

# Statutory Approvals Committee - minutes

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## Centre 0196 (Jessop Fertility)

### Special Direction application to virtually export and re-import embryos to and from Sweden.

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Date:	29 July 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
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.

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## The Committee had before it:

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- 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)
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## The following papers were considered by the committee:

- Executive Summary
  - Application for a Special Direction for the virtual export of embryos created with donor eggs in Sweden
  - Application for a Special Direction for the virtual re-import of embryos created with donor eggs in Sweden
  - Further Information form for both the virtual export and re-import of embryos
  - Email from proposed receiving centre confirming acceptance of embryos to be exported virtually
  - Executive Licensing Panel Minutes, 29 June 2021 – 2021 Renewal Inspection Report
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## 1. Background

- 1.1.** The person responsible (PR) at Centre 0196, Jessop Fertility, (the applicant) has applied for a Special Direction for the simultaneous export of four frozen embryos from Jessop Fertility, United Kingdom (UK) to the Reproduction Centre, Uppsala Akademiska Hospital, Sweden, and the re-import of the four frozen embryos from the Reproduction Centre, Uppsala Akademiska Hospital back to Jessop Fertility.
- 1.2.** The committee noted that the simultaneous export and re-import of the embryos is to take place virtually. The simultaneous export and import of the embryos will be a paper exercise rather than requiring the actual movement of the embryos, to ensure that the embryos can continue to be stored and used on a lawful basis.
- 1.3.** The committee noted the four frozen embryos had been created in Sweden with donor eggs and the patient's partner's sperm.
- 1.4.** The committee noted that the female partner had, due to medical reasons, undergone a donor egg IVF cycle while living in Sweden.
- 1.5.** The committee noted the couple now live in the UK and wish to continue their treatment in this country. The embryos are currently stored at Jessop Fertility but the import of the embryos into the UK in December 2020 was not compliant with General Direction 0006 version 7, which was in force at that time, and no Special Direction was sought or granted at the time.
- 1.6.** The committee noted that if the embryos could not be simultaneously exported and re-imported, the couple would have to begin the process of finding a suitable egg donor in the UK.
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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.
- 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) movement can be permitted without the need for a Special Direction if the conditions outlined in General Direction 0006 (GB) are satisfied.

**2.3.** The committee noted that this application for a Special Direction is being made as the embryos are currently not being stored on a lawful basis and cannot therefore be used. The centre is unable to simultaneously export and import the four frozen embryos from the UK to Sweden and back to the UK under General Direction 0006 (GB) (version 9), since the following requirements of paragraph 1 of Schedule 2 (Export) of General Direction 0006 (GB) cannot be met:

(f) 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 Direction 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving importing money or other benefits.

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

since the following requirements of paragraph 3 of Schedule 1 (Import) of General Direction 0006 (GB) cannot be met:

(e) 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 Direction 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving importing money or other benefits.

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

**2.5.** The committee noted that in the time between the PR's application and the application being considered by committee, 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 virtual export and import of the embryos.

**2.6.** The committee also noted that the executive is assured that the requirements in relation to the quality and safety standards of the embryos to be re-imported virtually, should the Special Direction be granted, had already been met at the time of the import in December 2020. The committee therefore agreed that requiring the PR to obtain an Importing Tissue Establishment (ITE) certificate would not be necessary.

**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 virtually export and then re-import the embryos, for use in the patient couple's treatment, under General Direction 0006 (GB) because the following requirements cannot be complied with:

Paragraph 1 of Schedule 2 (export) of General Direction 0006 (GB) -

(f) 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 Direction 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving importing money or other benefits.

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

Paragraph 3 of schedule 1 (import) of General Direction 0006 (GB) –

(e) 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 Direction 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving importing money or other benefits.

- 2.9.** The committee observed that, except for those cited at paragraph 1(f) and 1(h) of Schedule 2, and paragraph 3(e) of Schedule 1 the other relevant requirements of General Direction 0006 (GB) were satisfied.
- 2.10.** The committee noted that the embryos to be imported were created with donor eggs and sperm from the male patient. The committee noted that only altruistic egg donation is permitted in Sweden. The Swedish health service, the SKL, have set a national fixed sum of 5600SEK (approximately £476) per egg donation cycle which is lower than that allowed for UK donors. However this is not compliant with General Direction 0001 (version 4) which requires a record of the actual expenses incurred by the donor to be kept.
- 2.11.** The committee noted that the centre has not been able to confirm the amount of compensation given to the egg donor in Sweden and is unable to ascertain whether it is compliant with General Direction 0001.
- 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 couple's particular circumstances, the committee accepted that a refusal to allow their embryos to be exported and re-imported 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 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 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 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 couple's ECHR rights in these particular circumstances.

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### **3. Decision**

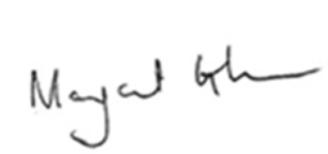
- 3.1.** The committee took into consideration that the embryos had been created using donor eggs and the patient's partner's sperm.
- 3.2.** In considering this application, the committee decided that given this particular non-compliance, it would be disproportionate not to allow the embryos to be exported and re-imported, given how distressing it would appear to be for the female patient to travel back to Sweden to continue her treatment. The committee also noted that except for the criterion relating to the recording of expenses, the embryos appear to have fulfilled all other criteria.
- 3.3.** The committee noted the patient statement and the difficulties the COVID-19 restrictions have placed on the family.
- 3.4.** Taking all 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 couple. 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 for the simultaneous export of four frozen embryos from Jessop Fertility, Sheffield Teaching Hospitals NHS Foundation Trust, Jessop Wing, Tree Root Walk, Sheffield, S10 2SF, United Kingdom (UK) to the Reproduction Centre, Uppsala Akademiska Hospital, 75185, Uppsala, Sweden, and the simultaneous re-import of the four frozen embryos from the Reproduction Centre, Uppsala Akademiska Hospital back to Jessop Fertility.

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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