

Statutory Approvals Committee – minutes

Centre 0327 (Boston Place)

Special Direction application to export embryos to the USA for use in treatment

Thursday, 29 August 2019

HFEA, Spey Meeting Room 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe	
Members of the Executive	Moya Berry Catherine Burwood	Committee Secretary Licensing Manager
Legal Adviser	Dawn Brathwaite	Mills & Reeve - LLP
Observers	Darryn Hale	DAC Beachcroft - LLP

Declarations of interest

- Members of the committee declared that they had no conflicts of interest in relation to this item.
- Apologies were received from Rachel Cutting and Tony Rutherford.

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
 - Letter from the receiving clinic confirming that they are willing to accept the embryos.
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1. Background

- 1.1. The Person Responsible (PR) at Centre 0327 (the applicant) has applied for a Special Direction for the export of 12 embryos from Boston Place to Reprotech Ltd. Florida, United States of America.
- 1.2. The patient couple have 12 embryos in storage at Boston Place. Unfortunately, the patient became very unwell and following lengthy treatment in the United States has only recently felt able to consider undergoing fertility treatment.
- 1.3. The committee noted the patient couple consented to 10 years storage of the embryos, which will expire on 7 October 2019. The patient couple have therefore asked Boston Place to transport their embryos to Reprotech Ltd. in Florida as there is less than 6 months remaining in the storage period.
- 1.4. The committee noted the embryos have been created by the patient couple's own gametes.

2. Consideration of application

Application

- 2.1. The committee considered the application, which included an executive summary, a Special Direction application form and Further Information form.
- 2.2. The committee noted that the Human Fertilisation and Embryology Act (as amended) permits the Authority to issue directions to allow exports of gametes or embryos to countries outside of the United Kingdom. Furthermore, the committee noted that in relation to the import and export of gametes and embryos outside of the European Economic Area and Gibraltar, movement can be permitted without the need for a Special Direction if the conditions outlined in General Directions 0006 are satisfied.
- 2.3. The committee noted that this application for a Special Direction is being made as the centre is unable to export the embryos to Reprotech Ltd. Florida, under General Directions 0006, since the following requirements of Schedule 4 are not met:
 - 1(c) The receiving centre has a traceability system in place which ensures that all gametes and embryos are traceable from procurement of gametes to patient treatment and vice versa.
 - 1(i) the remaining term of the relevant storage period for the gametes or embryos, as provided for in section 14 (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.
- 2.4. The committee noted the information that had been provided to support the Special Direction application. This included a letter from Reprotech Ltd. Florida, to accept 12 embryos for the purpose of cryostorage at their facility for use in the patient couple's own fertility treatment in the future.
- 2.5. In considering the application, the committee had regard to the principles (tests) derived from the decision of the Court of Appeal in *R v HFEA ex parte Blood* [1997] 2 All ER 687 and from rights arising under the Human Rights Act 1998.
- 2.6. **Principle 1**

The committee recognised that the centre is unable to export the gametes under General Direction 0006 because the receiving centre has a limited traceability system. The committee noted that Reprotech Ltd. Florida provides gamete and embryo storage services only. The couple will relocate the embryos to a treatment centre when they decide to undertake fertility treatment and have selected a clinic. As the treatment clinic is not yet known the couple cannot confirm that a traceability system is in place from procurement of gametes to treatment.

The committee noted that the consent for storage for the embryos expires on the 7 October 2019, which will be less than six months on the date they are to be exported.

The Committee noted that, except for section 1(d) and (e) of Schedule 1, all other requirements of General Directions 0006 were satisfied.

2.7. Principle 2

The committee considered whether a refusal would amount to an interference with the patient's rights under the EC Treaty to obtain medical treatment services in another member state. The committee noted that the patient's wishes to export embryos to a centre outside of the EU.

2.8. Principle 3

The committee recognised that rights under the European Convention on Human Rights (ECHR) are separate and distinct from those arising under the EC Treaty. The committee noted that the patient had been seriously unwell and had required lengthy treatment. It was only recently that she had felt able to consider fertility treatment in the United States where the patient couple now live. The committee also considered that consent to store the patient's embryos at Boston Place, expires on the 7 October 2019. The patient couple has therefore asked the clinic to transport the embryos from Boston Place to Reprotech Ltd. Florida as there is less than 6 months remaining in the in the storage period. The committee accepted that a refusal to allow the embryos to be exported could amount to an interference with the patient's rights to respect her private and family life under Article 8 and to found a family under Article 12 of the ECHR and that a refusal to grant the application would need to be justified.

2.9. Principles 4 and 5

The committee considered whether interference with the patient's rights under the ECHR could be justified and whether a refusal to grant the application would be disproportionate. The committee noted that the embryos have been created from the gametes of both patients. The committee also considered the effect of a refusal on the patient and whether this represented an isolated case or an undesirable precedent.

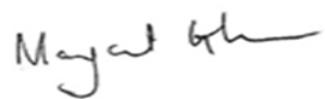
3. Decision

- 3.1.** The committee took into consideration that the patient had been very seriously ill and required lengthy treatment to facilitate recovery, and as a consequence, has only recently felt sufficiently well to consider undergoing further fertility treatment. The committee also took into consideration that consent to store the embryos expires on the 7 October 2019 meaning there is less than six months remaining of the storage period. The patient couple, who are now living in the United States, are unable to return to the United Kingdom for fertility treatment to complete their family.
- 3.2.** Taking all of these circumstances into account, the committee concluded that a refusal could not be justified and/or would amount to a disproportionate interference with the rights of the patient. The committee was also satisfied that granting the application in the exceptional circumstances of this case would not set an undesirable precedent.
- 3.3.** The committee, therefore, agreed to issue a Special Direction in the case for Centre 0327, to export from Boston Place, 16-20 Boston Place, London NW1 6ER, United Kingdom to Reprotech Ltd. 4661 Johnson Road, Suite 2 Coconut Creek, Florida 33073, United States of America, twelve embryos for storage prior to treatment by a patient couple, at a clinic yet to be selected.

4. Chairs signature

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

Signature

A handwritten signature in black ink, appearing to read "Margaret Gilmore". The signature is written in a cursive style with a long horizontal stroke at the end.

Name

Margaret Gilmore

Date

16 September 2019