	The Act does not refer to training explicitly, leading to uncertainty about what activities may be undertaken by trainees.	The Authority in the past did not have a clear remit to allow training in premises with a treatment licence, where that premises did not also have a research licence. Changing the law will reflect the clear need for this type of training, and thereby prevent treatment facilities requiring a research licence to provide on-site training.

Proposal		Current position	Regulatory impact
24	The Government will propose that the creation of hybrid and chimera embryos *in vitro*, should not be allowed. However, the Government also proposes that the law will contain a power enabling regulations to set out circumstances in which the creation of hybrid and chimera embryos *in vitro* may in future be allowed under licence, for research purposes only.	The Act allows the mixing of human and animal gametes under licence only for the purpose of testing the fertility of sperm (using a hamster egg). It does not refer to novel processes for the creation of embryos combining human and animal material.	The Government is aware of two research licence applications made to the HFEA under the current legislative/ regulatory arrangements that would fall within the scope of this proposal. These seek to create embryos by combining enucleated animal eggs with human cells (or cell nuclei). Projects of this type would not be allowed to proceed, unless regulations were made to allow the creation of such embryos for research under licence. The Government is carefully considering the recommendations of the House of Commons Science and Technology Committee on this matter.
25	RATE. The Government proposes to replace the HFEA and HTA with a single regulator – the Regulatory Authority for Tissue and Embryos. RATE will be the single competent authority acting as the regulator under the EU Blood, and Tissues and Cells Directives.	The HFEA and HTA are separately established statutory bodies. The Medicines and Healthcare products Regulatory Agency currently carries out the relevant regulatory functions in relation to the EU Blood Directive.	These proposals will, in principle, retain similar regulatory arrangements as at present, based on a scheme of licensing with an appropriate range of enforcement options. RATE will retain the regulatory functions and responsibilities of the HFEA and HTA to discharge those functions, taking into account the principles of good regulation.

Human Fertilisation and Embryology Act 1990

if amended: an illustrative text

This text is for illustrative purposes only

It shows the Human Fertilisation and Embryology Act 1990 (c. 37) as it would be following the amendments made by the draft Human Fertilisation and Embryology (Quality and Safety) Regulations (text shown in green) and by the current draft of the Human Tissue and Embryos Bill (text shown in blue).

CHAPTER 37

ARRANGEMENT OF SECTIONS

1 Meaning of "embryo", "gamete" and associated expressions.

(1) In this Act, (except in section 4A) -

(a) embryo means a live human embryo and does not include an inter-species embryo (as defined in section 4A(5)), and

(b) references to an embryo include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

(2) This Act, so far as it governs bringing about the creation of an embryo, applies only to bringing about the creation of an embryo outside the human body; and in this Act—

(a) references to embryos the creation of which was brought about *in vitro* (in their application to those where fertilisation or any other process by which an embryo is created is complete) are to those where fertilisation or any other process by which the embryo was created began outside the human body whether or not it was completed there, and

(b) references to embryos taken from a woman do not include embryos whose creation was brought about *in vitro*.

(3) This Act, so far as it governs the keeping or use of an embryo, applies only to keeping or using an embryo outside the human body.

(4) In this Act, (except in section 4A) -

(a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in section (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,

(b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and

(c) references to gametes are to be read accordingly.

(5) For the purposes of this Act, sperm is to be treated as partner-donated sperm if the donor of the sperm and the recipient of the sperm declare that they have an intimate physical relationship.

(6) If it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine, regulations may provide that in this Act (except in section 4A) “embryo”, “eggs”, “sperm” or “gametes” include things specified in the regulations which would not otherwise fall within the definition.

(7) Regulations made by virtue of subsection (6) –

(a) may not provide for anything containing any nuclear or mitochondrial DNA that is not human to be treated as an embryo or as eggs, sperm or gametes, but

(b) may make any amendment of section 4A(7) or (8) that appears to the Secretary of State to be appropriate in consequence of the provision falling within subsection (6).

1A References to Directives.

In this Act—

"the first Directive" means Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells,

"the second Directive" means Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, and

"the third Directive" means Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

2 Other Terms.

(1) In this Act—

"the Authority" means the Regulatory Authority for Tissues and Embryos,

"basic partner treatment services" means treatment services that are provided for a woman and a man together without using—

(a) the gametes of any other person, or

(b) embryos created outside the woman's body,

"competent authority", in relation to an EEA state other than the United Kingdom or in relation to Gibraltar, means an authority designated in accordance with the law of that state or territory as responsible for implementing the requirements of the first, second and third Directives,

"directions" means directions under section 23 of this Act,

"distribution", in relation to gametes or embryos intended for human application, means transportation or delivery, and related terms are to be interpreted accordingly,

"human application" means use in a human recipient,

"licence" means a licence under Schedule 2 to this Act and, in relation to a licence, "the person responsible" has the meaning given by section 17 of this Act,

“non-medical fertility services” means any services that are provided, in the course of a business, for the purpose of assisting women to carry children, but are not medical, surgical or obstetric services,

“nucleus”, in relation to an embryo, includes pronucleus and, accordingly, “nuclear DNA”, in relation to an embryo, includes DNA in the pronucleus of the embryo,

“processing”, in relation to gametes or embryos intended for human application, means any operation involved in their preparation, manipulation or packaging, and related terms are to be interpreted accordingly,

“procurement”, in relation to gametes or embryos intended for human application, means any process by which they are made available, and related terms are to be interpreted accordingly,

“serious adverse event” means—

(a) any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services—

(i) might lead to the transmission of a communicable disease, to death, or life- threatening, disabling or incapacitating conditions, or

(ii) might result in, or prolong, hospitalisation or illness, or

(b) any type of gametes or embryo misidentification or mix-up,

“serious adverse reaction” means an unintended response, including a communicable disease, in a donor of gametes intended for human application or a person who receives treatment services or non-medical fertility services, which may be associated with the procurement or human application of gametes or embryos and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or illness,

“store”, in relation to gametes or embryos, means preserve, whether by cryopreservation or in any other way, and “storage” and “stored” are to be interpreted accordingly, and

“traceability” means the ability—

(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,

(b) identify the donor and recipient of particular gametes or embryos,

(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and

(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety,

"treatment services" means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

(2) References in this Act to keeping, in relation to embryos or gametes, include keeping while preserved in storage.

(2A) For the purposes of this Act, a person who, from any premises, controls the provision of services for transporting gametes or embryos is to be taken to distribute gametes or embryos on those premises.

(2B) In this Act, any reference to a requirement of a provision of the first, second or third Directive is a reference to a requirement which that provision requires to be imposed.

(3) For the purposes of this Act, a woman is not to be treated as carrying a child until the embryo has become implanted.

2A Third party agreements

(1) For the purposes of this Act, a "third party agreement" is an agreement in writing between a person who holds a licence and another person which is made in accordance with any licence conditions imposed by the Authority for the purpose of securing compliance with the requirements of Article 24 of the first Directive (relations between tissue establishments and third parties) and under which the other person-

(a) procures, tests or processes gametes or embryos (or both), on behalf of the holder of the licence, or

(b) supplies to the holder of the licence any goods or services (including distribution services) which may affect the quality or safety of gametes or embryos.

(2) In this Act—

"relevant third party premises", in relation to a licence, means any premises (other than premises to which the licence relates)—

(a) on which a third party procures, tests, processes or distributes gametes or embryos on behalf of any person in connection with activities carried out by that person under a licence, or

(b) from which a third party provides any goods or services which may affect the quality and safety of gametes or embryos to any person in connection with activities carried out by that person under a licence;

"third party" means a person with whom a person who holds a licence has a third party agreement.

(3) References in this Act to the persons to whom a third party agreement applies are to—

(a) the third party,

(b) any person designated in the third party agreement as a person to whom the agreement applies, and

(c) any person acting under the direction of a third party or of any person so designated.

Activities governed by the Act

3 Prohibitions in connection with embryos

(1) No person shall bring about the creation of an embryo except in pursuance of a licence.

(1A) No person shall keep or use an embryo except—

(a) in pursuance of a licence, or

(b) in the case of-

(i) the keeping, without storage of an embryo intended for human application, or

(ii) the processing, without storage, of such an embryo,

in pursuance of a third party agreement.

(1B) No person shall procure or distribute an embryo intended for human application except in pursuance of a licence or third party agreement.

(2) No person shall place in a woman—

(a) an embryo other than a permitted embryo (as defined by section 3ZA), or

(b) any gametes other than permitted eggs or permitted sperm (as so defined).

(3) A licence cannot authorise—

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal, or

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use.

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day on which the process of creating the embryo began, not counting any time during which the embryo is stored.

3ZA Permitted eggs, permitted sperm and permitted embryos

(1) This section has effect for the interpretation of section 3(2).

(2) A permitted egg is one -

(a) which has been produced by or extracted from the ovaries of a woman, and

(b) whose nuclear or mitochondrial DNA has not been altered.

(3) Permitted sperm are sperm -

(a) which have been produced by or extracted from the testes of a man, and

(b) whose nuclear or mitochondrial DNA has not been altered.

(4) An embryo is a permitted embryo if -

(a) it has been created by the fertilisation of a permitted egg by permitted sperm, and

(b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered.

(5) Regulations may provide that -

(a) an egg can be a permitted egg, or

(b) an embryo can be a permitted embryo,

even though the egg or embryo had had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease.

(6) In this section -

(a) "woman" and "man" include respectively a girl and a boy (from birth), and

(b) "prescribed" means prescribed by regulations.

3A Prohibitions in connection with germ cells

(1) No person shall, for the purpose of providing fertility services for any woman, use female germ cells taken or derived from an embryo or a foetus or use embryos created by using such cells.

(2) In this section—

"female germ cells" means cells of the female germ line and includes such cells at any stage of maturity and accordingly includes eggs; and

"fertility services" means ,medical, surgical or obstetric services provided for the purposes of assisting women to carry children.

4 Prohibitions in connection with gametes.

(1) No person shall—

(a) store any gametes, or

(b) in the course of providing treatment services for any woman, use—

(i) any sperm, other than partner-donated sperm which has been neither processed nor stored,

(ii) the woman's eggs after processing or storage, or

(iii) the eggs of any woman,

except in pursuance of a licence.

(1A) No person shall procure, test, process or distribute any gametes intended for human application except in pursuance of a licence or a third party agreement.

(2) A licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use.

(3) No person shall place sperm and eggs in a woman in any circumstances specified in regulations except in pursuance of a licence.

(4) Regulations made by virtue of subsection (3) above may provide that, in relation to licences only to place sperm and eggs in a woman in such circumstances, sections 12 to 22 of this Act shall have effect with such modifications as may be specified in the regulations.

(5) Activities regulated by this section or section 3 or 4A of this Act are referred to in this Act as "activities governed by this Act".

4A Prohibitions in connection with genetic material not of human origin

(1) No person shall place in a woman -

(a) an embryo other than a human embryo,

(b) an inter-species embryo, or

(c) any gametes other than human gametes.

(2) No person shall -

(a) mix human gametes with the gametes of an animal,

(b) bring about the creation of an inter-species embryo, or

(c) keep or use an inter-species embryo,

except in pursuance of a licence.

(3) A licence cannot authorise the keeping or using of an inter-species embryo after the earliest of the following -

(a) the appearance of the primitive streak,

(b) the end of the period of 14 days beginning with the day on which the process of creating the inter-species embryo began, or

(c) the time when half the gestation or incubation period for any species whose nuclear or mitochondrial DNA is contained in the embryo has elapsed,

but any period during which the inter-species embryo is stored is not counted under paragraph (b) or (c).

(4) A licence cannot authorise placing an inter-species embryo in an animal.

(5) For the purpose of this Act an inter-species embryo is -

(a) an embryo created by using human gametes and the gametes of an animal,

(b) an embryo created by replacing the nucleus of an animal egg or a cell derived from an animal embryo with a human cell or the nucleus of a human cell,

(c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal,

(d) a human embryo that has been altered by the introduction of one or more animal cells, or

(e) any other embryo that contains both -

(i) any haploid set of human chromosomes, and

(ii) any haploid set of animal chromosomes or any other sequence of nuclear or mitochondrial DNA of an animal.

(6) For the purposes of this section an "animal" is an animal other than man.

(7) In this section "embryo" means a live embryo, including an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

(8) In this section -

(a) references to eggs are to live eggs, including cells of the female germ line at any stage of maturity, but not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,

(b) references to gametes are to eggs (as so defined) or to live sperm, including cells of the male germ line at any stage of maturity.

8A Duty of Authority to communicate with competent authorities of other EEA states

The Authority shall communicate to the competent authorities of EEA states other than the United Kingdom or of Gibraltar, and to the European Commission, such information in relation to serious adverse events and serious adverse reactions as is necessary for the purpose of enabling appropriate action to be taken, including where necessary the withdrawal from use of gametes and embryos that are intended for human application but are known or suspected to be unsuitable for such application.

