

Statutory Approvals Committee – minutes

Centre 0030 (Herts & Essex Fertility Centre)

Special Directions application to import embryos from the United States of America (USA) for patient's own use

Thursday, 30 November 2017

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members

Margaret Gilmore (Chair)
Anne Lampe
Tony Rutherford
Bobbie Farsides

Members of the Executive

Dee Knoyle

Committee Secretary

External adviser

Professor Shamima Rahman

Legal Adviser

Philip Grey

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
- Application form
- Special Directions further information form

1. Background

- 1.1. The Person Responsible at Herts & Essex Fertility Centre, centre 0030 has applied for Special Directions to import two embryos from the Genetics and IVF institute, Virginia, USA.
- 1.2. The couple seeking treatment with these embryos had previously been treated, unsuccessfully, in the UK in 2007, 2008 and 2009, using the female partners' own eggs and partner sperm. The female patient became post-menopausal in 2015 and required donor eggs for fertility treatment. Due to the shortage of suitable ethnically matched donor eggs in the UK, the couple travelled to the USA for treatment using donor eggs and partner sperm. Two fresh treatment cycles and two frozen embryo replacement cycles were unsuccessful and two embryos now remain in storage.
- 1.3. The centre is unable to import the embryos under General Direction 0006 because the embryos were created using eggs from a non-identifiable donor. The egg donor also received expenses greater than those permitted by General Direction 0001.
- 1.4. The couple are resident in the UK and now wish to arrange the transport of their two remaining frozen embryos to enable them to receive treatment in the UK.

2. Consideration of application

- 2.1. The committee noted that centre 0030 has applied for Special Directions to import two embryos from the Genetics and IVF institute, Virginia, USA

Human Fertilisation and Embryology Act 1990 (as amended) Section 24

General Directions 0006, Schedule 3, Part 1(e) and (h)

- 2.2. The committee noted that section 24(4) of the HFEA Act 1990 (as amended) permits the Authority to issue directions to allow the import of gametes or embryos from countries outside the United Kingdom. The committee further noted that, in relation to the import of gametes and embryos from outside the European Economic Area and Gibraltar, import can be permitted without the need for directions if the conditions in schedule 3 to General Directions 0006 are satisfied.

- 2.3. The committee noted that the centre is unable to import the embryos under General Direction 0006 because the requirements of part 1(e) and (h) of Schedule 3 cannot be met.

Part 1(e) of Schedule 3 of the General Direction provide as follows:

- 2.4. *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.*

Part 1(h) of Schedule 3 of the General Direction provide as follows:

- 2.5. *no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefits paid or 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.*

Identifiable gametes – patients used unidentifiable donor eggs

- 2.6. The centre is unable to comply with part 1(e) of the General Direction because the patients' embryos were created using eggs from a non-identifiable donor.
- 2.7. **Money or benefits paid or received in accordance with Directions 0001 – egg donor's expenses greater than those permitted**
- 2.8. The centre is unable to comply with part 1(h) of the General Direction because the patients' egg donor received expenses greater than those permitted by General Direction 0001.

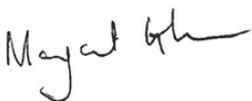
3. Decision

- 3.1. The committee had regard to General Direction 0006 and Directions 0001.
- 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. In considering the application, the committee had regard to the principles (tests) derived from the decision of the Court of Appeal in the *Blood* case and from rights arising under the Human Rights Act 1998.
- 3.4. The committee noted that Special Directions have been applied for because Part 1(e) and (h) of Schedule 3 of the General Direction could not be met.
- 3.5. The committee noted that the couple had treatment in the UK, using the female patient's own eggs and male partner's sperm but this was unsuccessful. The female patient became post-menopausal in 2015 and travelled to the USA to find ethnically matched donor eggs and had treatment with her partner's sperm. The couple travelled to the USA for treatment due to a shortage of donor eggs and long waiting list in the UK. The patients now have two embryos remaining in storage in the USA and would like to import them into the UK for their own use.
- 3.6. The committee considered whether a refusal to make Special Directions would be an interference with the patients' rights under Articles 8 and/or 12 of the European Convention on Human Rights and whether such interference would be justified and proportionate. The committee decided that refusal may amount to interference in that the patient's wish to import their embryos into the UK for treatment using the embryos created with the male partner's sperm. The committee agreed that a refusal to issue Special Directions to import the two remaining embryos into the UK would not be proportionate as the patients have been trying to have a child for over 10 years. The patients have expressed that due to their religious values they would not choose to allow the embryos to perish. The couple found the travel to the USA for treatment stressful and believe that they have a better chance of successful treatment if they stay in the UK.
- 3.7. The committee concluded that, taking all the factors into account, including the age of the patients and their history trying for a child of their own, the current case involves a highly exceptional set of circumstances and agreed to issue Special Directions to allow the import of the patients' two remaining embryos to Herts and Essex Fertility Centre, centre 0030 in the UK.
- 3.8. The committee considered that granting Special Directions for this application would not set an undesirable precedent which would undermine the imperative requirements identified.

4. Decision

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

Signature



Name

Margaret Gilmore

Date

19 December 2017