

Human Fertilisation and Embryology (Mitochondrial Donation) Regulations
Debate 24 February 2015, House of Lords, Main Chamber 2.30pm



We, the organisations listed, **support the draft Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015**. We do not support the fatal amendment. The Regulations as tabled will give families affected by serious mitochondrial disease a chance of having healthy children, something all families should be able to aspire to.

We note the clear will of the elected chamber, who voted by a large majority of 254 in favour of the Regulations on 3 February 2015.

Why support the regulations:

- **Provide reproductive choice to women who would otherwise have children with devastating mitochondrial disorders, which often result in early childhood death:** Almost 2,500 women of child-bearing age in the UK are at risk of transmitting mitochondrial disease to their children.¹ Estimates based on this figure suggest that 150 births per year in the UK risk passing on mitochondrial disease to the child. Mitochondrial donation would provide these families with the opportunity of having genetically-related and healthy children.
- **Acknowledge the rigorous scientific, ethical and public scrutiny of the techniques over the past seven years:** The Regulations are the culmination of seven years of extensive scrutiny: there have been independent ethical reviews, including that of the Nuffield Council on Bioethics,² three separate reviews of the scientific evidence on the techniques' safety by a specially convened independent panel of experts,³ and an extensive public consultation, independently validated,⁴ which has revealed broad public support.
- **Support the UK as world leaders in reproductive technologies to combat mitochondrial disease, with therapies approved within a robust regulatory framework:** Just as the UK was able to pioneer IVF technologies, our world class researchers and networked health service has afforded the UK some of the world's most extensive knowledge of mitochondrial disease. To harness this expertise, we believe it is entirely appropriate that the UK should be the first country to licence these pioneering technologies within a robust regulatory framework. The Regulations would only allow the techniques to be used on a case-by-case basis once the HFEA is satisfied of the necessity, safety and efficacy of use.

Why not to support the fatal amendment:

- **Unnecessary and unacceptable delay for patients for whom time is of the essence:** Time is precious for women at risk of passing on mitochondrial inherited disease to their children, especially where their window of fertility is limited. There are no scientific, ethical

¹ Gorman GS, Grady JP, Turnbull DM Mitochondrial Donation — How Many Women Could Benefit? N Engl J Med. 28 Jan 15

² [Nuffield Council on Bioethics \(2012\): Novel techniques for the prevention of mitochondrial DNA disorders](#)

³ HFEA, Expert review of scientific methods to avoid mitochondrial disease [2011](#), [2012](#), [2013](#)

⁴ [Watermeyer and Rowe \(2013\). Evaluation of the project: Mitochondrial Replacement Consultation](#)

or legal reasons to delay the approval of these Regulations. The decision to licence treatment for each patient will rightly be made by the HFEA on a case-by-case basis. Passing the Regulations now will allow this to happen without unnecessary and unacceptable delay once the HFEA is satisfied that any risks are acceptable.

- **No breach of EU or domestic law:** There is no breach of the European Clinical Trials Directive as the techniques are not ‘medicinal products’ and therefore outside of the scope of the Directive. The Regulations do not breach the Charter of Fundamental Rights of the European Union, as medical services such as the treatments in question are outside the scope of the Charter. The Explanation to the Charter makes it clear that a technique intended to treat disease would not be a ‘eugenic’ practice as referred to in the Charter.
- **In line with the will of Parliament indicated in the Human Fertilisation and Embryology Act 2008 (HFE Act):** One of the plain purposes of the Human Fertilisation and Embryology Act 2008 is to permit regulation-making powers to amend the definition of a ‘permitted egg’ and ‘permitted embryo’ for the purposes of preventing the transmission of serious mitochondrial disease.
- **Joint Parliamentary Committee to review science is not required:** The need for a Joint Committee was not envisaged by the provisions under which the Regulations have been introduced, set out in the HFE Act 2008. The provisions in HFE Act 2008 demonstrate the clear will of Parliament that regulation-making powers governing mitochondrial donation should be considered through normal Parliamentary processes.
- **Expert scrutiny has already been considerable:** Given the intense and unprecedented process of scrutiny of the science, ethics and public acceptability of mitochondrial donation that has taken place, both inside and outside Parliament, over the last seven years a further committee is not only unnecessary but would cause unacceptable delay for patients.
- **Role of Parliament:** The role of Parliament is to set the regulatory framework governing new technologies, informed by all relevant facts and viewpoints.
- **Three separate independent scientific reviews have not found any evidence that the techniques are unsafe:** Three independent scientific panels considered evidence from around the world with regard to the techniques, their safety, efficacy and developments in the field. They found no evidence to suggest the techniques are unsafe. No new technique can ever be said to be 100% safe. The hypothetical risks of using the techniques are far outweighed by the likely benefits to women eligible for treatment who would be given the chance to have children free from mitochondrial disease.

What the regulations do:

The key parts of the Regulations make provision to enable mitochondrial donation by doing the following:

- Allowing specific techniques (Maternal Spindle Transfer- ‘MST’ and Pronuclear Transfer ‘PNT’- ‘mitochondrial donation techniques’) to be undertaken on eggs and embryos for permitted use in IVF to avoid serious mitochondrial disease (Part 2);
- Requiring the HFEA to make a determination regarding whether the techniques can be used on a case-by-case basis. Specifically, the HFEA must be satisfied that there is a significant risk that any child born would otherwise have or develop serious mitochondrial disease (Regulation 8);

These Regulations are made pursuant to the regulation-making power conferred upon the Secretary of State under Section 32A(5) & (6) and 31ZA(2)(a), 35(a) & 43(1) & 32(a) of the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology Act 2008.

Further information on specific issues can be found at www.wellcome.ac.uk/mitochondrialdonation, or by contacting Sarah Rappaport (S.Rappaport@wellcome.ac.uk) or Nancy Lee (N.Lee@wellcome.ac.uk)