Scope of Licences

11 Licences for treatment, storage and research.

(1) The Authority may grant the following and no other licences—

(a) licences under paragraph 1 of Schedule 2 to this Act authorising activities in the course of providing treatment services,

(aa) licences under paragraph 1A of that Schedule authorising activities in the course of providing non-medical fertility services,

(b) licences under that Schedule authorising the storage of gametes and embryos, and

(c) licences under paragraph 3 of that Schedule authorising activities for the purposes of a project of research.

(2) Paragraph 4 of that Schedule has effect in the case of all licences.

Licence conditions

12 General conditions

(1) The following shall be conditions of every licence granted under this Act—

(a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible,

(aa) that any activities to which section 3(1A)(b) or (1B) or 4(1A) applies shall be carried on only on the premises to which the licence relates or on relevant third party premises,

(b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity),

(c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with,

(d) that proper records shall be maintained in such form as the Authority may specify in directions,

(e) that no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions,

(f) that, where gametes or embryos are supplied to a person to whom another licence applies, that person shall also be provided with such information as the Authority may specify in directions, and

(g) that the Authority shall be provided, in such form and at such intervals as it may specify in directions, with such copies of or extracts from the records, or such other information, as the directions may specify.

(2) Subsection (3) applies to—

(a) every licence under paragraph 1 or 1A of Schedule 2, and

(b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos intended for human application.

(3) It shall be a condition of every licence to which this subsection applies that—

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos,

shall be recorded and provided to the Authority upon request.

13 Conditions of licences for treatment.

(1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.

(2) Such information shall be recorded as the Authority may specify in directions about the following—

(a) the persons for whom services are provided in pursuance of the licence,

(b) the services provided for them,

(c) the persons whose gametes are kept or used for the purposes of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used,

(d) any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence,

(e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and

(f) such other matters as the Authority may specify in directions.

(3) The records maintained in pursuance of the licence shall include any information recorded in pursuance of subsection 2 above and any consent of a person whose consent is required under Schedule 3 to this Act.

(4) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.

(5) A woman shall not be provided with treatment services, unless account has been taken of the welfare of any child who may be born as a result of the treatment, and of any other child who may be affected by the birth.

(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper

counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

(6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

(6B) The reference in subsection (6A) to the intended second parent is a reference to -

(a) any man as respects whom the agreed fatherhood conditions in section 43 of the Human Tissue and Embryos Act 2007 ("the 2007 Act") are for the time being satisfied in relation to treatment provided to the woman being treated, and

(b) any woman as respects whom the agreed female parenthood conditions in section 50 of the 2007 Act are for the time being satisfied, in relation to treatment provided to the woman to be treated.

(6C) Where the person responsible receives from a person ("X") notice under section 43(1)(c) or 50(1)(c) of the 2007 Act of X's withdrawal of consent to X being treated as the parent of any child resulting from the provision of treatment services to a woman ("W"), the person responsible—

(a) must notify W in writing of the receipt of the notice from X, and

(b) no person to whom the licence applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified.

(6D) Where the person responsible receives from a woman ("W") who has previously given notice under section 43(1)(b) or 50(1)(b) of the 2007 Act that she consents to another person ("X") being treated as a parent of any child resulting from the provision of treatment services to W -

(a) notice under section 43(1)(c) or 50(1)(c) of the 2007 Act of the withdrawal of W's consent, or

(b) a notice under section 43(1)(b) or 50(1)(b) of the 2007 Act in respect of a person other than X,

the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b).

(7) Suitable procedures shall be maintained—

(a) for determining the persons providing gametes or from whom embryos are taken for use in pursuance of the licence, and

(b) for the purpose of securing that consideration is given to the use of practices not requiring the authority of a licence as well as those requiring such authority.

(8) In determining –

(a) the persons who are to provide gametes for use in pursuance of the licence in a case where consent is required under paragraph 5 of Schedule 3 for the use in question,

(b) the woman from whom an embryo is to be taken for use in pursuance of the licence, in a case where her consent is required under paragraph 7 of Schedule 3 for the use of the embryo, or

(c) which of two or more embryos to place in a woman,

persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition must not be preferred to those that are not known to have such an abnormality.

(9) No embryo appropriated for the purpose of training persons in the testing of embryos shall be kept or used for the provision of treatment services.

(10) The person responsible shall comply with any requirement imposed on that person by section 31ZC.

13A Conditions of licences for non-medical treatment services.

(1) The following shall be conditions of every licence under paragraph 1A of Schedule 2.

(2) The requirements of section 13(2) to (4) and (7) shall be complied with.

(3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such information as is proper.

14 Conditions of storage licences.

(1) The following shall be conditions of every licence authorising the storage of gametes or embryos—

(a) that gametes of a person shall be placed in storage only if -

(i) received from that person,

(ii) acquired in circumstances in which by virtue of paragraph 9 or 10 of Schedule 3 that person's consent to the storage is not required, or

(iii) acquired from a person to whom a licence or third party agreement applies,

(aa) that an embryo taken from a woman shall be placed in storage only if -

(i) received from that woman, or

(ii) acquired from a person to whom a licence or third party agreement applies,

(ab) that an embryo the creation of which has been brought about *in vitro* otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence or third party agreement applies,

(b) that gametes or embryos which are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services unless that person is a person to whom a licence applies,

(c) that no gametes or embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish, and

(d) that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions shall be included in the records maintained in pursuance of the licence.

(2) No information shall be removed from any records maintained in pursuance of such a licence before the expiry of such period as may be specified in directions for records of the class in question.

(3) The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.

(4) The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.

(5) Regulations may provide that subsection (3) or (4) above shall have effect as if for ten years there were substituted—

(a) such shorter period, or

(b) in such circumstances as may be specified in the regulations, such longer period,

as may be specified in the regulations.

14A Conditions of licences: human application.

(1) This section applies to—

(a) every licence under paragraph 1 or 1A of Schedule 2, and

(b) every licence under paragraph 2 of that Schedule, so far as authorising storage of gametes or embryos intended for human application.

(2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.

(3) In relation to any gametes or embryos imported into the United Kingdom from an EEA state other than the United Kingdom or from Gibraltar, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third

Directives shall be taken to be compliance with the conditions required by Schedule 3A.

(4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.

15 Conditions of research licences

(1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.

(2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.

(3) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.

(4) No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.

15ZA Conditions of licences relating to inter-species embryos etc

(1) If by virtue of regulations under sub-paragraph (3) of paragraph 3 of Schedule 2, any of the activities mentioned in that sub-paragraph can be authorised by a licence under that paragraph, regulations may provide for specified conditions to be conditions of-

(a) every licence under paragraph 3 of Schedule 2 authorising such activities, and

(b) every licence under paragraph 2 of that Schedule authorising the storage of inter-species embryos.

(2) Regulations made by virtue of this section may, in particular, exclude or modify –

(a) any of the provisions of sections 12, except subsection (1)(c) of that section, and

(b) any of the provisions of sections 14 and 15,

in their application to a licence falling within subsection (1)(a) or (b).

15A Duties of the Authority in relation to serious adverse events and serious adverse reactions.

(1) The Authority shall investigate serious adverse events and serious adverse reactions and take appropriate control measures.

(2) In investigating any serious adverse event or serious adverse reaction, the Authority shall, where it is appropriate to do so, arrange for—

(a) any premises to which a licence relates and any relevant third party premises to be inspected on its behalf, and

(b) a report on the inspection to be made to it.

(3) If the Authority receives a request from a competent authority in an EEA state other than the United Kingdom or in Gibraltar to carry out an inspection in relation to a serious adverse event or serious adverse reaction, the Authority must arrange for such an inspection to be carried out, for a report to be made of the inspection and for appropriate control measures to be taken.

Grant, revocation and suspension of licences

16 Grant of licence.

(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.

(2) The requirements mentioned in subsection (1) above are—

(a) that the application is for a licence designating an individual as the person under whose supervision the activities to be authorised by the licence are to be carried on,

(b) that either that individual is the applicant or—

(i) the application is made with the consent of that individual, and

(ii) the Authority is satisfied that the applicant is a suitable person to hold a licence,

(c) in relation to a licence under paragraph 1 or 1A of Schedule 2 or a licence under paragraph 2 of that Schedule authorising the storage of gametes or embryos intended for human application, that the individual—

(i) possesses a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or is otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications in the field of nursing, and

(ii) has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence,

(ca) in relation to a licence under paragraph 2 of Schedule 2 authorising storage of gametes or embryos not intended for human application or a licence under paragraph 3 of that Schedule, that the Authority is satisfied that the qualifications and experience of that individual are such as are required for the supervision of the activities,

(cb) that the Authority is satisfied that the character of that individual is such as is required for the supervision of the activities and that the individual will discharge the duty under section 17 of this Act,

(d) that the Authority is satisfied that the premises in respect of which the licence is to be granted are suitable for the activities, and

(e) that all the other requirements of this Act in relation to the granting of the licence are satisfied.

(3) The grant of a licence to any person may be by way of renewal of a licence granted to that person, whether on the same or different terms.

(4) Where the Authority is of the opinion that the information provided in the application is insufficient to enable it to determine the application, it need not consider the application until the applicant has provided it with such further information as it may require him to provide.

(5) The Authority shall not grant a licence unless a copy of the conditions to be imposed by the licence has been shown to, and acknowledged in writing by, the applicant and (where different) the person under whose supervision the activities are to be carried on.

17 The person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure—

(a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,

(b) that proper equipment is used,

(c) that proper arrangements are made for the keeping of gametes and embryos and for the disposal of gametes or embryos that have been allowed to perish,

(d) that suitable practices are used in the course of the activities,

(e) that the conditions of the licence are complied with,

(f) that conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with, and

(g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

(2) References in this Act to the persons to whom a licence applies are to—

(a) the person responsible,

(b) any person designated in the licence, or in a notice given to the Authority by the person who holds the licence or the person responsible, as a person to whom the licence applies, and

(c) any person acting under the direction of the person responsible or of any person so designated.

18 Revocation of licence

(1) The Authority may revoke a licence on application by—

(a) the person responsible, or

(b) the holder of the licence (if different).

(2) The Authority may revoke a licence otherwise than on application under subsection (1) if—

(a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading,

(b) it is satisfied that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17,

(c) it is satisfied that the person responsible has failed to comply with directions given in connection with any licence,

(d) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,

(e) it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are not suitable for the activities entrusted to the third party by the person who holds the licence,

(f) it ceases to be satisfied that the holder of the licence is a suitable person to hold the licence,

(g) it ceases to be satisfied that the person responsible is a suitable person to supervise the licensed activity,

(h) the person responsible dies or is convicted of an offence under this Act, or

(i) it is satisfied that there has been any other material change of circumstances since the licence was granted.

18A Variation of licence

(1) The Authority may on application by the holder of the licence vary the licence so as to substitute another person for the person responsible if—

(a) the application is made with the consent of that other person, and

(b) the Authority is satisfied that the other person is a suitable person to supervise the licensed activity.

(2) The Authority may vary a licence on application by—

(a) the person responsible, or

(b) the holder of the licence (if different).

(3) The Authority may vary a licence without an application under subsection (2) if it has the power to revoke the licence under section 18(2).

(4) The powers under subsections (2) and (3) do not extend to making the kind of variation mentioned in subsection (1).

(5) The Authority may vary a licence without an application under subsection (2) by—

(a) removing or varying a condition of the licence, or

(b) adding a condition to the licence.

(6) The powers conferred by this section do not extend to the conditions required by sections 12 to 15ZA of this Act.

19 Procedure in relation to licensing decisions

(1) Before making a decision—

(a) to refuse an application for the grant, revocation or variation of a licence, or

(b) to grant an application for a licence subject to a condition imposed under paragraph 1(2), 1A(2), 2(2) or 3(5) of Schedule 2,

the Authority shall give the applicant notice of the proposed decision and of the reasons for it.

(2) Before making a decision under section 18(2), 18A(3) or (5), the Authority shall give notice of the proposed decision and of the reasons for it to—

(a) the person responsible, and

(b) the holder of the licence (if different).

(3) Where an application has been made under section 18A(2) to vary a licence, but the Authority considers it appropriate to vary the licence otherwise than in accordance with the application, before so varying the licence the Authority shall give notice of its proposed decision and the reasons for it to –

(a) the person responsible, and

(b) the holder of the licence (if different).

(4) A person to whom notice is given under subsection (1), (2) or (3) has the right to require the Authority to give him an opportunity to make representations of one of the following kinds about the proposed decision, namely—

(a) oral representations by him, or a person acting on his behalf;

(b) written representations by him.

(5) The right under subsection (4) is exercisable by giving the Authority notice of the exercise of the right before the end of the period of 28 days beginning with the day on which the notice under subsection (1), (2) or (3) was given.

(6) The Authority may by regulations make such additional provision about procedure in relation to the carrying out of functions under sections 18 and 18A and this section as it thinks fit.

19A Notification of licensing decisions

(1) In the case of a decision to grant a licence, the Authority shall give notice of the decision to—

(a) the applicant, and

(b) the person who is to be the person responsible.

(2) In the case of a decision to revoke a licence, the Authority shall give notice of the decision to—

(a) the person responsible, and

(b) the holder of the licence (if different).

