Explanatory notes; these notes refer to the Human Tissue Bill as brought from the House of Commons on 29th June 2004 [HL Bill 94].

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HUMAN TISSUE BILL

EXPLANATORY NOTES

INTRODUCTION

1. These explanatory notes have been prepared by the Department of Health, in consultation with the National Assembly for Wales and the Northern Ireland Office, in order to assist the reader of the Bill and to help inform debate upon it. They do not form part of the Bill.

2. The explanatory notes are to be read in conjunction with the Bill and are not meant to be a comprehensive description of the Bill. So where a clause or part of a clause of the Bill does not seem to require any explanation or comment, none is given.

3. The Bill will extend to England, Wales and Northern Ireland, except for clause 50 and Schedule 5 (non-consensual DNA-analysis), which will apply throughout the UK. Clause 52 (power of museums to "de-accession" human remains) will also extend, as a matter of law, to the whole of the UK, but will only apply to named museums in England.

SUMMARY AND BACKGROUND

4. The purpose of the Human Tissue Bill is to provide a consistent legislative framework for issues relating to whole body donation and the taking, storage and use of human organs and tissue. It will make consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons. It will set up an over-arching authority which is intended to rationalise existing regulation of activities like transplantation and anatomical examination, and will introduce regulation of other activities like *post mortem* examinations, and the storage of human material for education, training and research. It is intended to achieve a balance between the rights and expectations of individuals and families, and broader considerations, such as the importance of research, education, training, pathology and public health surveillance to the population as a whole.

5. This Bill arises from concern raised by events at Bristol Royal Infirmary and the Royal Liverpool Children's Hospital (Alder Hey) 1999 - 2000. The *Kennedy* and *Redfern*

inquiries at these hospitals established that organs and tissue from children who had died had often been removed, stored and used without proper consent. A subsequent census by the Chief Medical Officer for England (2000) and the *Isaacs Report* (2003) showed that storage and use of organs and tissue from both adults and children without proper consent has been widespread in the past. It also became clear that the current law in this area was not comprehensive, nor as clear and consistent as it might be for professionals or for the families involved. In Northern Ireland the Report of the Human Organs Inquiry (June 2002) had reached a similar conclusion.

6. In advice to the Government, *The Removal, Retention and Use of Human Organs and Tissue from Post Mortem Examination* published in 2001, the Chief Medical Officer for England recommended that there should be a fundamental and broad revision of the law on human organs and tissues taken from adults or children, either during surgery or after death. A consultation document, *Human Bodies, Human Choices* was launched in July 2002, setting out proposals to review the current law in England and Wales. The broad approach to changing the law outlined in the consultation document drew a large degree of consensus and forms the basis of the proposals in the Bill. In May 2001, the Department of Culture Media and Sport set up a Working Group on Human Remains which reported in November 2003, recommending that the laws preventing repatriation of human remains by certain national museums should be relaxed.

TERRITORIAL APPLICATION: WALES

7. The Bill has been drafted in liaison and agreement with the Welsh Assembly. Except for clause 52, it deals with reserved matters and will apply equally in Wales. However, as it may impact on the National Health Service and other issues in Wales responsibility for which is transferred to the National Assembly for Wales, the Bill includes powers for the Assembly to appoint a member to the Human Tissue Authority. The Secretary of State will also be required to consult the Assembly on a range of issues, including statutory codes of practice. Clause 52 deals with museums. Responsibility for museums in Wales is transferred to the Assembly. So although the clause extends to England and Wales, the bodies to which this clause applies do not include museums in Wales.

THE BILL

8. The Bill will repeal and replace the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales. It will also repeal and replace the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992.

9. The Bill is in three parts and has eight schedules:

Part 1 is about consent. It sets out the requirement to obtain appropriate consent to carry out activities regulated under the Bill: storage and use of whole bodies, removal, storage and use of human material (organs, tissues and cells) from the bodies of deceased persons, and storage and use of material from living people, for purposes set out in Schedule 1. It defines

appropriate consent by reference to who may give it, and provides for a "nominated representative" who may make decisions about regulated activities after a person's death. Part 1 makes it an offence to carry out regulated activities without appropriate consent, makes it unlawful to use bodies or human material, once donated, for purposes other than those set out in Schedule 1 and establishes penalties. Part 1 also sets out what should happen to "existing holdings" of human material obtained before the consent provisions take effect. This Part also exempts coroners from the requirements of Part 1 of the Bill, and allows storage and use of human material, obtained from living persons, for specified purposes without consent.

Part 1 does not apply to the removal (as opposed to the storage and use) of human material from living persons. The current law will continue to apply to that. Nor does Part 1 affect the existing law on storage and use of human material for purposes other than those mentioned in Part 1.

Part 2 is about the regulatory system to be established to make sure that regulated activities are carried out in a proper manner. It sets up the Human Tissue Authority (HTA) with a remit covering removal, storage, use and disposal of human material. It also sets out the range of activities for which a licence from the HTA is required. It prohibits the conduct of those activities without a licence and establishes penalties for so doing. This Part also sets out who will be responsible for a licence, their duties under a licence and related procedures. It provides for the HTA to issue codes of practice concerning the proper conduct of activities within its remit, to issue Directions and make reports. Part 2 brings the regulation of all human organ transplants between living persons under the HTA and prohibits commercial dealing in human material. Part 2 also sets up, under the HTA, the Inspectorate of Anatomy & Pathology and the Inspectorate for Organs and Tissues for Human Use and sets out their functions.

