EXPLANATORY MEMORANDUM TO

THE HUMAN FERTILISATION AND EMBRYOLOGY (SPECIAL EXEMPTION) REGULATIONS 2009

2009 No. 1918

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 in 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 the following changes to the 1990 Act made by the Human Fertilisation and Embryology Act 2008 ("the 2008 Act"): the new definitions of embryo and gametes; and the regulation of human admixed embryos. The new regulations also make minor drafting changes. The Regulations are being re-made in consequence of the provisions of the 2008 Act 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 also used in the 1991 Regulations were amended by the 2008 Act. The 2008 Act also updates the 1990 Act to take account of technological advances which allow embryos to be created without the need for fertilisation and brings human admixed embryos within regulation. The Regulations have been updated to reflect these changes. Minor drafting changes have also been made.

4.2 The Regulations are consequential to the implementation of the provisions of the 2008 Act and do not represent any change to Government policy.

5. Territorial Extent and Application

5.1 The Regulations extend to all of the United Kingdom.

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[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 exceptions to the general position that a person who keeps or uses human embryos or who stores human gametes may only do so if they have a licence from the HFEA.

7.2 The first exception refers to cases where an offence under the 1990 Act is being investigated or proceedings are taking place in relation to such an offence. Embryos may be kept and examined and gametes may be stored without a licence from the HFEA in these specific circumstances. Any such embryos or gametes will have been seized by the Authority or transferred to a place where they are now on the instructions of the Authority.

7.3 However, access to the gametes or embryos should be limited to the people concerned with that particular investigation. The Regulations also specify that the containers holding any embryos or gametes must be labelled to ensure they are easily distinguishable from any other gametes and embryos kept in the same place and if possible they must be kept in such a way that their condition does not deteriorate.

7.4 The second exception effectively allows the storage of gametes without a licence, provided they are only to be used for certain purposes These purposes are:

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

7.5 However even if the gametes are intended for one of the purposes set out above, a storage licence must still be obtained if it is intended that one of the following activities will be carried out:

- the mixing of live sperm with live eggs,
- the bringing about of any human embryo
- the bringing about of any human admixed embryo
- 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

Stephanie Croker at the Department of Health Tel: 020 797 23054 or email: Stephanie.croker@dh.gsi.gov.uk can answer any queries regarding the instrument.