

Human Fertilisation and Embryology Authority

Minutes of the Statutory Approvals Committee

Meeting held at Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
30 July 2015

Minutes – Item 5

Centre 0301 (London Women’s Clinic, Wales) – Application for Special Directions to import sperm from Cryos International, Denmark

Members of the Committee:	David Archard (Chair, lay) Rebekah Dundas (Deputy Chair, lay) Sue Price (professional) Margaret Gilmore (lay) Bishop Lee Rayfield (lay)
Legal Adviser:	Jane Williams, Mills & Reeve
Members of the Executive:	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
- e-mail correspondence between Centre 0301 and Cryos International and between Centre 0301 and the Authority

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 centre 0301 has applied for Special Directions to import two straws of donor sperm from Cryos International, Denmark.
2. The committee noted that in 2013 donor sperm from Cryos International was imported and used in IVF for the patient, resulting in a successful pregnancy. The same patient now wishes centre 0301 to import sperm from the same donor to commence further IVF treatment. The applicant wishes to use the same donor, in order to create a full genetic sibling.
3. The committee noted that the Human Fertilisation and Embryology 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 licensed centre meets all seven requirements set out in section 1 of Schedule 1 to General Directions 0006, import is permitted without the need for Special Directions.
4. The committee noted that this application for Special Directions is being made because the centre considers that it is unable to import the donor sperm under the auspices of General Directions 0006 because it is not able to meet the requirements of section (c), (e) and (g) of Schedule 1 of General Directions 0006:
 - (c) 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;
 - (e) 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
 - (g) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice that is currently in force.
5. The committee noted that, at the time the samples were produced, the donor had not completed the relevant HFEA consent forms. The donor produced further samples, signed the relevant consent forms and registered as a HFEA donor.
6. The committee noted the opinion of the Executive that, where a donor has consented to the import of donor sperm to the UK and that consent has not been withdrawn, the requirement of section 1(c) of Schedule 1 to General Directions 0006 is satisfied.

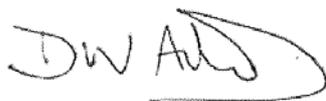
7. The committee accordingly concluded that the criteria in section 1(c) of Schedule 1 to General Directions 0006 have been fulfilled.
8. The committee noted that the donor sperm stored at Cryos International have not been screened for CMV (cytomegalovirus). The committee noted, however, that the Authority no longer requires donated gametes to be screened for CMV.
9. The committee accordingly concluded that the criteria in section 1(g) of Schedule 1 to General Directions 0006 have been fulfilled.
10. The committee noted that the samples in question were produced before the donor was signed off as 'UK compliant' and that it is therefore likely that the money or benefit received for the donation did not comply with the prescribed amounts set out in General Directions 0001 although there was no positive evidence of non-compliance.
11. The committee noted that the Authority places considerable importance on the principles of altruistic donation. Special Directions should not be granted routinely, or where the purpose or dominant effect appears to be to circumvent this policy.
12. The committee noted that the importance of creating full genetic siblings whenever possible is widely recognised, not least by the Authority.

Decision

13. The committee concluded that a refusal to issue Special Directions in this case would interfere with the right to respect for private and family life under Article 8 of the European Convention on Human Rights (ECHR).
14. The committee weighed the issue of the donor receiving money or benefit exceeding the prescribed amounts set out in General Directions 0001 against the interference with the patient's rights under Article 8 of the ECHR involved in denying her the only chance remaining to create a full genetic sibling to her child, given that this donor is no longer donating. After careful consideration, the committee concluded that, taking all factors into account, refusing this application would constitute an unjustified interference with the patient's Article 8 rights and that Special Directions should accordingly be issued.
15. The committee agreed to issue Special Directions in this case for centre 0301 to import two straws of donor sperm from Cryos International, Denmark.
16. The committee concluded that the current case involves a highly exceptional set of circumstances. Accordingly, granting this application for Special Directions would not set an undesirable precedent which would undermine the imperative requirements identified.

Signed:

Date: 12 August 2015

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

David Archard (Chair)