

# Statutory Approvals Committee - minutes

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## Centre 0035 (Oxford Fertility)

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

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Date:	12 August 2021
Venue:	HFEA, 2 <sup>nd</sup> Floor, 2 Redman Place, London E20 1JQ via Microsoft teams
Committee Members:	Margaret Gilmore (Chair) Emma Cave Anne Lampe Ruth Wilde Jason Kasraie
Legal Adviser:	Sarah Ellson – FieldFisher LLP
Members of the Executive:	Catherine Burwood – Licensing Manager (Secretary)
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.

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## 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) (July 2021)
- General Direction 0013 (GB) (December 2020)
- HFEA Standing Orders
- Special Direction Decision Tree - Import Export – (GB) (July 2021)

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## The following papers were considered by the committee:

- Executive update including table of egg availability data provided from centre 0035
- Email submission from centre 0035
- 29 July 2021 Statutory Approvals Committee (SAC) meeting minutes – Centre 0035, Special Direction application to export sperm to the United States of America (USA) for patients own use
- Previous paper set considered by SAC on 29 July 2021:
  - 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

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## 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, United Kingdom (UK) to Shady Grove Fertility, Rockville, United States of America (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, USA due to availability and to mitigate waiting times for each treatment cycle.
- 1.4. The committee noted that at the time of the 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. 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.
- 1.5. The committee noted that at its meeting on 29 July 2021, it had decided to adjourn the decision on whether to grant a Special Direction for the export of the sperm to the USA, pending further information. They requested that the applicant provide 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.

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## 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 as well information provided in response to the committee's request made at its meeting in July 2021.
- 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 (GB) (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 (GB) (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 (GB) (version 9) were satisfied.
- 2.8.** The committee noted that the sperm to be exported was provided by the male partner. The couple plan to create embryos using this sperm and donor eggs.
- 2.9.** The committee noted that the egg donor will remain fully anonymous to the couple and any resultant offspring, as donors recruited at their centre of choice 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 UK's exit from the European Union (EU).

#### **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 UK's previous membership of the EU.
- 2.13.** Based on the information submitted on the patient couple's particular personal circumstances, the committee accepted that a refusal to allow the export of the partner sperm 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 considered 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 had regard to the patient couple's particular circumstances. The committee considered the effect of a refusal on the couple and whether this represents an isolated case or an undesirable precedent.

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## **3. Decision**

- 3.1.** The committee agreed that there were likely to be viable alternatives to seeking treatment in the USA with anonymous donor eggs, that might progress treatment within a similar timeframe, and that would give any future child/ren the right to donor information, thus avoiding non-compliance with UK regulations.

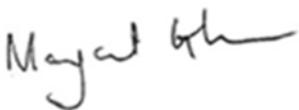
- 3.2.** However the committee could not be sure, in current circumstances, when UK treatment with donor eggs might be possible and noted that the patient couple believe that treatment will be quicker in the USA, rather than awaiting identifiable donor eggs and treatment in the UK and that this is an important factor in their decision to seek treatment in the USA.
- 3.3.** The committee considered the unique and particular circumstances of the patient couple. They noted that the male partner had needed to store his sperm prior to cancer treatment and was unable to do so in the USA due to Covid-19 restrictions. The committee noted that the male partner had applied for a visa to travel to the USA to freeze some sperm samples before his cancer treatment started. However the application to travel to the country for medical reasons, was denied by the US authorities. After his cancer treatment, the male partner will be infertile and therefore unable to produce further sperm.
- 3.4.** Taking the evidence provided 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.
- 3.5.** The committee therefore agreed to issue a Special Direction to export seven straws of sperm for use in treatment, from Oxford Fertility, Institute of Reproductive Sciences, Oxford Business Park North, Oxford, Oxfordshire, OX4 2HW, United Kingdom (UK) to Shady Grove Fertility, 601 Blackwell Road, Rockville, MD, 20850, United States of America (USA).
- 3.6.** As it is not known when travel to the USA might be possible, the committee encouraged the PR at Oxford Fertility to continue discussions with the patient couple about treatment options in the UK, which would be compliant with UK regulations and thus allow a donor conceived adult to access identifiable information about their donor, and felt that it might be prudent to retain some sperm in this country.

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## **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