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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make provision to enable mitochondrial donation.

Part 2 provides for specified eggs and embryos, which contain donated mitochondria, to be permitted for use in assisted conception treatment under section 3(2) of the Human Fertilisation and Embryology Act 1990 (“the 1990 Act”) in certain circumstances. Regulations 4 and 7 prescribe the process that such an egg or embryo (egg or embryo “P”) must have undergone, which involves the removal of nuclear DNA from an egg or embryo which has abnormal mitochondria (egg or embryo “B”) and the insertion of this material into an enucleated egg or embryo which has healthy mitochondria (egg or embryo “A”). Regulations 3(c) and 6(c) ensure that no other alterations can be made to the resulting egg or embryo (egg or embryo “P”) after this process has taken place. Regulation 5 provides that, in relation to the use of the technique for an egg, the Human Fertilisation and Embryology Authority (“the HFEA”) must have issued a determination in relation to the woman from whose ovaries egg B was extracted that there is a particular risk that any egg extracted her ovaries may have mitochondrial abnormalities caused by mitochondrial DNA. Regulation 8 provides that, in relation to the use of the technique for an embryo, the HFEA must have issued a determination that there is a particular risk that any embryo created by the fertilisation of eggs from the woman whose egg was used to create embryo B may have mitochondrial abnormalities caused by mitochondrial DNA. The HFEA must also be satisfied that there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease. Regulation 9 makes supplemental provision to provide that existing treatment licences do not enable the use of eggs and embryos permitted under the regulations and to ensure that any new licence issued will require express provision to enable the use of such eggs or embryos. Treatment licences are granted under Schedule 2 to the 1990 Act.

Part 3 of the Regulations applies the 1990 Act with modifications to provide for cases where mitochondrial donation has taken place. Regulations 11 to 15 modify the information provisions in the 1990 Act to enable children born following mitochondrial donation to access limited, non-identifying, information about their mitochondrial donor. Provision is also made for a mitochondrial donor to access limited, non-identifying, information about children born from their donation, although they will not be notified about requests for information. The Regulations modify the 1990 Act to clarify that mitochondrial donors are not related to any children who were, or might have been, born following treatment services using their donation and therefore no provision is made to allow access to information in connection with entering into a marriage, civil partnership or intimate physical relationship, nor to access information about other children who share the same donor. Regulation 16 modifies the consent provisions in Schedule 3 to the 1990 Act to provide that where a person has consented to the use of their egg or embryo in mitochondrial donation such consent cannot be withdrawn once all the nuclear DNA from egg or embryo B is inserted into egg or embryo A. Further modifications are made by regulation 17 to ensure that for the purposes of the consent provisions in the 1990 Act the resulting egg or embryo is not to be treated as the egg or embryo of the person whose mitochondrial DNA was used to create it. Regulation 18 makes modifications to section 54 of the Human Fertilisation and Embryology Act 2008 to provide that where a child has been born following treatment services a person who donated mitochondria is not eligible to apply for a parental order on the basis of that donation alone.

Regulation 19 makes amendments to the limit the application of the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 so that they do not apply to information requests under the 1990 Act about mitochondrial donations.

**Status:** *This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

A full impact assessment has been produced in relation to the Regulations and a copy is available from room 109 Department of Health, Richmond House, 79 Whitehall, London, SW1A 2NS and is published with the Explanatory Memorandum alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).