

Statutory Approvals Committee – minutes

Centre 0105 (London Women’s Clinic)

Special Direction application to export embryos to Tokyo, Japan

Thursday, 26 March 2020

HFEA Teleconference Meeting

Committee members	Margaret Gilmore (Chair) Emma Cave Anne Lampe Tony Rutherford Ruth Wilde
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Members of the Executive	Moya Berry Catherine Burwood	Committee Officer Licensing Manager
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Legal Adviser	Gerard Hanratty	Browne Jacobson LLP
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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:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members
- General Directions 0001 (2015)
- General Directions 0006 (2018)
- General Directions 0013 (2018)
- HFEA Standing Orders (2018)
- Special Directions Decision Tree (2018)

The following papers were considered by the committee:

- Executive Summary
 - Special Directions Application Form
 - Further information form
 - Letter from the proposed receiving centre confirming willingness to accept the embryos
 - Letter from the exporting centre explaining reasons for the transport
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1. Background

- 1.1.** The Person Responsible (PR) at Centre 0105 (the applicant) has applied for a Special Direction for the export of three frozen embryos from London Women's Clinic, United Kingdom (UK) to Oak Clinic Ginza, Japan.
- 1.2.** The committee noted the patient couple, due to personal circumstances, have returned back to Japan sooner than anticipated. The patient couple have three embryos in storage, following fertility treatment at the London Women's Clinic, and now wish to export them to Japan to continue their treatment.
- 1.4.** The committee noted the embryos were created from the couple's own gametes and have been genetically tested via pre-implantation genetic diagnosis (PGD) and are therefore vital for the patient couple's treatment in Japan.
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2. Consideration of application

Application

- 2.1.** The committee considered the application, which included an executive summary, a Special Direction application form and 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 exports of gametes or embryos to countries outside of the United Kingdom. Furthermore, the committee noted that in relation to the import and export of gametes and embryos outside Gibraltar and the European Economic Area (EEA), movement can be permitted without the need for a Special Direction if the conditions outlined in General Directions 0006 are satisfied.
- 2.3.** The committee noted that this application for a Special Direction is being made as the centre is unable to export the three frozen embryos to Oak Clinic Ginza, Japan, under General Directions 0006, since the following requirements of Schedule 4 of General Directions 0006 cannot be met:
1. (b) the receiving centre has a quality management system in place which has been certified by an internationally recognised body.
- 2.4.** The committee noted the information that had been provided to support the Special Direction application. This included a letter from Oak Clinic Ginza, Japan which confirms that they are willing to accept the embryos for use in treatment.
- 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 from rights arising under the Human Rights Act 1998.
- 2.6. Principle 1**
- The committee noted the non-UK centre was outside the EEA and Gibraltar, and discussed the centre's compliance with section 1(b), Schedule 4 of the General Directions 0006, noting the clinic the

patient couple wishes to transfer the embryos to, does not have a quality management system certified by an internationally recognised body. However, the committee acknowledged the receiving centre has its own formalised quality management system and noted that the clinic performs regular audits, undertakes quality indicator monitoring and follows a quality control protocol.

2.7. Principle 2

The committee noted the proposed export was to a country outside the EU and considered whether a refusal would amount to an interference with the couples wish to obtain medical treatment services because the embryos were essential for treatment. The committee acknowledged that the couple's own gametes were used to create the embryos, which had undergone genetic testing via PGD, and so were essential for treatment.

2.8. Principle 3

The committee recognised that rights under the European Convention on Human Rights (ECHR) are separate and distinct from those arising under the United Kingdom's previous membership of the EU. Based on the patient couple's particular personal circumstances, the committee accepted that a refusal to allow their embryos to be exported 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.

2.9. Principle 4

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 this represented an isolated case or an undesirable precedent.

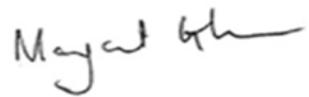
3. Decision

- 3.1.** The committee took into consideration the unique combination of factors leading to this application and the emotional and personal needs of the patient couple. The couple have three frozen embryos available for use and are keen for these to be exported for use in treatment in Japan where they are now living. The committee noted the embryos have been genetically tested and acknowledged the efforts and dedication the couple have gone through to generate the embryos. Further, the committee noted that the clinic in Japan did have a quality management system in place.
- 3.2.** Taking all of 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 particular case would not set an undesirable precedent.
- 3.3.** The committee therefore agreed to issue a special direction in the case of London Women's Clinic, 113-115 Harley Street, London, W1G 6AP United Kingdom (UK) to export three embryos to Oak Clinic Ginza, 7F Okura House 2-6-12, Ginza, Chou-ku, Tokyo 104-0061, Japan, for use in treatment.

4. Chairs 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".

Name

Margaret Gilmore

Date

23 April 2020