

## Human Fertilisation and Embryology Authority

### Minutes of the Statutory Approvals Committee

Meeting held at Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on  
**26 February 2015**

#### Minutes – Item 5

**Centre 0035 (Oxford Fertility Unit) – Application for Special Directions to export patient sperm to IVI Alicante, Alicante, Spain.**

<b>Members of the Committee:</b>	David Archard (Chair, lay) Jane Dibblin (lay) Sue Price (professional) Tony Rutherford (professional)
<b>Legal Adviser:</b>	Philip Grey, Mills and Reeve
<b>Members of the Executive:</b>	Sam Hartley – Head of Governance and Licensing Trent Fisher – Secretary

Declarations of Interest: members of the committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the committee:

- Executive Summary
- Application Form
- Additional information form
- Letter from proposed receiving centre
- Article and abstract (studies of advanced paternal age and risk of autism)
- SAC minutes from July 2014

The committee also had before it:

- HFEA Protocol for the conduct of licence committee meetings and hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and

- Guidance for members of Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

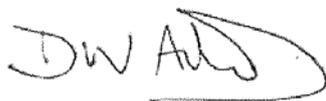
## Discussion

1. The committee noted that this centre has applied for special directions to export two straws of patient sperm to IVI Alicante, Alicante, Spain.
2. The committee noted that the HFEA Act 1990 (as amended) permits the Authority to issue directions to allow the export of gametes or embryos to countries outside the United Kingdom. Furthermore, the committee noted that if a licensed centre meets all requirements set out by General Directions 0006, of which there are nine, export is permitted without the need for a Special Direction.
3. The committee noted that this application for a Special Direction is being made because the centre is unable to export the sperm under the auspices of General Directions 0006 because they are not able to meet the requirements of section (d) and (f) of schedule 2 of General Directions 0006:
  - (d) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits; and
  - (f) the gametes or embryos are not exported if they cannot be lawfully used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre.
4. The committee noted specifically that the sperm will be used in the fertilisation of donor eggs that have been procured from an anonymous egg donor in the Spain. Creating an embryo from sperm and an anonymously donated egg in the UK would not be lawful. The committee regarded the UK requirements for identifying donors to be important. Special directions would not be granted routinely, or where the purpose or dominant effect appeared to be to circumvent those requirements.
5. The committee noted that the patient couple have undergone a total of seven fresh IVF cycles and one frozen embryo replacement cycle which have all been unsuccessful. On their latest cycle only one mature egg was obtained which failed to fertilise. The male partner is azoospermic and underwent an SSR in 2004 which has been used in all of their treatments.
6. The committee noted that the couple wish to seek treatment in Spain as the waiting times for egg donation are considerably shorter and the success rates are higher than treatment in the UK.

7. The committee noted that the gametes were provided by the male partner in 2004. The committee was advised by the legal advisor that under The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, gametes may only lawfully be stored for a period in excess of ten years if:
  - the person who provided the gamete in question has consented, in writing, to it being stored for over ten years for the provision of treatment services; and
  - within the initial ten year period, a registered medical practitioner has given a written opinion that the person providing the gametes is prematurely infertile or is likely to become prematurely infertile.
8. The committee considered that, in the light of the age of the stored gametes and the application to export them, it required confirmation that these specific statutory requirements for the storage of sperm beyond a 10-year period had been met.
9. The committee further noted that the application states 'In Spain, the choice and availability of donors is far greater and the couple could be matched immediately to a donor who fits their criteria' but that it was not clear exactly what the criteria were (other than being young). The committee considered that this information would be useful when assessing the merits of the case.
10. The committee asked the centre to provide further information so that the committee could consider the application, specifically:
  - A signed consent form from the centre stating the patient's sperm can be stored for a period in excess of ten years,
  - The accompanying written opinion, from within the initial ten-year period, from a registered medical practitioner regarding the male partner's infertility, and
  - An explanation of the criteria the patient couple have for a donor.
11. The committee agreed to adjourn consideration in order that further information could be obtained from the centre. The committee asked that the minutes were expedited in order that it could reconsider the application at its earliest possible next meeting.

Signed:

Date: 6 March 2015

A handwritten signature in black ink, appearing to read 'DWA', with a large, sweeping underline that extends to the right.

David Archard (Chair)