

**Government response to the recommendations made in the Chief Medical Officer's Expert Group report "Stem cell research: medical progress with responsibility" / presented to Parliament by the Secretary of State for Health by Command of Her Majesty, August 2000.**

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Great Britain. Department of Health.

**Publication/Creation**

London : Stationery Office, 2000.

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DEPARTMENT OF HEALTH

**GOVERNMENT RESPONSE  
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CHIEF MEDICAL OFFICER'S  
EXPERT GROUP REPORT  
“Stem Cell Research:  
Medical Progress with Responsibility”**

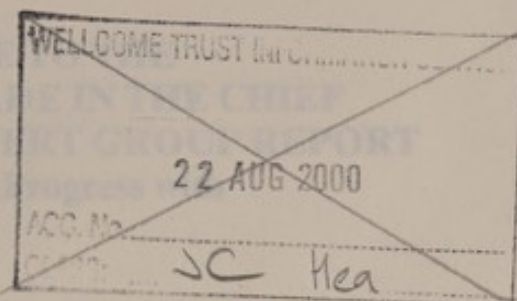
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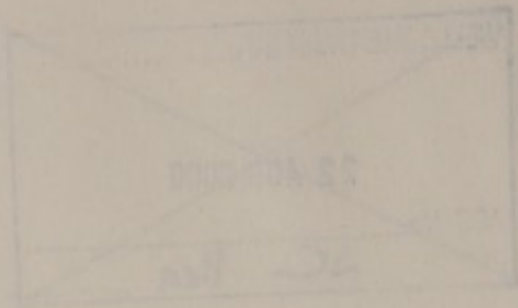
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DEPARTMENT OF HEALTH

# **GOVERNMENT RESPONSE TO THE RECOMMENDATIONS MADE IN THE CHIEF MEDICAL OFFICER'S EXPERT GROUP REPORT “Stem Cell Research: Medical Progress with Responsibility”**

*Presented to Parliament by the Secretary of State for Health  
By Command of Her Majesty  
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DEPARTMENT OF HEALTH

# GOVERNMENT RESPONSE TO THE RECOMMENDATIONS

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Presented to Parliament by the Secretary of State for Health  
By Command of Her Majesty  
August 2000

Cm 4833



# **GOVERNMENT RESPONSE TO THE RECOMMENDATIONS MADE IN THE CHIEF MEDICAL OFFICER'S EXPERT GROUP REPORT "Stem Cell Research: Medical Progress with Responsibility"**

## **Foreword**

In June 1999 the Government asked the Chief Medical Officer (CMO) to establish an Expert Advisory Group to advise on whether new areas of research using human embryos should be permitted that could lead to broader understanding of, and eventually new treatments for, diseased or damaged tissues or organs and mitochondrial diseases. This was in response to the joint Human Fertilisation and Embryology Authority/Human Genetics Advisory Commission Report '*Cloning issues in Reproduction Science and Medicine*' published in December 1998.

The Expert Advisory Group was asked to assess developments in stem cell research and research involving cell nuclear replacement and the likely timescales of the research; to establish more clearly the evidence of potential benefits for human health of such research; to consider possible alternatives to research involving embryos which might achieve the same ends and the potential technical and safety issues which might arise.

In particular, the Human Fertilisation and Embryology Authority/Human Genetics Advisory Commission Report had recommended that regulations under the Human Fertilisation and Embryology Act 1990 should be made to extend the purposes for which human embryos could be used in research. The CMO's Expert Group was asked to consider this recommendation in the light of its findings on scientific developments in such research and any new ethical issues such developments raised.

We welcome the Report from the CMO's Expert Group as an important contribution to this difficult debate. We are grateful to the Chief Medical Officer and the members of the Expert Group for undertaking such a careful and thorough review of this difficult and sensitive subject. The Report provides a clear and detailed assessment of the potential benefits of research across the whole range of possible sources of stem cells, including those derived from human embryos. It also discusses the justification for using embryos created by cell nuclear replacement (the 'therapeutic cloning' technique) for such research and the ethical issues that arise.