Part 3 deals with various important supplementary issues and general provisions. Clause 48 makes it clear that it is lawful for hospital authorities to take the minimum steps to preserve the organs of deceased persons whilst appropriate consent to transplantation is sought. Clause 49 provides for disposal of human material which is no longer to be kept. Clause 50 makes it an offence, with specified exceptions, for a person to have human material with a view to analysing its DNA without consent. Clause 52 creates a power for certain national museums to transfer human remains out of their collections if they think it appropriate to do so. This Part also contains general provisions including powers of inspection, entry, search and seizure, the power to make regulations and orders by way of statutory instruments, interpretation and consequential changes to existing statutes.

COMMENTARY ON CLAUSES

PART 1 - REMOVAL, STORAGE AND USE OF HUMAN ORGANS AND OTHER TISSUE FOR SCHEDULED PURPOSES

Clause 1: Authorisation of activities for scheduled purposes

10. Clause 1 is the foundation of the Bill. It establishes that consent from an appropriate person ("appropriate consent" as defined in clauses 2 and 3) is required before certain activities can be undertaken for particular purposes. These activities are storage and use of whole bodies, removal, storage and use of relevant material from the body of a deceased person, and storage and use of relevant material from a living person. The purposes to be regulated are listed in Schedule 1 and are referred to in these notes as "scheduled purposes". Relevant material from a human body is defined at clause 58 as any material consisting of, or including, human cells, with the exception of gametes, embryos outside the body (as defined in, and separately regulated by, the Human Fertilisation and Embryology Act 1990), and hair and nail from a living person. Cell lines are also excluded by virtue of clause 59(7), as is any other human material created outside the human body.

11. *Subsections (2) & (3)* deal with the special requirements for the lawful storage and use of a body for anatomical examination. These provisions are carried over from the Anatomy Act 1984.

12. *Subsections (4) to (9)* allow activities of the kind mentioned in subsections (1) to (3) to be done in certain cases without meeting the conditions for which those subsections provide. The exceptions relate to imported bodies and material and to bodies, and material from bodies, of persons who died before the coming into force of the new regime where there is a gap of more than 100 years between the date of death and the activity concerned. This will allow continued import of tissue for research and will exclude archaeological specimens from the consent provisions. There is also an exception for health-related research on material from living people where the material is not linked to an identifiable individual and the research has been ethically approved in accordance with regulations. It is anticipated that this ethical approval will be given by existing Research Ethics Committees.

13. *Subsection (10)* makes it lawful for relevant material, which has been obtained from a living person, to be stored and used for the limited purposes set out in Schedule 1 Part 2, without any consent. These purposes are ones considered intrinsic to the proper conduct of a patient's treatment (clinical audit, quality assurance and performance assessment - which could include evaluations of *in-vitro* diagnostic devices) or necessary for the public health of the nation (public health monitoring and health-related education and training).

14. *Subsection (11)* provides that the Secretary of State may vary, omit or add to the purposes set out in Schedule 1, by means of a statutory instrument, subject to affirmative resolution in both Houses. *Subsection (12)* excludes from the consent requirements of clause 1 the storage and use of relevant material in *in-vitro* diagnostic medical device testing where this is already regulated by Directive 98/79/EC. *Subsection (13)* is aimed at ensuring that

bodies and relevant material are not exported and re-imported simply to get around the consent requirements.

Clause 2: "Appropriate consent": children

15. Clause 2 sets out the meaning of "appropriate consent" in relation to activities regarding the body of a deceased child, or relevant material from living or deceased children. For the purposes of this clause, children are people under the age of 18.

16. Living children who are competent to do so may give their own consent. If they are not competent or choose not to decide, appropriate consent will be that of a person with parental responsibility for them. Competence is not defined in the Bill, but will be established according to common law principles (the "Gillick test").

17. Where a child has died, if he or she was competent and made an advance decision (to give or refuse consent), that will apply. *Subsections (4)* to *(6)* provide that consent of a competent child to have his or her body used for anatomical examination or public display must be in writing and witnessed. No-one other than a competent child may give consent to the use of his or her own body for purposes of anatomical examination or public display. Anatomical examination is defined in clause 59. *Subsection (5)* of this clause provides that prior written, witnessed consent to anatomical examination is only necessary in relation to material which is not excepted material (as defined in clause 12), that is, in relation to a whole body, or material which has come from a whole body during an anatomical examination. For other scheduled purposes, such as the carrying out of a *post mortem* examination or the use of organs for transplantation, the consent of someone with parental responsibility will be appropriate consent, but only if the child did not deal with the issue of consent. *Subsection (7)* provides that if a child has died and there is no-one with parental responsibility, someone in a "qualifying relationship" may give consent to removal, storage or use of the child's body or material from the body. (The group of next of kin etc who qualify for these purposes is given at clause 59(9) and dealt with further at clause 27(4)).

