Statutory Approvals Committee – minutes

Centre 0250 (GCRM Fertility)

Special Direction application to import six embryos from IVF Spain, Alicante, Spain, 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
- Letter to patient from centre 0250 (dated 9 October 2019)
- Letter from IVF Spain - Egg donor update (dated 2020)
- Letter from IVF Spain - Confirmation of legal status of surrogacy in Spain (dated 27 February 2020)

1. Background

1.1. The Person Responsible (PR) at GCRM Fertility, United Kingdom (UK) has applied for a Special Direction to import six embryos from IVF Spain, Alicante, Spain, for storage and use in treatment at GCRM Fertility, UK.

1.2. The embryos to be imported were created with eggs from a donor and the female patient's partner's sperm. IVF Spain has confirmed that, in Spain, gamete donation is anonymous, so the egg donor is not identifiable.

1.3. The couple had previously undergone three unsuccessful treatment cycles in the UK and, when these failed, they travelled to Spain for treatment using donated eggs. The couple had one further unsuccessful treatment cycle using donated eggs. The female patient was then subsequently diagnosed with cancer and, as a result of treatment, now requires surrogacy treatment, which is illegal in Spain.

1.4. The couple wish to continue their fertility treatment in the UK, where surrogacy is permitted.

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 within 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 GCRM Fertility is unable to import the six embryos from IVF Spain, Alicante, under General Direction 0006, because the following requirements of Schedule 1, paragraph 1 are not met:

> (b) 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.
>
> (d) before giving consent, the person(s) referred to in paragraph (c) has been given 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 they have been given any further information which they may require.
>
> (g) 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 that is currently in force.

2.4. The committee noted the information that had been provided to support the Special Direction application.

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 embryos under General Direction 0006 because the following requirements were not satisfied:

(b) 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.

(d) before giving consent, the person(s) referred to in paragraph (c) has been given 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 they have been given any further information which they may require; and

(g) 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 that is currently in force.

2.7. The committee observed that, except for those cited at paragraph 1(b), (d) and (g) of Schedule 1, the other relevant requirements of General Direction 0006 were satisfied.

2.8. The committee noted that the egg donor will remain fully anonymous to the couple and any resultant offspring. The supplying clinic has consent from the donor relinquishing all rights to the embryos created from her eggs and allowing international transportation of those embryos. However, it is not clear whether the donor is aware of the laws governing the use of embryos in treatment and parentage in the UK, and how they may differ from those in Spain. Finally, the egg donor has not been fully screened in accordance with standard licence condition T52b (screening for anti-hepatitis B core antibodies). The donor is also not compliant with UK professional body guidelines because she has not been screened for gonorrhoea.

2.9. **Principle 2**

The committee noted that the proposed import was from a country inside of the EU and considered whether a refusal would amount to an interference with the patient's wish to obtain medical treatment services under the Treaty on the Functioning of the European Union because the embryos were essential for that treatment.

2.10. **Principle 3**

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 the couple's particular personal circumstances, the committee accepted that a refusal to allow their frozen embryos to be imported would amount to an interference with their rights to respect for their private and family life under Article 8 and to found a family under Article 12 of the ECHR, and noted that any refusal to grant the application would therefore need to be justified and proportionate.

2.11. **Principle 4 and 5**

The committee considered whether interference with the couple's rights under the ECHR could be justified and whether a refusal to grant the application would be disproportionate. In doing so, the committee had regard to the patients' particular circumstances. The committee considered the effect of a refusal on the couple and whether their situation was likely to constitute an isolated example or whether granting the application would set an undesirable precedent.

3. Decision

3.1. The committee took into consideration the patient couple's exceptional and difficult circumstances. The couple had undergone three unsuccessful fertility treatment cycles in the UK and, when these failed, travelled to Spain for treatment using donated eggs. The couple had one further unsuccessful treatment cycle using donated eggs. Unfortunately, the female patient was subsequently diagnosed with cancer and, as a result of the treatment she received for the disease, now required surrogacy treatment. This would have to take place outside of Spain, where surrogacy is illegal.

3.2. With regard to screening, the committee noted that the PR at GCRM Fertility has confirmed that IVF Spain will attempt to contact the donor for retrospective screening. The committee felt it was important to remind the centre that, if it is not possible to get retrospective screening, they should discuss the risks with the patient couple to ensure a fully informed decision is made.

3.3. With regard to the anonymity of the donor, the committee requested that, if any non-identifiable information relating to the egg donor was obtainable from IVF Spain, this be placed on the HFEA donor register so as to be available to any child(ren) born as a result of this treatment, should (s)he wish to access it once they reach 18 years of age.

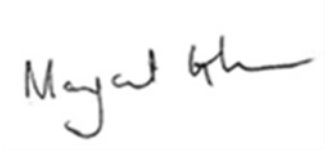
3.4. Taking all of these circumstances into account, the committee concluded that a refusal could not be justified and/or would amount to a disproportionate interference with the rights of the patient. The committee was satisfied that granting the application in the exceptional circumstances of this case would not set an undesirable precedent.

3.5. The committee therefore agreed to issue a Special Direction to enable GCRM Fertility, 21 Fifty Pitches Way, Cardonald Business Park, Glasgow, GS1 4FD, UK to import six embryos from IVF Spain, I. Avda Ansaldo, 13 02540, Alicante, Spain for treatment.

4. Chairs signature

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

Signature



Name
Margaret Gilmore

Date
24 June 2020