

Joint Committee on the Draft Human Tissue and Embryos Bill

Response from the Medical Research Council and Wellcome Trust

Introduction

The Medical Research Council (MRC) and the Wellcome Trust welcome the opportunity to respond to the Joint Committee's call for evidence on the Draft Human Tissue and Embryos Bill.

The Medical Research Council is dedicated to improving human health through excellent science. It invests on behalf of the UK taxpayer. Its work ranges from molecular level science to public health research, carried out in universities, hospitals and a network of its own units and institutes. The MRC liaises with the Health Departments, the National Health Service and industry to take account of the public's needs. The results have led to some of the most significant discoveries in medical science and benefited the health and wealth of millions of people in the UK and around the world.

The Wellcome Trust is the largest independent charity in the UK and the second largest medical research charity in the world. It funds innovative biomedical research, in the UK and internationally, spending around £500 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.

General Comments

We support the introduction of the draft Human Tissue and Embryos Bill. It provides an opportunity to modernise and update the law in an area that has moved on significantly in terms of scientific advances, international developments and public attitudes since the introduction of the Human Fertilisation and Embryology Act in 1990. Given the respective remits of the Wellcome Trust and the MRC, we will be confining our comments primarily to the research provisions of the draft Bill, the sections dealing with inter-species embryos and the proposal to establish the Regulatory Authority for Tissue and Embryos (RATE).

Whilst we welcome much of the draft Bill, there are aspects of it that we are concerned may be detrimental to research activities in this country. These include the proposals for the establishment of RATE and some aspects of the current proposals on inter-species embryos. We believe it is critical for the future of research, particularly stem cell research for which the UK is currently recognised as a world leader, that any changes to the regulatory framework have a reasonable shelf-life, and are carefully balanced so that they maintain public confidence and support good practice, whilst retaining a positive and enabling environment for research.

Part 1 of the draft Bill

RATE and the new regulatory architecture

Question 4a: What are your views on the transfers of the functions of the HFEA and HTA to a single new regulatory authority, RATE?

Question 4b: What are your views on the provisions in Schedule 1 about RATE's constitution and administration?

The MRC and the Trust are opposed to the transfer of the functions of the HFEA and the HTA to a single new authority, RATE, as we explained in a letter last year to Lord Warner.

We recognise the need to modernise and improve the legal and governance arrangements pertaining to the HFEA, and would support the application of the great majority of the provisions in the draft Bill designed for RATE to the HFEA. Changes of this nature, together with moves to make financial savings through the sharing of the back-office functions of the HFEA and HTA, should achieve important efficiencies.

However, we are unconvinced that further efficiencies could be achieved through the creation of a single authority, without creating other, greater disadvantages. Most importantly, we are concerned that the scope of RATE's remit will be too broad for it to manage its activities effectively and responsibly and that the costs and other risks associated with the transfer will outweigh any operational cost savings. Our reasoning is outlined below.

1. Scope of remit

- a) Under the proposals being considered, RATE will regulate a wide range of sectors, including anatomy, pathology, transplantation, blood transfusion, post mortem research, museums and galleries, fertility treatment, and embryo research. Most of the issues the HFEA and the HTA face in relation to these sectors are highly technical, and, we would suggest, raise a uniquely difficult and diverse combination of ethical, scientific and public policy issues. Clearly, it is impossible to create an authority in which the members have expertise in each and every issue likely to be brought before them. It is of course a question of degree, and a matter heavily dependent on the skills and experience of the particular individuals who ultimately serve on the body. However, in our view, the creation of a single authority, of which the majority of the members are lay, to cover the remits of both the HFEA and the HTA goes too far along the spectrum, and will place too much reliance on the small number of professionals on the authority, and too much power in the hands of the Expert Advisory Panels.
- b) We are also mindful that the remit of the HTA is already broad, and that its resources are thinly spread. To manage this, it rations its resources according to the relative risks of the various activities and sectors it regulates. One of the consequences of this quite legitimate approach is that two of the lower risk sectors, research and museums, have been given lower priority in the processing of licence applications. Most of the organisations seeking licences for research or display since September 2006 still operate on the basis of deemed licences

rather than full HTA licences. We are concerned that the wider remit will become impossible for a single authority to manage.

