

Statutory Approvals Committee – minutes

Centre 0094 (Barts Health Centre for Reproductive Medicine)

Special Directions application to export sperm to Pakistan for patient's own use

Thursday, 30 August 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Ruth Wilde	
Members of the Executive	Catherine Burwood Bernice Ash Paula Robinson Stevan Cirkovic	Committee Secretary Committee Secretary (Observer) Head of Planning and Governance (Observer) Policy Officer (Observer)
External adviser		
Legal Adviser	Jane Williams	Mills & Reeve LLP
Apologies	Anthony Rutherford	

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
- General Directions 0006 (2018)
- HFEA Standing Orders (2018)
- Special Directions Decision Tree (2018)

The following papers were considered by the committee:

- Executive summary
- Application form to export sperm
- Further information form
- Letter of acceptance from proposed receiving centre

1. Background

- 1.1. The Person Responsible (PR) at Barts Health Centre for Reproductive Medicine, centre 0094, has applied for the issue of Special Directions to export one vial of sperm to Pakistan.
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2. Consideration of application

- 2.1. The committee noted that centre 0094 has applied for Special Directions to export sperm to Pakistan for a patient's own use. A suitably completed application form and further information form was received by the Executive.
- 2.2. Prior to oncology treatment, the patient provided sperm samples to the centre for cryopreservation. The patient is now infertile and will require intracytoplasmic sperm injection (ICSI) treatment with his partner in order for them to conceive. The patient wishes to move some of the preserved sperm samples to Pakistan, as the couple wish to have treatment there.
- 2.3. The centre has assessed that it is unable to export the sperm under the auspices of General Direction 0006 because the following requirement of Schedule 4 cannot be fully met:
- paragraph 1(a): the receiving centre is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated.
- 2.4. The committee noted that paragraph 1(a) of Schedule 4 cannot be met as there is currently no government authority or legislation that governs, or quality assures, in vitro fertilisation (IVF) laboratories in Pakistan. The receiving centre has however been accredited with the International Organisation for Standardisation (ISO) since January 2017.
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3. Decision

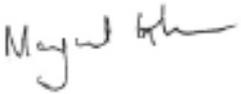
- 3.1. The committee had regard to General Direction 0006.
- 3.2. The committee had regard to the Authority's statutory duty to promote, in relation to activities governed by the Act, compliance with requirements imposed by or under the Act.
- 3.3. The committee noted that Special Directions have been applied for because paragraph 1(a) of Schedule 4 of the General Directions cannot be met.
- 3.4. The committee noted that the patient and his partner require fertility treatment in order to become parents, as the patient is infertile following treatment for cancer. Samples were frozen prior to his treatment, in 2014. The patient wishes to export one vial of sperm to Pakistan in order to have treatment there.
- 3.5. The committee considered whether it should vary the General Directions in order to address the inability to comply with the General Directions.
- 3.6. The committee noted that the receiving centre in Pakistan is ISO accredited, indicating that it operates to a certain standard of quality, and acknowledged that this may be the best standard that can realistically be achieved in Pakistan, in the absence of a regulatory framework akin to that established by the Human Fertilisation and Embryology Act 1990.
- 3.7. The committee considered whether a refusal to vary the General Directions would unjustifiably interfere with the patient's human rights, in particular Articles 8 and 12 of the European Convention on Human Rights (the right to respect for a private and family life, and the right to marry and found a family).

- 3.8.** The committee weighed the issue of the clinic's lack of accreditation under a regulatory framework akin to that existing in this country against the potential interference with the patient's rights under Articles 8 and 12 involved in denying him and his partner the chance to create a family now that the patient is infertile following treatment for cancer.
- 3.9.** After careful consideration, the committee, taking all factors into account, considered that a refusal to issue Special Directions to export this patient's sperm to a centre in Pakistan for use in treatment with his partner would constitute a disproportionate interference with his human rights.
- 3.10.** The committee concluded that the current case involved a highly exceptional set of circumstances and agreed to issue Special Directions to allow the export of the patient's sperm to the Australian Concept Infertility Medical Centre in Pakistan.
- 3.11.** The committee considered that granting Special Directions for this application would not set an undesirable precedent which would undermine the imperative requirements identified.
- 3.12.** The committee, therefore, determined that Special Directions should be granted.
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4. Decision

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

Signature



Name

Margaret Gilmore

Date

4 October 2018