(3) In the case of a decision to vary a licence on application under section 18A(1), the Authority shall give notice of the decision to—

(a) the holder of the licence, and

(b) (if different) the person who is to be the person responsible.

(4) In the case of any other decision to vary a licence, the Authority shall give notice of the decision to—

(a) the person responsible, and

(b) the holder of the licence (if different).

(5) In the case of a decision to refuse an application for the grant, revocation or variation of a licence, the Authority shall give notice of the decision to the applicant.

(6) Subject to subsection (7) a notice under subsection (2), (4) or (5) shall include a statement of the reasons for the decision.

(7) In the case of a notice under subsection (2) or (4) the notice is not required to include a statement of the reasons for the decision if the decision is made on an application under section 18(1) or 18A(2).

19B Applications under this Act

The Authority may by regulations make provision about applications under this Act and may, in particular, make provision about—

(a) the form and content of such an application,

(b) the information to be supplied with such an application, and

(c) procedure in relation to the determination of such an application.

20 Right to reconsideration of licensing decisions

(1) If an application for the grant, revocation or variation of a licence is refused, the applicant may require the Authority to reconsider the decision.

(2) Where the Authority decides to vary or revoke a licence, any person to whom notice of the decision was required to be given (other than a person who applied for the variation or revocation) may require the Authority to reconsider the decision.

(3) The right under subsections (1) and (2) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under section 19A.

(4) Subsections (1) and (2) do not apply to a decision on reconsideration.

20A Appeals committee

(1) The Authority shall maintain one or more committees to carry out its functions in pursuance of notices under section 20.

(2) A committee under subsection (1) is referred to in this Act as an appeals committee.

(3) An appeals committee shall consist of not less than five members of the Authority.

(4) The quorum for an appeals committee shall be three.

20B Procedure on reconsideration

(1) Reconsideration shall be by way of a fresh decision.

(2) On reconsideration—

(a) the person by whom reconsideration is required ("the appellant") shall be entitled to require that he or his representative be given an opportunity to appear before and be heard by the appeals committee dealing with the matter,

(b) at any meeting at which such an opportunity is given, the person who made the decision which is the subject of reconsideration shall be entitled to appear and be heard in person or by a representative, and

(c) the appeals committee dealing with the matter shall consider any written representations received from the appellant or the person who made the decision which is the subject of reconsideration.

(3) The appeals committee by which a decision is reconsidered in pursuance of a notice under section 20 shall give the appellant notice of its decision.

(4) If on reconsideration an appeals committee upholds the previous decision, the notice under subsection (3) shall include a statement of the reasons for the appeal committee's decision.

(5) The Authority may by regulations make such other provision about procedure in relation to reconsideration as it thinks fit.

(6) Where reconsideration of a decision is required under section 20(2) by only one of two persons by whom it could have been required it shall be treated for the purposes of this section as required by both of them.

(7) In this section "reconsideration" means reconsideration in pursuance of a notice under section 20.

21 Appeal on a point of law

A person aggrieved by a decision on reconsideration in pursuance of a notice under section 20 may appeal to the High Court or, in Scotland, the Court of Session on a point of law.

22 Power to suspend licence

(1) Where the Authority—

(a) has reasonable grounds to suspect that there are grounds for revoking a licence, and

(b) is of the opinion that the licence should immediately be suspended,

it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice.

(2) The Authority may continue suspension under subsection (1) by giving a further notice under that subsection.

(3) Notice under subsection (1) shall be given to the person responsible or where the person responsible has died or appears to be unable because of incapacity to discharge the duty under section 17—

(a) to the holder of the licence, or

(b) to some other person to whom the licence applies.

(4) Subject to subsection (5), a licence shall be of no effect while a notice under subsection (1) is in force.

(5) An application may be made under section 18(1) or section 18A(1) or (2) even though a notice under subsection (1) is in force.

Directions and guidance

23 Directions: general.

(1) The Authority may from time to time give directions for any purpose for which directions may be given under this Act or directions varying or revoking such directions.

(2) A person to whom any requirement contained in directions is applicable shall comply with the requirement.

(3) Anything done by a person in pursuance of directions is to be treated for the purposes of this Act as done in pursuance of a licence.

(4) Where directions are to be given to a particular person, they shall be given by serving notice of the directions on the person.

(5) In any other case, directions may be given—

(a) in respect of any licence (including a licence which has ceased to have effect), by serving notice of the directions on the person—

(i) who is the person responsible or the holder of the licence, if different, or

(ii) who was the person responsible or the holder of the licence, if different, and

(b) if the directions appear to the Authority to be general directions or it appears to the Authority that it is not practicable to give notice in pursuance of paragraph (a) above, by publishing the directions in such way as, in the opinion of the Authority, is likely to bring the directions to the attention of the persons to whom they are applicable.

24 Directions as to particular matters.

(1) If, in the case of any information about persons for whom treatment services, other than basic partner treatment services, were provided, the person responsible does not know that any child was born following the treatment, the period specified in directions by virtue of section 13(4) of this Act shall not expire less than 50 years after the information was first recorded.

(2) In the case of every licence under paragraph 1 or 1A of Schedule 2 to this Act, directions shall require information to be recorded and given to the Authority about each of the matters referred to in section 13(2)(a) to (e) of this Act.

(3) In relation to gametes or embryos that are not intended for human application, directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of gametes or embryos in the course of their carriage to or from any premises.

(3A) In relation to gametes and embryos that are intended for human application, directions may authorise the keeping of gametes or embryos by or on behalf of a person to whom a licence applies, in the course of their carriage—

(a) between premises to which licences relate,

(b) between such premises and relevant third party premises,

(c) between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state other than the United Kingdom or of Gibraltar which implement the first, second and third Directives, or

(d) between premises referred to in paragraphs (a) and (b) and tissue establishments in a country which is not an EEA state, pursuant to directions given under subsection (4),

in such circumstances and subject to such conditions as may be specified in directions.

(4) Directions may authorise any person to whom a licence applies to receive gametes or embryos from outside the United Kingdom or to send gametes or embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of the Act to have effect with such modifications as may be specified in the directions.

(4A) In giving any directions under subsection (4), authorising any person to whom a licence applies to import into the United Kingdom from a country which is not an EEA state, or to export from the United Kingdom to such a country, gametes or embryos intended for human application, the Authority shall—

(a) include directions specifying the measures that persons to whom a licence applies shall take to ensure that all such imports or exports meet standards of quality and safety equivalent to those laid down in the Act, and

(b) have regard to ensuring traceability.

(4B) If, by virtue of regulations under sub-paragraph (3) of paragraph 3 of Schedule 2, any of the activities mentioned in that sub-paragraph can be authorised by a licence under that paragraph, regulations may make provision requiring or authorising the giving of directions in relation to particular matters related to such activities and specified in the regulations.

(4C) Regulations made by virtue of subsection (4B) may, in particular, make provision in relation to inter-species embryos corresponding to that made by subsection (3) or (4) in relation to embryos.

(5A) Directions may make provision for the purpose of dealing with a situation arising in consequence of -

(a) the variation of a licence, or

(b) a licence ceasing to have effect.

(5B) Directions under subsection (5A)(a) may impose requirements -

(a) on the holder of the licence,

(b) on the person who is the person responsible immediately before or immediately after the variation, or

(c) on any other person, if that person consents.

(5C) Directions under subsection (5A)(b) may impose requirements -

(a) on the person who holds the licence immediately before the licence ceases to have effect,

(b) on the person who is the person responsible at that time, or

(c) on any other person if that person, consents.

(5D) Directions under subsection (5A) may in particular, require anything kept, or information held in pursuance of the licence to be transferred in accordance with the directions.

(5E) Where a licence has ceased to have effect by reason of the death or dissolution of its holder, anything subsequently done by a person before directions are given under subsection (5A) shall, if the licence would have been authority for doing it, be treated as authorised by a licence.

(11) Where the Authority proposes to give directions specifying any animal for the purposes of paragraph 1(1)(f) or 3(2) of Schedule 2 to this Act, it shall report the proposal to the Secretary of State; and the directions shall not be given until the Secretary of State has laid a copy of the report before each House of Parliament.

(12) Directions may require a unique code to be assigned to each donation of gametes and embryos intended for human application received pursuant to a licence.

(13) The Authority may give directions as to the information to be provided to it and any measures to be taken by the person responsible in the event of—

(a) any occurrence which may adversely influence the quality or safety of gametes or embryos intended for human application,

(b) any adverse incident which may be linked to the quality or safety of gametes or embryos intended for human application, or

(c) any misidentification or mix-up of gametes or embryos intended for human application.

(14) In this section, “tissue establishment” has the meaning given by Article 3(o) of the first Directive.

25 Code of practice

(1) The Authority shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom the licence applies.

(2) The guidance given by the code shall include guidance for those providing treatment services about the account to be taken of the welfare of children who may be born as a result of treatment services and of other children who may be affected by such births.

(3) The code may also give guidance about the use of any technique involving the placing of sperm and eggs in a woman.

(4) The Authority may from time to time revise the whole or any part of the code.

(5) The Authority shall publish the code as for the time being in force.

(6) A failure on the part of any person to observe any provision of the code shall not of itself render the person liable to any proceedings, but—

(a) the Authority shall, in considering whether there has been any failure to comply with any conditions of a licence and, in particular, conditions requiring anything to be "proper" or "suitable", take account of any relevant provision of the code, and

(b) the Authority may, in considering, where it has power to do so, whether or not to vary or revoke a licence, take into account any observance of or failure to observe the provisions of the code.

26 Procedure for approval of code

(1) The Authority shall send a draft of the proposed first code of practice under section 25 of this Act to the Secretary of State within twelve months of the commencement of section 5 of this Act.

(2) If the Authority proposes to revise the code or, if the Secretary of State does not approve a draft of the proposed first code, to submit a further draft, the Authority shall send a draft of the revised code or, as the case may be, a further draft of the proposed first code to the Secretary of State.

(3) Before preparing any draft, the Authority shall consult such persons as the Secretary of State may require it to consult and such other persons (if any) as it considers appropriate.

(4) If the Secretary of State approves a draft, he shall lay it before Parliament and, if he does not approve it, he shall give reasons to the Authority.

(5) A draft approved by the Secretary of State shall come into force in accordance with directions.

Status

27 Meaning of "mother".

(1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.

(2) Subsection (1) above does not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman’s child.

(3) Subsection (1) above applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

28 Meaning of "father".

(1) Subject to subsections (5A) to (5I) below, this section applies in the case of a child who is being or has been carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination.

(2) If—

(a) at the time of the placing in her of the embryo or the sperm and eggs or of her insemination, the woman was a party to a marriage, and

(b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage,

then, subject to subsection (5) below, the other party to the marriage shall be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her insemination (as the case may be).

(3) If no man is treated, by virtue of subsection (2) above, as the father of the child but—

(a) the embryo or the sperm and eggs were placed in the woman, or she was artificially inseminated, in the course of treatment services provided for her and a man together by a person to whom a licence applies, and

(b) the creation of the embryo carried by her was not brought about with the sperm of that man,

then, subject to subsection (5) below, that man shall be treated as the father of the child.

(4) Where a person is treated as the father of the child by virtue of subsection (2) or (3) above, no other person is to be treated as the father of the child.

(5) Subsections (2) and (3) above do not apply—

(a) in relation to England and Wales and Northern Ireland, to any child who, by virtue of the rules of common law, is treated as the legitimate child of the parties to a marriage,

(b) in relation to Scotland, to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage, or

(c) to any child to the extent that the child is treated by virtue of adoption as not being the man's child.

(5A) If—

(a) a child has been carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,

(b) the creation of the embryo carried by her was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in the woman after his death,

(c) the woman was a party to a marriage with the man immediately before his death,

(d) The man consented in writing (and did not withdraw the consent)—

(i) to the use of his sperm after his death which brought about the creation of the embryo carried by the woman or (as the case may be) to the placing in the woman after his death of the embryo which was brought about using his sperm before his death, and

(ii) to being treated for the purposes mentioned in subsection (5I) below as the father of any resulting child,

(e) the woman has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (5I) below as the father of the child, and

(f) no-one else is to be treated as the father of the child by virtue of subsection (2) or (3) above or by virtue of adoption or the child being treated as mentioned in paragraph (a) or (b) of subsection (5) above,

then the man shall be treated for the purpose mentioned in subsection (5I) below as the father of the child.

(5B) If—

(a) a child has been carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,

(b) the creation of the embryo carried by her was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in the woman after his death,

(c) the woman was not a party to a marriage with the man immediately before his death but treatment services were being provided for the woman and the man together before his death either by a person to whom a licence applies or outside the United Kingdom,

(d) the man consented in writing (and did not withdraw the consent)—

(i) to the use of his sperm after his death which brought about the creation of the embryo carried by the woman or (as the case may be) to the placing in the woman after his death of the embryo which was brought about using his sperm before his death, and

(ii) to being treated for the purposes mentioned in subsection (5I) below as the father of any resulting child,

(e) the woman has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (5I) below as the father of the child, and

(f) no-one else is to be treated as the father of the child by virtue of subsection (2) or (3) above or by virtue of adoption or the child being treated as mentioned in paragraph (a) or (b) of subsection (5) above,

Then the man shall be treated for the purpose mentioned in subsection (5I) below as the father of the child.