The Government accepts the Report's recommendations in full and will bring forward legislation where necessary to implement them as soon as the Parliamentary timetable allows. Regulations necessary to extend the purposes for which embryos may be used in research are 'affirmative', and are subject to a debate and a vote in both Houses. The Government intends to make this a free vote. The Government welcomes the opportunity for a full discussion of the important issues raised by the CMO's Expert Group Report.

The Government continues to regard the deliberate cloning of human beings as ethically unacceptable and, although there are already adequate safeguards in place, it will bring forward legislation when Parliamentary time allows to set out unequivocally the ban on reproductive cloning by the cell nuclear replacement technique.



## **GOVERNMENT RESPONSE TO THE RECOMMENDATIONS MADE IN THE CHIEF MEDICAL OFFICER'S EXPERT GROUP REPORT "Stem Cell Research: Medical Progress with Responsibility"**

### **Stem cell research and cell nuclear replacement: extensions to the purposes for which embryos may be used in research.**

**Recommendation 1. Research using human embryos (whether created by *in vitro* fertilisation or cell nuclear replacement) to increase understanding about human disease and disorders and their cell based treatments should be permitted, subject to the controls in the Human Fertilisation and Embryology Act 1990.**

1. The Government recognises that research involving embryos is a sensitive subject on which there are divergent views. For some people any research involving embryos is unacceptable, while for others the potential benefits of the research may be weighed against the respect due to an embryo at the very earliest stages of its development.
2. Following consideration of these issues by the Warnock Committee in the early 1980s and extensive debate in both Houses, the Human Fertilisation and Embryology Act 1990 (the 1990 Act) allows for research involving embryos for specified purposes under very strict conditions. It also provides for an extension of those purposes under the same conditions. Given these conditions, and on the basis of the scientific and medical benefits which could arise from research to extract stem cells from embryos at a very early stage in their development, the Government accepts that such an extension should be made to allow for research to increase understanding about human disease and disorders and their cell-based treatments.
3. The Report explains that research using embryos created by cell nuclear replacement has unique potential benefits in terms of understanding how to produce compatible tissue for treatment and how adult cells might in future be reprogrammed. The Government recognises that the creation of embryos by cell nuclear replacement will be unacceptable to some people. However, we have assessed carefully the scientific and ethical case presented in the Report and conclude that such research should be allowed, but only under the very stringent safeguards set by the 1990 Act.

**Recommendation 2. In licensing any research using embryos created by cell nuclear replacement, the Human Fertilisation and Embryology Authority should satisfy itself that there are no other means of meeting the objectives of the research.**

**Recommendation 3. Individuals whose eggs or sperm are used to create the embryos to be used in research should give specific consent indicating whether the resulting embryos could be used in a research project to derive stem cells.**



4. The Government believes that the system of controls on embryo research operated by the Human Fertilisation and Embryology Authority provides stringent safeguards and a sound basis for regulating these extended research purposes. The Government welcomes and endorses these additional Recommendations. Recommendation 2 reinforces the requirement under the Human Fertilisation and Embryology Act 1990 for the Authority to satisfy itself, for any individual research project, that the use of embryos is necessary for meeting the objectives of that research. Requiring explicit consent from individuals whose eggs or sperm are used to create embryos which are subsequently used in research to derive stem cells provides an additional level of control and reassurance which the Government welcomes. The Government asks the Human Fertilisation and Embryology Authority to incorporate such a provision as a condition in relevant research licences.
5. In accepting Recommendations 1 to 3 the Government recognises the considerable potential of this research to provide the basis for treatments for a wide range of sometimes very serious conditions which strike all parts of the population, including the very young and the elderly. The Government respects the views of those people who believe that human embryos should not be used in any research. However, the Government considers that the potential benefits of such research, and the treatments it may lead to, justify the addition of the new research purposes identified, given that such research is subject to very strict safeguards in the 1990 Act.

