

Response to the Scrutiny Committee's consultation on the draft Human Tissues and Embryos Bill

We welcome the opportunity to respond to this consultation from the Joint Committee on the draft Human Tissues and Embryos Bill which was published by the Government on 17 May 2007. This submission has been approved on behalf of the Royal Society by Professor David Read FRS, the Vice-President and Biological Secretary.

Summary

- The UK has an international reputation as a leader in stem cell science, and we believe that it is vital that progress in this area continues as it has the potential to limit or even end the suffering of people with conditions such as Alzheimer's, Parkinson's and motor neuron disease.
- This area is advancing rapidly and the regulatory framework should ensure that as appropriately validated scientific developments offering potential benefits emerge they can be responsibly pursued. As it stands the Bill does not facilitate this and there is not enough flexibility for researchers to take advantage of scientific developments in a timely manner.
- We are particularly concerned by the proposal to prohibit the creation of interspecies embryos in the Bill. The creation of cytoplasmic hybrid embryos for research purposes may overcome the shortage of human eggs available for medical research and should be allowed to proceed, subject to licence by the Regulator. There is currently no scientific need for the creation of pure hybrids but in such a rapidly moving field this may not always be the case.
- We are supportive of the approach recommended by the House of Commons Science and Technology Committee whereby legislation would allow all types of human-animal chimera or hybrid embryos to be created for research purposes under licence by the Regulator.
- The Bill outlines the merger of the functions of the Human Fertilisation and Embryology Authority (HFEA) and Human Tissue Authority (HTA) to form RATE. We are concerned that the remit of RATE will be too large for it to operate in a timely and effective manner.
- Public engagement should only be undertaken if there is a genuine commitment and opportunity to take account of the outcomes in the development of policy. The techniques used must be methodologically rigorous, based on principles of effective public engagement, and any support material must be scientifically sound.

Draft bill overall

Qs 1 & 2 Are the proposals in the draft Bill necessary, sufficient and workable? Could the proposed outcomes be achieved by better means? Does the regulatory architecture set out in the draft Bill contain the right balance between:

- Parliamentary control via primary legislation and secondary legislation (regulation making powers);*
- Regulation by the regulatory body (or bodies);*
- Appropriate flexibility and freedom for clinicians and researchers; and*
- Appropriate opportunities for individuals to access treatment.*

We have addressed question 1 and question 2(i)-(iii). The UK has an international reputation as a leader in stem cell science, and we believe that it is vital that progress in this area continues as it has the potential to limit or even end the suffering of people with conditions such as Alzheimer's, Parkinson's and motor neuron disease. The area of stem cell research is advancing rapidly and the regulatory framework should ensure that as appropriately validated scientific developments offering potential benefits emerge they can be responsibly pursued. We do not believe that the Bill allows this because there is an insufficient role for the regulatory body (currently the HFEA). We support a permissive approach whereby the Regulatory body – with access to appropriate scientific and ethical advice – make judgements on proposals for research in such a way as to allow the flexibility for researchers to take advantage of scientific developments in a timely manner.

We have specific concerns, outlined below, about the proposal to ban interspecies-embryos in the Bill (although we welcome the indication from the Government that they will now make some exceptions to this) and about the new regulatory architecture.

Q 3 How should Parliament and the regulatory body or bodies ensure an appropriate ethical framework to secure and maintain public confidence?

The HFEA can draw on the advice of its ethical committee or from organisations such as the Nuffield Council on Bioethics. Stakeholder and public dialogue could be used to determine whether the ethical framework secures and maintains public confidence.

RATE and the new regulatory architecture

Q 4 What are your views on the proposed transfer of the functions of the HFEA and HTA to a single new regulatory authority, RATE?

We are concerned that the remit of RATE will be too large for it to operate in a timely and effective manner. The HFEA and the HTA have each struggled with the breadth of expertise necessary to deal with all the relevant issues they currently cover. We do not believe that a combined authority, with a substantially lay Board, can deal with its much larger remit without over reliance upon sub-committees, expert advisory panels and working groups. We fear this will make RATE a very large and unwieldy regulator, and reduce its efficiency, effectiveness and coherence. For example it will be difficult for a predominantly lay Board, with a wide ranging remit, to properly evaluate the advice that it is receiving from its panels. The HFEA has, over a period of time, developed unique ethical experience and expertise. It operates in an area of great sensitivity, where scientific and technological advances that will have profound ethical and social implications for patients and society in general are moving at a rapid pace. The remit of the HFEA requires expert and sensitive regulation. A different set of skills and experience will be required in relation to the HTA. The proposed merger of HFEA and HTA risks diminishing the much needed expertise, to the detriment of both functions.

Q 6 Should the regulatory body or bodies be allowed to make charges for licenses?

It is our understanding that the Government wishes to see the level of operating costs recovered from HFEA licence fees increased – the HFEA currently recovers less than half of its operating costs via licence fees. We are worried that, following the merger, licence fees will increase to a point where the costs become prohibitive.

Definitions

Q7 (a) Do you agree with new definitions in the draft Bill of ‘embryo’, ‘egg’, ‘sperm’, ‘gamete’, ‘nucleus’? If not, how would you propose to amend them? (b) Should the Secretary of State have the regulation-making power to expand these definitions as proposed in the draft Bill?

We welcome the fact that the new definitions are more comprehensive than before. It is appropriate that the Secretary of State should be able to expand these definitions in the light of developments in science or medicine. The Secretary of State should ensure that s/he has access to appropriate scientific advice to ensure that expansion to these definitions is done on a timescale that does not unduly hamper scientific research.

