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 couple's own use

Thursday, 26 April 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Anthony Rutherford	
Members of the Executive	Dee Knoyle Bernice Ash Paula Robinson Catherine Burwood Clare Ettinghausen	Committee Secretary Committee Secretary (Observer) Head of Planning & Governance (Observer) Senior Governance Manager (Observer) Director of Strategy & Corporate Affairs (Observer)
External adviser		
Legal Adviser	Gerard Hanratty	Browne Jacobson 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
- General Directions 0001 (2015)
- General Directions 0006 (2018)
- General Directions 0013 (2018)
- HFEA Standing Orders (2018)
- Special Directions Decision Tree (2018)

The following papers were considered by the committee:

- Executive summary
- Original application form
- Original Special Directions further information form
- New application form
- New Special Directions further information form
- Minutes of the Statutory Approvals Committee meeting 30 November 2017
- Special Directions issued 19 December 2017

1. Background

1.1. The Person Responsible (PR) at Herts & Essex Fertility Centre, centre 0030 has applied for Special Directions to import two frozen embryos from the Genetics and IVF institute, Virginia, USA.

1.2. The patient couple had previously been treated, unsuccessfully, in the UK in 2007, 2008 and 2009, using the female partner's 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 and used donor eggs and partner sperm. Two fresh treatment cycles and two frozen embryo replacement cycles were unsuccessful and two embryos remain in storage in the USA.

1.3. The couple are resident in the UK and wish to arrange the transport of their two remaining embryos to enable them to receive treatment in the UK.

1.4. The centre is unable to import the two embryos under General Direction 0006 because the embryos were created using donor eggs from a non-identifiable donor. The egg donor also received expenses greater than those permitted by General Direction 0001.

1.5. The PR at centre 0030 originally applied for Special Directions to import the two embryos from the Genetics and IVF institute, Virginia, USA. This application was considered by the Statutory Approvals Committee on 30 November 2017 and the committee agreed to grant the centre Special Directions, in force from 19 December 2017 to 19 March 2018. However, the PR was unable to undertake the import of the two embryos within the set three-month period due to delays getting the required paperwork from the Genetics and IVF institute.

2. Consideration of application

Application

2.1. The committee noted that the PR at centre 0030 has applied for Special Directions to import two embryos from the Genetics and IVF institute, Virginia, USA for a patient couple's own use and that this is a second application. The first application was approved and Special Directions were issued but have now expired.

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

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 and export of gametes and embryos for countries outside of the United Kingdom. The committee further noted that, in relation to the import and export of gametes and embryos outside of the European Economic Area and Gibraltar, transactions can be permitted without the need for directions if the conditions outlined in General Directions 0006 are satisfied.

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

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

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

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

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

2.4. The centre is unable to comply with part 3 (e) of the General Direction because the patients' embryos were created using eggs from a non-identifiable donor.

Money or benefits paid or received in accordance with Directions 0001 – egg donor's expenses greater than those permitted

2.5. The centre is unable to comply with part 3 (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 Directions 0001, 0006 and 0013.

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 the female patient became post-menopausal in 2015 and the couple travelled to the USA for treatment due to a shortage of ethnically matched 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.

3.4. The committee noted that Special Directions have been applied for because Part 3 (e) and (h) of Schedule 3 of the General Direction could not be met.

3.5. In considering the original application on 30 November 2017, 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. 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 had 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 had also agreed that a refusal to issue Special Directions to import the two remaining embryos into the UK would not be proportionate as the patients had being trying to have a child for over 10 years. The patients had also 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 believed that they have a better chance of successful treatment if they stay in the UK.

3.6. The committee originally concluded that, taking all these factors into account, including the age of the patients and their history trying for a child of their own, the case involved a highly exceptional set of circumstances and agreed, in November 2017, 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.

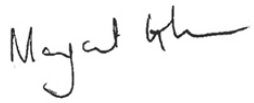
3.7. The committee noted that, for this second application, the PR has confirmed that there has not been any change in the specific circumstances or details of the proposed import, relative to the details provided in the original application, which was considered in November 2017. Therefore, the committee agreed to grant Special Directions to centre 0030 for a further three months, to come into force from the date the HFEA issues the centre's Importing Tissue Establishment (ITE) certificate, as required by the European Union Directive, which the centre has recently applied for.

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

10 May 2018