

Statutory Approvals Committee – minutes

Centre 0185 (CARE Manchester)

Special Directions application to export eggs to 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 with the following annexes:
 - Annex A: Special Direction Application submitted by CARE Manchester including the 'Further information form' and document headed 'Principles'
 - Annex B: The Human Fertilisation and Embryology (Statutory Storage period for Embryos and Gametes) Regulations 2009
 - Annex C: Medical Practitioner's Statement dated 9 March 2016
 - Annex D: Schedule 1 and Section 5 of the Interpretation Act 1978
 - Annex E: Elizabeth Warren -v- Care Fertility (Northampton) Limited and Others
 - Annex F: Samantha Jefferies v (1) BMI Healthcare Ltd and (2) HFEA
 - Annex G: R v Human Fertilisation and Embryology Authority, ex parte Blood

1. Background

- 1.1. The Person Responsible (PR) at centre 0185 has applied for Special Directions to export 19 cryopreserved eggs to Pacific Fertility Centre in California, USA.
- 1.2. The eggs were first placed in storage on 16 February 2005 at IVI Midland, centre 0008, known at that time as Midland Fertility Services based in the UK, when written consent for storage was given for a period of 10 years, expiring on 16 February 2015. The frozen eggs were received at CARE Manchester, centre 0185, currently storing them, in July 2013 having been exported to the USA, stored there for a period and then imported back into the UK.
- 1.3. A further consent to storage of the eggs for a period of three years was obtained on 21 August 2013. However, although the patient had signed a consent form and consented to storage beyond the initial ten-year period, there was no medical practitioner's statement provided until 9 March 2016, which was after expiry of the ten-year period. Although the consent obtained on 21 August 2013 may have satisfied the requirement for consent under paragraph 4(3)(a) of the 2009 Regulations, there was no medical practitioner's statement in existence at that time as required by paragraph 4(3)(b). The result of this is that the patient's gametes were not lawfully in storage from 16 February 2015 when the initial ten-year storage period expired.

2. Consideration of application

- 2.1. The committee noted that centre 0185 has applied for Special Directions to export eggs to the USA for the patient's own use. A suitably completed application form and further information form was received by the Executive.

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

General Directions 0006, Schedule 4, Part 1(h) and (i)

- 2.2. The committee noted that Section 24(4) of the 1990 Act provides a power to make Directions and confers a broad power on the Authority to permit the export of a person's gametes. Pursuant to this power the Authority has issued General Direction 0006 ('the General Direction'). However, this application arises because the requirements of the General Direction have not been met and therefore the committee is asked to consider whether, in the particular circumstances of this case, there are grounds to exercise the power under section 24(4) to permit the export of these eggs.
- 2.3. The committee noted that the centre is unable to export the eggs under General Direction 0006 because the requirements of part 1(h) and (i) of Schedule 4 cannot be met.
Part 1 (h) and (i) of Schedule 4 of the General Direction provide as follows:
- 2.4. *(h) 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; and*
- 2.5. *(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.*

Consent to Storage - lapsed

- 2.6.** The centre is unable to comply with paragraph 1(h) of the General Direction because the patient's consent lapsed on 16 February 2015 and although the patient has since completed a further consent, that consent is not valid for the purposes of the legislation. In the absence of valid and effective consent, the ongoing storage and use of those gametes would not be lawful in the UK.
- 2.7.** By section 4(1)(a) of the 1990 Act, the centre is prohibited from storing any gametes except in pursuance of a licence. Storage of gametes without valid and effective consent as required by paragraph 8(1) would not be 'in pursuance of a licence' and may amount to a criminal offence.

Remaining term of the relevant storage period – less than six months before export

- 2.8.** The centre is unable to comply with the requirements of paragraph 1(i) of the General Directions because the statutory storage period has lapsed and since storage cannot be extended under the Regulation, there is no 'remaining term of the relevant storage period'.

3. Decision

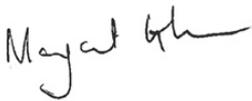
- 3.1.** The committee had regard to General Direction 0006.
- 3.2.** The committee had regard to the Authority's statutory duty to promote, in relation to activities governed by the Act, compliance with requirements imposed by or under the Act.
- 3.3.** In considering the application, the committee 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(h) and (i) of Schedule 4 of the General Direction could not be met.
- 3.5.** The committee noted that the centre is unable to demonstrate compliance with the requirements of paragraph 4 of the 2009 Regulations and therefore cannot lawfully continue to store the patient's gametes. Since the patient does not wish to allow her gametes to perish and lawful storage beyond ten years is not possible in the UK, the centre has chosen to make this application to export the gametes to the Pacific Fertility Centre in California where the patient had previously stored her eggs and is familiar with the centre.
- 3.6.** The committee acknowledged that there is currently no medical treatment available which could offer this patient the chance to have a child using her partner's sperm. The couple wish to continue storage of the eggs in the hope that future medical advances might be made, which would enable them to have a child using their own gametes.
- 3.7.** The committee noted that the consent had lapsed due to an administrative error made by centre 0185 and agreed that the patient was not at fault.
- 3.8.** 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 wishes to export her eggs made from her own genetic material for future treatment in California, USA using her partner's sperm. The committee agreed that a refusal to issue Special Directions to export the eggs to California would not be proportionate as the patient has no alternative treatment options using her own eggs in the UK.

- 3.9.** The committee also considered that the patient had stored her eggs when she was younger and her eggs may not be of the same quality if she were to produce eggs for storage now, therefore reducing her chances of successful treatment in the future.
- 3.10.** The committee concluded that, taking all the factors into account, the current case involves a highly exceptional set of circumstances and agreed to issue Special Directions to allow the export of the patient's eggs to Pacific Fertility Centre, 55 Francisco Street, Suite 500, San Francisco, California, 94133, USA for the patient's own use.
- 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.
-

4. Decision

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

Signature



Name

Margaret Gilmore

Date

19 December 2017