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
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 three frozen embryos from Melbourne IVF, Australia to The Centre for Reproductive and Genetic Health, United Kingdom (UK).

1.2. The committee noted, that whilst in Australia, the couple has previously had successful treatment, resulting in one child and wish to undergo further treatment in the UK to have a second child.

1.3. The committee noted that the embryos had been created and stored when the female patient was younger. The couple wish to use these embryos rather than undergoing a further cycle, which may have a potentially lower chance of success, as the female patient is now older. Furthermore the female patient has a balanced translocation, increasing her risk of having a chromosomally unbalanced pregnancy that could lead to either miscarriage or the birth of a child with a congenital malformation and/or intellectual disability. The committee noted that these embryos have been genetically tested and were found to have no chromosomal imbalance detected.

1.4. The committee noted that as an Australian citizen, the female patient can return to Australia for treatment if she quarantines for 2 weeks, due to Covid-19 restrictions. Her husband, a British citizen, cannot accompany her. Following embryo transfer, the patient would be unable to leave Australia for 6 weeks in order for her to be monitored for potential complications. As she has a young child, she is unable to be away from the infant for such a long period of time.

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 three frozen embryos from Australia under General Direction 0006 (GB) (version 9), since the following requirements 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 couple'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 the HFEA's standard licence conditions and the Code of Practice. This is because the screening tests were not carried out within three months before the female patient first provided her gametes for use in treatment and did not include testing for Hepatitis B core. Whilst the male patient was screened within three months of first providing his gametes for use in treatment, this did not include testing for Hepatitis B core.

2.9. The committee noted that in Australia there are no national guidelines regarding timing of screening pre-treatment. Melbourne IVF require screening tests to be taken within two years of treatment. Hepatitis B core is not routinely tested in Australia. All screening results taken pre-treatment were negative. The patients have been re-tested at their GP for HIV, Hepatitis C, Hepatitis B core and Hepatitis B surface, and all results are negative.

2.10. The committee also noted that the female patient has a balanced translocation. This means that she has an increased risk of having a chromosomally unbalanced pregnancy that could lead to either miscarriage or the birth of a child with a congenital malformation and/or intellectual disability and these embryos have been genetically tested and were found to have no chromosomal imbalance detected.

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 patient was younger are essential for treatment and if they could not be imported the couple would have to undergo a further cycle of fertility treatment, with a potentially lower chance of success as the female patient is now older. In addition the female patient has a balanced translocation, increasing her risk of having a chromosomally unbalanced pregnancy that could lead to either miscarriage or the birth of a child with a congenital malformation and/or intellectual disability and these embryos have been genetically tested and were found to have no chromosomal imbalance detected.

2.15. **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 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 wish to have a genetic sibling for their child. They wish to undergo treatment in the UK using the embryos they created in Australia, to have a second child.

3.2. The committee noted that if the embryos could not be imported the couple would have to undergo a further fresh cycle of fertility treatment, with a potentially lower chance of success as the female patient is now older. In addition the female patient has a balanced translocation, increasing her risk of having a chromosomally unbalanced pregnancy that could lead to either miscarriage or the birth of a child with a congenital malformation and/or intellectual disability and these embryos have been genetically tested and were found to have no chromosomal imbalance detected.

3.3. The committee also considered the impact of the couple being unable to travel to Australia because of Covid-19 restrictions. The committee also considered the impact of the couple being unable to travel to Australia because of Covid-19 restrictions. The patient's husband, a British citizen, would be unable to accompany his partner, and following embryo transfer, the patient would be unable to leave Australia for 6 weeks in order for her to be monitored for potential complications. As she has a young child, if she had to travel to Australia for treatment, she would be separated from the infant for a considerable period of time, which could cause emotional distress to both her and her child.

3.4. The committee noted that in Australia there are no national guidelines regarding timing of screening pre-treatment. However, Melbourne IVF require screening tests to be taken within 2 years of treatment. Screening results taken pre-treatment were negative and the committee noted that both patients have since been re-tested at their GP for HIV, Hepatitis C, Hepatitis B core and Hepatitis B surface, and all results are negative.

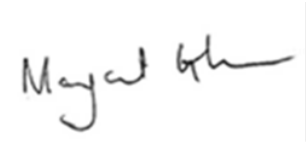
3.5. Taking all these circumstances into account, the committee concluded that a refusal could not be justified and/or would amount to a disproportionate interference with the rights of the patients. The committee was also satisfied that granting the application in the exceptional circumstances of this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

3.6. The committee therefore agreed to issue a Special Direction to import three embryos for use in treatment, from Melbourne IVF, 344 Victoria Parade, East Melbourne, Victoria 3002, 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