

Human Fertilisation and Embryology Bill

House of Commons Committee Stage, 2 June 2008

Prepared by the Academy of Medical Sciences, Medical Research Council and the Wellcome Trust.

The Academy of Medical Sciences, Medical Research Council and the Wellcome Trust support the Human Fertilisation and Embryology Bill, which will modernize the law in this field and ensure that important scientific and medical research on human and human admixed embryos can be undertaken within a robust regulatory and ethical framework.

We have previously circulated briefings on several aspects of the Bill relating to research (see details at the end of this briefing). In this document, we focus on amendments tabled at Committee Stage of the Bill, concerning the following issues affecting research:

1. Consent and use of existing cell lines
2. Consent provisions relating to children and to mentally incapacitated adults
3. Storage of Embryos and Human Admixed Embryos
4. The powers of the Human Fertilisation and Embryology Authority (HFEA) to delegate and contract out its functions

1. Consent and use of existing cell lines (Amendments 7, 10, 102 and 107)

We have previously expressed concern about the consent provisions in Schedule 3 of the Bill, which extend the requirement to obtain *specific* consent for the use of any human cells to create an embryo.

As currently set out in the Bill, the consent requirements will block research uses of many existing holdings of cell lines that have been collected over many years, often from patients with specific rare conditions. These existing holdings may be important for research into the origins, development and treatment of the diseases from which the original patient donors suffered. Where possible, consent should be obtained for the use of such materials from these patients. But this is not possible in *all* cases, for example, where a cell line has been irreversibly anonymised and the original donor cannot be identified. We are concerned that the significant time and resources invested in creating these cell lines will be wasted, and that blocking their use for research is contrary to the interests of patients.

To address this, we have previously supported amendments tabled in the House of Lords that provide an exception to the consent requirements for the use of existing cell lines (now tabled in the House of Commons as Amendments 7 and 10). **We welcome the Government's recognition of the need for an amendment along these lines (Amendments 102 and 107). Subject to the concern described below, we support these amendments**, which we believe will allow important research to proceed in appropriate circumstances whilst ensuring that the interests of the original cell donors are protected.

We have one remaining concern in relation to amendment 102, insofar as it relates to existing cell lines, as follows. Clause 15G sets out a number of conditions that

must be met in relation to persons whose human (somatic) cells are to be used for research. Condition B (clause 15G(3)) applies if the Researcher 'R' "does not have any reason to believe P [the person] to have died". Condition C (clause 15G(4)) applies if the person has died.

We are concerned that researchers will frequently find themselves falling between conditions B and C. For many existing holdings of cell lines, a researcher may have some reason to believe a person has died, perhaps because the donors are of a particular age or had been suffering from a lethal disease. However, the researcher cannot be certain because contact with the original donor was not maintained. In such a situation, the researcher would not be able to meet either condition B or C.

We propose that Condition B(b) in clause 15(G)3 of amendment 102 should be replaced with "R does not know P to have died", which would eliminate this concern.

2. Consent provisions relating to children and to mentally incapacitated adults (Amendments 10, 65-103 and 109-114)

We have previously raised concerns that the consent provisions in Schedule 3 of the Bill do not make provision for consent to be given by parents on behalf of their children to use cells to generate embryos or human admixed embryos. The effect of this would be that research into childhood diseases, including lethal genetic disorders, using somatic cell nuclear transfer (SCNT) to create embryonic stem cells could not go ahead.

We fully support the amendments put forward that allow for consent to be given by those with parental responsibility, thereby permitting the use of children's cells for research in very limited circumstances and subject to strict safeguards (Amendments 10, 65-101 and 109-114).

We also support the various provisions relating to consent arrangements for adults who lack capacity (including amendments 102 and 103), which will bring the provisions in line with those in the Human Tissue Act 2004 and the Mental Capacity Act 2005.

3. Storage of Embryos and Human Admixed Embryos (Amendments 5 and 34)

We oppose the amendment to reduce the storage limit for Embryos and Human Admixed Embryos from 10 to 7 years (Amendment 5 and 34). The nature of research means that future needs cannot always be anticipated in advance and it will be important to maintain these precious resources. We emphasise that, particularly where genetic disorders are concerned, a generation may pass before the full value of a research sample is recognised.

4. Power of the HFEA to delegate and contract out its functions (Amendment 25)

We oppose the amendment that would prevent the Human Fertilisation and Embryology Authority (HFEA) from being able to delegate or contract out certain of its functions (Amendment 25).

Permitting the HFEA to contract out certain routine, low-risk functions would make it more consistent with the operations of the Human Tissue Authority (HTA) and would represent a more modern, streamlined process of regulation. It would also ensure that other regulators, such as the HTA and Medicines and Healthcare products Regulatory Agency (MHRA), can work effectively with the HFEA, allowing the possibility of joint inspections and/or review processes, which would avoid any duplication in operations.

At the moment, every HFEA decision must be taken before the full Authority – a disproportionate requirement that leads to unnecessary delays, for example in routine, lower-risk licensing decisions concerning issues that have previously been considered by the HFEA. Allowing the HFEA to delegate certain decisions of this nature to, say, a sub-committee of the full Authority would bring a more proportionate approach to regulation, with decisions graded according to risk or novelty. This would allow lower-risk applications to be processed quickly while ensuring that the full Authority can focus more of its resources on new, more complex and difficult issues.

Briefing Contacts

Previous joint briefings can be found at the following sites:

Academy of Medical Sciences: <http://www.acmedsci.ac.uk/p47prid51.html>

Medical Research Council
<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004497>

Wellcome Trust <http://www.wellcome.ac.uk/hfe>

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