

Statutory Approvals Committee – minutes

Centre 0185 (CARE Manchester)

Special Directions application to export eggs to the United States of America (USA) for patient couple's own use

Thursday, 31 January 2018

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

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Ruth Wilde Rachel Cutting Emma Cave	
Members of the Executive	Dee Knoyle Bernice Ash Paula Robinson Sandrine Oakes Nicola Lawrence	Committee Secretary Committee Secretary (Observer) Head of Planning and Governance (Observer) Inspector (Observer for Induction) Inspector (Observer for Induction)
External adviser		
Legal Adviser	Tom Rider	Field Fisher 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:

- 9th 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
- Special Directions Application Form
- Further information form
- Email from Person Responsible (PR) confirming receiving centre.
- Email from the proposed receiving centre confirming acceptance of sperm
- Receiving centre's certificate of compliance
- Receiving centre's FDA registration
- Receiving Centre state licence

1. Background

- 1.1. The Person Responsible (PR) at CARE Manchester, centre 0185 has applied for Special Directions to export eggs to The Sperm and Embryo Bank of New Jersey Inc, in the USA for a patient couple's own use.
-

2. Consideration of application

Application

- 2.1. The committee noted that a suitably completed application has been submitted on the correct form. The PR has confirmed the proposed receiving centre is The Sperm and Embryo Bank of New Jersey Inc. located in the USA, which differs from the application form as the patient had changed her choice of centre to export to.

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 4, Part 1 (h) and (i)

- 2.3. The committee noted that the centre is unable to export the eggs under General Direction 0006 because the requirements of Schedule 4, part 1 (h) and (i) cannot be met.

Schedule 4 of the General Direction provide as follows:

Part 1

- (h) the gametes or embryos are not exported if they could not lawfully be used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre
- (i) the remaining term of the relevant storage period for the gametes or embryos, as provided for in section 15 (3) or (4) or by Regulations made under section 15 (5) of the HFE Act 1990 amended, and the period for which the gametes and embryos may remain stored in accordance with the consent(s) of the relevant gamete provider(s), are not less than 6 months from the date on which they are to be exported.

Storage period has expired – eggs cannot be lawfully stored or used in treatment in the UK or abroad

- 2.4. The centre is unable to comply with Schedule 4, part 1 (h) and (i) of the General Direction 0006 for the reasons outlined below.
- 2.5. The committee noted that the ten-year statutory storage period for the eggs ended on 1 December 2018. Under the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ('the 2009 Regulations') it is possible to extend storage beyond the statutory ten-year period provided that the relevant provisions of the Regulations can be met. These conditions are:

- (a) The person who provided the gamete in question has consented in writing to the gametes being stored for a period in excess of ten years for the provision of treatment services; and
- (b) On any day within the relevant period a registered medical practitioner has given a written opinion that the person who provided the gamete or, where they are not that person, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

- 2.6.** The eggs were originally stored in December 2008. The reason for storage was due to the male partner being azoospermic and therefore unable to provide sperm on the day of planned treatment.
- 2.7.** The female patient's records were reviewed by the centre's Medical Director in August 2018. The Medical Director's opinion was that the patient did not meet the conditions of the 2009 Regulations for extending storage as the female patient was not prematurely infertile at the time of storage and she is not currently prematurely infertile. The centre has advised the female patient that storage could not be extended.
- 2.8.** The committee noted that it would be unlawful to continue to store these eggs in the UK.
- 2.9.** The committee also noted that it would be unlawful to use the eggs for treatment in the UK.
HFEA Act 1990 amended - Section 14 (3) or (4) or 15 (5)
- 2.10.** The committee noted that the remaining term of the relevant storage period for the gametes or embryos, and the period for which the gametes and embryos may remain stored in accordance with the consent(s) of the relevant gamete provider(s), are not to be less than 6 months from the date on which they are to be exported.

3. Decision

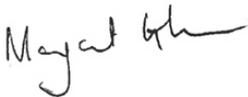
- 3.1.** The committee had regard to:
 - The Human Fertilisation and Embryology Act 1990 (as amended)
 - Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ('the 2009 Regulations')
 - HFEA General Directions 0006
 - The Human Rights Act 1998:
 - Article 8 - respect for private and family life
 - Article 9 – freedom of thought, conscience and religion
 - Article 12 - right to marry and found a family
- 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 patient wishes to export her 7 eggs to The Sperm and Embryo Bank of New Jersey Inc, located in the USA, for future fertility treatment with her partner's sperm.
- 3.4.** The committee noted that Special Directions have been applied for because Schedule 4, Part 1 (h) and (i) of the General Direction could not be met.

- 3.5.** 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. The committee considered whether a refusal to make Special Directions would be an interference with the patients' Human Rights and whether such interference would be justified and proportionate. The committee agreed that refusal may amount to interference in this case. The committee considered the patient's age and that she is now peri menopausal, and wants to ensure that any future treatment can take place using her own eggs. The patient's husband is azoospermic. Assuming that at a future point, medical advances allow the use of the patient's partner's sperm, it may provide the couple with a chance to have a genetically linked child. These eggs are essential to the patient's future treatment.
- 3.6.** Taking all of these factors into account, including the age of the patient and medical history of the patient's partner, the committee agreed that this case involved a highly exceptional set of circumstances and agreed to issue Special Directions to allow the export of the patient's 7 eggs to The Sperm and Embryo Bank of New Jersey Inc, 187 Mill Lane, Mountain Side View, New Jersey 07092, USA.
- 3.7.** 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

25 February 2019