

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, 24 May 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe	
Members of the Executive	Dee Knoyle Bernice Ash Paula Robinson Catherine Burwood Mhairi West	Committee Secretary Committee Secretary (Observer) Head of Planning and Governance (Observer) Senior Governance Manager (Observer) Inspector (Observer - Induction)
External adviser		
Legal Adviser	Sarah Ellson	Fieldfisher 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
- Application form (4937)
- Further information form
- 'Principles' document
- Minutes of the Statutory Approvals Committee meeting 30 November 2017
- Special Direction reference: S.D.2017/03/0185/a issued 19 December 2017

1. Background

- 1.1. The Person Responsible (PR) at CARE Manchester, centre 0185 has applied for the re-issue of Special Directions to export 19 cryopreserved eggs to Pacific Fertility Centre in California, USA.
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2. Consideration of application

- 2.1. The committee noted that centre 0185 has re-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.
- 2.2. The committee noted that the PR at centre 0185 previously applied for Special Directions to export 19 eggs to Pacific Fertility Centre, USA which was considered by the Statutory Approvals Committee on 30 November 2017. The committee previously agreed to grant Special Directions which came into force on 19 December 2017 and remained in force until 19 March 2018.
- 2.3. The committee noted that the PR has not been able to undertake the export of these eggs under these Special Directions because there were some difficulties with the US centre, involving a delay in getting the patient consent forms signed and the lab in the USA having a tank failure and being unable to accept samples. The PR halted the export of the eggs until the receiving centre had completed its investigation relating to the recent incident of the failure of one of its storage tanks.
- 2.4. The committee accepted that there had not been any changes in circumstances or details of the original application.
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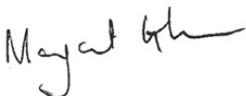
3. Decision

- 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 circumstances where nothing had changed in relation to the application and the earlier Special Directions had simply lapsed before the export could take place, the committee agreed to re-issue the Special Directions allowing the eggs to be exported. It did so on the same basis as it had in November, and adopted the same reasoning as is set out in the minutes from 30 November 2017.
- 3.4. The Special Direction is for an export of a patient's eggs therefore it is not subject to the requirements of the Human Fertilisation and Embryology (Amendment) Regulations 2018.
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4. Decision

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

Signature



Name

Margaret Gilmore

Date

19 June 2018