(5C) If—

(a) a child has been carried by a woman as the result of the placing in her of an embryo,

(b) the embryo was created at a time when the woman was a party to a marriage,

(c) the creation of the embryo was not brought about with the sperm of the other party to the marriage,

(d) the other party to the marriage died before the placing of the embryo in the woman,

(e) the other party to the marriage consented in writing (and did not withdraw the consent) —

(i) to the placing of the embryo in the woman after his death, and

(ii) to being treated for the purposes mentioned in subsection (5I) below as the father of any resulting child,

(f) the woman has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other party to the marriage to be treated for the purpose mentioned in subsection (5I) below as the father of the child, and

(g) no-one else is to be treated as the father of the child by virtue of subsection (2) or (3) above or by virtue of adoption or the child being treated as mentioned in paragraph (a) or (b) of subsection (5) above,

then the other party to the marriage shall be treated for the purpose mentioned in subsection (5I) below as the father of the child.

(5D) If—

(a) a child has been carried by a woman as the result of the placing in her of an embryo,

(b) the embryo was not created at a time when the woman was a party to a marriage but was created in the course of treatment services provided for the woman and a man together either by a person to whom a licence applies or outside the United Kingdom,

(c) the creation of the embryo was not brought about with the sperm of that man,

(d) the man died before the placing of the embryo in the woman,

(e) the man consented in writing (and did not withdraw the consent) —

(i) to the placing of the embryo in the woman after his death, and

(ii) to being treated for the purposes mentioned in subsection (5I) below as the father of any resulting child,

(f) the woman has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (5I) below as the father of the child, and

(g) no-one else is to be treated as the father of the child by virtue of subsection (2) or (3) above or by virtue of adoption or the child being treated as mentioned in paragraph (a) or (b) of subsection (5) above,

then the man shall be treated for the purpose mentioned in subsection (5I) below as the father of the child.

(5E) In the application of subsections (5A) to (5D) above to Scotland, for any reference to a period of 42 days there shall be substituted a reference to a period of 21 days.

(5F) The requirement under subsection (5A), (5B), (5C) or (5D) above as to the making of an election (which requires an election to be made either on or before the day on which the child was born or within the period of 42 or, as the case may be, 21 days from that day) shall nevertheless be treated as satisfied if the required election is made after the end of that period but with the consent of the Registrar General under subsection (5G) below.

(5G) The Registrar General may at any time consent to the making of an election after the end of the period mentioned in subsection (5F) above if, on an application made to him in accordance with such requirements as he may specify, he is satisfied that there is a compelling reason for giving his consent to the making of such an election.

(5H) In subsections (5F) and (5G) above "the Registrar General" means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland, or (as the case may be) the Registrar General for Northern Ireland.

(5I) The purpose referred to in subsections (5A) to (5D) above is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in (as the case may be) a register of live-births or still-births kept under the Births and Deaths Registration Act 1953 or the Births and Deaths Registration (Northern Ireland) Order 1976 or a register of births or still-births kept under the Registration of Births, Deaths and Marriages (Scotland) Act 1965.

(6) Where—

(a) the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to this Act was used for a purpose for which such consent was required, or

(b) the sperm of a man, or any embryo the creation of which was brought about with his sperm, was used after his death,

he is not, subject to subsections (5A) and (5B) above, to be treated as the father of the child.

(7) The references in subsection (2) above and subsections (5A) to (5D) above to the parties to a marriage at the time there referred to—

(a) are to the parties to a marriage subsisting at that time, unless a judicial separation was then in force, but

(b) include the parties to a void marriage if either or both of them reasonably believed at that time that the marriage was valid; and for the purposes of this subsection it shall be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the marriage was valid.

(8) This section applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(9) In subsection (7)(a) above, "judicial separation" includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

29 Effect of sections 27 and 28.

(1) Where by virtue of section 27 or 28 of this Act a person is to be treated as the mother or father of a child, that person is to be treated in law as the mother or, as the case may be, father of the child for all purposes.

(2) Where by virtue of section 27 or 28 of this Act a person is not to be treated as the mother or father of a child, that person is to be treated in law as not being the mother or, as the case may be, father of the child for any purpose.

(3) Where subsection (1) or (2) above has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.

(3A) Subsections (1) to (3) above do not apply in relation to the treatment in law of a deceased man in a case to which section 28(5A), (5B), (5C) or (5D) of this Act applies.

(3B) Where subsection (5A), (5B), (5C) or (5D) of section 28 of this Act applies, the deceased man—

(a) is to be treated in law as the father of the child for the purpose referred to in that subsection, but

(b) is to be treated in law as not being the father of the child for any other purpose.

(3C) Where subsection (3B) above has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.

(3D) In subsection (3C) above “enactment” includes an enactment comprised in, or in an instrument made under, an Act of the Scottish Parliament or Northern Ireland legislation.

(10) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 27(1) or 28(2) to (4) or (5A) to (5I), read with this section, affects—

(a) the succession to any dignity or title of honour or renders any person capable of succeeding to or transmitting a right to succeed to any such dignity or title, or

(b) the devolution of any property limited (expressly or not) to devolve (as nearly as the law permits) along with any dignity or title of honour.

(11) In relation to Scotland—

(a) those provisions do not apply to any title, coat of arms, honour or dignity transmissible on the death of the holder thereof or affect the succession thereto or the devolution thereof, and

(b) where the terms of any deed provide that any property or interest in property shall devolve along with a title, coat of arms, honour or

dignity, nothing in those provisions shall prevent that property or interest from so devolving.

Information

31 Register of information.

(1) The Authority shall keep a register which shall contain any information obtained by the Authority which falls within subsection (2) and which—

(a) is obtained by the Authority, or

(b) immediately before the coming into force of section 32 of the Human Tissue and Embryos Act 2007, was contained in a register kept under this section by the Human Fertilisation and Embryology Authority.

(2) Information falls within this subsection if it relates to—

(a) the provision for any identifiable individual of treatment services other than basic partner treatment services,

(b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm which has not been stored, in the course of providing non-medical fertility services for any identifiable individual,

(c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,

(d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services,

(e) the use of an embryo taken from any identifiable woman,

or if it shows that any identifiable individual is a relevant individual.

(3) Information does not fall within subsection (2) if it was provided to the Authority for the purposes of any voluntary contact register as defined in section 31ZE(1).

(4) In this section "relevant individual" means an individual who was or may have been born in consequence of—

(a) treatment services, other than basic partner treatment services, or

(b) the procurement or distribution of any sperm (other than partner donated sperm which has not been stored) in the course of providing non-medical fertility services.

31ZA Request for information as to genetic parentage etc.

(1) A person who has attained the age of 18 ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2), and the Authority shall do so if—

(a) the information contained in the register shows that the applicant is a relevant individual, and

(b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person ("the donor") other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that—

(a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information),

(b) stating whether or not that information shows that, but for the relevant statutory provisions, the applicant and a person specified in the request as a person whom the applicant proposes to marry or with whom the applicant proposes to enter into a civil partnership, would or might be related, or

(c) stating whether or not the information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so—

(i) the number of those other persons

(ii) the sex of each of them, and

(iii) the year of birth of each of them.

(3) The Authority need not comply with a request made under subsection (2)(c) by any applicant, if it considers that special circumstances exist which increase the likelihood that compliance with the request would enable the applicant -

(a) to identify the donor, in a case where the Authority is not required by regulations under subsection (2)(a) to give the applicant information which identifies the donor, or

(b) to identify any person about whom information is given under subsection (2)(c).

(4) Regulations cannot require the Authority to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Authority or, as the case may be, the Human Fertilisation and Embryology Authority could not have been required to give information of the kind in question.

(5) A person who has not attained the age of 18 ("the minor") may by notice to the Authority specifying another person ("the intended spouse or civil partner") as a person whom the minor proposes to marry or with whom the minor proposes to enter into a civil partnership, require the Authority to comply with a request under subsection (6), and the Authority shall do so, to the extent it is able, if—

(a) the information shows that the minor is a relevant individual,

(b) the minor has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(6) The minor may request the Authority to give the minor notice stating whether or not the information contained in the register shows that, but for the relevant statutory provisions, the minor and the intended spouse or civil partner would or might be related.

(7) In this section—

"relevant individual" has the same meaning as in section 31;

"the relevant statutory provisions" means sections 27 to 29 of this Act and Part 3 of the Human Tissue and Embryos Act 2007.

31ZB Power of Authority to inform donor of request for information

(1) Where—

(a) the Authority has received from a person ("the applicant") a notice containing a request under subsection (2) of section 31ZA, and

(b) compliance by the Authority with its duty under that section has involved or will involve giving the applicant information relating to a person other than the parent of the applicant who would or might, but for the relevant statutory provisions, be a parent of the applicant ("the donor"),

the Authority may notify the donor that a request under section 31ZA(2) has been made, but may not disclose the identity of the applicant or any information relating to the applicant.

(2) In this section "the relevant statutory provisions" has the same meaning as in section 31ZA.

31ZC Provision to donor of information about resulting children

(1) This section where a person ("the donor") has consented under Schedule 3 (whether before or after the coming into force of this section) to the use, for the purposes of treatment services provided under a licence, of-

(a) the donor's gametes, or

(b) an embryo the creation of which was brought about using the donor's gametes.

(2) In subsection (1) "treatment services" do not include treatment services provided to the donor, or to the donor and another person together.

(3) The donor may by notice request the appropriate person to give the applicant notice stating—

(a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory be a parent by virtue of the use of gametes or embryos to which the consent relates,

(b) the sex of each of those persons, and

(c) the year of birth of each of those persons.

(4) Subject to subsection (5) and (6), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if if the appropriate person does so, must comply with the request.

(5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify any of the persons falling within subsection (3)(a) to (c).

(6) Where the person who held the licence referred to in subsection (1) continues to hold a licence under paragraph 1 of Schedule 2, the Authority need not comply with a request under subsection (3) made to the Authority unless the donor has previously made a request under that subsection to the person responsible and the person responsible –

(a) has notified the donor that the information concerned is not held, or

(b) has failed to comply with the request within a reasonable period.

(7) In this section-

"the appropriate person" means -

(a) in a case where the person who held the licence referred to in subsection (1) continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or

(b) the Authority;

"the relevant statutory provisions" has the same meaning as in section 31ZA.

31ZD Provision of information about donor-conceived genetic siblings

(1) For the purposes of this section, two relevant individuals are donor conceived genetic siblings of each other, if a person ("the donor") who is not the parent of either of them would or might, but for the relevant statutory provisions, be the parent of both of them.

(2) Where—

(a) the information on the register shows that a relevant individual ("A")is the donor-conceived genetic sibling of another relevant individual ("B"),

(b) A has provided information ("the agreed information") to the Authority with the request that it should be disclosed to any donor-conceived genetic sibling of A, and

(c) the conditions in subsection (3) are satisfied,

the Authority shall disclose the agreed information to B.

(3) The conditions referred to in subsection (2)(c) are –

(a) that each of A and B has attained the age of 18,

(b) that B had requested the disclosure to B of information about any donor-conceived genetic sibling of B,

(c) that each of A and B has been given a suitable opportunity to receive proper counselling about the implications of disclosure under subsection (2), and

(d) that disclosure of information under subsection (2) will not lead to A or B identifying the donor unless –

(i) the donor has consented to the donor's identity being disclosed to A or B, or

(ii) were A or B to make a request under section 31ZA(1), the Authority would be required by regulations under section 31ZA(2)(a) to give A or B information which would identify the donor.

(4) In this section-

(a) "the relevant individual" has the same meaning as in section 31; and

(b) "the relevant statutory provisions" has the same meaning as in section 31ZA.

31ZE Power of Authority to keep voluntary contact register

(1) In this section and section 31ZF a voluntary contact register means a register of persons who -

(a) have expressed their wish to receive information about any person to whom they are genetically related as a consequence of the provision to any person of treatment services in the United Kingdom before 1 August 1991, and

(b) have attained the age of 18.

(2) The Authority may -

(a) set up a voluntary contact register in such manner as it thinks fit,

(b) keep a voluntary contact register in such manner as it thinks fit,

(c) determine criteria for eligibility for inclusion on the register and the particulars that may be included,

(d) charge a fee to persons who wish their particulars to be entered on the register,

(e) arrange for samples of the DNA of such persons to be analysed at their request,

(f) make such arrangements as it thinks fit for the disclosure of information on the register between persons who appear to the Authority to be genetically related, and

(g) impose such conditions as it thinks fit to prevent a person (A) from disclosing information to a person to whom A is genetically related (B) where that information would identify any person who is genetically related to both A and B.

(3) The Authority may make arrangements with any person by whom a voluntary contact register is kept before the commencement of this section for the supply by that person to the Authority of the information contained in the register maintained by that person.

31ZF Financial assistance for person setting up or keeping voluntary contact register

(1) The Authority may, instead of keeping a voluntary contact register, give financial assistance to any person who sets up or keeps a voluntary contact register.