- c) Finally, we note that the two existing Authorities regulate their respective sectors in quite different ways. For example, the HFEA licenses research on an individual project basis, whereas the HTA licenses the storage of tissue for research on the basis of premises. This reflects a quite different culture and significant diversity in operations, in part deriving from a difference in the underlying legal framework (which will not be addressed in the draft Bill). These differences are likely to make the transition process particularly challenging, and may well mean that the scope for achieving real efficiencies or cost savings is limited.

2. Cost implications

- a) Documents supporting this draft Bill suggest it will cost £2-6million to create a new Authority, against estimated (gross) cost savings in day to day operations (the main rationale for the merger) of £700k a year. It could therefore take more than eight years for the savings to offset the costs of the transfer. Given the concerns above, and the inevitable upheaval associated with a transfer, we do not feel that any long-term cost-savings are sufficient to justify the proposed transfer.
- b) It is proposed that RATE's regulatory activities will be self funding, through revenue from licensing. We have been assured, and would like it confirmed, that the costs of the transfer will not be met through licensing income. We would also want to be assured that there will be no cross-subsidisation between the activities regulated under the HFEAct and the activities regulated under the HTAct, or between the specific activities within that (e.g. between licensing of fertility treatment and licensing of embryo research).

We view this draft Bill as an opportunity to improve and modernise the governance and functioning of the existing regulatory bodies (for example, to ensure that the HFEA can delegate certain functions to staff, or sub-committees, and is required to operate according to good regulatory practices). It also provides an opportunity to look again at the range of activities that are currently being licensed by the two Authorities, to reassess priorities in light of the HTA's first year's experience (noting the resource difficulties mentioned above), and the HFEA's much more extensive experience, and ensure that we have bodies that are fit for purpose going into the future.

Question 5: Would the proposed funding of the regulatory body or bodies allow it (or them) to carry out its functions fully and effectively?

We cannot comment on the quantum of any funding, as a draft budget is not available to us. However, we have made comments on the basic structure of the funding arrangements in our answers to question 4 above and question 6 below.

Question 6: Should the regulatory body or bodies be allowed to make charge for licences?

In addition to the issues we raise in response to question 4, whilst we are not opposed to the principle of charging licence fees, we are concerned to ensure that any charging is

not excessive, or disproportionate, bearing in mind the nature of the activity and the bodies likely to be carrying it out and the licensing activity involved is not prohibitive.

We consider that a full cost-recovery model is neither viable (assuming the principles above) nor appropriate, as we believe that costs unrelated to licensing (such as policy development and horizon-scanning) should be borne centrally by Government rather than by licence-holders. We understand that this is accepted, and that a partial cost recovery model has been proposed accordingly.

We are concerned that the burden of the licence fees under the Human Tissue Act is seen as prohibitive by smaller research tissue collections, as well as by the museum/ arts sector (in relation to public display and research), and therefore does not fully meet the criteria above.

Part 2 of the Draft Bill

Definitions

Question 7a: Do you agree with the new definitions in the draft Bill of 'embryo', 'egg', 'sperm', 'gamete', 'nucleus'? If not, how would you propose to amend them?

