Statutory Approvals Committee - minutes

Centre 0044 (The Centre for Reproductive and Genetic Health)

Special Direction application to import embryos from Australia

Date:	4 October 2021
Venue:	HFEA, 2nd Floor, 2 Redman Place, London E20 1JQ via Microsoft Teams
Committee Members:	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Jason Kasraie
Legal Adviser:	Gerard Hanratty - Browne Jacobson LLP
Members of the Executive:	Moya Berry - Committee Officer Catherine Burwood - Licensing Manager (observer)
Observers:	Jonathan Herring - Authority Member (HFEA)
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)

The following papers were considered by the committee:

- Executive Summary
- Redacted application form
- Further Information form

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 seven frozen embryos from Fertility Specialist of Western Australia, Australia to The Centre for Reproductive and Genetic Health, United Kingdom (UK).

1.2. The committee noted that the embryos had been created when the female patient was younger so the likelihood of successful treatment using these embryos, rather than any created now, is increased. Additionally the patient previously suffered medical complications whilst undergoing a fresh stimulation cycle of fertility treatment, so would like to avoid further fresh stimulation treatment cycles.

1.3. The committee noted, that whilst in Australia, the couple has previously had successful treatment with their embryos, resulting in one child and wish to undergo further treatment in the UK using the embryos they created in Australia to have a second child.

1.4. The committee noted the couple are British citizens residing in Australia but have now decided to return to the UK to pursue further treatment to complete their family.

1.5. The committee also noted the particular difficulties the patient couple may face if they have to travel back to Australia to use their existing embryos in treatment. As the couple are both British citizens, it is likely that travel would not be possible due to the current Covid-19 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 seven frozen embryos from the Australia), since the following requirements of Schedule 1 of General Direction 0006 (GB), paragraph 3 cannot be met:

> (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 embryos, for use in the patient's treatment, under General Direction 0006 (GB) because the following requirements cannot be complied with:

> (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 (j) of Schedule 1, the other relevant requirements of General Direction 0006 (GB) were satisfied.

2.8. The committee noted the screening tests carried out on the couple prior to treatment were not in accordance with HFEA's standard licence conditions and the Code of Practice. This is because they were not carried out within three months before the couple first provided their gametes for use in treatment.

2.9. The committee noted that both patients were tested for HIV, Hepatitis C and Hepatitis B Surface in August 2018 and all results were negative. However, as the embryos were created and stored in August 2019, the screening results are nine months pre-embryo creation. The committee noted that further screening results taken in November 2019, for both patients, were all negative, but only the female patient was tested for Hepatitis B Core as this is not routinely tested for in Australia.

2.10. The committee noted the information from the clinic regarding the screening regulations in Australia. The clinic explained that there are no national guidelines with respect to the timing of screening. The clinic confirmed that it has its own policy whereby all screening bloods are taken pre-treatment and thereafter updated yearly. The clinic confirmed that the screening results taken from the couple pre-treatment were negative, as were the results taken post embryo creation. Samples were also stored in a screened tank with other screened samples and have never been stored with unscreened samples.

2.11. **Principle 2**

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

2.12. **Principle 3**

2.13. 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 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.

2.14. The committee noted that the embryos created when the patients were younger are essential for treatment and if they could not be imported the couple would have to undergo a further fresh cycle of fertility treatment, with a potentially lower chance of success. The committee noted the personal circumstances of the family and the potential for serious complications that the female patient may suffer if the embryos could not be imported, and she were required to undergo a further fresh cycle of fertility treatment.

2.15. **Principle 4 and 5**

The committee considered whether interference with the patients' 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 patients ECHR rights in these particular circumstances.

3. Decision

3.1. The committee noted that the couple already has one child born using their embryos and that they now wish to return to the UK to undergo fertility treatment to have a second child.

3.2. The committee noted the female patient's previous past medical history and the established complications she suffered as a result of the fertility treatment.

3.3. The committee noted that the embryos had been created when the female patient was younger so there is a potential increase in the likelihood of successful treatment using these embryos. The committee also considered the effect that any delay, as a result of the patient being unable to bring her embryos to the UK, could have on her obstetric risk.

3.4. The committee noted that as the couple are both British citizens, once they have returned to the UK, travel back to Australia to have treatment would likely be very difficult due to the current Covid-19 restrictions.

3.5. The committee noted that in Australia there are no national guidelines regarding timing of screening pre-treatment. However the committee noted the confirmation from the clinic that all screening results that were taken since the creation of the embryos were negative, as were the results taken post embryo creation.

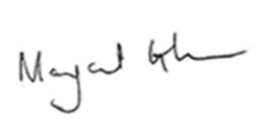
3.6. Taking all these circumstances into account, the committee concluded that a refusal could not be justified and/or would amount to a disproportionate interference with the rights of the patient. The committee was also satisfied that granting the application in the exceptional circumstances of this case would not set an undesirable precedent.

3.7. The committee therefore agreed to issue a Special Direction to import seven embryos for use in treatment, from Fertility Specialists of Western Australia, Bethesda Hospital, 25 Queenslea Drive, Claremont, Western Australia 6010, Australia 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

27 October 2021