

Statutory Approvals Committee - minutes

Centre 0295 (Bristol Centre for Reproductive Medicine (BCRM))

Application for Special Directions to Export Embryos to Ukraine

Monday, 23 January 2017

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

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Tony Rutherford	
Members of the Executive	Dee Knoyle Siobhain Kelly	Secretary Interim Head of Corporate Governance
External adviser		
Legal Adviser	Tom Rider	Field Fisher
Observers	Bobby Farsides Bernice Ash Anjeli Kara	Member (Induction) Committee Secretary Regulatory Policy Manager

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.
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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:

Papers Enclosed:

- Executive summary
 - Application form
 - Further information form
 - Letter from the receiving centre required by General Directions 0008
 - Supporting letter from treating clinician
 - Copy of the receiving centre's licence / accreditation submitted in support of the application

1. Consideration of application

- 1.1.** The committee considered an application from Bristol Centre for Reproductive Medicine, Centre 0295, for Special Directions to export embryos to Adonis Medical Center of Private Higher Educational Institution, Kiev, Ukraine.
- 1.2.** The committee noted that section 24(4) of the HFEA Act 1990 (as amended) permits the Authority to issue directions to allow the export of gametes or embryos to countries outside the United Kingdom.
- 1.3.** The committee further noted that, in relation to the export of embryos outside of the European Economic Area and Gibraltar, export can be permitted without the need for directions if the conditions in schedule 4 to General Directions 0006 are satisfied.
- 1.4.** The committee noted that the centre was unable to export the embryos under General Directions 0006 because conditions (b) and (c) of paragraph 1 of schedule 4 have not been satisfied:
- "The receiving centre has a quality management system in place which has been certified by an internationally recognised body";
 - "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. The centre's traceability procedures should also encompass all materials or equipment that could have an impact on the quality or safety of the gametes and embryos."
- 1.5.** The committee agreed that Special Directions should not be routinely granted and not where the purpose or dominant effect appears to be to circumvent the requirements of the Act and/ or those contained in General Directions 0006.
- 1.6.** The committee noted from the centre's application that the receiving centre is licensed in Ukraine but it does not hold certification from an internationally recognised body for its quality management system as this is not a requirement under the regulations in place in Ukraine. However, it is stated that the licensing and accreditation processes in the Ukraine require suitable and appropriate facilities and equipment to be in place before any licence is issued.
- 1.7.** The committee noted that these embryos were created using the couple's own genetic material. They were frozen at centre 0295 prior to the female partner's treatment for cervical cancer, which rendered her infertile and unable to carry a pregnancy.
- 1.8.** The committee further noted that the couple live in India and it is proposed that the embryos be exported for treatment in the Ukraine involving a surrogate mother.

The committee noted that it was submitted in the application that it is not practically possible for the couple to enter into a surrogacy arrangement in the UK since they do not have a friend or family member willing to assist and they cannot engage one of the UK's non-profit agencies to match them with a UK surrogate while they live abroad.

2. Decision

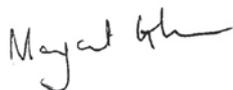
- 2.1.** The committee had regard to its decision tree.
- 2.2.** The committee agreed that all the requirements of schedule 4 to General Directions 0006 were not met.
- 2.3.** The committee considered whether a refusal to make Special Directions would be an interference with the patients' rights under Articles 8 and/ or 12 of the ECHR. The committee decided that refusal may amount to interference in that the couple wish to export embryos made from their own genetic material for treatment in the Ukraine involving a surrogate mother in order to found a family. The embryos are essential to the treatment.

- 2.4.** The committee went on to consider whether such interference would be justified and proportionate. 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. It recognised that, when setting the requirements in schedule 4 to General Directions 0006, the Authority attached considerable importance to the receiving centre having a quality management system in place which has been certified by an international recognised body and to the receiving centre having a traceability system in place which ensures that all embryos are traceable from procurement to treatment.
- 2.5.** However, the committee decided that, on balance, refusal to make Special Directions would not be justified or proportionate in the exceptional circumstances of this case, where the embryos are essential to the treatment, and due to the location and particular personal circumstances of the couple, there is no realistic opportunity for the treatment to be undertaken in the UK. This also represents the couple's only opportunity to found a family using their own genetic material.
- 2.6.** The committee thereafter agreed to grant Special Directions to Bristol Centre for Reproductive Medicine, Centre 0295, to export embryos to Adonis Medical Center of Private Higher Educational Institution, Kiev, Ukraine.
- 2.7.** The committee considered that granting Special Directions for this application would not set an undesirable precedent which would undermine the imperative requirements identified.
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3. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

10 February 2017