Clause 3: "Appropriate consent": adults

18. Clause 3 sets out the meaning of "appropriate consent", in relation to activities concerning the body of a deceased adult or relevant material from a person who is (at the time of the activity) a living or deceased adult. If the adult is alive his own consent is required. *Subsections (3)* to *(5)* provide that after death, the adult's consent, given in advance in writing and witnessed, is required for purposes of anatomical examination or public display. As explained in the previous paragraph, anatomical examination is relevant only in relation to a whole body or material which has come from a whole body during an anatomical examination. For other scheduled purposes, if the adult made no prior decision, a person nominated by him in accordance with clause 4 to make decisions after his death or, failing that, someone in a "qualifying relationship" (as listed in clause 59(9) and dealt with further at clause 27(4)) may give consent.

Clause 4: Nominated Representatives

19. This clause sets out how an adult aged 18 or over can make a valid appointment of one or more "nominated representative(s)", who may give consent after the adult's death to storage or use of his or her body, or removal, storage and use of relevant material from his or her body for scheduled purposes. *Subsection (6)* says that where two or more people are appointed as nominated representative, they will be assumed to be able to act alone unless the appointment says they must act jointly.

Clause 5: Prohibition of activities without consent

20. *Subsection (1)* penalises the carrying-out of any of the activities to which clause 1(1), (2) or (3) applies if done without appropriate consent. This means that where there is consent to use material for one purpose, it may not be used for another. However, a person does not commit an offence if he reasonably believed that the appropriate consent was in place, or that the activity was not one in relation to which consent was required.

21. *Subsection (2)* penalises a person who knowingly makes a false representation to another person that appropriate consent has been given or is not needed. *Subsections (3) to (6)* relate to offences and penalties in connection with anatomical examination which have been transferred from the Anatomy Act 1984.

Clause 6: Activities involving material from adults who lack capacity

22. This clause enables the Secretary of State to specify in regulations the circumstances in which there is to be deemed to be consent to activities regulated by the Bill in relation to adults who lack capacity to consent for themselves, where a decision of theirs about such matters is not already in force. It is envisaged that the regulations will provide for consent to be deemed to be in place where the activity would be in the adult's best interests - for example, it could be in their best interests to donate tissue to a close relative for transplantation. The regulations will also be able to provide that where consent has been given by a proxy in accordance with Schedule 1 to the Medicines For Human Use (Clinical Trials) Regulations 2004/1031, storage and use of material from the adult lacking capacity as part of the trial should be treated as done with consent. The Mental Capacity Bill, which was introduced in Parliament on 17 June, may well amend the Human Tissue Bill in due course, but the regulation-making power is necessary for the period before the Mental Capacity Bill is in force (expected to be after the Human Tissue Bill is implemented). The regulations might also be able to take account of the debates in Parliament on the Mental Capacity Bill concerning research involving those who lack capacity to consent.

Clause 7: Powers of court to dispense with the need for consent

23. *Subsections (1) and (2)* of this clause allow a court to make an order deeming consent to be in place in relation to relevant material from a living person who is untraceable, but where the material could be used to provide information which may be relevant to another

person. This is expected to be a rarely-used power, but it may be important where valuable information could be obtained about the treatment and diagnosis of the applicant for the order.

24. *Subsection (3)* enables the Secretary of State to make regulations which would provide a similar power for a court to deem consent to be in place where relevant material or a body could be used for health-related research. It is envisaged that this power would be exercised only in rare and unusual cases where the research would be in the overwhelming public interest, for example, where a person has died of an unknown virus which has the potential to spread among the general population.

Clause 8: Restriction of activities in relation to donated material

25. This clause provides that, where the body of a deceased person or relevant material from a human body is the subject of any consent under clause 1, it may not be used, or stored for use, for purposes other than the following: (a) a purpose listed in Schedule 1, (b) medical diagnosis or treatment, (c) disposal or (d) another purpose excepted by regulations. It will be an offence to use such material for any other purpose. The offence will not apply where a person believes on reasonable grounds that the body or material is not relevant material which is the subject of appropriate consent. The regulation-making power is intended to be used to ensure that legitimate uses of tissue which may come to light in future will not be criminalised.

Clause 9: Existing Holdings

26. This clause deals with "existing holdings", namely, a body, or relevant material, which is already held for use for a scheduled purpose when the new regime comes into force. In such a case, the effect of the clause is that use, or storage for use, for a scheduled purpose is authorised under clause 1(1) without the need for appropriate consent. However, this does not apply to storage and use of bodies or material in relation to which there is an authority under the Anatomy Act 1984 and where the anatomical examination is not concluded before the Bill comes into force. Such bodies and material are dealt with in clause 10. The code of practice to be issued by the HTA under clause 26 will deal with the storage, use and disposal of existing holdings.

Clause 10: Existing Anatomical Specimens

27. This clause provides for what should be done, once the consent provisions of the Bill take effect, about bodies and parts of bodies already donated for dissection under the Anatomy Act 1984, but where the anatomical examination of them has not been concluded. The Anatomy Act provides that bodies might be kept for up to three years with the donor's or his next of kin's authority and body parts might be kept for longer. This clause provides that the terms of the authority given under the Anatomy Act 1984 are to be treated as "appropriate consent" to anatomical examination. In addition, if the existing authority allowed parts of the body to be held after conclusion of the examination and the examination was not in fact concluded before the consent provisions in the Bill came into force, the authority is to be treated as "appropriate consent" to storage for the purposes of education and research.

