

Statutory Approvals Committee – minutes

Centre 0185 (CARE Manchester)

Application to extend Special Direction to export eggs to Beacon CARE Fertility Dublin, Republic of Ireland, for cryostorage.

Thursday, 28 May 2020

HFEA, 10 Spring Gardens, London, SW1A 2BU via Teleconference

Committee members	Margaret Gilmore (Chair) Emma Cave Anne Lampe Tony Rutherford Ruth Wilde	
Members of the Executive	Moya Berry Catherine Burwood	Committee Officer Licensing Manager
Legal Adviser	Jane Williams	Mills & Reeve LLP
Observer	Bernadette O'Leary	Clinical Inspector, Induction

Declarations of interest

- Members of the committee 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

The following papers were considered by the committee:

- Re-Application Executive Summary

Part 1 - previous application

- Executive Summary
- Application Form for the export of frozen eggs to Beacon CARE Fertility, Dublin, Ireland
- Further information form
- Letter from the proposed receiving centre confirming acceptance of gametes
- Patient Statement
- 2019-12-12 Statutory Approvals Committee minutes, Special Direction application to export eggs to Beacon CARE Fertility, Dublin, Republic of Ireland, for cryostorage

Part 2

- Email from PR
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1. Background

- 1.1.** In September 2019, the Person Responsible (PR) at CARE Manchester, United Kingdom (UK), centre 0185, applied to export twelve frozen eggs of the patient to Beacon CARE Fertility, Dublin, Republic of Ireland, for cryostorage.
- 1.2.** The eggs had been placed in cryostorage in the UK in October 2009 but, due to her personal circumstances, the patient did not have sufficient opportunity to find a suitable partner with whom to start a family before the 10-year period for which gametes can usually be stored in the UK expired on the 23 October 2019. The patient's circumstances did not make her eligible for extended storage beyond the 10-year period.
- 1.3.** The centre is unable to export the eggs under General Directions because of the following requirements of paragraph 1 of Schedule 2 of General Direction 0006:
- (f) the gametes or embryos are not exported if they cannot be lawfully 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
 - (g) 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 14(5) of the Human Fertilisation and Embryology Act 1990 as amended, and the period for which the gametes and embryos may remain in storage 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.
- 1.4.** The previous export application made by centre 0185 was considered by the Statutory Approvals Committee on the 12 December 2019 and the committee agreed to grant the centre a Special Direction, which came into force from the 6 January 2020. A time period of six months was specified and therefore the Special Direction expires on the 6 July 2020.
- 1.5.** The centre anticipates that it will be unable to export the twelve eggs before 6 July 2020 because of the likelihood of further delays due the patient being a serving member of the armed forces. The eggs had been due to be moved from CARE Manchester to Beacon CARE Fertility, Dublin, Ireland for cryostorage during the Easter period, while the patient was on leave, but this was prevented because of COVID-19 restrictions.
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2. Consideration of application

- 2.1.** The committee noted that the Human Fertilisation and Embryology Act 1990 (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 export of gametes and embryos to Gibraltar and the European Economic Area (EEA), this can be permitted without the need for a Special Direction if the conditions outlined in General Direction 0006 are satisfied.
- 2.2.** The committee noted that the centre is unable to export the embryos under General Direction 0006, because of paragraph 1(f) and (g) of Schedule 2 of General Direction 0006:
- (f) the gametes or embryos are not exported if they cannot be lawfully 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
 - (g) 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 14(5) of the Human Fertilisation and Embryology Act 1990 as amended, and the period for which the gametes and

embryos may remain in storage 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.

2.3. The committee noted that the patient had not been able to extend the statutory storage period of her gametes beyond the 10-year period because the following criteria set out in regulation 4 of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 could not be satisfied:

(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.

3. Decision

3.1. 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.

3.2. The committee had regard to the Act which permits the Authority to issue directions to allow the export of gametes or embryos to countries outside of the United Kingdom. Furthermore, the committee noted that if a licensed centre meets all the requirements set out in paragraph 1 of schedule 2 to General Direction 0006, export is permitted without a Special Direction.

3.3. The committee carefully considered the reasons, provided by the PR, for the delay in exporting the twelve eggs from the UK to Beacon CARE Fertility, Dublin for cryostorage, including the restrictions imposed because of the current Covid-19 pandemic.

3.4. The committee noted that, for the purposes of this extension application, the PR has confirmed that there has not been any change in the specific circumstances or details of the proposed export since the original application, which was considered in December 2019. This was confirmed by the executive.

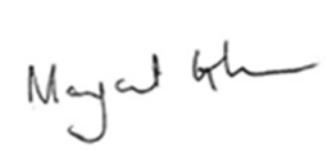
3.5. In considering the original application on the 12 December 2019, the committee had had regard to the principles (tests) derived from the decision of the Court of Appeal in *R v HFEA ex parte Blood* (1997) 2 All ER 687 and from rights arising under the Human Rights Act 1998. The committee had considered whether a refusal to issue a Special Direction would be an interference with the patient's rights under Article 8 and Article 12 of the European Convention on Human Rights and whether such interference would be justified and proportionate. The committee had concluded that a refusal would amount to a disproportionate interference with the rights of the patient and could not be justified. In considering the extension application, the committee applied these tests again and agreed that the analysis remained valid.

3.6. Given the unique circumstances of this case, the committee therefore agreed to issue a Special Direction to export twelve frozen eggs, from CARE Manchester, 108-112 Daisy Bank Road, Victoria Park, Manchester M14 5QH United Kingdom (UK) to Beacon CARE Fertility Dublin, Beacon Court, Sandyford, Dublin 18, Republic of Ireland, for cryostorage. The committee decided that the Special Direction should remain in force for two years.

4. Chair's 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", enclosed in a thin black rectangular border.

Name

Margaret Gilmore

Date

24 June 2020