(2) Financial assistance under subsection (1) may be given in any form, and in particular, may be given by way of—

(a) grants,

(b) loans,

(c) guarantees, or

(d) incurring expenditure for the person assisted.

(3) Financial assistance under subsection (1) may be given on such terms and conditions as the Authority considers appropriate.

(4) A person receiving assistance under subsection (1) must comply with the terms and conditions on which it is given, and compliance may be enforced by the Authority.

31A The Authority's register of licences.

(1) The Authority shall keep a register recording the grant, suspension or revocation of—

(a) every licence under paragraph 1 or 2 of Schedule 2 authorising activities in relation to gametes or embryos intended for use for human application, and

(b) every licence under paragraph 1A of Schedule 2.

(2) The register shall specify, in relation to each such licence—

(a) the activities authorised,

(b) the address of the premises to which the licence relates,

(c) the name of the person responsible and, if applicable, the nominal licensee, and

(d) any variations made.

(3) The Authority shall make such of the information included in the register available to the public in such manner as it considers appropriate.

31B The Authority's register of serious adverse events and serious adverse reactions.

(1) The Authority shall keep a register containing information provided to it under this Act about any serious adverse event or serious adverse reaction.

(2) The Authority shall make such of the information included in the register as it considers appropriate available to the public in such manner as it considers appropriate.

32 Information to be provided to Registrar General

(1) This section applies where a claim is made before the Registrar General that a person is or is not the parent of a child and it is necessary or desirable for the purpose of any function of the Registrar General to determine whether the claim is or may be well-founded.

(2) The Authority shall comply with any request made by the Registrar General by notice to the Authority to disclose whether any information on the register kept in pursuance of section 31 of this Act tends to show that the person may be the parent of the child by virtue of any of the relevant statutory provisions and, if it does, disclose that information.

(2A) In subsection (2) "the relevant statutory provisions" means –

(a) section 28 of this Act, and

(b) sections 41 to 53 of the Human Tissue and Embryos Act 2007.

(3) In this section and section 33A of this Act, "the Registrar General" means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or the Registrar General for Northern Ireland, as the case may be.

33A Disclosure of information

(1) No person shall disclose any information falling within section 31(2) which the person obtained in the person's capacity as -

(a) a member or employee of the Authority,

(b) any person exercising functions of the Authority by virtue of section 4 or 5 of the Human Tissue and Embryos Act 2007 (including a person exercising such functions by virtue of either of those sections as a member of staff or as an employee),

(c) any person engaged by the Authority to provide services to the Authority,

(d) any person employed by, or engaged to provide services to, a person mentioned in paragraph (c),

(e) a member or employee of the Human Fertilisation and Embryology Authority,

(f) a person to whom a licence applies,

(g) a person to whom a third party agreement applies, or

(h) a person to whom directions have been given.

(2) Subsection (1) does not apply where -

(a) the disclosure is made to a person as a member or employee of the Authority or as a person exercising functions of the Authority as mentioned in subsection (1)(b),

(b) the disclosure is made to or by a person falling within subsection (1)(c) for the purpose of the provision of services which that person is engaged to provide to the Authority,

(c) the disclosure is made by a person mentioned in subsection (1)(d) for the purpose of enabling a person falling within subsection (1)(c) to provide services which that person is engaged to provide to the Authority,

(d) the disclosure is made to a person to whom a licence applies for the purpose of that person's functions as such,

(e) the disclosure is made to a person to whom a third party agreement applies for the purpose of that person's functions under that agreement,

(f) the disclosure is made in pursuance of directions given by virtue of section 24,

(g) the disclosure is made so that no individual to whom the information relates can be identified,

(h) the disclosure is of information falling within section 31(2)(a) and is made with the consent required by subsection (4),

(i) the disclosure is of information falling within section 31(2)(b) to (e) and is made -

(i) with the consent of the individual to whom it relates, and

(ii) with the consent of any other individual who may be identified from that information,

(j) the disclosure is of information which shows that an individual who has attained the age of 18 is a relevant individual and is made -

(i) with the consent of that individual,

(ii) in a case where the disclosure of that information would also disclose any information falling within section 31(2)(a), with the consent required by subsection (4), and

(iii) with the consent of any other individual who may be identified from that information,

(k) the disclosure is of information which has been lawfully made available to the public before the disclosure is made,

(l) the disclosure is made in accordance with sections 31ZA to 31ZD,

(m) the disclosure is required or authorised to be made –

(i) under regulations made under section 33C, or

(ii) in relation to any time before the coming into force of the first regulations under that section, regulations made under section 251 of the National Health Service Act 2006,

(n) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) for the purpose of carrying out the Authority's duties under section 8A,

(o) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) in pursuance of an order of a court under section 34 or 35,

(p) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to the Registrar General in pursuance of a request under section 32,

(q) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to any body or person discharging a regulatory function for the purpose of assisting that body or person to carry out that function,

(r) the disclosure is made for the purpose of establishing in any proceedings relating to an application for an order under subsection (1) of section 60 of the Human Tissue and Embryos Act 2007 whether the condition specified in paragraph (a) or (b) of that subsection is met,

(s) the disclosure is made under section 3 of the Access to Health Records Act 1990,

(t) the disclosure is made under Article 5 of the Access to Health Records (Northern Ireland) Order 1993, or

(u) the disclosure is made necessarily for -

(i) the purpose of the investigation of any offence (or suspected offence), or

(ii) any purpose preliminary to proceedings, or for the purposes of, or in connection with, any proceedings.

(3) Subsection (1) does not apply to the disclosure of information in so far as -

(a) the information identifies a person who, but for sections 27 to 29 of this Act or Part 3 of the Human Tissue and Embryos Act 2007, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, and

(b) the disclosure is made for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent.

(4) For the purpose of subsection (2)(h) and (j)(ii), the consent required by this subsection is—

(a) where any person is identifiable from the information, the consent of that person, or

(b) where treatment services were provided to two persons together and both persons are identifiable, if disclosure is made for the purpose of disclosing information about the provision of treatment services to one of them, the consent of that person.

(5) For the purposes of subsection (2)(h), (i) and (j), consent to disclosure given at the request of another shall be disregarded unless, before it is given, the person requesting it takes reasonable steps to explain to the individual from whom it is requested the implications of compliance with the request.

(6) Information falling within section 31(2) cannot be disclosed by virtue of subsection (2)(h), (i) or (j) to a person who has not attained the age of 18.

(7) Paragraph (u) of subsection (2), so far as relating to disclosure for the purpose of the investigation of an offence or suspected offence, or for any purpose preliminary to, or in connection with proceedings, does not apply—

(a) to disclosure of information enabling a person to be identified as a person whose gametes were used in accordance with consent given under paragraph 5 of Schedule 3 for the purposes of treatment services or non-medical fertility services, in consequence of which an identifiable individual was, or may have been, born, or

(b) to disclosure, in circumstances in which subsection (1) of section 34 of this Act applies, of information relevant to the determination of the question mentioned in that subsection, made by any person acting in a capacity mentioned in paragraphs (c) to (h) of subsection (1).

(8) In the case of information which relates to the provision of treatment services for any identifiable individual, subsection (1) does not apply to disclosure in an emergency, that is to say, disclosure made—

(a) by a person who is satisfied that it is necessary to make the disclosure to avert an imminent danger to the health of an individual with whose consent the information could be disclosed under subsection (2)(h), and

(b) in circumstances where it is not reasonably practicable to obtain that individual's consent.

(9) In the case of information which shows that any identifiable individual was, or may have been, born in consequence of treatment services, subsection (1) does not apply to any disclosure which is necessarily incidental to disclosure under subsection (2)(h) or (8).

(10) Subsection (1) does not apply to the disclosure to any individual of information which—

(c) falls within section 31(2) of this Act by virtue of any of paragraphs (a) to (e) of that section, and

(d) relates only to that individual or, in the case of an individual treated together with another, only to that individual and that other.

(11) In subsection (2)—

(a) in paragraph (j) "relevant individual" has the same meaning as in section 31,

(b) in paragraph (q) “regulatory function” has the same meaning as in section 32 of the Legislative and Regulatory Reform Act 2006 (c. 51), and

(c) in paragraph (u) references to “proceedings” include any formal procedure for dealing with a complaint.

33B Power to provide for additional exceptions from section 33A(1)

(1) Regulations may provide for additional exceptions from section 33A(1).

(2) No exception may be made under this section for -

(a) disclosure of a kind mentioned in paragraph (a) or (b) of section 33A(7), or

(b) disclosure in circumstances in which section 32 of this Act applies of information having the tendency mentioned in subsection (2) of that section, made by any person acting in a capacity mentioned in paragraphs (c) to (h) of section 33A(1).

33C Disclosure for the purposes of medical research

(1) Regulations may make such provision for and in connection with requiring or regulating the processing of protected information for the purposes of medical research as the Secretary of State considers necessary or expedient—

(a) in the interests of improving patient care, or

(b) in the public interest.

(2) Regulations under subsection (1) may, in particular, make provision—

(a) for requiring or authorising the disclosure or other processing of protected information to or by persons of any prescribed description subject to compliance with any prescribed conditions (including conditions requiring prescribed undertakings to be obtained from such persons as to the processing of such information),

(b) for securing that, where prescribed protected information is processed by a person in accordance with the regulations, anything done by that person in so processing the information must be taken to be lawfully done despite any obligation of confidence owed by the person in respect of it,

(c) for the establishment of one or more bodies to exercise prescribed functions in relation to the processing of protected information under those regulations,

(d) as to the membership and proceedings of any such body, and

(e) as to the payment of remuneration and allowances to any member of any such body and the reimbursement of expenses.

(3) Regulations under subsection (1) may enable any approval given under regulations made under section 251 of the National Health Service Act 2006

(control of patient information) to have effect for the purposes of the regulations under subsection (1) in their application to England and Wales.

(4) Subsections (1) to (3) are subject to subsections (5) to (7).

(5) Regulations under this section may not make provision for or in connection with the processing of protected information in a manner inconsistent with any provision made by or under the Data Protection Act 1998 (c. 29).

(6) Subsection (5) does not affect the operation of provisions made under subsection (2)(b).

(7) Before making any regulations under this section the Secretary of State shall consult such bodies appearing to the Secretary of State to represent the interests of those likely to be affected by the regulations as the Secretary of State considers appropriate.

(8) In this section—

"prescribed" means prescribed by regulations made by virtue of this section,

"processing", in relation to information, means the use, disclosure, or obtaining of the information or the doing of such other things in relation to it as may be prescribed for the purposes of this definition, and

"protected information" means information falling within section 31(2).

34 Disclosure in interests of justice.

(1) Where in any proceedings before a court the question whether a person is or is not the parent of a child by virtue of sections 27 to 29 of this Act or Part 3 of the Human Tissue and Embryos Act 2007 falls to be determined, the court may on the application of any party to the proceedings make an order requiring the Authority—

(a) to disclose whether or not any information relevant to that question is contained in the register kept in pursuance of section 31 of this Act, and

(b) if it is, to disclose so much of it as is specified in the order,

but such an order may not require the Authority to disclose any information falling within section 31(2)(c) to (e) of this Act.

(2) The court must not make an order under subsection (1) above unless it is satisfied that the interests of justice require it to do so, taking into account—

(a) any representations made by any individual who may be affected by the disclosure, and

(b) the welfare of the child, if under 18 years old, and of any other person under that age who may be affected by the disclosure.

(3) If the proceedings before the court are civil proceedings, it—

(a) may direct that the whole or any part of the proceedings on the application for an order under subsection (2) above shall be heard in camera, and

(b) if it makes such an order, may then or later direct that the whole or any part of any later stage of the proceedings shall be heard in camera.

(4) An application for a direction under subsection (3) above shall be heard in camera unless the court otherwise directs.

35 Disclosure in interests of justice: congenital disabilities, etc.

(1) Where for the purpose of instituting proceedings under section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of the child, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.

(2) Where, for the purposes of any action for damages in Scotland (including any such action which is likely to be brought) in which the damages claimed consist of or include damages or solatium in respect of personal injury (including any disease and any impairment of physical or mental condition), it is necessary to identify a person who would or might be the parent of a child but for relevant statutory provisions, the court may, on the application of any party to the action or, if the proceedings have not been commenced, the prospective pursuer, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.

(2A) In subsections (1) and (2) "the relevant statutory provisions" means -

(a) sections 27 to 29 of this Act, and

(b) Part 3 of the Human Tissue and Embryos Act 2007.

(3) Subsections (2) to (4) of section 34 of this Act apply for the purposes of this section as they apply for the purposes of that.

(4) After section 4(4) of the Congenital Disabilities (Civil Liability) Act 1976 there is inserted—

"(4A) In any case where a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, any reference in section 1 of this Act to a parent includes a reference to a person who would be a parent but for sections 27 to 29 of the Human Fertilisation and Embryology Act 1990.".

