EXPLANATORY MEMORANDUM TO

THE HUMAN FERTILISATION AND EMBRYOLOGY (PROCEDURE ON APPLICATIONS AND EXECUTION OF WARRANTS) REGULATIONS 2010

2010 No. 726

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1. The Human Fertilisation and Embryology (Procedure on Applications and Execution of Warrants) Regulations 2010 ("the Regulations") fulfil two purposes. Firstly, where the Licence Committee of the Human Fertilisation and Embryology Authority (HFEA) are determining an application for the grant, revocation or variation of a licence at a hearing, the Regulations provide power to require the production of evidence or attendance by a witness.

2.2. Secondly, the Regulations set out the information that must be included in the statement that is given to the occupier of premises ("the appropriate statement"), when a warrant is being executed.

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

3.1. Regulation 10 of the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009[1] previously made provision for attendance at a hearing or to produce documents. That regulation was reported by the Committee in its 23rd Report of 2008-9 on the ground of doubtful vires and was subsequently revoked.[2]

4. Legislative Context

4.1. The Human Fertilisation and Embryology Authority may only execute a warrant to enter and search premises if they can provide the occupier of the premises to which the warrant relates with a copy of the warrant and an appropriate statement.

4.2. It is a requirement of Schedule 3B to the Human Fertilisation and Embryology Act 1990 ("the 1990 Act") as amended by the Human Fertilisation and Embryology Act 2008 ("the 2008 Act") that the contents of the appropriate statement be prescribed by the Secretary of State in regulations. Without an appropriate statement, the HFEA cannot lawfully execute a warrant, which Parliament has clearly provided for them to do. The regulation is therefore necessary.

4.3. Regulation 2 empowers the HFEA Licence Committee when it is hearing representations about a proposed decision to summons witnesses and require documents. This power is limited to the determination of applications, therefore the Licence Committee cannot use this power in relation to hearings about proposed

[1] S.I. 2009/1397. The Regulations were made by the HFEA under powers conferred by section 19(6) of the 1990 Act.

[2] Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) (Amendment) Regulations 2009 S.I. 2009/2088

decisions on revocations, suspensions and variations of licences, which are not the result of an application, but brought at the instigation of the HFEA.

4.4. This is the first time the powers concerned have been exercised.

5. Territorial Extent and Application

5.1. This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1. The Regulations fulfil two purposes. They set out the powers available to the HFEA Licence Committee to summons witnesses or require the production of documentary evidence and set out the information to be included in the appropriate statement necessary for executing a warrant.

7.2. The Regulations set out details of powers the HFEA Licence Committee have to summons witnesses and documentary evidence. This power is only applicable to cases where an application is being determined, and not those resulting from action at the instigation of the HFEA.

7.3. The Regulations set out details of the information that should be included in an appropriate statement. A warrant cannot be executed without an appropriate statement to accompany it.

7.4. The regulation making power in Schedule 3B reflects that of the Human Tissue Act 2004[3], which also allows for regulations to set out the information that must be included in the appropriate statement for a warrant to be executed.

- ***Consolidation***

7.5. These are new powers and consolidation is not applicable.

8. Consultation outcome

8.1. The Department of Health has worked closely with the HFEA whilst drafting these Regulations.

8.2. It was not thought necessary to hold a formal 12 week consultation on the Regulations for two reasons. The regulations follow through the policy intentions of the 1990 Act, as amended.

8.3. Secondly, the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009, which contained provision about attendance at Licence Committee hearings and the production of documents, was fully consulted upon. During the course of the consultation on these regulations, no objections were raised to the use of powers to summons witnesses and documentary evidence by the HFEA.

[3] Schedule 5 to the Human Tissue Act 2004

8.4. The consultation report on the HFEA licensing Regulations can be found on the Department of Health website.

9. Guidance

9.1. The HFEA will communicate with licensed centres about the appropriate statement and the changes to the powers to summons evidence by the Licence Committee.

10. Impact

10.1. The impact on business, charities or voluntary bodies will be negligible.

10.2. The impact on the public sector will be negligible.

10.3. An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1. The legislation applies to small business. Many licensed clinics (which are predominantly private sector based) and research centres fall within the definition of small businesses (having less than 20 staff).

11.2. The Regulations are likely to have a neutral impact on firms employing less than 20 staff. The increased clarity around the powers of the Licence Committee and the execution of warrants will be of benefit to all licensed centres, regardless of their size.

12. Monitoring & review

12.1. The HFEA will undertake monitoring and review of the licensing process. 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.

12.2. In addition to this, a review of the regulations will be undertaken as part of the work reviewing the 2008 Act, which will take place in November 2012.

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.