Whilst we are broadly supportive of the definitions contained in the draft Bill, we have concerns and seek clarification about the following:

- a) The definition of 'embryo' – we would like clarification that this definition does not include embryoid bodies or tissue that is converted into cells that behave like embryonic stem cells.
- b) The meaning of 'live' in the definition of embryos or gametes – we would like clarification about the meaning of this term, including for example, whether gametes removed from a dead fetus used to create stem cell lines would be considered 'live' or not?
- c) The meaning of sub-section (e) in the definition of 'inter-species embryo' ("any other embryo that contains both – (i) any haploid set of human chromosomes and (ii) any haploid set of animal chromosomes or any other sequences of nuclear or mitochondrial DNA of an animal") – whilst we welcome sub-sections (a) to (d) under the definition of 'inter-species embryo' and believe it is important to define this term on the face of the Bill, we believe (e) is unclear and potentially too broad in scope. However, we accept that a fifth category is helpful, to cover future techniques that are as yet unknown. We would therefore advocate alternative wording to (e), and suggest one of two possible approaches:
 - i) amending the current wording to read as follows: "any other embryo whose modal karyotype contains both – (i) any haploid set of human chromosomes and (ii) any haploid set of animal chromosomes or any other sequences of nuclear or mitochondrial DNA of an animal" or;
 - ii) replacing (e) with a regulation-making power allowing the Secretary of State to add further techniques to those listed in (a)-(d) that would result in essentially the same cell or tissue type.

Question 7b: Should the Secretary of State have the regulation-making power to expand these definitions as proposed in the draft Bill?

We believe the Secretary of State should have the regulation-making power to expand these definitions subject to the requirement that any decisions are based on actively seeking the best available scientific and ethical advice. This flexibility is essential given the speed of scientific advances and the development of knowledge in the field to ensure that the legislation remains up to date and continues to reflect the legislators' general intentions. Further to our comments in response to question 7a, we also believe this power should apply to the definition of 'inter-species embryo'.

Inter-species embryos (ISEs)

Question 8: Do you support:

- (i) the approach signalled by the Government in the White Paper,*
- (ii) the new approach announced by the Government; or*
- (iii) the approach recommended by the Commons Science and Technology Committee?*

We endorse:

- a) Defining ISEs on the face of the draft Bill, using the definitions contained sub-sections (a)-(d) of the definition of ISE in the draft Bill, with modifications to sub-section (e) as described in our response to question 7a above;
- b) Clearly stipulating what may be implanted in a woman and prohibiting the implantation of anything else;
- c) Requiring that all ISE research must be licensed and making provision for such licences to be granted on the same basis under the HFE Act and the 2001 Research Purposes Regulations as human embryo research generally;
- d) Stipulating an absolute limit on ISE culture of the appearance of the primitive streak (taken to be 14 days development).

Our approach is broadly in line with that recommended by the House of Commons Science and Technology Committee. It would place ISE research on the same legal basis as all other human embryo research currently permitted under licence.

Our approach differs slightly to that proposed by the Government in the draft Bill in that:

1. We would not propose to ban 'true hybrid' research. Although, we are not aware of any research currently being planned that involves the use of true hybrids, we do not understand the logic behind the distinction between true hybrids and other inter-species embryos, especially given that the creation of a true hybrid is already specifically allowed for the hamster sperm penetration test.
2. We do not support the restriction on the development of ISEs beyond half the gestational or incubation period of all species involved. We do not see why this restriction is necessary or appropriate, in addition to the restrictions applicable to human embryos on development beyond the appearance of the primitive streak and development past 14 days. It is likely to restrict some types of research involving

ISEs that contain small amounts of material from species with a gestation period of less than 28 days (e.g. mice) and limit the usefulness of the embryos (because some research depends on taking the embryos close to 14 days of development).

We do not support the approach signalled by the Government in the White Paper for the reasoning outlined in our written response to the House of Commons Science and Technology Committee's review of the Government's proposals in February. (Please refer to Annex 1)

Research Licences

Question 8: How should Parliament approach legislating for those purposes for which licences for research may be granted in the future (arising out of future research) but that are not yet determined? Should judgments be left to the regulatory body or bodies to determine?