Mitochondrial donation

35A Mitochondrial donation

(1) Regulations may provide for any of the relevant provisions to have effect subject to specified modifications in relation to cases where-

(a) an egg which is a permitted egg for the purposes of section 3(2) by virtue of regulations made under section 3ZA(5), or

(b) an embryo which is a permitted embryo for those purposes by virtue of such regulations,

has been created from material provided by two women.

(2) In this section "the relevant provisions" means –

(a) the following provisions of this Act -

(i) section 31 (register of information)

(ii) sections 31ZA to 31ZD (provision of information), and

(iii) Schedule 3 (consents to use of gametes or embryos), and

(b) section 60 of the Human Tissue and Embryos Act 2007 (parental orders).

Fees

35B Fees

(1) The Authority may charge a fee in respect of any of the following.

(a) an application for a licence,

(b) the grant or renewal of a licence,

(c) an application for the revocation or variation of a licence, or

(d) the exercise by the Authority of any other function under this Act—

(i) in relation to a licence,

(ii) in relation to premises which are or have been premises to which a licence relates,

(iii) in relation to premises which are or have been relevant third party premises in relation to a licence, or

(iv) in relation to premises which, if an application is granted, will be premises to which a licence relates or relevant third party premises.

(2) The amount of any fee charged by virtue of subsection (1) is to be fixed in accordance with a scheme made by the Authority with the approval of the Secretary of State and the Treasury.

(3) In fixing the amount of any fee to be charged by virtue of that subsection, the Authority may have regard to the costs incurred by it in exercising its functions under this Act or under Part 1 of the Human Tissue and Embryos Act 2007.

(4) The Authority may also charge such fee as it thinks fit in respect of any of the following -

(a) the giving of notice under section 31ZA(1) or (5),

(b) the provision of information under section 31ZA(2) or (6), 31ZB(1) or 31ZD.

(5) In fixing the amount of any fee to be charged by virtue of subsection (4) the Authority may have regard to the costs incurred by it in exercising the function to which the fee relates.

(6) Different fees may be fixed under this section for different circumstances.

Surrogacy

36 Amendment of Surrogacy Arrangements Act 1985.

(1) After section 1 of the Surrogacy Arrangements Act 1985 there is inserted—

"Surrogacy arrangements unenforceable.

1A. No surrogacy arrangement is enforceable by or against any of the persons making it."

(2) In section 1 of that Act (meaning of "surrogate mother", etc.)—

(a) in subsection (6), for "or, as the case may be, embryo insertion" there is substituted "or of the placing in her of an embryo, of an egg in the process of fertilisation or of sperm and eggs, as the case may be,", and

(b) in subsection (9), the words from "and whether" to the end are repealed.

Abortion

37 Amendment of law relating to termination of pregnancy.

(1) For paragraphs (a) and (b) of section 1(1) of the Abortion Act 1967 (grounds for medical termination of pregnancy) there is substituted—

" (a) that the pregnancy has not exceeded its twenty-fourth week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman or any existing children of her family; or

(b) that the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman; or

(c) that the continuance of the pregnancy would involve risk to the life of the pregnant woman, greater than if the pregnancy were terminated; or

(d) that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped."

(2) In section 1(2) of that Act, after "(a)" there is inserted "or (b)".

(3) After section 1(3) of that Act there is inserted -

"(3A)The power under subsection (3) of this section to approve a place includes power, in relation to treatment consisting primarily in the use of such medicines as may be specified in the approval and carried out in such manner as may be so specified, to approve a class of places."

(4) For section 5(1) of that Act (effect on Infant Life (Preservation) Act 1929) there is substituted -

"(1) No offence under the Infant Life (Preservation) Act 1929 shall be committed by a registered medical practitioner who terminates a pregnancy in accordance with the provisions of this Act."

(5) In section 5(2) of that Act, for the words from "the miscarriage" to the end there is substituted -

"a woman's miscarriage (or, in the case of a woman carrying more than one foetus, her miscarriage of any foetus) is unlawfully done unless authorised by section 1 of this Act and, in the case of a woman carrying more than one foetus, anything done with intent to procure her miscarriage of any foetus is authorised by that section if -

(a) the ground for termination of the pregnancy specified in subsection (1)(d) of that section applies in relation to any foetus and the thing is done for the purpose of procuring the miscarriage of that foetus, or

(b) any of the other grounds for termination of the pregnancy specified in that section applies".

Conscientious objection

38 Conscientious objection

(1) No person who has a conscientious objection to participating in any activity governed by this Act shall be under any duty, however arising, to do so.

(2) In any legal proceedings the burden of proof of conscientious objection shall rest on the person claiming to rely on it.

(3) In any proceedings before a court in Scotland, a statement on oath by any person to the effect that he has a conscientious objection to participating in a particular activity governed by this Act shall be sufficient evidence of that fact for the purpose of discharging the burden of proof imposed by subsection (2) above.

Enforcement

38A Powers of members and employees of the Authority

(1) Schedule 3B (which makes provision about powers of inspection, entry, search and seizure) has effect.

(2) Nothing in this Act makes it unlawful for a member or employee of the Authority to keep any embryo, inter-species embryo or gametes in pursuance of that person's functions as such.

Offences

41 Offences.

(1) A person who—

(a) contravenes section 3(2), 3A or 4A(1) or (2) of this Act, or

(b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,

is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.

(2) A person who—

(a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,

(aa) contravenes section 3(1B) of this Act,

(b) keeps any gametes in contravention of section 4(1)(a) of this Act,

(ba) uses any gametes in contravention of section 4(1)(b),

(bb) contravenes section 4(1A) of this Act,

(c) contravenes section 4(3) of this Act, or

(d) fails to comply with any directions given by virtue of section 24(5D) of this Act,

is guilty of an offence.

(3) If a person—

(a) provides any information for the purposes of the grant of a licence, being information which is false or misleading in a material particular, and

(b) either he knows the information to be false or misleading in a material particular or he provides the information recklessly,

he is guilty of an offence.

(4) A person guilty of an offence under subsection (2) or (3) above, is liable—

(a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and

(b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.

(5) A person who discloses any information in contravention of section 33A of this Act is guilty of an offence and liable—

(a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and

(b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.

(8) Where a person to whom a licence applies or the holder of the licence gives or receives any money or other benefit, not authorised by directions, in respect of any supply of gametes or embryos, he is guilty of an offence.

(9) A person guilty of an offence under subsection (8) above is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both.

(10) It is a defence for a person ("the defendant") charged with an offence of doing anything which, under section 3(1) or (1A), 4(1) or 4A(2), cannot be done except in pursuance of a licence to prove -

(a) that the defendant was acting under the direction of another, and

(b) that the defendant believed on reasonable grounds -

(i) that the other person was at the material time the person responsible under a licence, a person designated by virtue of section 17(2)(b) of this Act as a person to whom a licence applied, or a person to whom directions had been given under section 24(5A) to (5D), and

(ii) that the defendant was authorised by virtue of the licence or directions to do the thing in question.

(10A) It is a defence for a person ("the defendant") charged with an offence of doing anything which, under section 3(1A) or (1B) or 4(1A), cannot be done except in pursuance of a licence or a third party agreement to prove -

(a) that the defendant was acting under the direction of another, and

(b) that the defendant believed on reasonable grounds -

(i) that the other person was at the material time the person responsible under a licence, a person designated by virtue of section 17(2)(b) of this Act as a person to whom a licence applied, a person to whom a third party agreement applied, or a person to whom directions had been given under section 24(5A) to (5D), and

(ii) that the defendant was authorised by virtue of the licence, third party agreement or directions to do the thing in question.

(11) It is a defence for a person charged with an offence under this Act to prove—

(a) that at the material time he was a person to whom a licence or third party agreement applied or to whom directions had been given, and

(b) that he took all such steps as were reasonable and exercised all due diligence to avoid committing the offence.

42 Consent to prosecution

No proceedings for an offence under this Act shall be instituted—

(a) in England and Wales, except by or with the consent of the Director of Public Prosecutions, and

(b) in Northern Ireland, except by or with the consent of the Director of Public Prosecutions for Northern Ireland.

43 Keeping and examining gametes and embryos in connection with crime, etc

(1) Regulations may provide—

(a) for the keeping and examination of gametes or embryos, in such manner and on such conditions (if any) as may be specified in regulations, in connection with the investigation of, or proceedings for, an offence (wherever committed), or

(b) for the storage of gametes, in such manner and on such conditions (if any) as may be specified in regulations, where they are to be used only for such purposes, other than treatment services, as may be specified in regulations.

(2) Nothing in this Act makes unlawful the keeping or examination of any gametes or embryos in pursuance of regulations made by virtue of this section.

(3) In this section "examination" includes use for the purposes of any test.

44 Civil liability to child with disability

(1) After section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) there is inserted—

"**1A** Extension of section 1 to cover infertility treatments

(1) In any case where—

(a) a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled,

(b) the disability results from an act or omission in the course of the selection, or the keeping or use outside the body, of the embryo carried by her or of the gametes used to bring about the creation of the embryo, and

(c) a person is under this section answerable to the child in respect of the act or omission,

the child's disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child.

(2) Subject to subsection (3) below and the applied provisions of section 1 of this Act, a person (here referred to as "the defendant") is answerable to the child if he was liable in tort to one or both of the parents (here referred to as "the parent or parents concerned") or would, if sued in due time, have been so; and it is no answer that there could not have been such liability because the parent or parents concerned suffered no actionable injury, if there was a breach of legal duty which, accompanied by injury, would have given rise to the liability.

(3) The defendant is not under this section answerable to the child if at the time the embryo, or the sperm and eggs, are placed in the woman or the time

of her insemination (as the case may be) either or both of the parents knew the risk of their child being born disabled (that is to say, the particular risk created by the act or omission).

(4) Subsections (5) to (7) of section 1 of this Act apply for the purposes of this section as they apply for the purposes of that but as if references to the parent or the parent affected were references to the parent or parents concerned."

(2) In section 4 of that Act (interpretation, etc)—

(a) at the end of subsection (2) there is inserted -

"and references to embryos shall be construed in accordance with section 1 of the Human Fertilisation and Embryology Act 1990",

(b) in subsection (3), after "section 1" there is inserted "1A", and

(c) in subsection (4), for "either" there is substituted "any".

45 Regulations

(1) The Secretary of State may make regulations for any purpose for which regulations may be made under this Act.

(1A) Subsection (1) does not enable the Secretary of State to make regulations by virtue of any of sections 19(6), 19B and 20B(5) (which confer regulation-making powers on the Authority).

(2) The power to make regulations under this Act shall be exercisable by statutory instrument.

(3) The power to make regulations under this Act may be exercised -

(a) either in relation to all cases to which the power extends, or in relation to those cases subject to specified exceptions, or in relation to any specified cases or classes of case, and

(b) so as to make, as respects the cases in relation to which it is exercised -

(i) the full provision to which the power extends or any less provision (whether by way of exception or otherwise);

(ii) the same provision for all cases in relation to which the power is exercised, or different provision as respects the same case or class of case for different purposes;

(iii) any such provision either unconditionally, or subject to any specified condition.

(3A) Any power of the Secretary of State or the Authority to make regulations under this Act includes power to make such transitional, incidental or supplemental provision as the Secretary of State or the Authority considers appropriate.

(4) The Secretary of State shall not make regulations by virtue of any of the provisions specified in subsection (4A) unless a draft has been laid before and approved by a resolution of each House of Parliament.

(4A) Those provisions are -

section 1(6);

section 3(3)(c);

section 3ZA(5);

section 4(2) or (3);

section 15ZA;

section 24(4B);

section 31ZA(2)(a);

section 33B;

section 33C;

section 35A;

section 43;

paragraph 1(1)(g), 1ZC, 2(1A), 3(3) 3A(1)(c) of Schedule 2;

paragraph 13 of Schedule 3.

(5) A statutory instrument containing regulations made by the Secretary of State shall, if made without a draft having been approved by resolution of each House of Parliament, be subject to annulment in pursuance of a resolution of either House of Parliament.

(6) In this Act "regulations" means regulations under this section.

46 Notices

(1) This section has effect in relation to any notice required or authorised by this Act to be given to or served on any person.

(2) The notice may be given to or served on the person—

(a) by delivering it to the person,

(b) by leaving it at the person's proper address, or

(c) by sending it by post to the person at that address.

(3) The notice may—

(a) in the case of a body corporate, be given to or served on the secretary or clerk of the body,

(b) in the case of a partnership, be given to or served on any partner, and

(c) in the case of an unincorporated association other than a partnership, be given to or served on any member of the governing body of the association.

(4) For the purposes of this section and section 7 of the Interpretation Act 1978 (service of documents by post) in its application to this section, the proper address of any person is the person's last known address and also—

(a) in the case of a body corporate, its secretary or its clerk, the address of its registered or principal office, and

(b) in the case of an unincorporated association or a member of its governing body, its principal office.

(5) Where a person has notified the Authority of an address or a new address at which notices may be given to or served on him under this Act, that address shall also be his proper address for the purposes mentioned in subsection (4) above or, as the case may be, his proper address for those purposes in substitution for that previously notified.

