

**Department of Health: Review of the Human Fertilisation and Embryology Act: a public consultation****Response by the Wellcome Trust****November 2005****Introduction**

1. The Wellcome Trust (the Trust) is pleased to submit its comments to the Department of Health on its 'Review of the Human Fertilisation and Embryology Act: a public consultation'. In developing this response, we have drawn on our own views as an independent research-funding organisation, as well as consulting with a number of researchers funded by the Trust who work in this field. The Trust's views are limited to the research context.
2. Previous relevant submissions in this area include two sets of written comments to the Science and Technology Select Committee for their inquiry on 'Human reproductive Technologies and the law' and, following publication of the Committee's report, comments to the Department of Health on the Committee's recommendations.
3. The Trust recognises that complex ethical issues arise from developments in human reproductive technologies. It funds research in this area through its Biomedical Ethics funding programme<sup>1</sup>. Trust funded research projects include research relevant to both the biomedical research and the treatment provisions in the legislation. Three of our biomedical ethics grantholders (Dr Stephen Wilkinson from Keele university, Dr Benjamin Capps from Bristol university and Anna Smajdor, from Imperial College) are also submitting comments on this review as part of submissions from their respective universities.
4. The Trust is an independent UK based biomedical research charity, established under the will of Sir Henry Wellcome. The mission of the Trust is to foster and promote research with the aim of improving human and animal health. It has awarded a number of grants for stem cell research, which will include embryonic stem cell studies. These are:
  - From October 2003 to October 2005 the Trust has awarded grants totalling approximately £11.7 million for stem cell research. These range from large programme grants to fellowships, PhD studentships and technology transfer grants.
  - In 2004, the Trust also committed £3 million over five years towards a £6 million partnership with the Juvenile Diabetes Research Foundation (JDRF) in an effort to promote the UK's contribution to stem-cell research.
  - In addition, a substantial amount of stem cell research is undertaken at two Wellcome Trust Centres: the Wellcome Trust/Cancer Research UK Gurdon Institute of Cancer and Developmental Biology at Cambridge, and the Wellcome Trust Centre for Cell Matrix Research at Manchester.

<sup>1</sup> For examples of relevant grants, see: [www.wellcome.ac.uk/doc\\_wtx023206.html](http://www.wellcome.ac.uk/doc_wtx023206.html)

## General comments

5. Legislation governing human reproductive technologies must be proportionate, and not create any unnecessary bureaucratic or financial burdens for researchers. The Trust endorses the aim of having an oversight procedure that would reduce unnecessary bureaucracy: it is essential that procedures are streamlined, efficient and that they take place within reasonable time limits, which is especially important given the statutory limitations on the storage of embryos (also, see our comments below on question 23). The Trust also believes that it is vital for fees to be set at a reasonable level in order not to hinder research or render it prohibitively expensive (see our comments below on question 67).

Legislation should also have the support of the public and be flexible enough to accommodate future scientific and technological developments.

## QUESTIONS AND PROPOSALS FOR CONSULTATION

### 6. QUESTIONS 1 AND 2

*'The Government believes that both the development and use of human reproductive technologies, and their regulation in response to public concerns, should continue to be subject to legislation. (Paragraph 2.7).'*

*'On balance, the Government believes that the current model of regulation, whereby Parliament sets the prohibitions and parameters within which an independent statutory authority licenses activities, has worked well and should continue. (Paragraph 2.14).'*

The Wellcome Trust endorses both these proposals.

### 7. QUESTIONS 4 AND 5:

*'The Government believes that legislation should make clear that all human embryos outside the body are within the scope of regulation and subject to the control of the statutory licensing authority regardless of the manner of their creation. (Paragraph 2.20).'*

*'The Government considers that the best approach is to define the forms of embryo which may be placed in a woman and in what circumstances, and to regulate other forms of embryo insofar as these are created and used for research. (Paragraph 2.22).'*

The Trust agrees that all human embryos outside the body, however they were created, should fall within the scope of the legislation. We endorse the proposal at Question 5, which aims to ensure that the legislation is flexible enough to accommodate future scientific and technological developments.

