

# Statutory Approvals Committee – minutes

## Centre 0250 (GCRM Fertility)

### Special Direction application to import one embryo from Shady Grove Fertility, United States of America for patient's own use.

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:

- Executive Summary
- Special Direction Application Form
- Further information form
- Further Information request- email from GCRM Fertility
- Patient supporting information

---

## 1. Background

- 1.1. The Person Responsible (PR) at GCRM Fertility, United Kingdom (UK) has applied for a Special Direction to import one embryo from Shady Grove Fertility, USA, for storage and use in treatment of the patient at GCRM Fertility, UK.
- 1.2. The embryo to be imported was created as part of a batch, using donated eggs and donated sperm, for use in the patient's own treatment at Shady Grove Fertility, USA. The patient previously gave birth to a child as a result of the treatment and has one unused embryo and some frozen donor sperm for future use. The patient now wishes to have further treatment in the UK, using the one embryo, to produce a full sibling for her child.
- 1.3. The committee noted that the patient is unable to have any further treatment at Shady Grove Fertility, USA as the age limit for treatment with donor eggs at this clinic is 50 years and 11 months. The patient is now over the permitted age limit.
- 1.4. The donor sperm used to create the embryos will also be imported but, unlike the donor eggs used, is considered by the Executive to be compliant with HFEA requirements, so can be imported under General Direction 0006.

---

## 2. Consideration of application

- 2.1. The committee considered the application, which included an executive summary, a Special Direction application form, and a Further Information form.
- 2.2. The committee noted that the Human Fertilisation and Embryology Act 1990 (as amended) permits the Authority to issue directions to allow imports of gametes or embryos from countries outside of the United Kingdom. Furthermore, the committee noted that, in relation to the import of gametes and embryos from countries outside of 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.
- 2.3. The committee noted that this application for a Special Direction is being made as the centre is unable to import the embryo from Shady Grove Fertility under General Direction 0006, because the following requirements of Schedule 3, paragraph 3, are not met:
  - (e) the person who provided the gametes is (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, are) identifiable.
  - (f) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being imported into the United Kingdom
  - (g) before giving consent, the person(s) referred to in paragraph (f) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the United Kingdom as in the country from which the gametes or embryos are to be imported, and have been given further information which they may require
  - (h) no money or other benefit has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving importing money or other benefits

(j) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice currently in force.

**2.4.** The committee noted the information that had been provided to support the Special Direction application. This included supporting information from the patient.

**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 import the embryo, for use in the patient's treatment, under General Direction 0006 because the following requirements cannot be complied with:

(e) the person who provided the gametes is (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, are) identifiable

(f) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being imported into the United Kingdom

(g) before giving consent, the person(s) referred to in paragraph (f) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the United Kingdom as in the country from which the gametes or embryos are to be imported, and have been given further information which they may require

(h) no money or other benefit has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving importing money or other benefits

(j) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice currently in force

**2.7.** The committee observed that, except for those cited at paragraph 3(e), (f), (g), (h) and (j) of Schedule 3, the other relevant requirements of General Direction 0006 were satisfied.

**2.8.** However, the committee noted, in particular, the requirements of paragraph 3(e) which had not been met, as identifying data had not been registered at the centre in the USA. In similar vein, the committee registered the non-compliance with General Direction 0005 regarding the reporting of information about treatment (specifically information about the egg donor in this case) to the HFEA register.

**2.9.** The committee also expressed concern that the criterion in paragraph 3(j) could not be satisfied because of the absence of karyotyping and cytomegalovirus testing.

## **2.10. Principle 2**

The committee acknowledged the patient's wishes to import the embryo from a country outside of the EEA and considered whether a refusal would amount to an interference with the patient's rights.

## 2.11. Principles 3, 4 and 5

The committee recognised that rights under the European Convention on Human Rights (ECHR) are separate and distinct from those arising under the Treaty on the Functioning of the European Union. Based on all of the patient's circumstances, the committee accepted that a refusal to allow her frozen embryo to be imported would amount to an interference with the patient's rights to respect for her private and family life under Article 8 and to found a family under Article 12 of the ECHR and that any refusal to grant the application would need to be justified and proportionate.

---

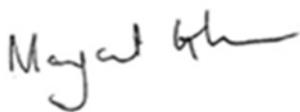
## 3. Decision

- 3.1.** The committee noted that the embryo had been created from donor sperm and a donor egg and had been placed in storage in the United States of America. The committee also noted that the patient already has one child, born two and half years previously, from the same batch of embryos and now wishes to have a full sibling. However, the patient is now unable to have fertility treatment in the USA because of her age.
- 3.2.** After very careful consideration of the application, the committee concluded that it had insufficient information before it, in order to decide whether or not to grant the Special Direction sought.
- 3.3.** In order for the application to be progressed, the committee decided that it would require the PR at centre 0250 to carry out an assessment of the risks of not having the screening information required by General Direction 0006 as being part of assuring the welfare of a child born as the result of treatment. The committee noted that a request had been made to the PR about these issues, but the centre's Inspector had not received a response.
- 3.4.** In addition, the committee requested that the PR give consideration to providing any non-identifying information about the characteristics of the egg donor that Shady Grove Fertility might hold, which could be placed on the HFEA donor register, so as to be available to any resulting donor-conceived child should (s)he wish to access it once (s)he reaches 18 years of age.
- 3.5.** Taking all of these circumstances into account, the committee concluded that the application should be adjourned pending the expeditious provision of further information regarding this special direction to import one embryo for use in treatment from Shady Grove Fertility, 9601 Blackwell Road, Rockville MD 20850, USA to GCRM Fertility, 21 Fifty Pitches Way, Cardonald Business Park, Glasgow GS1 4FD, UK.
- 

## 4. Chair's signature

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

### Signature



### Name

Margaret Gilmore

### Date

3 June 2020