47 Index

The expressions listed in the left-hand column below are respectively defined or (as the case may be) are to be interpreted in accordance with the provisions of this Act listed in the right-hand column in relation to those expressions.

Expression	Relevant provision
Activities governed by this Act	Section 4(5)
Appeals Committee	Section 20A(2)
Authority	Section 2(1)
Basic partner treatment services	Section 2(1)
Carry, in relation to a child	Section 2(3)
Competent authority	Section 2(1)
Directions	Section 2(1)
Distribution, in relation to gametes or embryos intended for human application	Section 2(1)
Embryo (except in section 4A)	Section 1
First Directive	Section 1A
Gametes, eggs or sperm (except in section 4A)	Section 1
Human application	Section 2(1)
Inter-species embryo	Section 4A(5)
Keeping, in relation to embryos or gametes	Section 2(2)
Licence	Section 2(1)
Non-medical fertility services	Section 2(1)
Nucleus and nuclear DNA (in relation to an embryo)	Section 2(1)
Partner-donated sperm	Section 1(5)
Person responsible	Section 17(1)
Person to whom a licence applies	Section 17(2)

Person to whom a third party agreement applies	Section 2A(3)
Processing, in relation to gametes or embryos intended for human application	Section 2(1)
Procurement, in relation to gametes or embryos intended for human application	Section 2(1)
Relevant third party premises, in relation to a licence	Section 2A(2)
Second Directive	Section 1A
Serious adverse event	Section 2(1)
Serious adverse reaction	Section 2(1)
Statutory storage period	Section 14(3) to (5)
Store, and similar expressions, in relation to embryos or gametes	Section 2(1)
Third Directive	Section 1A
Third party	Section 2A(2)
Third party agreement	Section 2A(1)
Traceability	Section 2(1)
Treatment services	Section 2(1)

48 Northern Ireland

(1) This Act (except sections 33A(2)(s) and 37) extends to Northern Ireland.

49 Short title, commencement etc.

(1) This Act may be cited as the Human Fertilisation and Embryology Act 1990.

(2) This Act shall come into force on such day as the Secretary of State may by order made by statutory instrument appoint and different days may be appointed for different provisions and for different purposes.

(3) Sections 27 to 29 of this Act shall have effect only in relation to children carried by women as a result of the placing in them of embryos or of sperm and eggs, or of their artificial insemination (as the case may be), after the commencement of those sections.

(4) Section 27 of the Family Law Reform Act 1987 (artificial insemination) does not have effect in relation to children carried by women as the result of their artificial insemination after the commencement of sections 27 to 29 of this Act.

(5) Schedule 4 to this Act (which makes minor and consequential amendments) shall have effect.

(6) An order under this section may make such transitional provision as the Secretary of State considers necessary or desirable and, in particular, may provide that where activities are carried on under the supervision of a particular individual, being activities which are carried on under the supervision of that individual at the commencement of sections 3 and 4 of this Act, those activities are to be treated, during such period as may be specified in or determined in accordance with the order, as authorised by a licence (having, in addition to the conditions required by this Act, such conditions as may be so specified or determined) under which that individual is the person responsible.

(7) Her Majesty may by Order in Council direct that any of the provisions of this Act shall extend, with such exceptions, adaptations and modifications (if any) as may be specified in the Order, to any of the Channel Islands.

SCHEDULE 2

ACTIVITIES FOR WHICH LICENCES MAY BE GRANTED

Licences for treatment

Section 11 etc

1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services—

(a) bringing about the creation of embryos *in vitro*,

(b) procuring, keeping, testing, processing or distributing embryos,

(c) procuring, testing, processing, distributing or using gametes,

(ca) using embryos for the purpose of training persons in the testing of embryos,

(d) other practices designed to secure that embryos are in a suitable condition to be placed in a woman,

(e) placing any permitted embryo in a woman,

(f) mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of testing the fertility or normality of the sperm, but only where anything which forms is destroyed when the test is complete and, in any event, not later than the two cell stage, and

(g) such other practices, apart from practices falling within section 4A(2), as may be specified in, or determined in accordance with, regulations.

(2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.

(3) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services.

(4) A licence under this paragraph cannot authorise altering the nuclear or mitochondrial DNA of a cell while it forms part of an embryo, except for the purpose of creating something that will by virtue of regulations under 3ZA(5) be a permitted embryo.

(4A) A licence under this paragraph cannot authorise the use of embryos for the purpose mentioned in sub-paragraph (1)(ca) unless the Authority is satisfied that the proposed use of embryos is necessary for that purpose.

(5) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

(6) In this paragraph, references to a permitted embryo are to be read in accordance with section 3ZA.

Embryo testing

1ZA (1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes—

(a) establishing whether the embryo has a gene, chromosome or mitochondrial abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

(c) in a case where there is a particular risk that the embryo may have an abnormality affecting the X or Y chromosomes, establishing the sex of the embryo,

(d) in a case where a person ("the sibling") who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a life-threatening medical condition which could be treated by umbilical cord blood stem cells, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and

(e) in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.

(2) A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) or (c) unless the Authority is satisfied-

(a) in relation to the abnormality of which there is a particular risk, and

(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),

that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

(3) In considering under paragraph 1(3) whether the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) or (c) is necessary or desirable for the purpose of providing treatment services, the Authority must have regard to—

(a) the extent to which the disability, illness or other medical condition involves intellectual, physical, emotional or psychological impairment, having regard to the treatment available,

(b) where relevant, the likely age of onset of the disability, illness or other medical condition in question,

(c) where any illness or other medical condition is a progressive disorder, the likely rate of degeneration,

(d) the proportion of those having the abnormality in question who are likely to be affected, and

(e) the reliability of the test to be applied.

(4) In considering under paragraph 1(3) whether the testing of embryos for the purpose mentioned in subsection (1)(d) is necessary or desirable for the purpose of providing treatment services, the Authority must have regard to—

(a) any alternative sources of tissue which are or may become available for treating the sibling, and

(b) the likely long-term effect of awareness of the testing on any child who results from an embryo that was subject to testing.

Sex selection

1ZB (1) A licence under paragraph 1 cannot authorise any practice designed to secure that any resulting child will be of one sex rather than the other.

(2) Sub-paragraph (1) does not prevent the authorisation of any testing of embryos that is capable of being authorised under paragraph 1ZA.

(3) Sub-paragraph (1) does not prevent the authorisation of any other practices designed to secure that any resulting child will be of one sex rather than the other in a case where—

(a) there is a particular risk that a woman will give birth to a child with an abnormality affecting the X or Y chromosomes, and

(b) the Authority is satisfied that the abnormality involves a significant risk falling within paragraph 1ZA(2).

(4) In considering under paragraph 1(3) whether any practice designed to secure that result in a case falling within subparagraph (3) is necessary or desirable for the purpose of providing treatment services, the Authority must have regard to the matters specified in paragraph 1ZA(3)(a) to (e).

Power to amend paragraphs 1ZA and 1ZB

1ZC (1) Regulations may amend paragraph 1ZA (embryo testing)

(2) Regulations under this paragraph which amend paragraph 1ZA may make any amendment of sub-paragraphs (2) to (4) of paragraph 1ZB (sex selection) which appears to the Secretary of State to be necessary or expedient in consequence of the amendment of paragraph 1ZA.

(3) Regulations under this paragraph may not enable the authorisation of-

(a) the testing of embryos for the purpose of establishing their sex, or

(b) other practices falling within paragraph 1ZB(1),

except on grounds relating to the health of any resulting child.

Licences for non-medical fertility services

1A (1) A licence under this paragraph may authorise any of the following in the course of providing non-medical fertility services—

(a) processing sperm, and

(b) distributing sperm.

(1A) A licence under this paragraph cannot authorise the procurement or distribution of sperm to which there has been applied any process designed to secure that any resulting child will be of one sex rather than the other.

(2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such a manner as may be specified.

(3) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

Licences for storage

2 (1) A licence under this paragraph or paragraph 1 or 3 of this Schedule may authorise the storage of gametes or embryos or both.

(1A) If regulations so provide, a licence under this paragraph or paragraph 3 may authorise the storage of inter-species embryos (whether or not the licence also authorises the storage of gametes or embryos or both).

(2) Subject to the provisions of this Act, a licence authorising such storage may be granted subject to such conditions as may be specified in the licence and may authorise storage in such manner as may be so specified.

(3) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

Licences for Research

3 (1) A licence under this paragraph may authorise any of the following-

(a) bringing about the creation of embryos in vitro,

(b) keeping or using embryos,

for the purpose of a project of research specified in the licence.

(2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.

(3) If regulations so provide, a licence under this paragraph may authorise other activities which fall within section 4A(2) (activities involving genetic material of animal origin) for the purpose of a project of research specified in the licence.

(4) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or interspecies embryos is necessary for the purposes of the research.

(5) Subject to the provisions of this Act, a licence under this section may be granted subject to such conditions as may be specified in the licence.

(6) A licence under this section may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.

(7) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.

(8) This paragraph has effect subject to paragraph 3A.

Purposes for which activities may be licensed under paragraph 3

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority -

(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) ("the principal purposes"),

(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in subparagraph (2)(a) or (b), or

(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are -

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,

(f) developing more effective techniques of contraception,

(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or

(h) increasing knowledge about the development of embryos.

General

4 (1) A licence under this Schedule can only authorise activities to be carried on -

(a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or 4(1A) applies, on relevant third party premises, and

(b) under the supervision of an individual designated in the licence.

(1A) A licence which authorises activities falling within paragraph 1 or 1A above may not also authorise activities falling within paragraph 3 above.

(2) A licence cannot—

(b) apply to more than one project of research,

(c) authorise activities to be carried on under the supervision of more than one individual, or

(d) apply to premises of the person who holds the licence in different places.

SCHEDULE 3

CONSENTS TO USE OF GAMETES OR EMBRYOS

Consent

Section 12 etc

1 (1) A consent under this Schedule, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing and, subject to sub-paragraph (2), must be signed by the person giving it.

(2) A consent under this Schedule by a person who is unable to sign because of illness, injury or physical disability ("the incapacitated person"), and any notice under paragraph 4 by such a person varying or withdrawing a consent under this Schedule, is to be taken to comply with the requirement of sub-paragraph (1) as to signature if it is signed at the direction of the incapacitated person, in the presence of the incapacitated person and in the presence of at least one witness who attests the signature.

(3) In this Schedule "effective consent" means a consent under this Schedule which has not been withdrawn.

2 (1) A consent to the use of any embryo must specify one or more of the following purposes—

(a) use in providing treatment services to the person giving consent, or that person and another specified person together,

(b) use in providing treatment services to persons not including the person giving consent,

(ba) use for the purpose of training persons in the testing of embryos, or

(c) use for the purposes of any project of research,

and may specify conditions subject to which the embryo may be so used.

(2) A consent to the storage of any gametes or any embryo must—

(a) specify the maximum period of storage (if less than the statutory storage period), and

(b) state what is to be done with the gametes or embryo if the person who gave the consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it,

and may specify conditions subject to which the gametes or embryo may remain in storage.

(3) A consent under this Schedule must provide for such other matters as the Authority may specify in directions.

(4) A consent under this Schedule may apply—

(a) to the use or storage of a particular embryo, or

(b) in the case of a person providing gametes, to the use or storage of any embryo whose creation may be brought about using those gametes,

and in the paragraph (b) case the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to a particular embryo or particular embryos.

Procedure for giving consent

3 (1) Before a person gives consent under this Schedule—

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and

(b) he must be provided with such relevant information as is proper.

(2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 below.

Variation and withdrawal of consent

4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes or embryo to which the consent is relevant.

(2) The terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used—

(a) in providing treatment services,

(aa) in training persons in the testing of embryos, or

(b) for the purposes of any project of research.

4A Where, while an embryo the creation of which was brought about in vitro is in storage but before it is used as mentioned in paragraph 4(2), one of the persons whose gametes were used to bring about the creation of the embryo ("the first gamete donor") gives the person keeping the embryo notice withdrawing the consent of the first gamete donor to the storage of the embryo-

(a) the person keeping the embryo must as soon as possible take all reasonable steps to notify the other person whose gametes were used to bring about the creation of the embryo ("the second gamete donor") of the withdrawal of consent by the first gamete donor, and

(b) storage of the embryo remains lawful until-

(i) the end of the period of 12 months beginning with the day on which notice was received from the first gamete donor, or

(ii) if, before the end of that period, the person keeping the embryo receives notice from the second gamete donor withdrawing the consent of the second gamete donor to the storage of the embryo, the time when that notice is received.

Use of gametes for treatment of others

5 (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.

(2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.

(3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

In vitro fertilisation and subsequent use of embryo

6 (1) A person's gametes must not be used to bring about the creation of any embryo *in vitro* unless there is an effective consent by that person to any embryo the creation of which may be brought about with the use of those gametes being used for one or more of the purposes mentioned in paragraph 2(1)(a), (b) and (c) above.

(2) An embryo the creation of which was brought about *in vitro* must not be received by any person unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) above of the embryo.

(3) An embryo the creation of which was brought about *in vitro* must not be used for any purpose unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.

(4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

Embryos obtained by lavage, etc

7 (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.

