

Statutory Approvals Committee - minutes

Centre 0341 (The Fertility & Gynaecology Academy)

Special Direction application to import embryos from Canada.

Date:	29 April 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:	Darryn Hale – DAC Beachcroft LLP
Members of the Executive:	Moya Berry - Committee officer Catherine Burwood - Licensing Manager
Observers:	Julia Chain - HFEA Chair (Induction) Tim Child - HFEA Authority Member (Induction) Neil Ward - Mills & Reeve LLP (New Legal Adviser)
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 Licencing and Approvals Pack
 - General Direction 0001 (2015)
 - General Direction 0006 (2020)
 - General Direction 0013 (2018)
 - HFEA Standing Orders
 - Special Direction Decision Tree - Import Export - for use 31 Dec-30 June - GB
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The following papers were considered by the committee:

- Executive Summary
 - Redacted application form
 - Further Information form
 - Patient Statement in support of the application
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1. Background

- 1.1.** The person responsible (PR) at Centre 0341, The Fertility & Gynaecology Academy, (the applicant) has applied for a Special Direction for the import of four frozen embryos from the New Life Fertility Centre, Toronto, Canada to The Fertility & Gynaecology Academy, United Kingdom (UK).
- 1.2.** The committee noted the four frozen embryos had been created with donated eggs and the male patient's sperm.
- 1.3.** The committee noted, that while residing in Canada, the patient couple have previously had successful treatment with embryos created using eggs from the same donor and the male partner's sperm, resulting in one child.
- 1.4.** The committee noted the couple now live in the UK and wish to have further treatment to complete their family with a full genetic sibling for their first child.
- 1.5.** The couple initially travelled to Canada for IVF treatment to find an egg donor to match the ethnic origin of the patients as this had not been possible in the UK. The committee noted the particular difficulties the couple had experienced in trying to travel to Canada to complete their treatment due to current COVID travel restrictions.
- 1.6.** The committee noted that if the embryos could not be imported, the couple would have to begin the process of finding a suitable egg donor in the UK and would be unable to create a full genetic sibling to their existing child. The couple also feel it is unlikely that they would be able to have egg donor treatment in the UK due to the limited availability of donors that match their ethnic origin.

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 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 four frozen embryos from Canada under General Direction 0006 (GB)

(version 8), since the following requirements of Schedule 2 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.

(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 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. 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 in the patient couple's treatment, under General Direction 0006 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.

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

2.7. The committee observed that, except for those cited at paragraph 3 (e) and (h) of Schedule 2, the other relevant requirements of General Direction 0006 were satisfied.

2.8. The committee noted that the embryos to be imported were created with donor eggs and sperm from the male patient. The committee noted that the egg donor has been asked and has not consented to be identified and therefore will remain anonymous to the couple and any resultant offspring, as donors in Canada are able to remain non-identifiable.

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

2.10. Principle 2

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

2.11. Principle 3

The committee recognised that rights under the European Convention on Human Rights (ECHR) continue to apply notwithstanding the United Kingdom'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 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.

2.12. 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, balanced against the impact on the couple's ECHR rights in these particular circumstances.

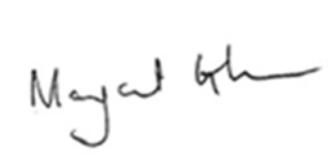
3. Decision

- 3.1.** The committee took into consideration that the embryos had been created using donor eggs and the patient couple's sperm. The committee noted that the couple already has one child born using embryos created from this egg donor and male partner 's sperm, and now wish to have a full genetic sibling for their child.
 - 3.2.** The committee noted that if the embryos could not be imported the couple would have to begin the process of finding a suitable egg donor in the UK and any subsequent children born would not be a full genetic sibling for their first child.
 - 3.3.** The committee noted that the couple had initially travelled to Canada as they had not been able to find an ethnic match donor in the UK.
 - 3.4.** The committee noted the patient statement and the difficulties the restrictions have caused the family.
 - 3.5.** The committee noted that the donor had been asked but did not give consent to be identified. The committee expressed their concern that the donor did not consent to be identifiable to the existing child and to any offspring yet to be born but recognised that this was her right under Canadian regulations.
 - 3.6.** 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.
 - 3.7.** The committee therefore agreed to issue a Special Direction to import four embryos for use in treatment, from The New Life Fertility Centre, 4250 Sherwoodtowne Blvd, Mississauga ON L4Z 2G6, Toronto, Canada to The Fertility & Gynaecology Academy, 57A Wimpole Street, London, W1G 8YP, United Kingdom.
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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 on a white background. The signature appears to read "Margaret Gilmore" in a cursive script.

Name

Margaret Gilmore

Date

1 June 2021