Inter-species embryos such as cytoplasmic hybrid embryos

Q 8 Do you support:

- (i) the approach signalled by the Government in the White Paper [ie prohibition of hybrid and chimera embryos on the face of the Bill],*
- (ii) the new approach announced by the Government [ie permit entities listed in clause 17(2) 4A b-d]; or*
- (iii) the approach recommended by the Commons Science and Technology Committee? [ie permissive, allowing the creation of all types of human-animal chimera or hybrid embryos for research purposes]*

We are supportive of the creation of cytoplasmic hybrid embryos for research purposes, which may ultimately lead to therapeutic benefits. The proposed technique is one of a number of routes being investigated to overcome the shortage of human eggs available for medical research. Whether this technique will prove to be a viable method of generating stem cells and establishing stem cell lines is not clear at present. However, stem cell research is still in its early stages and it is essential that we do not close off this and other avenues for development given the potential benefit of such work.

We are therefore supportive of the approach recommended by the House of Commons Science and Technology Committee (HoC S&T Committee) whereby legislation would allow all types of human-animal chimera or hybrid embryos to be created for research purposes under licence by the Regulator (HoC S&T Committee, 2007). This would allow the Regulator, based on advice from its scientific and ethical committees, to make timely decisions on research proposals, thus allowing valuable research to be carefully regulated but proceed without undue delay.

We welcome the announcement by the Government that, based on the HoC S&T Committee’s advice, it will allow for legislation that provides for certain inter-species entities to be created for research purposes under licence by the Regulator within a 14-day limit. This would include cytoplasmic hybrid embryos. However, our understanding is that the Government proposes to continue to ban the creation of any embryo either created using human and animal gametes (ie “pure hybrids”) or that which contains “both a haploid set of human chromosomes and a haploid set of animal chromosomes or any other sequence of nuclear or mitochondrial DNA of an animal” (ie as described in clause 17(2) inserted section 4A(5)(a) and (e) respectively). We are unclear as to the intention of the latter clause (e) and recommend that this is clarified. While we are not aware of any scientific need for the creation of pure hybrids, this may not always be the case and we are concerned that the time taken to amend this legislation in Parliament could significantly delay the pursuit of an important area of research. Hence our support for the HoC S&T Committee’s permissive approach.

Q8 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 such judgements be left to the regulatory body or bodies to determine?

The list of purposes for which a licence can be granted appears to cover all those areas that research is currently addressing. Once again the Regulator, informed by the best scientific and ethical advice along with the outcome of ongoing public dialogue, would be best placed to determine whether these purposes need changing in the future.

Q9 How should Parliament or the regulatory body or bodies take public views and public engagement into account?

While public views and the outcomes of public dialogue are not the only factors that Parliament or any regulatory body will need to consider they are important. Rather than undertaking public dialogue related to every development in stem cell and embryo research, we suggest that it should be based around scenarios of possible future developments (ie upstream dialogue). Parliament and the regulatory body/bodies will need to consider the balance between representative public engagement, and engagement with stakeholder and special interest groups.

Public engagement should only be undertaken if there is a genuine commitment and opportunity to take account of the outcomes in the development of policy. The techniques used must be methodologically rigorous, based on principles of effective public engagement, and any support material must be scientifically sound. Meeting these conditions will require a corresponding level of funding and allocation of time. Centrally commissioned and organised public engagement is advantageous, particularly where it is linked to a particular issue where policy is being developed. However, providing that it meets the conditions outlined above, engagement activities undertaken independently in other sectors (eg learned societies, civil society and academia) may also be taken into account.

Consent to storage and use of gametes and embryos

Q 11 What are your views on the proposed changes to consent provisions?

We are content with the proposed changes and recognise that they are necessary to secure and retain public confidence.

Storage limits

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

We welcome the doubling of the maximum storage time from 5 to 10 years. Leaving storage periods completely open would greatly complicate proper auditing. We cannot currently envisage a situation in which even longer storage would be vital to research but this may not always be the case and so this limit should be kept under review.

Legislating for future scientific development

Q17 In certain places, the draft Bill seeks to legislate now to regulate future scientific developments that are necessarily uncertain. In particular, it seeks to make provision: for Parliament to pass Regulations to allow relevant provisions of the Act to have effect in cases where an egg or an embryo has been created from mitochondrial material provided by 2 women (sometimes called "artificial gametes") (clause 34); and for Parliament to pass Regulations making the sale, supply and advertisement of sperm sorting kits an offence, if such kits are developed in the future (clause 65). Is it either desirable or appropriate for Parliament to seek to legislate in this way for future technology, both in general terms and in the particular cases identified? Is such legislation likely to be legally effective?

This question relates to the potential applications of scientific developments, rather than the areas of research themselves. This is an area where the Regulator might be best placed to consider whether a particular application is appropriate. They will be able to react in a timely manner and with a contemporary understanding of public acceptability of the application in question. They will have the option to consult with stakeholders and the public if they feel it is necessary.

Reference

House of Commons Science and Technology Select Committee (2007) *Government proposals for the regulation of hybrid and chimera embryos*. HC 272-I The Stationery Office Limited, London

Please send any comments or enquires about this response to:

Dr Anne Simpson, The Royal Society, 6-9 Carlton House Terrace, London SW1 5AG

Email: anne.simpson@royalsoc.ac.uk tel: +44 (0)20 7451 2530 fax: +44 (0)20 7451 2692