### 8. QUESTIONS 18

*'The Government believes that on balance, the HFE Act's existing requirements for written consent remain proportionate and appropriate, and provide a valuable protection of the wishes of patients and donors. Do you agree? (Paragraph 4.10).'*

The Trust endorses this position.

## 9. QUESTION 23

*'Do you think that the law should continue to set statutory maximum storage periods for gametes and embryos and if so how should these be determined? (Paragraph 4.25).'*

*'If you think that the law should continue to set statutory maximum storage limits, should the storage limits for donation be brought into line with the storage periods for treatment? (Paragraph 4.26).'*

The Trust suggests that the 5 year statutory time limit for storing embryos could be extended for the purposes of research, whilst recognizing the importance of setting clear time limits for fertility treatment. The availability of embryos for research is limited and they could still provide a useful source of stem cells beyond this period. The Trust maintains that the use of such embryos for research, instead of allowing them to perish, would be a valuable public benefit. It is not yet clear how long these embryos could remain in storage and still be valuable for research purposes and we would therefore suggest that provisions should allow for them to be stored indefinitely, until it becomes clearer to the scientific community that such embryos lose their research value after a certain period of time. Regarding consent for the purposes of storage, the Trust would expect the law to reflect the position that the consent endures until it has been withdrawn.

## 10. QUESTIONS 47 AND 48

*'If the HFEA's data register is to continue to collect information on all licensed treatments, should the dataset be expanded to facilitate more effective follow-up research? (Paragraph 6.40).'*

*'Alternatively, if the HFEA's data register is to be restricted to information on licensed treatments involving donated gametes or embryos, should licensed clinics be required to maintain local databases of additional information for research? (Paragraph 6.41).'*

The Trust supports measures that would maximize the availability of data that could provide a valuable contribution to research in this area. We therefore endorse the proposal since it would enable data collection to be expanded, with the proviso that relevant safeguards are in place to protect patients and donors (see question 49 below). We suggest that the first option, which centralizes the data at a single source, would be the most efficient approach, though the local collection of data would also be valuable.

## 11. QUESTION 49

*'The Government proposes that the confidentiality provisions of the HFE Act should be revised so that information about assisted reproduction treatment is treated in the same way as other medical information and subject to the same safeguards. Do you agree? (Paragraph 6.44).'*

The Trust endorses this proposal. We believe that existing legal safeguards and professional codes of conduct in relation to other types of medical information are sufficient to protect the privacy interests of patients and there is no real justification for treating this type of information any differently. The Trust believes that easier access to the HFEA database could facilitate important and valuable research on, for example, the prevalence of adverse health outcomes for children born as a result of certain reproductive techniques.

## 12. QUESTION 57

*'In common with the Science and Technology Committee, the Government believes that there is no case at present for either an extension or a reduction to the 14 day time limit for keeping an embryo. Any change would remain a matter for Parliament. (Paragraph 9.15).'*

The Trust agrees with the Government and the Select Committee about the appropriateness of the 14 day rule for human embryo research, unless convincing justification is provided for a change.

## 13. QUESTIONS 58, 59 AND 60

*'The Government believes that research undertaken on embryos using the cell nuclear replacement technique for the purpose of studying mitochondrial diseases should be permissible in law, subject to licensing. (Paragraph 9.22).'*

*'Further, the Government invites views on removing the current prohibition on "replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of any person, another embryo or a subsequent development of an embryo" for research purposes, subject to licensing. (Paragraph 9.23).'*

*'The Government invites views on whether the law should permit altering the genetic structure of an embryo for research purposes, subject to licensing. (Paragraph 9.28).'*

The Trust would support allowing these practices for research purposes. . A relaxation on these prohibitions could provide a valuable contribution to biomedical research and, in our view, does not compromise the moral status the embryo was deemed by Parliament to have.

