

Statutory Approvals Committee - minutes

Centre 0044 (The Centre for Reproductive and Genetic Health)

Special Direction application to import eggs 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:

- 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
 - 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 23 eggs from Cryogram, Colorado, United States of America (USA) to the United Kingdom (UK).
- 1.2. The committee proceeded on the understanding that the eggs were those of the patient now seeking treatment and noted that the patient wishes to import the eggs which were procured at a younger age. The eggs are currently stored at Cryogram, Colorado, which is a storage bank. They were originally procured at CT Fertility which is no longer operational.
- 1.3. The committee noted that centre 0044 is unable to determine whether the procurement and processing of the eggs has taken place in appropriate facilities and following procedures that minimise bacterial or other contamination in accordance with General Direction 0006 (GB) (version 9). Additionally, the centre is unable to verify whether the eggs meet the UK requirements on screening in accordance with the HFEA's standard licence conditions and the Code of Practice currently in force.
- 1.4. The committee noted that the patient is a resident in the UK and is said to be unable to travel to the USA due to current Covid-19 travel restrictions.

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 eggs 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:
 - (d) the procurement and processing of the gametes or embryos has taken place in appropriate facilities and following procedures that minimise bacterial or other contamination.
 - (j) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the HFEA's standard licence conditions and the Code of Practice currently in force.
- 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 eggs, for use in the patient's treatment, under General Direction 0006 (GB) because the following requirements cannot be complied with:

(d) the procurement and processing of the gametes or embryos has taken place in appropriate facilities and following procedures that minimise bacterial or other contamination.

(j) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the HFEA's standard licence conditions and the Code of Practice currently in force.

2.7. The committee observed that, except for those cited at paragraph 3 (d) and (j) of Schedule 1 (version 9), the other relevant requirements of General Direction 0006 (GB) were said to be satisfied.

2.8. Principle 2

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

2.9. 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's particular circumstances, the committee accepted that a refusal to allow her eggs to be imported would amount to an interference with her 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.

2.10. 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 patient's particular circumstances. The committee considered the effect of a refusal on the patient and whether her 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.

2.11. Notwithstanding the above, the committee considered whether interference would be proportionate in this case. The committee noted the impracticalities of travel to the USA for treatment due to the Covid-19 restrictions. In addition, the committee noted that the eggs are currently in a storage bank and that the most extensive risks, from non-compliance with the requirements above, would be to the informed and consenting patient and not any child born. It noted that whilst the applicant centre could not confirm whether virology tests were performed prior to procurement of the eggs the centre has virology results for the patient taken post sample procurement. It also noted that the closure of the original procuring centre in the US is the reason why the applicant centre cannot determine whether the procurement and processing took place in appropriate facilities.

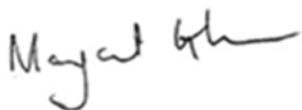
3. Decision

- 3.1.** The committee considered how the patient has 23 of her own eggs stored in the USA and that she would be required to find a new fertility clinic in the USA in order to continue treatment there. Due to the Covid-19 pandemic, travel to the USA is currently severely restricted. The committee considered that the clinic is obliged to explain any risks to the patient and obtain their informed consent, and recommended that this include any theoretical risks to the future child that may follow from non-compliance with virology screening.
- 3.2.** 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.
- 3.3.** The committee therefore agreed to issue a Special Direction to import the patient's 23 eggs for use in treatment, from Cryogam, Colorado, 2216 Hoffman Dr # B, Loveland, CO 80538, 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



Name

Margaret Gilmore

Date

19 August 2021