28. *Subsection (6)* is intended to ensure that, where authority under the Anatomy Act has been given on terms, the authority under the Bill which is based on that authority is also subject to those terms.

Clause 11: Coroners

29. In order to maintain the current legal position regarding coroners, this clause exempts from the requirements of Part 1 of the Bill anything done for the functions of a coroner or under his authority. This includes both his statutory functions and his common law authority. *Subsection (2)* provides that if a body or material from it may be needed for the purposes of the coroner, the authority conferred by clause 1 to act in relation to the body or material does not apply.

Clause 12: Interpretation of Part 1

30. This clause defines 'excepted material' which is relevant to the references in clauses 2 and 3 to anatomical examination.

PART 2 - REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE

The Human Tissue Authority

Clause 13: The Human Tissue Authority

31. This clause establishes the HTA as a body corporate and gives effect to Schedule 2 (which includes provision about the membership of the Authority, its organisation and financial matters).

Clause 14: Remit

32. *Subsection (1)* lists the activities within the HTA's remit. The activities include disposal of bodies and relevant material stored or used for scheduled purposes. *Subsection (3)* excludes from the remit of the HTA activities done in relation to material from bodies, or bodies, where the person died before the Bill comes into force and has been dead for at least 100 years. *Subsection (4)* provides that the Secretary of State may by order add to the activities within the remit of the HTA. *Subsection (5)* defines "relevant material" in this section as excluding blood or anything derived from blood for the purpose of transplantation. Blood and blood products for transfusion will be regulated upon implementation of Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

Licensing

Clause 16: Licence Requirements

33. *Subsection (1)* prohibits the carrying on of activities to which the clause applies without a licence. *Subsection (2)* sets out the activities to which the licence requirement applies. *Subsection (3)* provides that the Secretary of State may by regulations specify circumstances in which storage of relevant material by a person who intends to use it for a scheduled purpose is excepted from the licence requirement. This will allow distinction to be made between tissue banks, for example, and individuals using tissue in research projects, who will not then require to be licensed. *Subsection (4)* excludes from the licensing requirement activities done in relation to material from bodies, or bodies, where the person died before the Bill comes into force and has been dead for at least 100 years. *Subsection (5)* provides that the Secretary of State may by regulations add, remove or alter the description of an activity listed in the clause. *Subsection (7)* excludes from the licence requirement storage incidental to transportation. It also excludes use of blood or blood products for transplantation, and storage of blood or blood products for use for that purpose. Schedule 3 contains the detailed procedures for granting, varying, revoking and suspending licences. Licensing functions under the Schedule are conferred on the HTA.

Clause 17: Persons to whom licence applies

34. This clause defines who is permitted to act under the authority conferred by a licence: the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on (the "designated individual"), any other person notified to the HTA by the designated individual as a person to whom the licence applies, and any person acting under the direction of either of the first two.

Clause 18: Duty of the designated individual

35. This clause provides that the individual designated in the licence is responsible for securing that the other persons to whom the licence applies are suitable to participate in the licensed activity, that suitable practices are used and that all licence conditions are complied with.

Clause 19: Right to reconsideration of licensing decisions

36. This clause provides that an applicant may require the HTA to reconsider licensing decisions in respect of a refusal of an application to grant, revoke or vary a licence, or a licence holder or designated person may require the HTA to reconsider a decision to revoke or vary a licence. *Subsection (3)* provides that notice of exercise of the right to reconsideration must be given to the HTA by the appellant within 28 days of the HTA giving notice of the decision.

Clause 20: Appeals Committee

37. This clause requires the HTA to maintain one or more appeals committees composed of not less than 5 (with a quorum of 3) members of the HTA. The appeals committee will be responsible for dealing with requests for reconsideration of HTA decisions under clause 19.

Clause 21: Procedure on reconsideration

38. This clause sets out the procedure for reconsideration of licensing decisions, which will be by way of fresh decision. *Subsection (5)* provides that the HTA may by regulations make other provision in relation to the procedure on reconsideration as it thinks fit.

Clause 23: Conduct of licensed activities

39. This clause provides that directions issued by the HTA may impose particular requirements relating to the conduct of activities authorised by a licence. *Subsection (2)* says directions may be general, applicable to particular kinds of licence or to an individual licence. *Subsection (3)* makes it a statutory requirement that they are complied with by those to whom they apply.

Clause 24: Changes of licence circumstance

40. *Subsections (1)* to *(3)* provide that directions may be made for the purpose of dealing with a situation in consequence of the variation of a licence or the ceasing of a licence to have effect, and identify the persons on whom requirements may be imposed. *Subsection (5)* provides that in the event of the death or dissolution of a licence holder, anything done before directions are given will be treated as authorised, provided it would have been authorised by the licence holder's licence (were it still in force).

Clause 25: Breach of licence requirement

41. This clause establishes the offence of carrying on a licensed activity otherwise than under the authority of a licence granted under clause 16(1), unless the person carrying on the activity reasonably believes the activity is not licensable or that he acts under the authority of a licence. *Subsection (2)* sets out penalties for the offence.