## 14. QUESTION 61

*'The Government invites views on whether the law should permit the creation of human-animal hybrid or chimera embryos for research purposes only (subject to the limit of 14 days culture in vitro, after which the embryos would have to be destroyed). (Paragraph 9.35).'*

The Trust believes that the law should permit the creation of human-animal hybrid or chimera embryos for research purposes, subject to ethical approval by a body with the relevant experience and expertise. We recognise that this is a complex area that could raise a number of concerns and believe that firm controls are necessary, although care should be taken to ensure they do not inappropriately stifle potentially valuable avenues of research that could ultimately deliver public health benefits.

However, we question the appropriateness of imposing the same time limit for the destruction of the embryo as applies to fully human embryos (14 days). This is because the nature of such creations can range over a broad continuum (depending on the level and type of human chromosomal material present) and therefore the 14 day limit might not necessarily coincide with the emergence of the primitive streak, as it does in the case of fully human embryos. We recognize that the stage at which the 'primitive streak' might emerge may be unclear and may vary between different types of embryo. We therefore recommend that a regulation-making power is introduced into the new legislation to allow the Secretary of State, in consultation with the scientific community, to vary the time limits for chimera/ hybrid embryos.

## 15. QUESTIONS 62 AND 63

*'The Government invites views on whether the current list of legitimate purposes for licensed research involving embryos remains appropriate. (Paragraph 9.38).'*

*'The Government believes that the purposes for which research using embryos may legitimately be undertaken should, as now, be defined in law and research projects should continue to be approved by a national body in order to ensure compliance with the law, national consistency and appropriate ethical oversight. (Paragraph 9.41).*

The Trust believes that any special status the embryo may have is not compromised by its use for important research purposes. We agree that embryos should not be used for trivial research purposes and therefore we support regulatory controls to ensure this. However, it is important to note that most current research is at a fundamental level informing our understanding of how embryonic stem cells can be identified and manipulated to produce cell lines. This work is essential to unlock the potential embryonic stem cells offer in treating conditions that seriously affect health, for example treating spinal injuries or diabetes.

It is essential that the legislative and regulatory framework enables both fundamental research of this nature as well as research on all serious health related conditions, including injuries and diseases and disorders. We welcome the Government's reassurance in paragraph 9.37 of the consultation document that "it is confident that basic research is permissible under the current list of legitimate research purposes" but ask for further clarification as to whether the regulations extend to research related to serious injuries (e.g. spinal cord injuries) or other serious conditions. We wonder whether, for the sake of clarification, the addition of ', condition or injury' after 'serious disease' in paragraphs 2(b) and (c) of the research purposes regulations (SI No 188/ 2000) is necessary to clarify this.

#### **16. QUESTION 64**

*'The Government invites views on what, if any, additional regulatory requirements should apply to the procurement and use of gametes for purposes of research. (Paragraph 9.45).'*

The Trust does not believe that further regulation of this activity is necessary or appropriate beyond the requirements contained in the 1990 Human Fertilisation and Embryology Act (in the context of the provision of fertility treatment) and in the Human Tissue Act 2004 (in relation to DNA testing).

#### **17. QUESTION 67**

*'The Government proposes that:*

- *RATE will be an executive non-departmental public body. Its primary function will be to consider applications for licences to undertake those activities which Parliament decides should be subject to licensing. It will be funded principally from fees levied on licence-holders ... (Paragraph 10.5).'*

The Trust is concerned about the proposal that RATE will be funded principally from fees levied on license holders. It is vital that fees are set at a reasonable level in order for important research not to be hindered or rendered prohibitively expensive.

#### **18. QUESTION 69**

*'The Government proposes that:*

...

- *RATE will publish summaries of embryo research licence applications received. (Paragraph 10.7).'*

The Trust endorses this proposal.

We hope these comments are helpful, and would welcome the opportunity to comment at any future stages of the consultation process.