

# Statutory Approvals Committee – minutes

## Centre 0336 (Simply Fertility)

### Special Direction application to import embryos from IVI Madrid, Spain, for patient's own use.

Thursday, 29 October 2020

HFEA, 10 Spring Gardens, London, SW1A 2BU via Teams Meeting

Committee members	Margaret Gilmore (Chair) Anne Lampe Tony Rutherford Ruth Wilde	
Members of the Executive	Moya Berry Catherine Burwood	Committee Officer Licensing Manager
Legal Adviser	Eve Piffaretti	Blake Morgan - LLP
Observer	Bernice Ash Jane Darragh	Committee Officer Research Manager (Induction)

## Declarations of interest

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

## Apologies:

- Apologies were received from Emma Cave

## 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

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## 1. Background

- 1.1. The Person Responsible (PR) at Simply Fertility, has applied for a Special Direction to import four embryos from IVI Madrid, Spain, for storage and use in treatment at Simply Fertility, UK.
- 1.2. The embryos to be imported were created at a licensed centre and were cryopreserved in an IVF cycle with pre-implantation genetic screening at IVI Madrid, Spain when the female partner was 41 years old. The female partner is now 44 years old and wishes to have further treatment using the embryos.
- 1.3. The couple feel it is currently unsafe to travel to Spain for further treatment during the Covid-19 pandemic, as this would be against UK guidance and also because of underlying health conditions. Therefore, embryo import to the UK is the only way to allow the couple's treatment to progress in a timely manner.

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## 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 Simply Fertility is unable to import the four embryos from IVI Madrid, under General Direction 0006, because the following requirements of Schedule 1, paragraph 1 are not met:
  - (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:

  - (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(g) of Schedule 1, the other relevant requirements of General Direction 0006 were satisfied.
- 2.8. The committee noted that pre-screening was performed more than three months prior to commencing treatment which is in line with Spanish screening regulations but not UK regulations for a first treatment cycle. Subsequent virology screening performed in the UK in September 2020 has confirmed that these results are negative, meaning the gamete providers were not infected with HIV, hepatitis B or hepatitis C when the gametes were procured and embryos created.

## 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 patients' wishes 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 patients' 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 patients' 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.

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## 3. Decision

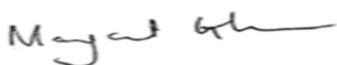
- 3.1. The committee took into consideration the couple's circumstances during this time when it is not currently practical, given the Government's advice, to travel to Spain due to the Covid-19 pandemic and on-going health care issues.
- 3.2. With regard to screening, the committee noted that the PR at Simply Fertility has confirmed the centre has undertaken further screening of the couple for Blood-Borne Viruses (BBVs) in September 2020 and these results are negative. This means the gamete providers were not infected with HIV, hepatitis B or hepatitis C when the gametes were procured, and embryos created.
- 3.3. 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 patients. The committee was satisfied that granting the application in the exceptional circumstances of this case would not set an undesirable precedent.
- 3.4. The committee therefore agreed to issue a Special Direction to enable Simply Fertility, Baddow Hospital, Simply Fertility Ltd, West Hanningfield Road, Great Baddow, Chelmsford, Essex, CM2 8HN, UK to import four embryos from IVI Madrid Avendia del Tago, 68 28023 Madrid, Spain, for treatment.

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## 4. Chairs signature

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

### Signature



### Name

Margaret Gilmore

### Date

16 November 2020