Codes of Practice

Clause 26: Preparation of codes

42. *Subsection (1)* provides that the HTA may prepare and issue codes of practice giving guidance and setting standards in relation to activities within its remit. *Subsections (2)* and *(3)* list the matters which must be dealt with in the codes of practice prepared by the HTA.

Clause 27: Provision with respect to consent

43. *Subsection (1)* provides that in a code of practice dealing with consent the HTA must lay down standards relating to obtaining consent from a person in a qualifying relationship. *Subsection (3)* provides that the HTA may lay down different standards for obtaining consent in exceptional cases, for example, a blood relative lower down the hierarchy than a partner or spouse may have a greater interest in obtaining information about their deceased relative's health where this may be relevant to their own health. *Subsection (4)* sets out the hierarchy of people close to a deceased person who are eligible to give "appropriate consent" to the activities listed in clause 1(1) to (3) (other than for the purposes of anatomical examinations or public display). If there is more than one person in an eligible class who is competent to give consent, the consent of any one of them would suffice. *Subsection (9)* provides that the Secretary of State may amend the hierarchy by order.

Clause 28: Effect of codes

44. This clause provides that, while failure to observe a provision of a code of practice will not itself make a person liable to any proceedings, the HTA may take account of observance or failure to observe a provision of a code of practice dealing with a matter that is subject to a licence requirement when carrying out its licensing functions.

Clause 29: Approval of codes

45. This clause provides that draft codes of practice dealing with matters that are subject to a licence requirement must be approved by the Secretary of State and laid before Parliament by him. The code may not be issued by the HTA until it has been before Parliament for 40 days with no resolution not to approve it having been made by either House.

Anatomy

Clause 30: Possession of anatomical specimens away from licensed premises

46. This clause and the following one transpose provisions of the Anatomy Act 1984 relating to control of possession of anatomical specimens. This clause makes it an offence to keep anatomical specimens away from licensed premises. Exceptions are provided for possession authorised by a designated individual for authorised purposes, for persons in lawful possession of bodies immediately after death and for possession for the purpose of transport to licensed premises or premises where the specimen is to be used for the purpose of education, training or research. These exceptions are intended, for example, to allow an anatomy teacher to take a specimen away from a dissecting room to a lecture theatre for teaching purposes, and to allow undertakers to deliver bodies to the medical school. An exception is also provided where the person has possession for the purposes of functions of or under the authority of a coroner.

Clause 31: Possession of former anatomical specimens away from licensed premises

47. This clause makes it an offence for a person to have a former anatomical specimen in his possession away from licensed storage premises. As under the preceding clause, exceptions are provided for possession authorised by a designated individual for authorised purposes, for possession for the purposes of transport to licensed premises or premises where the former specimen is to be used for the purpose of education, training or research. There are also exceptions where the person has possession for the purposes of decent disposal or where he has possession for the purposes of functions of, or under, the authority of a coroner.

Trafficking

Clause 32: Prohibition of commercial dealings in human material for transplantation

48. This clause transposes the existing prohibition on buying or selling organs from the Human Organ Transplants Act 1989, and extends the prohibition to cover all human material (subject to certain exceptions) intended to be used for transplantation. Advertising for suppliers of material for reward is also prohibited. *Subsection (3)* allows the HTA to designate a person who may lawfully engage in trade in human material (for example, the National Blood Service will continue to be allowed to purchase blood from abroad). *Subsection (7)* provides that reimbursement for expenses connected with transporting, removing, preparing, preserving or storing the body of a deceased person or relevant human material is not prohibited. *Subsection (6)* allows for the possibility of commercial tissue banks by allowing licence-holders to receive more than just expenses in relation to these activities. *Subsection (7)* also provides that it is not an offence to provide expenses or recompense for loss of earnings given to an individual supplying human material, and allows for costs incurred by others to be passed along a chain of suppliers. *Subsection (9)* makes clear that the material covered by the prohibition excludes gametes and embryos (as defined in, and regulated by, the Human Fertilisation and Embryology Act 1990), and material which has become property by reason of the application of human skill. Cell lines are excluded from the clause by virtue of clause 59(7).

Transplants

Clause 33: Restriction on transplants involving a live donor

Clause 34: Information about transplant operations

49. These clauses are transposed from the Human Organ Transplants Act 1989. Clause 33 sets out the offence and penalties related to the removal and transplantation of organs and other material from living donors in circumstances other than those provided for in regulations made under this clause. These include circumstances where the HTA is satisfied that no reward has been given in relation to the transplant. Clause 34 replicates the existing requirement for information about organ transplants to be supplied to the specified authority (UK Transplant). Failure to supply information, or the supply of false information, is an offence under this clause.

Inspectorates

Clause 35: Inspectorate of Anatomy and Pathology

Clause 36: Remit of Inspectorate of Anatomy and Pathology

50. These clauses establish and set out the constitution and remit of the Inspectorate of Anatomy and Pathology. The Inspectorate will be responsible for carrying out such of the functions of the HTA as are within its remit.