**Recommendation 4. Research to increase understanding of and develop treatments for mitochondrial diseases using the cell nuclear replacement technique in human eggs, which are to be fertilised subsequently by human sperm, should be permitted, subject to the controls in the Human Fertilisation and Embryology Act 1990.**

6. The Government accepts this Recommendation and notes that it would be achieved by the Regulations necessary to give effect to the first Recommendation. The use of the cell nuclear replacement technique to create a healthy egg for a woman with a mitochondrial disorder is not reproductive cloning as the newly created egg will still need to be fertilised *in vitro* with the partner's sperm. Any resulting child would receive its genetic material from its mother and its father and mitochondrial DNA from the donor egg. Any proposed research will be subject to the same strict safeguards under the 1990 Act.



## **Stem cell research and cell nuclear replacement: other recommendations concerning research on human embryos and human embryonic stem cells.**

**Recommendation 5.** The progress of research involving stem cells which have been derived from embryonic sources should be monitored by an appropriate body to establish whether the research is delivering the anticipated benefits and to identify any concerns which may arise.

7. The Government accepts that the progress of research involving stem cells derived from embryonic sources should be monitored to establish whether the research is delivering the anticipated benefits and to identify any concerns which may arise. The Government will ask the Human Fertilisation and Embryology Authority to work with the Human Genetics Commission to fulfil this remit and to advise Health and Science Ministers of their findings from time to time.

**Recommendation 6.** The mixing of human adult (somatic) cells with the live eggs of any animal species should not be permitted.

8. The Government agrees with the Report's conclusion that the mixing of human adult (somatic) cells with the live eggs of any animal species should not be permitted. Primary legislation to give effect to this Recommendation will be brought forward when the Parliamentary timetable allows. In the meantime the Government calls on bodies funding research to make it clear that they will not fund or support research involving the creation of such hybrids.

**Recommendation 7.** The transfer of an embryo created by cell nuclear replacement into the uterus of a woman (so called 'reproductive cloning') should remain a criminal offence.

9. The Government has made its position on reproductive cloning absolutely clear on a number of occasions. On 26 June 1997, the then Minister for Public Health stated in response to a Question in Parliament:

*"We regard the deliberate cloning of human beings as ethically unacceptable. Under United Kingdom law, cloning of individual humans cannot take place whatever the origin of the material and whatever the technique is used".*

This remains the Government's position. The Report from the Human Fertilisation and Embryology Authority and the Human Genetics Advisory Commission considered that the safeguards currently in place in the United Kingdom are wholly adequate to forbid human reproductive cloning. The transfer of an embryo created by cell nuclear replacement into the uterus of a woman will continue to be a criminal offence. However, to put the matter beyond any doubt and to ensure that research using the cell nuclear replacement technique to create embryos does not inadvertently lead to reproductive cloning, the Government will bring forward primary legislation to give added clarity to the ban on human reproductive cloning, when the Parliamentary timetable permits.



**Recommendation 8. The need for legislation to permit the use of embryo-derived cells in treatments developed from this new research should be kept under review.**

10. The Government accepts the need to keep under review the possibility of legislation to permit the use of embryo-derived cells in treatments for diseased or damaged tissues should the research prove successful. The Human Fertilisation and Embryology Authority and Human Genetics Commission will be asked to advise on whether new legislation is needed in the light of their monitoring of progress in the research.

**Recommendation 9. The Research Councils should be encouraged to establish a programme for stem cell research and to consider the feasibility of establishing collections of stem cells for research use.**

11. The Government accepts this Recommendation and calls on the Research Councils to establish a programme for stem cell research focussing on the derivation of stem cell lines from all sources (including embryos), the production of stem cell lines by cell nuclear replacement, reprogramming the somatic cell nucleus to derive stem cell lines and the differentiation of stem cell lines for therapeutic purposes.
12. The Department of Health will seek to encourage Research Councils to give priority to this research through its Concordats with them.
13. The Government supports the Recommendation that Research Councils should consider the feasibility of establishing collections of stem cells for research use to avoid the need for researchers continually to create new cell lines or to import cell lines, and calls on the Research Councils to do so.





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