

Human Fertilisation and Embryology Bill

Brief on the House of Commons Report Stage 22 October 2008

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

The Academy of Medical Sciences, Association of Medical Research Charities, the Medical Research Council and the Wellcome Trust support the aspects of the Human Fertilisation and Embryology (HFE) Bill relating to research, which will modernise 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 support the key provisions of the Bill as they relate to research, including the provisions regulating the creation of human admixed embryos, and exceptions to the specific consent provisions for the use of existing cell lines and cell lines derived from children for research only. We welcome the support given to the provisions for research and regulations involving human admixed embryos during the Committee Stage of the Bill. Our previous briefs on the above issues can be found on the websites listed at the end of this briefing.

In this briefing, we focus on amendments relating to medical and scientific research tabled for debate at Report Stage. We oppose the following amendments:

1. amendments regarding introduction of a 'Committee of Inquiry' or 'Review Board' (Amendment NC8 and NC25)
2. amendments to clauses regarding gametes and human admixed embryos (Amendments NC24, 47 and 50)
3. amendments seeking more stringent licensing conditions (Amendments 38, 39, 51 -55, and 74)
4. amendments which prohibit germ line modification so far as it relates to research (Amendments 41, 42; 46, 49, and 67)
5. amendments purporting to remove exceptions to consent for use of cell lines derived from children and mentally incapacitated adults for research. (Amendments 56-63 and 82)

We support the following amendments:

6. amendments clarifying consent provisions where the donor is believed to have died (Amendments 21-26)

1. Amendments regarding introduction of 'Committee of Inquiry' or 'Review Board' (NC8 and NC25)

We fully accept the need for review of human and human admixed embryo research, however we do not support these amendments which call for the creation of *additional* review bodies with devolved powers. The requirement for review of the necessity of research activities is already enshrined on a case by case basis in the licensing mechanism of the Human Fertilisation and Embryology Authority (HFEA). This applies both when licences are initially granted and when considered for renewal. The HFEA also has the power (and indeed the duty) to withdraw licences at any time, should the continuation of a licence be inappropriate. The HFEA is therefore readily able to respond rapidly to developments in science and ethics at any time. The HFEA also has a general responsibility to report on its activities and to keep information about the activities it regulates under review. We do not see what additional function a Committee of Inquiry or Review Board would serve that cannot be carried out by the HFEA, the Government and/or by Parliamentary mechanisms. (Amendment NC8)

We believe that any additional monitoring of the necessity and effectiveness of the provisions of the Bill once enacted should be carried out by Parliament itself, including the various Parliamentary Select Committees, and not by another body created in addition to the statutory regulator, Government and existing Parliamentary mechanisms. (Amendment NC25)

2. Amendments amending clauses regarding gametes and human admixed embryos (Amendment NC24, 47, 50)

We oppose the amendments which would have the effect of limiting valuable research which can be undertaken using human gametes in animals. (Amendment NC24 and 50) While we recognise that gametes are special, in that they are cells involved in reproduction, the reasons for studying human gametes in the context of an animal is to learn more about how gametes develop and function. This is important in the study of male infertility. Research of this nature is sufficiently regulated under existing human and animal legislation and the creation of 'human admixed embryos' is already covered under licence provisions. Procedures directly involving animals are already licensed by the Home Office and therefore do not need to be covered by this Bill.

We do not believe the addition of a further sub-clause (f) under the definition of human admixed embryo under Clause 4 is necessary. The entities covered by this additional sub-clause (f) are in our view already covered by the rest of the definition. (Amendment 47)

3. Amendments seeking more stringent licensing conditions (Amendments 38, 39, 51-55 and 74)

We oppose the amendments which would require researchers seeking a research licence from the HFEA to meet impossibly stringent requirements as a condition of obtaining a licence from the HFEA. (Amendments 38, 39 and 74) The requirement to demonstrate that research is likely to 'achieve its specified purpose' before being undertaken runs contrary to the fundamental nature of experimental science in which outcomes are sometimes unpredictable. The 1990 HFE Act and the current draft of the Bill already enable the HFEA to operate a rigorous process of review for all research licence applications. Licences will only be granted for a specific research purpose where the HFEA is satisfied that the use of embryos or human admixed embryos is necessary. Furthermore, research funding will only be granted following a process of scientific peer review, to determine the validity of the proposed work and its proposed utility, based on the best available evidence.

The nature of scientific research is that it is experimental, and it is not possible to predict outcomes in advance with complete certainty. The legislation should enable researchers to pursue the most effective approaches to addressing pressing scientific and medical needs, as judged by both the independent regulator – the HFEA – and by experts with up-to-date knowledge of this rapidly advancing field.

4. Amendments which prohibit germ line modification so far as it relates to research (Amendments 41, 42, 46, 49 and 67)

We oppose the above amendments which have the effect of prohibiting all research which involves germ line modification¹. These amendments are unnecessary because genetic modification for reproductive purposes is already prohibited under the Bill, and thus these amendments only serve to create additional unnecessary restrictions on important research techniques in germ line modification. Such techniques are important in exploring mitochondrial diseases, therefore the amendments would also serve to prevent research on ways to avoid mitochondrial disease via nuclear transfer between affected and unaffected eggs or zygotes. They would also block other valuable research as it is not possible to distinguish between methods for germline and for somatic cell modification.

¹ The germline is the line of germ cells in a developing individual that contain genetic information that may be passed on to a child. Sex cells such as the egg and sperm form part of the germline. Other cells that do not form part of the germline are known as somatic cells, eg liver cells.

5. Amendments purporting to remove exceptions to consent for use of cell lines derived from children and mentally incapacitated adults for research (amendments 56-63 and 82)

We oppose the amendments that would remove provisions in the current Bill that provide exceptions for the use of cell lines derived from children for research. Such provisions would ensure that in exceptional cases, cell lines relevant to rare childhood diseases which can often lead to death in childhood can be used for research. This would only occur where the proposed research has been carefully scrutinised by the appropriate regulatory bodies and would lead towards a better understanding of devastating illnesses, and possibly future treatments.

The provisions in the current draft which allow consent arrangements for adults who lack capacity will bring the provisions in line with those in the Human Tissue Act 2004 and the Mental Capacity Act 2005. The ability to use existing holdings of cell lines may be important for research into the origins, development and treatment of disease from which the original patient donors suffered. We believe that prohibiting the use of cell lines where the donor consented would be contrary to the interest of patients.

6. Amendments clarifying consent provisions where donor is believed to have died (Amendments 21-26)

We have previously expressed concern that researchers may not be able to meet consent conditions for the use of existing holdings of cell lines, particularly in cases where a researcher believes that a cell/tissue donor may have died, but the loss of contact means that this cannot be conclusively established. This could result in researchers falling in between condition B (Clause 15G (3)), which applies if the "Researcher 'R' does not have any reason to believe P [the person] to have died" and condition C (clause 15G (4)) which applies if the person has died. 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 support these amendments which will eliminate this concern by providing a robust basis for consent where a researcher has reasonable grounds to believe that a donor has died (e.g. the age of the tissue collection) and where the available information does not suggest that the donor would have objected to the use of their cells for embryo research.

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Briefings provided at earlier stages of this Bill's passage through Parliament are available on the websites of the above organisations