Clause 37: Inspectorate of Organs and Tissue for Human Use

Clause 38: Remit of Inspectorate of Organs and Tissue for Human Use

51. These clauses establish and set out the constitution and remit of the Inspectorate of Organs and Tissue for Human Use. The Inspectorate will be responsible for carrying out such of the functions of the HTA as are within its remit.

Clause 39: Duties in relation to discharge of functions of Inspectorates

52. This clause provides that the inspectorates must have regard to the principles set out by the HTA, and that the HTA will in turn monitor the functioning of the inspectorates.

General

Clause 40: Agency arrangements and provision of services

53. This clause enables the HTA to make arrangements with other public bodies for the carrying out of any of the HTA's functions by the other body or its staff or for the other body to provide administrative, professional or technical services to the HTA.

Clause 41: Annual Report

54. This clause requires the HTA to prepare an annual report to be submitted to the Secretary of State, the National Assembly for Wales and the relevant Northern Ireland department, and for the Secretary of State and the relevant Northern Ireland Department to lay a copy before each House of Parliament and before the Northern Ireland Assembly respectively.

Clause 42: Directions

55. This clause makes provision with respect to the giving of directions by the HTA under Part 2, which must be in writing.

Clause 43: Duties in relation to carrying out functions

56. This clause sets out how the HTA must carry out its functions and the matters to which it must have regard in doing so.

Exceptions

Clause 44: Criminal Justice purposes

57. This clause deals with excluding activities done for criminal justice purposes from the relevant provisions of Part 2 of the Bill. The intention is for all coroners' *post mortem* examinations carried out in premises to be subject to regulation, so even where these are carried out also for criminal justice purposes, they will not be excluded from Part 2 of the Bill. *Subsection (2)* of the clause achieves this. *Subsection (1)* excludes from the regulatory regime of Part 2 of the Bill other activities done for criminal justice purposes. Examples of activities excluded from regulation by this clause might be *post mortem* examinations authorised by a coroner in a criminal case to take place at the site of discovery of a body (which would not need a licence) and disposal of material which has been removed from a body during a *post mortem* examination in a criminal case (which would not be within the HTA's remit and not subject to any code of practice on this subject).

Clause 45: Religious relics

58. This clause excludes the public display of religious relics and storage of such relics for the purpose of public display, from the remit of the HTA, from the requirement for a licence and from the remit of the Inspectorate of Anatomy & Pathology. It applies to relics displayed in places of public religious worship or associated places.

PART 3 - MISCELLANEOUS AND GENERAL

Miscellaneous

Clause 48: Preservation for transplantation

59. This clause makes it lawful to retain the body of a dead person and preserve organs in the body which may be suitable for transplantation, while consent to use the organs is sought, provided the preservation involves the minimum steps necessary and the least invasive procedures.

Clause 49: Surplus tissue

60. This clause allows any human material which comes from a body during medical treatment, diagnostic testing or research, or "relevant material" (as defined in clause 58)

which is no longer required for scheduled purposes, to be disposed of. *Subsection (4)* makes it clear that the reference to lawful disposals in the clause is not intended to affect the lawfulness or otherwise of other disposals of human material.

Clause 50: Non-consensual analysis of DNA

61. It is an offence under clause 50(1) to have any bodily material (that is, any material which has come from a human body and which consists of or contains human cells) intending to analyse the DNA in it without qualifying consent, subject to certain exceptions. This offence applies to the whole of the UK. The offence does not apply if the results of the analysis are to be used for excepted purposes and these are listed in Part 2 of Schedule 5. These include general purposes such as medical treatment and criminal justice purposes, as well as more specific matters which largely reflect what may be done without consent under Part 1 of the Bill, with modifications for Scotland where necessary. Paragraph 11 of Schedule 5 also has the effect that, if consent to use material has been obtained under clause 1(1) of the Bill, it is not necessary to obtain a separate consent where that use involves DNA analysis.

62. What constitutes qualifying consent is set out in Part 1 of Schedule 5. It may be given to analysis of DNA for any purpose. It can be given by the person from whose body the material came or someone with parental responsibility if the person is a child. Once the person has died, consent may be given by anyone who stood in a qualifying relationship (as listed in clause 59(9)) with the deceased immediately before he died. The hierarchy referred to in clause 27(4) does not apply to this list.

63. Certain material is outside the scope of the offence altogether and this includes material from a person who died more than 100 years ago and embryos outside the body (as these are subject to separate regulation by the Human Fertilisation & Embryology Act 1990). Also outside the scope of the offence are existing holdings of material where the identity of the person from whom it came is not known, and is not likely to become known. There is also an exemption if the person reasonably believes the material they have to be excepted.

General

Clause 51: Power to give effect to Community obligations

64. This clause contains a power to amend the Bill at a later date by regulations subject to the affirmative procedure in order to implement Community obligations in relation to human material. This clause has in view Directive 2004/23/EC of 31st March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, which is due to be implemented by 7th April 2006. The power in this clause will allow any necessary amendments to be made to the Bill by regulations.

Clause 52: Power to de-accession human remains

65. This clause confers a power upon the bodies listed in *subsection (1)* ("listed institutions") to de-accession human remains.

