

Statutory Approvals Committee – minutes

Item 3

Centre 0008 (IVI Midland)

Special Direction application to export one embryo to Northern Cyprus

Thursday, 27 June 2019

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

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Rachel Cutting Ruth Wilde	
Members of the Executive	Moya Berry Catherine Burwood	Committee Secretary Licensing Manager (Observer)
Legal Adviser	Sarah Ellson	Fieldfisher - LLP
	Dee Knoyle Vicky Brown	Committee Secretary Inspector

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
- General Directions 0001 (2015)
- General Directions 0006 (2018)
- General Directions 0013 (2018)
- HFEA Standing Orders (2018)
- Special Direction Decision Tree (2018)

The following papers were considered by the committee:

- Executive Summary
- Application Form redacted
- Email from Centre 0008 providing further information
- Further information form
- Treatment Summary from the Centre
- A letter from the proposed receiving centre confirming willingness to accept the embryo (redacted)
- A letter from the patient providing further information
- ISO 9001-2015 certificate for quality management system from the receiving centre
- Certificate of Incorporation from receiving centre
- 'Embryology Association Certificate' of Participation
- An explanation of the certificates from the receiving centre
- Letter from Health Ministry confirming inspection and approval on the 22 March 2019
- Department of Health Ministry Certificate

1. Background

- 1.1. The Person Responsible (PR) at IVI Midland, Centre 0008 (the applicant) has applied for a Special Direction for the export of one embryo to Dogus Fertility Clinic, Elite Research and Surgical Hospital in Nicosia, Northern Cyprus.
- 1.2. The patient couple have one embryo in storage at IVI Midland and as a consequence of surgery, require a surrogate to achieve a pregnancy. The couple have been unable to source a suitable surrogate in the UK despite a number of attempts and now wish to export their embryo to the proposed receiving centre for a 'commercial surrogacy' arrangement.
- 1.3. The embryo was placed in storage on the 5 August 2017 and the patient couple have consented to 10 years storage.

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 because the receiving centre cannot satisfy the following requirements of Schedule 4 of General Direction 0006 which prohibits any export of donor gametes to the centre without consideration by the Statutory Approvals Committee:
 - (a) Initially centre 0008 thought that the proposed receiving centre was not accredited, designated, authorised or licensed under the laws or other measures of Northern Cyprus. A letter initially submitted from the proposed receiving centre indicates that it is authorised, but this appears to be a certificate indicating only that the clinic is a registered company. Subsequent evidence provided by the proposed receiving centre indicates that they are suitably accredited.
 - (c) Evidence of a traceability system has not been provided to the satisfaction of the exporting centre.
 - (h) Embryos cannot be exported if they could not lawfully be used in licensed treatment services in the manner or circumstances in which it is proposed that the embryos be used by the receiving centre. It is understood that the surrogate will be paid for this service, but insufficient evidence has been provided to determine whether the surrogate will be paid over and above reasonable expenses. Commercial surrogacy is not lawful in the UK.
- 2.4. 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.

2.5 Principle 1

The committee recognised that the centre is unable to export the embryo under General Direction 0006 because, whilst the exporting centre has concluded that the receiving centre does have the appropriate accreditation, evidence of a traceability system cannot be provided to the satisfaction of the exporting centre.

The exporting centre has also provided information that the surrogate will be paid for this service, but it is not clear whether this payment will be over and above reasonable expenses. The centre has sought further information, but it had not been provided. The Committee noted that, given the provision of evidence that demonstrates that the proposed receiving centre is suitably accredited, except for section 1(c) and (h) of Schedule 1, all other requirements of General Directions 0006 were satisfied.

2.6. Principle 2

The committee considered whether a refusal would amount to an interference with the patient couple's rights under the EC Treaty to obtain medical treatment services in another member state. The committee noted that the patient couple wish to export the embryo for use in treatment in a clinic in Northern Cyprus, which is outside of the EU.

2.7. 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 couple have made several attempts to find a surrogate in the UK, but these have been unsuccessful. The couple wish their only stored embryo to be exported to a country that makes all the arrangements for surrogacy, including sourcing the surrogate. The committee accepted that a refusal to allow the embryo to be exported could amount to an interference with the couple's rights to respect for their private and family lives 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.

2.8. Principles 4 and 5

The panel then considered whether interference with the patient couple's rights under the ECHR could be justified and whether a refusal to grant the application would be disproportionate. The committee noted the embryo has been created from the gametes of both patients and is understood to be their only chance of having a child that is genetically related to both parents. The committee noted that 'commercial surrogacy' is not lawful in the UK. Embryos cannot be exported if they could not lawfully be used in licensed treatment services in the manner or circumstances in which it is proposed that the embryos be used by the receiving centre. The committee also considered the effect of a refusal on the patient couple and whether this represented an isolated case or an undesirable precedent.

3. Decision

- 3.1.** The committee took into consideration the fact that over the past three years, the patient couple have made eight attempts to find a potential surrogate in the UK, all of which have been unsuccessful. The committee respected the time and commitment taken by the couple in attempting to secure a surrogate in the UK. The couple have one embryo in storage and are now keen for the embryo to be exported to a country that makes all the arrangements for surrogacy, including recruiting the surrogate.
- 3.2.** However, the committee raised serious concerns about the lack of transparency and the insufficient information that had been given to the patient couple with regard to payment for the 'commercial surrogacy' arrangement. The clinic's application indicated that the surrogate would get paid but because the costs were said to be part of a package it was unclear what such payments would be. The committee therefore strongly recommended the receiving clinic provide the couple with sufficient information regarding the surrogacy arrangements. The committee was clear that any Special Direction would not vary the requirement that the embryo is not to be exported if it 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 embryo be used by the receiving centre.
- 3.3.** With regard to traceability, the committee felt that it was important to recommend that the clinic ensures that, in the absence of a compliant traceability system, the receiving clinic keep and

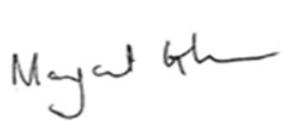
maintain accurate records of matters such as batch numbers and expiry dates of any materials coming into contact with the exported embryo.

- 3.4.** 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 couple. The committee was also satisfied that granting the application in the exceptional circumstances of this case would not set an undesirable precedent.
- 3.5.** The committee, therefore, agreed to issue a Special Direction in the case of IVI Midland Centre 0008, in the UK to export one embryo to Dorgus Fertility Clinic, Elite Research and Surgical Hospital Amasaya sokak, Sehit Erdogan yildiz caddesi, lefkosa 99010, Nicosia, Northern Cyprus for use in providing treatment services to the patient couple.
-

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", written on a white background.

Name

Margaret Gilmore

Date

22 July 2019