EXPLANATORY MEMORANDUM TO

THE HUMAN FERTILISATION AND EMBRYOLOGY (SPECIAL EXEMPTION) REGULATIONS 2009

2009 No.

1. This Explanatory Memorandum has been prepared by Department of Health and is laid before Parliament by Command of Her Majesty. This Memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The Human Fertilisation and Embryology (Special Exemption) Regulations ("the Regulations") provide for two exemptions to the requirements of the Human Fertilisation and Embryology Act 1990 ("the 1990 Act") that all persons keeping or using human embryos or storing human gametes may only do so if they have a licence from the Human Fertilisation and Embryology Authority ("the HFEA"). The Human Fertilisation and Embryology (Special Exemption) Regulations 1991 ("the 1991 Regulations")[1] are being re-made to take account of changes to the definitions of "gamete" and "embryo" in the 1990 Act made by the Human Fertilisation and Embryology Act 2008 ("the 2008 Act") and to make minor changes to the drafting. The Regulations are re-made for technical reasons and do not reflect a change in Government policy.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 The Regulations are made under sections 43 and 45 of the 1990 Act. They replace the 1991 Regulations. It was decided to re-make the 1991 Regulations as the definitions of "gamete" and "embryo" in the 1990 Act which are used in the 1991 Regulations were amended by the 2008 Act. Minor drafting changes have also been made.

4.2 The Regulations do not represent any change to Government policy.

5. Territorial Extent and Application

5.1 The Regulations extend to all of the United Kingdom.

[1] S.I 1991/1588

6. European Convention on Human Rights

The Minister of State for Public Health has made the following statement regarding Human Rights:

In my view the provisions of the Human Fertilisation and Embryology (Special Exemptions) Regulations 2009 are compatible with the Convention rights.

7. Policy background

7.1 The Regulations set out two exemptions to the general position that a person who keeps or uses human embryos or stores human gametes may only do so if they have a licence from the HFEA.

7.2 The first exemption refers to cases where an offence under the 1990 Act is being investigated. Embryos may be kept and examined and gametes may be stored without a licence from the HFEA in this specific circumstance.

7.3 However, access to the gametes or embryos should be limited to those persons concerned with the particular investigation. The Regulations also specify that they must be labelled to ensure they are easily distinguishable from gametes and embryos stored for other purposes.

7.4 The second exemption effectively allows scientists undertaking research using gametes, but not creating embryos to store the gametes without a licence from the HFEA. The Regulations set out the specific research purposes where the exemption applies. These research purposes are:

- research on gametes,
- the development or testing of pharmaceutical or contraceptive products,
- teaching requiring the use of gametes.

7.5 The Regulations specify activities that cannot be undertaken under this exemption. These are:

- the mixing of live sperm with live eggs,
- using the gametes for purposes that may not be authorised by a HFEA licence,
- supplying gametes to a licence holder for a purpose for which they hold a licence,
- supplying gametes for money or any other benefit unless this would be allowed by HFEA Directions,
- exporting gametes from the UK.

7.6 The gametes must be clearly labelled and access to them should be limited only to those persons participating in the activities set out in paragraph 7.4.

8. Consultation outcome

8.1 The Regulations do not represent a change in Government policy, therefore they were not consulted on.

9. Guidance

9.1 The HFEA will continue to provide guidance on the Regulations. The existing guidance on the 1991 Regulations can be found on the HFEA website: www.hfea.gov.uk

10. Impact

10.1 The impact on business, charities or voluntary bodies will be minimal as the Regulations do not represent a change to Government policy.

10.2 The impact on the public sector is minimal as the Regulations do not represent a change to Government policy.

10.3 An Impact Assessment has not been prepared for the Regulations because the policy set out in the Regulations is not being changed.

11. Regulating small business

11.1 The Regulations apply to small business.

11.2 Many licensed clinics (which are predominantly private sector based) and research centres fall within the definition of small businesses (having less that 50 staff) and so can be considered to be small businesses. The Regulations do not represent a change to Government policy and therefore centres will not need to amend practices.

12. Monitoring & review

12.1 The HFEA has specific functions to monitor developments in their field of interest and, including to advise Ministers as required. The effectiveness of the HFEA will be monitored primarily through the usual procedures for the oversight of arm's length bodies, including clearance and monitoring of business plans and annual accountability reviews.

13. Contact

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