

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 March 2015

Minutes – item 5

Centre 0078 (Hammersmith IVF) – Special Directions to import embryos from the USA

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| Members of the Committee: | David Archard (Chair, lay) Sue Price (professional) Debbie Barber (professional) Tony Rutherford (professional) |
| Legal Adviser: | Dawn Brathwaite – Mills & Reeve |
| Members of the Executive: | 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
- Special Directions further information form
- Minutes from the Compliance Committee meeting on 7 November 2012
 - Special Directions minutes, import sperm from USA, centre 163
- documents submitted in support of the application

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)
- guidance for members of the 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 the publication of Authority and committee papers.

Discussion

1. The committee noted that the centre has applied for Special Directions to import nine embryos from HRC Fertility, Pasadena, California, USA.
2. The committee noted that the HFE Act 1990 (as amended) permits the Authority to issue directions to allow the import of gametes or embryos from countries outside the United Kingdom. Furthermore, the committee noted that if a licenced centre meets all requirements set out by section 1 of schedule 3 of General Directions 0006, of which there are ten, import is permitted without the need for Special Directions.
3. The committee noted that this application for Special Directions is being made because the centre is unable to import the embryos under the auspices of General Directions because it is not able to meet the requirements of:
 - a) section 1(e) of schedule 3 of General Directions 0006: the person who provided the gametes is (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, are) identifiable;
 - b) section 1(f) of schedule 3 of General Directions 0006: the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being imported into the United Kingdom; and
 - c) section 1(g) of Schedule 3 of General Directions 0006: before giving consent, the person(s) referred to in paragraph (f) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the United Kingdom as in the country from which the gametes or embryos are to be imported, and have been given further information which they may require.
4. 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 in June 2011 whilst the patient was living in the USA she was diagnosed with breast cancer. Before undergoing treatment she had eggs extracted and embryos created with the use of donated sperm. The patient later had her ovaries removed to reduce the risk of reoccurrence of cancer.
6. The committee noted that due to circumstances outside her control, the patient has returned to live in the UK. The patient now wishes to import the embryos to commence IVF treatment. The patient has stated that she is unable to return to the USA and commence treatment due to caring responsibilities in this country and the considerable financial cost of flights, as well as the impact the stress would have on her chances of a successful birth.
7. The committee noted that the donor used to create the embryos is currently unidentifiable as the centre in USA is unable to contact him because he is no longer part of the program.
8. The committee noted that without the import of the embryos the patient would be unable to carry a biological child as she is now infertile following cancer treatment.
9. The committee were reminded by their legal adviser that any previous decision made in relation to import of gametes or embryos would not determine the outcome for future applications for Special Directions as each application must be decided on the individual circumstances of each case.
10. The committee were further advised by the legal adviser that the Special Directions, if granted, should provide the mechanism by which the imported embryos can be used by the centre. Section 24(4) of the HFEA Act 1990 provides that [special] directions may authorise any person to whom a licence applies to receive gametes from outside the United Kingdom ;in such circumstances and subject to such conditions as may be specified in the directions...'. The Committee accepts the legal advice that the remit of the power to make directions is quite broad and permit conditions which can include 'use', quality and safety.

Decision

11. The committee concluded that refusal to issue Special Directions in this case would interfere with the patients' right in EU Law to obtain medical treatment abroad as the applicant wishes to import her embryos to a UK centre for treatment.
12. The committee also concluded that a refusal would interfere with the applicant's Article 8 right of the European Convention of Human Rights, right to respect for private and family life.

13. The committee concluded that having regard to the impact on the applicant given that this was her only chance of founding a family that was biologically related to her, the donor had consented at the time the gamete was created and the applicant found herself in circumstances outside her control., that Special Directions should be issued.
14. The committee therefore agreed to grant a Special Direction in this case for the import and use of the nine embryos held at HCR Fertility.
15. The committee concluded that the current case involves a highly exceptional set of circumstances. Accordingly, granting Special Directions for the application would not represent an undesirable precedent, which would undermine the imperative requirements identified.

Signed:

Date: 7 April 2015

A handwritten signature in black ink, appearing to read 'DWA' followed by a stylized flourish.

David Archard (Chair)