66. *Subsection (2)* enables listed institutions to transfer human remains from their collections if it appears to them appropriate to do so for any reason whether or not it relates to their other functions.

67. *Subsection (3)* provides that if it appears to a listed institution that human remains are mixed or bound up with non-human material and it is undesirable or impracticable to separate them, the power to de-accession the human remains extends also to the associated non-human material. This has the effect of enabling artefacts such as mummies (where non-human material is integral to the human remains) to be de-accessioned intact. The provision does not extend to grave chattels that are buried with but are separate from human remains found in a grave.

68. *Subsection (4)* provides that the power contained in subsection (2) does not affect any trust or condition subject to which a listed institution may hold human remains.

Clause 53: Powers of inspection, entry, search and seizure

69. This clause gives effect to Schedule 6, which provides a power for persons authorised by the HTA to inspect certain records, enter, search and inspect premises and seize things on the premises in connection with the HTA's regulatory functions.

Clause 55: Prosecutions

70. This clause specifies that proceedings regarding offences relating to appropriate consent, commercial dealing in tissue and payment for transplants will be instituted only with the consent of the Director of Public Prosecutions.

Clause 63: Transition

71. This clause provides for the fact that the maximum penalties in the Bill reflect the provisions of the Criminal Justice Act 2003. Until such time as the relevant provisions of the 2003 Act are in force, the maximum penalties are to be read as those which apply under the law currently in force.

EUROPEAN CONVENTION ON HUMAN RIGHTS

72. Convention issues arise in relation to several provisions in the Bill. The Department is satisfied that the regime established by Part 1 of the Bill for consent for use of human bodies

and material protects the rights of people under Article 8 of the Convention to respect for private and family life, which includes the right to bodily integrity, autonomy and self-determination.

73. Article 6(1) of the Convention requires that, in any determination of civil rights and obligations, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial. This will be relevant for some licensing decisions taken by the HTA. The Department considers that the provisions of Part 2 of the Bill which relate to the reconsideration of licensing decisions comply with the requirements of Article 6 of the Convention.

74. Licensing decisions under Part 2 might also engage rights under Article 10 of the Convention (freedom of expression) and Article 1 of the First Protocol to the Convention (protection of property) in individual cases. The Department is satisfied that any interference with an individual's rights under Article 10 of the Convention is justified if it is proportionate to the ends of the prevention of crime, for the protection of health or morals and the protection of the rights of others. The Department is also satisfied that the powers are compatible with Article 1 of the First Protocol to the Convention as any interference strikes a fair balance between the protection of an individual's right to property and the public interest as a whole.

75. The provisions of Schedule 6 give various powers to persons duly authorised by the HTA to require production of records and to inspect and take copies of records produced and to enter and inspect licensed premises. They may be authorised by warrant to enter and inspect premises in connection with a suspected offence. They also have powers to seize things found on premises that have been entered and inspected. The exercise of these powers may constitute an interference with rights under Article 8 of the Convention and Article 1 of the First Protocol to the Convention. The Department's view is that the safeguards in the Schedule are sufficient to guard against abuse and will ensure that any interference with an individual's rights under Article 8 of the Convention is proportionate to the ends of the prevention of crime, for the protection of health or morals and the protection of the rights and freedoms of others. The Department also takes the view that the powers are compatible with Article 1 of the First Protocol to the Convention as any interference strikes a fair balance between the protection of an individual's right to property and the public interest as a whole.

76. Section 19 of the Human Rights Act 1998 requires the Minister in charge of a Bill in either House of Parliament to make a statement about the compatibility of the provisions of the Bill with the Convention rights (as defined in section 1 of that Act). The statement has to be made before second reading. On 28th June 2004, the Lord Warner made the following statement:

> "In my view the provisions of the Human Tissue Bill are compatible with the Convention rights."

ESTIMATE OF PUBLIC SECTOR FINANCIAL COST AND PUBLIC SECTOR MANPOWER EFFECTS

Training and implementation regarding consent

77. The main impact of implementation of the legislation will be felt across the Health Service. Staff involved with bereavement, *post mortem* examinations, and other tissue retention activities will need to ensure that their work is in line with the requirements of the new legislation. In support of this, £2.7 m per annum has been included in the NHS baseline for the development of bereavement services in England from 2003/04. This enables English trusts to develop services that will be compliant with the new consent requirements of the Bill. *Post mortem* examination consent forms, and guidance on their use, have already been issued so that Trusts will already be moving towards procedures that enable them to work in accordance with the standards set out under the Bill.

78. This work is supported by central training initiatives. £300,000 per annum for three years, commencing in 2003/04, has been identified and provided for English central training initiatives to support the development of new procedures for consent around *post mortem* examinations and communication with families and next of kin at the time of bereavement.

79. As the provision of Health Services in Wales and Northern Ireland is a devolved issue, there will be similar resource implications for Wales and Northern Ireland to support this legislation.

80. The other area in which there may be an impact in terms of training following implementation, is in relation to Coroners and Coroners' Officers. In England and Wales, coroner law falls within the responsibility of the Home Office, while the costs of the service are met by relevant local authorities. In Northern Ireland, the service is the responsibility of the Northern Ireland Courts Service.