The legislative framework in the HFE Act as amended by the draft Bill already proscribes certain research purposes (excluding, for example, trivial research). This provides fairly detailed guidance to, and is a significant limitation on, the regulator in the exercise of its discretion as to the types of research activities that may be permitted in the future. In that light, we believe that it is appropriate for such decisions to be made by the regulatory body or bodies, provided that (as is proposed), Parliament sets out clearly what **material** is within the scope of the legislation and the remit of the regulator, the **fundamental safeguards** and any **prohibitions**, and the **main principles** that need to be respected. The framework needs to be clear enough so that the regulator can assess Parliament's intentions (and such that their decisions are able to stand up to judicial review). This approach allows the regulators, who will have access to specific scientific and ethical advice, the necessary flexibility to make timely decisions about individual research proposals.

Question 9: How should Parliament or the regulatory body or bodies take public views and public engagement into account?

It is important that both Parliament and regulators have access to up-to-date public attitudes and opinions; and that methods of feeding this information into decision-making processes continue to be developed. The MRC and Wellcome both have active programmes in place to monitor public opinion and engage in dialogue. For example, the MRC along with the Biotechnology and Biological Sciences Research Council have recently been given funding from the DTI's Sciencewise scheme to develop a programme of public dialogue on the science and issues of stem cell research. The Wellcome Trust, through its Society Awards scheme is funding 'Human embryos, human stem cells: a collaborative science-arts feature documentary'¹, a project which aims to bring contemporary stem cell research and its personal, political and socio-economic implications to life in a feature documentary. It offers diverse audiences – scientists and film-makers, patients and the public, educators, regulators and school students – new opportunities to engage with the issues and with each other throughout this project's two year duration. In addition to feeding into, and taking account of, programmes such as

¹ This project is being carried out by Clare Blackburn at the Institute for Stem Cell Research, University of Edinburgh.

these, Parliament and regulators should ensure that activities aimed at incorporating public attitudes are based on genuine dialogue processes.

Storage limits

Question 14: Do you support the proposal to extend the storage period from 5 to 10 years? Should the storage period for gametes and embryos be limited by statute at all?

Whilst we welcome an extension in the storage period of gametes and embryos for research purposes, we understand that the decision to limit the storage for research purposes to 10 years only is purely a pragmatic decision and not based on scientific or ethical grounds. We see no reason to limit patients' autonomy in this way. We believe a longer storage period for research purposes should be permitted so that if a patient wishes and gives consent, the potential value of this precious and valuable resource can be maximised for future research. We appreciate that an indefinite storage period may not be a practical option but would advocate a storage period of at least 50 years (as this would be within the normal lifespan of the average donor).

Register of information and access to the Register

Question 15: What are your views on the provisions about the Register and access to it in clauses 31, 32 and 33 of the draft Bill?

We welcome the recognition within the draft Bill that steps need to be taken to facilitate use of some of the data held by the HFEA for treatment and research, subject to appropriate regulation.

It is vital that the new law allows prospective follow-up on an **individual** basis of all women who have been treated with assisted reproductive technologies (and possibly in the future, men), their offspring and, where appropriate, the women egg donors (who are themselves treated) with respect to their future health (and for children, their social care, welfare and education) outcomes. This is to ensure that any unknown medium- and long-term effects of receiving or being born as a result of IVF treatment are recognised. It requires effective identification of recipients of treatment and of offspring and reliable linkage to other records, such as medical records, death and cancer registries. We also believe that there should be the facility for anonymised data to be disclosed for research without the requirement for specific consent.

We would welcome further review of how these vital and sensitive data should be curated allowing confidence in their security but also maximising relevant linkage to provide vital information about long term effects of IVF treatment. In particular we would invite the Committee to consider whether the HFEA (or RATE, if formed) is the most appropriate custodian of these data given that it is also the regulator of this sector.

The provision of a body authorised to disclose information where consent is not available is a positive step. However, we cannot comment further on this section of the draft Bill without further information as to the content of the Regulations relating to it. We are also aware that the realisation of the aims of these provisions is heavily dependent on the availability of suitable resources, about which no information has been provided at this point.

