Statutory Approvals Committee - minutes

Centre 0250 (GCRM Fertility)

Special Direction application to import one embryo from USA

Date:	29 July 2021
Venue:	HFEA, 2nd Floor, 2 Redman Place, London E20 1JQ via Microsoft Teams
Committee Members:	Margaret Gilmore (Chair) Emma Cave Anne Lampe Ruth Wilde
Legal Adviser:	Sarah Ellson - FieldFisher LLP
Members of the Executive:	Moya Berry - Committee officer Catherine Burwood - Licensing Manager (observer) Dee Knoyle - Committee Officer (observer)
Observers:	Jonathan Herring - HFEA Authority Member
Apologies:	No apologies were received for the meeting
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:

- HFEA Code of Practice 9th edition
- Standard Licensing and Approvals Pack
- General Direction 0001 (2015)
- General Direction 0006 (GB) (July 2021)
- General Direction 0013 (GB) (December 2020)
- HFEA Standing Orders
- Special Direction Decision Tree - Import Export – (GB) (July 2021)

The following papers were considered by the committee:

- Executive update
- Minutes of the meeting which originally considered application 7223 for a Special Direction to import one embryo from the USA
- Full paper set originally considered by the Statutory Advisory Committee on May 28, 2020:
  - Executive Summary
  - Redacted application form
  - Further information form
  - Further information form request for further information from Inspector
  - Patient supporting information

1. Background

1.1. The person responsible (PR) at Centre 0250, GCRM Fertility, (the applicant) has applied for a Special Direction for the import of one frozen embryo from Shady Grove Fertility, United States of America (USA), to GCRM Fertility, United Kingdom (UK).

1.2. The committee noted that at its meeting on 28 May 2020, it had decided to adjourn the decision on whether to grant a Special Direction for the import of the embryo to the UK, pending further information providing details that the PR at centre 0250 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 a request had been made to the PR prior to the submission of the original application, however the centre's Inspector had not received a response before the May 2020 meeting.

1.3. In addition, the committee requested that the PR consider 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 they wish to access it once they reach 18 years of age.

1.4. The committee noted the embryo had been created with eggs and sperm from gamete donors and the patient has had one child following treatment in the USA. The committee noted the patient no longer meets the criteria for treatment in the US clinic.

1.5. The committee noted the patient lives in the UK and wishes to have further treatment to complete her family with a full genetic sibling for her first child.

1.6. The committee noted the donor sperm used to create the embryo is compliant with HFEA requirements and could be imported to be used to try for a half sibling for the patient's existing child if treatment with her one embryo is unsuccessful.

2. Consideration of the 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 its initial decision in May 2020 to adjourn the application to grant a Special Direction pending further information.

2.3. The committee noted that the Human Fertilisation and Embryology Act (as amended) permits the Authority to issue directions to allow import and export of gametes or embryos from/to countries outside of the UK. Furthermore, the committee noted that in relation to the import and export of gametes and embryos outside of Great Britain (GB) movement can be permitted without the need for a Special Direction if the conditions outlined in General Direction 0006 (GB) are satisfied.

2.4. The committee noted that this application for a Special Direction is being made as the centre is unable to import the embryo from the USA under General Direction 0006 (GB) (version 9), since the following requirements of paragraph 3 of Schedule 1 of General Direction 0006 cannot be 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.

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

2.6. The committee noted that in the time between the PR's application and the application being considered by the committee, at this meeting, version 9 of General Direction 0006 (GB) came into force on 1 July 2021. The committee agreed that the new version does not materially change the regulatory requirements for this import.

2.7. In considering the application, the committee had regard to its decision tree and 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 rights arising under the Human Rights Act 1998.

2.8. **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 (GB) 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.

(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.

2.9. The committee observed that, except for those cited at paragraph 3 (e), (f), (g) (h) and (j) of Schedule 1 (version 9), the other relevant requirements of General Direction 0006 (GB) were satisfied.

2.10. The committee noted that the embryo to be imported was created with donor eggs and sperm. The committee noted that the donor sperm used to create the embryo is compliant with HFEA requirements and could be imported to be used to try for a half sibling to the patient's existing child if treatment with the embryo is unsuccessful.

2.11. The committee noted that the centre has not been able to confirm the amount of compensation given to the egg donor in the USA and is unable to ascertain whether it is compliant with General Direction 0001 (version 4).

2.12. **Principle 2**
This principle is no longer applicable, following the UK's exit from the European Union.

2.13. **Principle 3**
The committee recognised that rights under the European Convention on Human Rights (ECHR) continue to apply notwithstanding the UK's exit from the European Union. Based on the patient's particular circumstances, the committee accepted that a refusal to allow her embryo to be imported would amount to an interference with her rights to a 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.

2.14. **Principle 4 and 5**
The committee considered whether interference with the patient'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 patient's particular circumstances. The committee considered the effect of a refusal on the patient and whether their situation was likely to constitute an isolated example or whether granting the application would set an undesirable precedent. The committee was mindful of the general pressing social need behind the principles set out General Directions 0001 and 0006 (GB), balanced against the impact on the patient's ECHR rights in these particular circumstances.

3. Decision

3.1. The committee was very grateful for the submission of evidence provided by the PR, who in response to the committee's request for further information, has sought an expert opinion from a specialist consultant virologist with an interest in congenital infections with Cytomegalovirus (CMV) and Human Cytomegalovirus (HCMV). The specialist has concluded that any other eggs recovered at the same time as those taken previously, are highly unlikely to be infected with HCMV or lead to a symptomatic child.

3.2. The committee noted that the PR has not been able provide any retrospective karyotype of the egg donor, whose gametes were used to create the embryo. However the PR has confirmed that the egg donor underwent comprehensive genetic screening, and no disease-causing mutations were detected.

3.3. With regard to the committee's request to provide any non-identifying information about the characteristics of the egg donor that could be placed on the HFEA donor register, the PR has confirmed that they have gathered a significant amount of non-identifying information about the egg donor, that they intend to supply to the HFEA donor register.

3.4. The committee noted that the patient no longer meets the criteria for treatment in the US clinic but has one child born using embryos created with eggs and sperm from the same gamete donors and that treatment with the embryo in question is the only chance this patient has to have a full genetic sibling for her existing child.

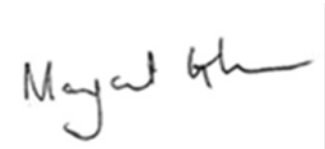
3.5. Taking all of the additional evidence into account, the committee concluded that a refusal could not be justified and/or would amount to a disproportionate interference with the rights of the patient. The committee was also satisfied that granting the application in the exceptional circumstances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

3.6. The committee therefore agreed to issue a Special Direction to import one embryo for use in treatment, from Shady Grove Fertility, 9601 Blackwell Road, Rockville MD 20850, United States of America to GCRM Fertility, 21 Fifty Pitches Way, Glasgow, G51 4FD, United Kingdom.

4. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

19 August 2021