

Statutory Approvals Committee - minutes

Centre 0035 (Oxford Fertility)

Special Direction application to export sperm to the United States of America (USA) for patients own use

Date:	29 July 2021
Venue:	HFEA, 2 nd Floor, 2 Redman Place, London E20 1JQ via Teams Meeting
Committee Members:	Margaret Gilmore (Chair) Emma Cave Anne Lampe Ruth Wilde
Legal Adviser:	Sarah Ellson – FieldFisher LLP
Members of the Executive:	Dee Knoyle - Committee Officer Moya Berry - Committee Officer Catherine Burwood – Licensing Manager
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:

- 9th edition of the HFEA Code of Practice
- Standard Licensing and Approvals Pack
- General Direction 0001 (2015)
- General Direction 0006 (GB) (v.9) (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 Summary
- Special Direction Application form
- Further Information form
- Redacted letter from the proposed receiving centre confirming willingness to accept the straws of sperm
- Redacted letter from patients

1. Background

- 1.1. The person responsible (PR) at Centre 0035, Oxford Fertility, (the applicant) has applied for a Special Direction for the export of seven straws of sperm from Oxford Fertility, Oxfordshire, UK to Shady Grove Fertility, Rockville, USA.
- 1.2. The committee noted that the male partner has cancer and is undergoing treatment with a good prognosis. However, the cancer treatment will render him infertile. Prior to treatment he had stored sperm samples which he now wishes to use in treatment with his female partner who is in her late 40s.
- 1.3. The couple are planning to create embryos using donor eggs. The couple have investigated the availability of donor eggs in the UK and found that they are in short supply. The couple have decided to use donor eggs from Shady Grove Fertility, Rockville, in the USA due to availability and to avoid long waiting times for each treatment cycle.
- 1.4. The committee noted that at the time of this application, it was not possible for the male partner and his female partner to travel to the USA due to travel restrictions related to the Covid-19 pandemic. The male partner had applied for a visa to travel to the USA to freeze some sperm samples before his cancer treatment had started, however his application was refused by the US Embassy in the UK due to Covid-19 pandemic related travel restrictions. Once the sperm has been exported and received by Shady Grove Fertility, the couple plan to continue their treatment in the USA when travel restrictions have been lifted.

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 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), Gibraltar and the European Economic Area (EEA), movement can be permitted without the need for a Special Direction if the conditions outlined in General Direction 0006 (version 9) are satisfied.
- 2.3. The committee noted that this application for a Special Direction is being made as the centre is unable to export the seven straws of sperm to Shady Grove Fertility, Rockville, USA under General Directions 0006 (version 9), since the following requirements of Schedule 2 cannot be met:
 - (h) The gametes or embryos are not to be exported if they could not be lawfully used in licensed treatment services in the United Kingdom in the manner or circumstance in which it is proposed that the gametes or embryos be used by the receiving centre.
- 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 will have 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.

Principle 1

2.6. The committee recognised that the centre is unable to export the male partner's sperm, for use in the patient couple's treatment, under General Direction 0006 (version 9), because the following requirements of Schedule 2 cannot be complied with:

(h) The gametes or embryos are not to be exported if they could not be lawfully used in licensed treatment services in the United Kingdom in the manner or circumstance in which it is proposed that the gametes or embryos be used by the receiving centre.

2.7. The committee observed that, except for those cited at paragraph 1 (h) of Schedule 2, the other relevant requirements of General Direction 0006 (version 9) were satisfied.

2.8. The committee noted that the sperm to be exported was provided by the male partner.

2.9. The committee noted that the couple plan to create embryos using the male partner's sperm with donor eggs, and that the egg donor will remain fully anonymous to the couple and any resultant offspring, as donors in the USA are non-identifiable.

2.10. The committee noted that the egg donor will receive payment and the amount of compensation given to the egg donor in the USA has not been confirmed and may not be compliant with General Direction 0001 (version 4).

Principle 2

2.11. This principle is no longer applicable, following the United Kingdom's exit from the European Union.

Principle 3

2.12. The committee recognised that rights under the European Convention on Human Rights (ECHR) are separate and distinct from those arising under the United Kingdom's previous membership of the EU.

2.13. Based on the information submitted on the patient couple's particular personal circumstances, the committee will decide whether or not a refusal to allow the export of the male partner's sperm to Shady Grove Fertility in the USA, would amount to an interference with their rights to a private and family life under Article 8 and to found a family under Article 12 of the ECHR, understanding that any refusal to grant the application would need to be justified and proportionate.

Principle 4 and 5

2.14. The committee will consider 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. In doing so, the committee will have regard to the patient couple's particular circumstances. The committee will also consider the effect of a refusal on the couple and whether this represents an isolated case or an undesirable precedent.

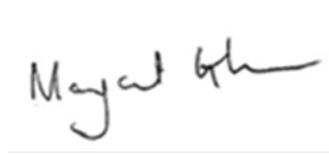
3. Decision

- 3.1.** The committee considered that this application for a Special Direction is being made as the centre is unable to export the seven straws of sperm to Shady Grove Fertility, Rockville, USA under General Directions 0006 (version 9), since the requirements of Schedule 2, 1(h), as mentioned above, cannot be met.
- 3.2.** The committee considered that the male partner has cancer and is undergoing treatment leaving him azoospermic. He wishes to use the sperm samples he produced and stored at Oxford Fertility before his cancer treatment started, to create embryos for treatment with his female partner, using donor eggs. The committee understands that the female partner is in her late 40s and wishes to start treatment as soon as possible. The committee considered that the patient couple state they wish to use donor eggs from Shady Grove Fertility in the USA because of the availability of donor eggs and lack of waiting time for each treatment cycle.
- 3.3.** The committee considered that, in 2005, UK laws around donor information access changed. Anonymity was removed following consultation, which concluded that many donor-conceived people have a desire and interest in finding out about their genetic origins. Standard Licence Condition T54 requires that identifiable donors be used in licensed treatment, with some exceptions. The committee considered that, in this case, the egg donor will remain fully anonymous to the couple and any resultant offspring, as donors in the USA are non-identifiable.
- 3.4.** The committee also considered that the amount of compensation given to the egg donor in the USA may not be compliant with General Direction 0001 (version 4) which limits compensation provided to donors to levels considered commensurate with compensation for inconvenience rather than payment, therefore not undermining the altruistic rationale for donation.
- 3.5.** After careful deliberation, the committee decided to adjourn its decision as to whether to grant a Special Direction to export the male partner's sperm to the USA. The committee decided that, in line with the process for other similar applications, clarity on the patient couple's special circumstances was necessary in order for this application to be progressed. The committee has requested further details of the circumstances of the couple, which may justify a Special Direction being granted. This includes details and evidence of:
- The attempts made by or on behalf of the patient couple to source donor eggs from centres in the UK and the individual findings about availability and waiting times.
 - An explanation of how treatment might reasonably be expected to begin sooner by exporting the male partner's sperm to the USA to create embryos using donor eggs given Covid-19 travel restrictions to the USA.
- 3.6.** The committee agreed that if this information can be provided quickly, the committee could resume consideration of this application within 2-4 weeks.

4. Chair's 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", enclosed in a thin black rectangular border.

Name

Margaret Gilmore

Date

30 July 2021