

Statutory Approvals Committee - minutes

Centre 0044 (The Centre for Reproductive and Genetic Health)

Special Direction application to import embryos from USA

Date:	12 August 2021
Venue:	HFEA, 2 nd 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.

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:

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- Executive summary
 - Redacted application form
 - Further information form
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1. Background

- 1.1. The person responsible (PR) at Centre 0044, The Centre for Reproductive and Genetic Health, (the applicant) has applied for a Special Direction for the import of four embryos from Utah Fertility Center, United States of America (USA) to the United Kingdom (UK).
- 1.2. The committee noted the male couple have previously had two successful treatments with embryos created using the same donor eggs and partner sperm and wish to have further treatment with an identified surrogate in the UK to complete their family with a full genetic sibling for their children.
- 1.3. The import of the embryos is not compliant with General Direction 0006 (GB) (version 9) because the amount of compensation given to the egg donor in the USA was in excess of that permitted by General Direction 0001 (version 4).

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 centre is unable to import the embryos from the USA under General Direction 0006 (GB) (version 9), since the following requirements of Schedule 1 of General Direction 0006 (GB) cannot be met:
 - (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.
- 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 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.
- 2.6. **Principle 1**

The committee recognised that the centre is unable to import the embryos, for use with a surrogate, under General Direction 0006 (GB) because the following requirements cannot be complied with:

 - (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.

- 2.7.** The committee observed that, except for those cited at paragraph 3 (h) of Schedule 1 (version 9), the other relevant requirements of General Direction 0006 (GB) were satisfied.
- 2.8.** The committee noted that the embryos to be imported were created with donor eggs and partner sperm. The committee noted that the egg donor received \$4500 for the donation.
- 2.9. Principle 2**
This principle is no longer applicable, following the UK's exit from the European Union.
- 2.10. 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 patients' particular circumstances, the committee accepted that a refusal to allow their embryos to be 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.
- 2.11. 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 patients' 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.
- 2.12.** The committee noted that the patient couple would alternatively be required to fly to the USA to find a new surrogate, in order to have the chance to create a full sibling for their existing children. This may not be possible at present due to current Covid-19 restrictions and would potentially involve further delays and significant additional stress for the couple.

3. Decision

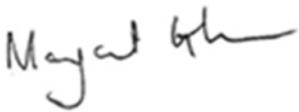
- 3.1.** The committee considered how the patients already have a surrogate arranged in the UK and that the embryos they wish to import had been created from the same donor and patient sperm as those used to create their existing children. The surrogate is unable to travel to the USA and Covid-19 restrictions may mean it is not possible for the patients to travel themselves, in order to find a new surrogate.
- 3.2.** The committee understood that the couple wished to have a further child/children who would be a full genetic sibling(s) to their existing children and decided that it would not be proportionate to expect the couple to make alternative arrangements to use these existing embryos considering the Covid-19 restrictions.
- 3.3.** 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.
- 3.4.** The committee therefore agreed to issue a Special Direction to import four embryos for use in treatment, from Utah Fertility Center, 1446 S Pleasant Grove Blvd, Pleasant Grove, UT 84062,

United States of America to The Centre for Reproductive and Genetic Health, 230-232 Great Portland Street, London, W1W 5QS, United Kingdom.

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". The signature is written in a cursive style with a long horizontal flourish at the end.

Name

Margaret Gilmore

Date

19 August 2021