

**REVIEW OF THE HUMAN FERTILISATION & EMBRYOLOGY ACT:
A PUBLIC CONSULTATION.
DEPARTMENT OF HEALTH 2005**

This pro forma repeats all of the questions and proposals in the above titled consultation document. The boxes below will expand as you type. When completed it should be e-mailed to review-hfe-act@dh.gsi.gov.uk

The closing date for responses is Friday 25 November.

Personal details	
Title:	
Names:	Prepared by Dr Susan Wallace with Dr Ireena Dutta on behalf of the East of England Stem Cell Network
Organisation: (if relevant)	East of England Stem Cell Network (EESCN)
Address:	Cambridge Genetics Knowledge Park Strangeways Research Laboratory 2 Wort's Causeway Cambridge
Postcode:	CBI 8RN
E-mail address:	ireena.dutta@srl.cam.ac.uk or eescn@srl.cam.ac.uk

Questions and proposals for consultation

***** NB We have only included the questions to which we have prepared responses, and removed those to which we have no response *****

Research

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).

We agree with this position.

58. 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).

We agree with this position.

59. 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).

We agree with the Government’s comments that there is no reason to distinguish in law between using CNR on eggs and CNR on embryos for the purposes of research. We encourage the Government to relax this rule in order to enable a broader range of research to be conducted in the UK.

60. 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).

We support changing the law to allow the altering of the genetic structure of an embryo for research purposes, subject to licensing. We welcomed the news of the license granted to the Newcastle Centre for Life to study the transmission of mitochondrial diseases from mother to child and we encourage further research in this area. Such a change could also allow the future development of gene therapy as a form of treatment.

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 issue of chimeras is a difficult one with many ethical questions attached but one that needs to be addressed as the science progresses. We agree with the House of Commons Science and Technology Committee that if this research is to be permitted, it must be done with the proposed regulations in place (a clear definition of a hybrid and chimera, destruction within 14 days, not to be implanted). The issue of defining a chimera is particularly important in this context and it may be the case that a single definition is not appropriate. Instead a range of categorisation depending on the percentage of human cells contained within it or the type of tissue used may be more useful. Such a range of definitions may also have an impact on how long such chimeras are kept viable before destruction. The “14 day rule” is likely to require regular review, as it may well be the case that significant scientific benefit may be gained by monitoring the development of these chimeras over the longer-term. It is also important that the techniques leading to the generation of embryonic chimaeras be distinguished from studies in which immunodeficient adult mice are used as recipients for human cellular transplantation. Whereas the former present novel ethical challenges, the latter procedures are well-established activities that are already fully regulated under the Animals (Scientific Procedures) Act 1986. Therefore, care should be taken to ensure that any definitions of chimeras used in the legislation do not impose unforeseen limitations on researchers, but allow relevant research work to progress in a transparent manner that maintains public confidence.

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

We believe that at this time the current list of legitimate purposes for licensed research is appropriate. However, with science progressing quickly, we stress the need for the Government to be flexible in reviewing the list regularly in order to ensure that it and the research can move together at an acceptable pace.

63. 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).

We agree with the Government on this view. Local bodies will not necessarily have the expertise to adequately judge compliance with the law. Consistency in decision-making is also needed in this sensitive area of research and cannot be guaranteed by devolving responsibility for review to local bodies.

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).

We suggest that the Government may wish to consider aligning the regulatory requirements being considered for donation of gametes and embryos for reproductive purposes with those that apply to the procurement and use of gametes for the purposes of research. These have been widely considered and have public support. However, we do not agree that women should receive a discount in the cost of the treatment as a 'benefit-in-kind' for donation for research purposes, as their donation is not assisting another woman to have a child. Providing such a discount may be seen as coercive and this must be avoided if public and scientific support for this research is to continue. In addition, there must be continued separation between those requesting donations for research and those conducting the research. In light of the globalisation of scientific research, the issue of procurement of gametes from outside the UK also needs to be addressed. Any organisation supplying gametes for use in the UK should agree to be subject to the same level of scrutiny as that provided to UK/EU suppliers of gametes, including being open to HFEA inspection. Penalties for non-compliance should also be established. It is anticipated that this mechanism will allow for the use of gametes donated from overseas within an appropriate ethical and regulatory framework.

65. The Government invites comments on the desirability of allowing the creation of embryos for the *treatment* of serious diseases (as distinct from *research* into

developing treatments for serious diseases which is already allowed). (Paragraph 9.47).

As embryo research progresses, increasing expertise will enable researchers to create embryos that will be able to aid in the treatment of serious diseases. It is a next logical step and it is wise for the Government to be aware of the possibilities. CNR is already being used to create healthy babies, preventing the transmission of mitochondrial disease; no doubt other examples will soon appear. UK law should be flexible enough to ensure that legitimate research that has public support is not prohibited because the Act has again lagged behind the science. Given this context, we suggest that the wording in the Act be changed in such a way that the HFEA will be able to consider applications for treatment licenses when therapies using created embryos are proven beneficial to patients.

THANK YOU