

HFEA Statutory Approvals Committee Meeting **29 August 2013**

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 2

Centre 0070 (The Bridge Centre) – Application for Special Directions

Members of the Committee: David Archard (lay) Chair Sue Price (professional) Rebekah Dundas (lay) Debbie Barber (professional) Jane Dibblin (lay)	Committee Secretary: Lauren Crawford Legal Adviser: Graham Miles, Morgan Cole
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Declarations of Interest: members of the Committee declared that they had no conflicts in relation to this item.

The following papers were considered by the Committee

- Cover sheet
- Executive Summary
- Application form
- Correspondence from proposed transferring

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)
- 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

The Application

1. The Committee considered an application by the Centre for a Special Direction to import four embryos from IVI Valencia, Spain.

2. The Centre was unable to import the embryos under the auspices of General Directions 0006 because they would not meet the requirements of conditions (a) and (b) in Schedule 1 to the General Directions, namely:
 - (a) both persons whose gametes were used to create the embryos are not identifiable as the embryos were created using donor eggs from a non-identifiable Spanish donor and the patient's partner's sperm, and
 - (b) the egg donor had not consented to the export of the embryos.
3. The Committee noted that the couple already have a child from the same egg donor and now wished to import the remaining four embryos for a sibling pregnancy. The embryos were created in August 2005. The couple wished to import the embryos as the woman on whose behalf the Special Direction is sought has had breast cancer, for which she has received treatment and would not now be able to carry a pregnancy. The couple have to resort to surrogacy, which is not permitted in Spain.
4. The Committee was invited to consider licence condition SLC T54, which is a standard licence stating that embryos from non-identifiable donors must not be used in treatment services, other than in specified exceptional circumstances. The Committee was invited to consider whether treatment services could lawfully be provided in accordance with one of those exceptions, if a Special Direction were to be made in this case.

Legal Advice

5. The Legal Adviser advised that it was appropriate for the Committee to consider the issue concerning licence condition SLC T54 before deciding whether to make a Special Direction. The interpretation of the licence condition might be relevant to the exercise of discretion involved in making a Special Direction.
6. Licence Condition SLC T54 states:

Gametes from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

- (a) The gametes were supplied to the centre before 1 April 2005; and**
- (b) The woman having treatment (or the person that she is having treatment with) has a child that was conceived from the gametes before 1 April 2006; and**
- (c) The gametes are to be used to create a genetically related sibling for that child**

Embryos from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

- (a) The embryos were created before 1 April 2005; and**
- (b) The woman having treatment (or the person that she is having treatment with) has a child that was conceived from the embryos before 1 April 2006; and**
- (c) The embryo is to be used to create a genetically related sibling for that child.**

Embryos which were created before 1 April 2006, and which were created using the gametes of the woman to be treated (or the person that she is being treated with) and the gametes of a non-identifiable donor, may continue to be used in treatment (regardless of whether or not there are any existing genetically related siblings).

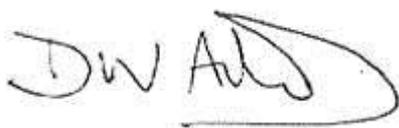
7. The Legal Adviser advised that SLC T54 envisaged three exceptional circumstances. The first and second exceptions were concerned with the creation of a genetically related sibling, as in this case. However, the first exception did not apply as the gametes had not been supplied to the licensed centre in the UK before 1 April 2005. The second exception did not apply because the embryos had been created before 1 April 2005.
8. In considering the third exception and interpreting the meaning of 'woman to be treated', the Committee was entitled to consider the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009. These regulations defined 'person to be treated' as including, either:
 - 'the woman whom it is intended will be provided with treatment services using the embryo or gamete in question', (which, in this case, would be the surrogate), or
 - 'the woman who the embryo in question has been allocated to by a person to whom a licence applies', (which in this case would be the woman on whose behalf the special directions are sought).
9. Given that the embryos were created before 1 April 2006 and were created using the sperm of the male partner of the couple on whose behalf a Special Direction is sought, the Committee may be satisfied that the third exception to SLC T54 would apply. If so satisfied, the Committee could take into account when determining the application for a Special Direction that, had all of the previous treatment taken place in the UK, the treatment services could lawfully be carried out, despite the fact that the egg donor is not identifiable.

The Committee's Decision

10. Although the egg donor has not consented to the embryos being exported to the UK, the Committee noted that the exporting centre has stated that, under Spanish law, an egg donor is not required to give written consent to the storage of export of gametes or embryos.
11. The Committee noted that, as surrogacy is required which cannot be carried out in Spain, the only way in which the couple could have a genetically related sibling is by the embryos being imported to the UK. The Committee was satisfied that a refusal to make a Special Direction would involve interference with the couple's rights to obtain medical treatment services abroad and an interference with their rights under Articles 8 and /or 12 of the European Convention on Human Rights. The Committee concluded that interference with these rights would not be justified or proportionate in the particular circumstances of this case.
12. Without the Special Direction to import the embryos, the couple would be unable to have a genetically related sibling for their existing child and that it was reasonable for the couple to seek to achieve this. It would be in the interests of both siblings to use the same donor and the siblings would be equal in their knowledge about of the donor.
13. It would be excessive in this case to seek to uphold the principle of donor by refusing the application for a Special Direction. In making this determination, the Committee took into account the fact that, had the treatment services to date been carried out in the UK rather than in Spain, the treatment services could lawfully be carried out notwithstanding the fact that the egg donor is not identifiable.
14. The Committee agreed to make the Special Direction authorising the import of the four embryos from IVI Valencia, Spain.

Signed:

Date: 12/09/2013

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

David Archard (Chair)