81. The Home Office is currently undertaking a major review of coroners' services. An initial report on this review was published in June 2003, and this will be taken forward in a co-ordinated fashion alongside the reports from the Shipman Inquiry. Legislation is anticipated as a consequence of the review of coroners' services, and this will clearly take account of those provisions of the Human Tissue Bill that may affect coroners. The Home Office will work with the Department of Health to facilitate relevant training, development and implementation requirements at that time. Meanwhile, the funding available through the Department of Health for training and development initiatives around *post mortem* examinations and bereavement services is available to coroners' officers in England as they have been invited to participate in those training initiatives. Again, there will be separate resource implications for Wales and Northern Ireland.

82. In the case of living patients, practice guidance for the NHS in England and Wales has been issued by the Department of Health in *"Good Practice in Consent"* (Nov 2001) and the *"Interim statement on the use of human tissue and organs"* (April 2003). These make it clear that consent should be obtained to using tissue for purposes unrelated to the patient's

treatment. Similar guidance on consent regarding living patients has been issued in Northern Ireland. NHS pathology services should therefore be meeting these standards or be in the process of complying.

The Human Tissue Authority (HTA)

83. The Retained Organs Commission was funded by the Department of Health at a cost of £1m per year. Her Majesty's Inspector of Anatomy and the Unrelated Live Transplants Regulatory Authority are also funded by the Department of Health. It is expected that this funding, totalling around £1.15m, will be available to the new body as it takes on the same or extended functions. The HTA will also generate income from licences and inspection fees. It will be a non-departmental public body and is expected to have a staff of up to 25.

Anatomy Schools

84. The HTA will charge fees for licences and inspections. Transferring regulation of anatomy schools (about 30 in number) which are largely in the academic sector, from Her Majesty's Inspector of Anatomy (HMIA) to the HTA, will transfer the cost of licensing and inspection from the Department of Health to the anatomy schools. The fees would likely be about £2,000 for the first year and £1,000 per year thereafter, with biennial inspections.

Pathology Laboratories, Tissue Banks, Medical Teaching Collections, Public Mortuaries and Museums

85. NHS pathology laboratories where *post mortem* examinations are undertaken, or human tissue is stored for research or education will need to be licensed and inspected by the HTA. It is estimated that there are about 300 of these. The likely cost of licences would be £2,000 initially, with a charge of £1,000 per year, with biennial inspections.

86. Tissue banks storing material for education and research purposes, tissue collections for medical education, and public mortuaries undertaking coroners' *post mortem* examinations, will need to be licensed and inspected on the same basis. Most existing tissue banks are funded by the NHS or a mix of NHS/academic institutions/MRC and the Wellcome Foundation. Public mortuaries are declining in number but about 20 remain which will need to be licensed. Public mortuaries are run by local authorities and charge fees to coroners, who in turn are paid by local authorities. Where public mortuaries do not also store human material, the scope of inspections and licence fees is likely to be reduced.

87. Public institutions/museums holding or displaying human remains which are from a person who died less than 100 years ago will also need to be licensed and inspected. Few museums hold such material in their permanent collections. The cost to those institutions will reflect the cost of licensing and inspection, and is likely to be proportionate to the volume of material they keep or display.

88. Tissue banks which process, store and distribute tissue for human use (transplantation), of which there are about 345 in the public sector, will be subject to a more

extensive licensing and inspection regime, including safety and quality issues. The Department of Health has underwritten the costs of setting up and running a voluntary scheme to regulate these for the UK since 1999. The MHRA currently charges fees directly for regulating pharmaceutical manufacturers and wholesalers by a regime of licensing and inspection for compliance with Good Manufacturing Practice and Good Distribution Practice. Charges, based on this regime, to individual tissue banks undertaking sterile processing, would currently be approximately £5,000 in the first year to cover the costs of initial application and inspection, with subsequent annual recurring costs, including biennial re-inspection, of approximately £1,500. The costs for banks undertaking storage and distribution only would be less; approximately £2,000 in the first year, with annual recurring costs of approximately £700. These costs will be transferred to the tissue banks which are likely to pass them to the NHS. (These costs anticipate what will become obligatory for regulation under an EU Directive on Tissues and Cells which must be implemented by April 2006.)

Inspection staff

89. The HTA will have the power to commission other bodies to carry out inspections on its behalf, such as new CHAI and the MHRA, since these will already be carrying out inspections in this field. In this way the burden of inspection on those to be inspected should be minimised, as well as the demands on the pool of appropriately qualified and trained staff to carry out the work.

SUMMARY OF REGULATORY IMPACT ASSESSMENT (RIA)

90. The Regulatory Impact Assessment indicates that the legislation on consent and the new regulatory regime for pathology services, tissue banks and public display of human remains will not have a significant impact on the business, charitable and voluntary sectors. The Small Business Service agrees that the Bill will have no significant impact on small business.

COMMENCEMENT DATE

91. The substantive provisions of the Bill will come into force on days appointed by the Secretary of State by order, not intended to be before November 2005. This will allow the HTA to be set up and codes of practice to be prepared.

HUMAN TISSUE BILL

EXPLANATORY NOTES

These notes refer to the Human Tissue Bill
as brought from the House of Commons on 29th June 2004
[HL Bill 94]

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