(2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.

(3) This paragraph does not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.

Storage of gametes and embryos

8 (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.

(2) An embryo the creation of which was brought about *in vitro* must not be kept in storage unless there is an effective consent, by each person whose gametes were used to bring about the creation of the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.

(3) An embryo taken from a woman must not be kept in storage unless there is an effective consent by her to its storage and it is stored in accordance with the consent.

(4) Sub-paragraph (1) has effect subject to paragraphs 9 and 10; and sub-paragraph (2) has effect subject to paragraph 4A(b).

Cases where consent not required for storage

9 (1) The gametes of a person ("the child donor") may be kept in storage without the child donor's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by the child donor before the child donor attains the age of 18 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the child donor is expected to undergo medical treatment and that in the opinion of the registered medical practitioner-

(a) the treatment is likely to cause a significant impairment of the fertility of the child donor, and

(b) the storage of the gametes is in the best interests of the child donor.

(4) Condition C is that, at the time when the gametes are first stored, either—

(a) the child donor has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) the child donor has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.

(5) Condition D is that the child donor has not, since becoming competent to deal with the issue of consent to the storage of the gametes-

(a) given consent under this Schedule to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that he does not wish them to continue to be stored.

10 (1) The gametes of a person ("the patient") may be kept in storage without the patient's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by the patient after the patient has attained the age of 16 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the patient is expected to undergo medical treatment and that in the opinion of the registered medical practitioner-

(a) the treatment is likely to cause a significant impairment of the patient's fertility,

(b) the patient lacks capacity to consent to the storage of the gametes,

(c) the patient is likely to regain that capacity, and

(d) the storage of the gametes is in the patient's best interests.

(4) Condition C is that, at the time when the gametes are first stored, the patient lacks capacity to consent to their storage.

(5) Condition D is that the patient has not, after regaining capacity to give a consent under this Schedule—

(a) given consent to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that the patient does not wish them to continue to be stored.

11 References in paragraphs 9 and 10 to capacity to consent are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

12 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death.

Creation of inter-species embryo and subsequent use of embryo

13 (1) If by virtue of regulations under sub-paragraph (3) of paragraph 3 of Schedule 2 a licence under that paragraph authorises the carrying out of any activity falling within section 4A(2) but not within sub-paragraph (2) of that paragraph, a person's gametes must not be used for the purpose of that activity

unless there is an effective consent by that person complying with any conditions prescribed by regulations.

(2) An inter-species embryo must not be used for the purposes of a project of research unless there is an effective consent by any person whose gametes were used to bring about the creation of the embryo to the use of the inter-species embryo for that purpose.

14 An inter-species embryo must not be kept in storage unless there is an effective consent by any person whose gametes were used to bring about the creation of the inter-species embryo and the inter-species embryo is stored in accordance with the consent.

SCHEDULE 3ZA

CIRCUMSTANCES IN WHICH OFFER OF COUNSELLING REQUIRED AS CONDITION OF LICENCE FOR TREATMENT

PART 1

KINDS OF TREATMENT IN RELATION TO WHICH COUNSELLING MUST BE OFFERED

1 The treatment services involve the use of the gametes of any person and that person's consent is required under paragraph 5 of Schedule 3 for the use in question.

2 The treatment services involve the use of any embryo the creation of which was brought about *in vitro*.

3 The treatment services involve the use of an embryo taken from a woman and the consent of the woman from whom the embryo was taken was required under paragraph 7 of Schedule 3 for the use in question.

PART 2

EVENTS IN CONNECTION WITH WHICH COUNSELLING MUST BE OFFERED

4 A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 43 of the Human Tissue and Embryos Act 2007 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.

5 The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

6 A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 50 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.

7 The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

SCHEDULE 3A

SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

Traceability and coding system

Section 14A

1 Licence conditions shall require that all persons to whom a licence applies adopt such systems as the Authority considers appropriate to secure—

(a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive, and

(b) in relation to the coding of information, compliance with the requirements of Article 25 (coding of information) of the first Directive and Article 10 (European coding system) of the third Directive.

2 Licence conditions imposed in accordance with paragraph 1 may specify the coding system which must be applied in relation to gametes and embryos intended for human application.

Serious adverse events and serious adverse reactions

3 Licence conditions shall require such—

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

to be in place as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.

Third party agreements and termination of licensed activities

4 For the purpose of securing compliance with the requirements of Articles 21(5) (tissue and cell storage conditions) and 24 (relations between tissue establishments and third parties) of the first Directive, licence conditions shall specify the requirements that must be met in relation to the termination of storage activities authorised by the licence and in relation to third party agreements.

Requirements for procurement of gametes and embryos

5 Licence conditions shall require all persons to whom a licence applies who are authorised to procure gametes or embryos, or both, to comply with the requirements (including as to staff training, written agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

Selection criteria and laboratory tests required for donors of reproductive cells

6 In relation to partner-donated sperm which is not intended to be used without processing or storage, licence conditions shall require compliance with the selection criteria for donors and the requirements for laboratory tests laid down in section 2 (partner donation (not direct use)) of Annex III (selection criteria and laboratory tests required for donors of reproductive cells) to the second Directive.

7 In relation to donations of gametes or embryos other than partner-donated sperm or partner-created embryos, licence conditions shall require compliance with the selection criteria for donors and the requirements for laboratory tests laid down in section 3 (donations other than by partners) of Annex III to the second Directive.

8 Licence conditions shall require that the laboratory tests required by sections 2 and 3 of Annex III to the second Directive to be carried out for the purpose of selecting gametes or embryos for donation, meet the requirements of section 4 (general requirements to be met for determining biological markers) of Annex III to the second Directive.

Donation and procurement procedures and reception at the tissue establishment

9 In relation to—

(a) donation and procurement procedures, and

(b) the reception of gametes and embryos at the premises to which a licence relates or at relevant third party premises,

licence conditions shall require compliance with the requirements of Article 15(3) (selection, evaluation and procurement) and Article 19(4) to (6) (tissue and cell reception) of the first Directive and with the requirements laid down in the provisions of the second Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

1. Donation and procurement procedures	**Relevant provisions of the second Directive**
Consent and donor identification (record of consent, method of identification, donor review)	Annex IV, point 1.1
Donor evaluation: other than partner-donated sperm and partner-created embryos and autologous donors (assessment of donor's medical and behavioural information)	Annex IV, point 1.2
Procurement procedures for gametes and embryos (requirements relating to procurement procedures and instruments)	Annex IV, point 1.3
Donor documentation (record of donor and the procurement)	Annex IV, point 1.4
Packaging (requirements as to packaging and shipping containers)	Annex IV, point 1.5
Labelling of procured gametes and embryos (minimum labelling requirements)	Annex IV, point 1.6
Labelling of the shipping container (minimum labelling requirements)	Annex IV, point 1.7
2. Reception of tissues and cells at the tissue establishment	**Relevant provisions of the second Directive**
Verification upon arrival (procedures for verification and requirements for quarantine until verification)	Annex IV, points 2.1 to 2.3
Registration of data (other than in respect of partner-donated sperm and partner-created embryos)	Annex IV, point 2.4
Registration of data (partner-donated sperm and partner-created embryos)	Annex IV, point 2.5

Requirements for holding a licence under paragraph 1, 1A or 2 of Schedule 2

10 Licence conditions shall require compliance with the requirements laid down in the provisions of the third Directive listed in the right-hand column, the

subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Organisation and management (requirements as to organisational structure, management systems, and third party agreements)	Annex I, Part A
Personnel (number, competence, responsibilities and training)	Annex I, Part B
Equipment and materials (appropriate for use, validation, maintenance, and specifications)	Annex I, Part C
Facilities and premises (suitability, environment, storage, and maintenance)	Annex I, Part D
Documentation and records (standard operating procedures, document control, record reliability)	Annex I, Part E
Quality review (quality management system, investigations, corrective action, and reviews)	Annex I, Part F

Requirements for holding a licence for gametes and embryo preparation processes

11 In respect of gametes and embryos preparation processes, licence conditions shall require compliance with—

(a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and

(b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Reception of gametes and embryos at the tissue establishment	Annex II, Part A
Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating	Annex II, Part C

procedure)	
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F

Interpretation of this Schedule

12 In this Schedule, "partner-created embryos" means embryos created using the gametes of a man and a woman who declare that they have an intimate physical relationship.

SCHEDULE 3B

POWERS OF INSPECTION, ENTRY, SEARCH AND SEIZURE

Inspection of statutory records

1 (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of this Act.

(2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—

(a) in a visible and legible form, or

(b) in a form from which they can be readily produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

Entry and inspection of licensed premises

2 (1) A duly authorised person may at any reasonable time enter and inspect any premises to which a licence relates or relevant third party premises.

(2) The power in sub-paragraph (1) is exercisable for purposes of the Authority's functions in relation to licences and third party agreements.

Entry and search in connection with suspected offence

3 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—

(a) that an offence under this Act is being, or has been committed on any premises, and

(b) that any of the conditions in sub-paragraph (2) is met in relation to the premises,

the justice of the peace may by signed warrant authorise a duly authorised person, together with any constables, to enter the premises, if need be by force, and search them.

(2) The conditions referred to are—

(a) that entry to the premises has been, or is likely to be refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;

(b) that the premises are unoccupied;

(c) that the occupier is temporarily absent;

(d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) In relation to Scotland, the reference in sub-paragraph (1) to a justice of the peace includes a reference to a sheriff.

Execution of warrants

4 (1) Entry and search under a warrant under paragraph 3 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.

(2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—

(a) produce the warrant to the occupier, and

(b) give the occupier -

(i) a copy of the warrant, and

(ii) an appropriate statement.

(4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—

(a) produce the warrant to that other person,

(b) give that other person -

(i) a copy of the warrant, and

(ii) an appropriate statement, and

(c) leave a copy of the warrant in a prominent place on the premises.

(5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.

(6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

(7) Where the premises in relation to which a warrant under paragraph 3 is executed are unoccupied or the occupier is temporarily absent, the person executing the warrant shall when leaving the premises, leave them as effectively secured as the person found them.

Seizure on the course of inspection of search

5 (1) A duly authorised person entering and inspecting premises under paragraph 2 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for -

(a) the purposes of the Authority's functions relating to the grant, revocation, variation or suspension of licences, or

(b) the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction.

(2) A duly authorised person entering or searching premises under a warrant under paragraph 3 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Act.

(3) Where a person has power under sub-paragraph (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving that thing or preventing interference with it.

(4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of sub-paragraph (1) or (2) a person ("P") seizes anything, P shall leave on the premises from which the thing was seized a statement giving particulars of what P has seized and stating that P has seized it.

Powers: supplementary

6 (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(2) Power under this Schedule to inspect or search any premises includes, in particular—

(a) power to inspect any equipment found on the premises,

(b) power to inspect and take copies of any records found on the premises, and

(c) in the case of premises to which a licence relates or premises which are relevant third party premises in relation to a licence, power to observe the carrying-on on the premises of the licensed activity.

(3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

7 (1) A person's right to exercise a power under this Schedule is subject to his producing evidence of the person's entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall—

(a) prepare a written report of the inspection and search, and

(b) if requested to do so by the appropriate person, give him a copy of the report.

(3) In sub-paragraph (2), the "appropriate person" means—

(a) in relation to premises to which a licence relates, the person responsible, or

(b) in relation to any other premises, the occupier.

Enforcement

8 A person who —

(a) fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 6(3), or

(b) intentionally obstructs the exercise of any right under this Schedule,

is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Interpretation

9 In this Schedule—

(a) "duly authorised person", in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision, and

(b) "licensed activity", in relation to a licence, means the activity which the licence authorises to be carried on.

SCHEDULE 4

MINOR AND CONSEQUENTIAL AMENDMENTS

Family Law Reform Act 1969 (c. 46.)

1 In section 25 of the Family Law Reform Act 1969 (interpretation), at the end of the definition of "excluded" there is added "to section 27 of the Family Law Reform Act 1987 and to sections 27 to 29 of the Human Fertilisation and Embryology Act 1990".

Family Law Reform (Northern Ireland) Order 1977 (S.I. 1977/1250 (N.I. 17))

5 In Article 13 of the Family Law Reform (Northern Ireland) Order 1977 (interpretation), at the end of the definition of "excluded" there is added "and to sections 27 to 29 of the Human Fertilisation and Embryology Act 1990".

Adoption (Scotland) Act 1978 (c. 28.)

6 In section 15 of the Adoption (Scotland) Act 1978 (adoption by one person), in subsection (3)(a) (conditions for making an adoption order on application of one parent), after "found" there is inserted "or, by virtue of section 28 of the Human Fertilisation and Embryology Act 1990, there is no other parent".

Adoption (Northern Ireland) Order 1987 (S.I. 1987/2203 (N.I. 22))

7 In Article 15 of the Adoption (Northern Ireland) Order 1987 (adoption by one person), in paragraph (3)(a) (conditions for making an adoption order on the application of one parent), after "found" there is inserted "or, by virtue of section 28 of the Human Fertilisation and Embryology Act 1990, there is no other parent".

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