Part 4 of the draft Bill and other provisions

Legislating for future scientific development

Question 17: Is it either desirable or appropriate for Parliament to seek to legislate in this way for future technology, both in general terms and in particular cases identified? Is such legislation likely to be legally effective?

It is essential for Parliament to seek to legislate as far as possible for future technology – to protect the public, retain public confidence, and support and maintain the UK's position as a world leader in biomedical research. Of course there is a limit on the extent to which Parliament can predict future activity and make provision for this, but we entirely support the Government's expressed intention to future-proof the legislation as far as is possible. Experience has taught us that science in this field moves incredibly quickly, and the legislation struggles to keep up the pace. Nevertheless, internationally, this is something at which the UK is relatively successful, and this has been an important feature of our international scientific standing.

Legislators obviously need to seek to achieve an appropriate balance – avoiding excessive detail in primary legislation and turning to secondary legislation in suitable cases, whilst ensuring that the legislation is sufficiently clear to provide researchers and the public with certainty and confidence about what is expected and required. Our responses to other questions reflect our views in specific cases on where the balance should lie. On the whole, we believe the draft Bill successfully achieves this.

Other issues

Question 19: Are there any other provisions in the draft Bill, or provisions you would like to see in the draft Bill, on which you would like to give your views?

There are two aspects of the Human Tissue Act 2004 that have caused particular difficulty in practice since its entry into force in 2005. These relate to the definition of 'relevant material' and licensing of premises for storage of tissue from the living for research. There is some uncertainty about the legislators' intentions in these areas and/or a question about whether the original aims are fully being met in these regards. The draft Bill provides an opportunity to address these problems.

1. The definition of 'relevant material' – in particular, the status of waste material and material that is normally acellular.

The Human Tissue Act defines 'relevant material' as material other than gametes which consists of or includes human cells but excludes hair and nail from the body of a living person. In practice, this definition often captures material that is primarily acellular – including bodily waste such as urine and faeces – but which occasionally contains a small amount of cellular material (e.g. urine may contain cells if it is contaminated with blood). Treating this type of material in the same way as tissue such as brains or other whole organs is difficult to defend ethically and in public policy terms. But perhaps more importantly, it raises significant practical difficulties in that it is frequently very difficult to tell whether the material contains cells, and yet it is stored on a significant scale for a wide range of research purposes. For many organisations, this is obliging them to handle and process this material according to the same regulatory requirements as

blood and other tissue to cover the possibility that small amounts of it may incidentally contain cells and therefore be subject to the Act.

We do not believe it was Parliament's intention to capture material that is normally acellular under the Act, and the practical problems that the uncertainty creates are causing unnecessary and disproportionate effort and expense.

We would therefore recommend that the definition of 'relevant material' in the Act should be slightly modified to specifically exclude material that is normally acellular, including faeces, urine and other waste products (perhaps by list). We would emphasise that if there were cells in such material, researchers would still be subject to the specific provisions relating to DNA, which would require consent to hold the DNA for the purposes of analysis.

We would also recommend that the Act provides for the Secretary of State to be given the regulation-making power to reduce or extend the definition of 'relevant material' within the scope of what was intended by Parliament to address further anomalies of this nature should they emerge in the future.

2. Licensing of ante mortem tissue

We have described above that the HTA is already struggling to administer licences within its current workload. In the past nine months most research and museum licences have not been issued – they are proving time consuming and burdensome to administer, and yet relatively low risk. This can only get worse with the proposed creation of RATE, and the desire to create further budgetary efficiencies. Exceptions have already been made to the licensing requirement for tissue taken ante mortem under section 16 of the HTAct. However, for research and display, the exceptions are partial only. For research, there is still confusion about the circumstances in which a licence is or is not required. This confusion has added to the burden of administering the licensing process.

In light of the proposed creation of RATE, and given the desire to achieve further budgetary efficiencies, we would recommend a slight reconsideration as to scope of the licensing regime, in particular, the proportionality and need for a licence in addition to consent to store tissue taken ante mortem for research or to use it for public display, given the obvious burden of administration.

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