

Statutory Approvals Committee – minutes

Centre 0008 (IVI Midland)

Special Directions application to Export Sperm to Spain for patient's own use

Thursday, 27 July 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members

Margaret Gilmore (Chair)
Anne Lampe
Ruth Wilde
Bobbie Farsides

Members of the Executive

Dee Knoyle

Secretary

External adviser

Legal Adviser

Dawn Brathwaite

Mills & Reeve LLP

Observers

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

The following papers were considered by the committee:

- Executive Summary
- Special Directions Application Form
- Further Information form
- Letter from the receiving centre required by General Directions (0008)

1. Background

- 1.1. IVI Midland, centre 0008 has applied for Special Directions to export seven vials of sperm, for a patient's own use, to IVI Barcelona located in Spain.
- 1.2. The patient wishes to use an anonymous egg donor from Spain to create embryos. The centre is unable to export if they cannot lawfully be used in licensed treatment services in the UK in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre. The centre is unable to export due to the proposed use of an anonymous egg donor to create embryos which is not lawful in the UK.

2. Consideration of application

- 2.1. The committee considered the application which included an executive summary, Special Directions application form and a letter from the receiving centre.
- 2.2. The committee noted that the HFE 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, in relation to the export of gametes within the EEA, where the conditions set out by schedule 2 of General Directions 0006, of which there are seven, are all satisfied, export is permitted without the need for a Special Direction.
- 2.3. The committee noted that since 1 April 2005, the HFEA had required donors to be identifiable, to enable donor conceived children, potentially, to have access to information about their gamete donor. This reflected recognition of the rights (under Article 8 of the ECHR) of children born from IVF to information in respect of their genetic identity.
- 2.4. The committee noted that the Authority has placed importance on the principles of known donation. The HFEA has a statutory duty to uphold the scheme and uphold compliance with the Act, and as a consequence, Special Directions would not be granted routinely or where the purpose or dominant effect appeared to be to circumvent those requirements set out in General Directions 0006
- 2.5. The Court of Appeal, in considering the Blood case, set out a list of tests that the Authority would need to meet in considering an application to overrule the provisions of General Directions 0006.
- 2.6. The principle tests have been applied to this particular application.

Principle 1

- 2.7. The committee noted that the centre is unable to export the patient's sperm under General Directions 0006 because the requirements of part 1(b) of Schedule 2 cannot be met:
b) 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.
- 2.8. The committee noted that the couple want to pursue treatment in Spain using an anonymous egg donor as they do not want to wait for a suitable donor to become available in the UK.
- 2.9. The committee noted that the patient's sperm was stored before he had surgery and treatment for colorectal cancer, which may have resulted in infertility.

Principles 2, 3,4 and 5

- 2.10.** The committee considered whether a refusal would be an interference with the individual's right to obtain medical services abroad and/or rights under the Human Rights Act 1998, for example; the right to marry and found a family (under Article 12); the right to respect for private and family life (under Article 8); the right not to be discriminated against because of age (under Article 14).
 - 2.11.** The committee noted that the patient wishes to export his sperm to Spain to be used with his partner using donated eggs. Egg donation is anonymous in Spain and therefore it is not covered by the General Direction.
 - 2.12.** The committee noted that an alternative to exporting sperm samples would be to request that the patient travels to Spain to produce another sample of sperm. However, in this case it has been stated that the patient had sperm stored prior to undergoing surgery and treatment for colorectal cancer which may have resulted in infertility.
 - 2.13.** The committee noted an alternative to travelling to Spain for treatment is for the couple to have treatment using donor eggs in the UK. However, in this case it has been stated that the couple do not wish to wait for a suitable donor to become available in the UK.
 - 2.14.** The committee noted that no information was provided as to whether the patient could produce a sample and/or could produce viable sperm. The Legal Adviser pointed out that the application simply stated that he had treatment which 'may' have resulted in infertility and the committee had to consider what conclusions they could therefore draw from this on the facts.
 - 2.15.** The committee noted that no information was provided as to why this particular couple would have to wait for a suitable donor in the UK, and the length of such wait. The committee is aware from publicly available information that the waiting time for Caucasian donors within a 50 mile radius of this clinic is 3-6 months. No reason has been offered as to the peculiar circumstances of this couple that would take them outside of this waiting time.
 - 2.16.** The committee noted that these were important facts in determining whether a refusal would be an interference with the patients' rights under the HRA 1998, having regard to the social imperative here and the need for any interference to be proportionate.
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3. Decision

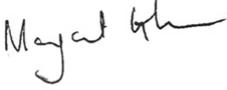
- 3.1.** The committee had regard to its decision tree.
- 3.2.** The committee noted that the patient wishes to export his sperm to Spain to be used with his partner using an anonymous egg donor. The committee considered the grounds for the application being the possible infertility of the patient and the desire of the couple not to wait for a suitable donor to become available here.
- 3.3.** After careful consideration and after taking all factors into account including the Principles as set out in the Blood case, and after working through the decision tree, the committee was unable to grant Special Directions in this particular case for the following reasons:
 - a) The committee decided that it did not have adequate information to conclude that the patient, having been treated for cancer, was definitely not now able to produce viable sperm which could enable him to travel to Spain to give a new sample.
 - b) The committee decided it did not have adequate information from the patient concerning waiting times for a suitable egg donor in the UK, in particular information on the type of donor and the waiting times available within an appropriate distance, to this particular clinic.

- 3.4.** The committee therefore concluded that without further information, even where Articles 8 and/or 12 have been engaged, interference in the rights outlined in the HRA, 1998, can be justified.
- 3.5.** The committee concluded that the information provided did not amount to exceptional circumstances and therefore decided in this particular case that Special Directions would not be granted.
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4. Chair's signature

- 4.1.** I confirm this is a true and accurate record of the meeting.

Signature

A handwritten signature in black ink, appearing to read "Margaret Gilmore", is contained within a white rectangular box.

Name

Margaret Gilmore

Date

14 August 2017