



Statutory Approvals Committee - minutes

Centre 0055 (The James Cook University Hospital) – application for Special Directions to export embryos to Reprofit International, Czech Republic

Thursday, 28 January 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Committee members	David Archard (Chair) Rebekah Dundas (Deputy chair) Sue Price Margaret Gilmore	
Members of the Executive	Trent Fisher	Secretary
Legal Adviser	Tom Rider	Fieldfisher
Observers	Dr Jenny Carmichael	

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- executive summary
- application form
- special directions further information form
- letter from recipient centre

1. Consideration of application

- 1.1. The committee noted that the centre has applied for Special Directions to export five embryos to the Reprofit International, Czech Republic.
- 1.2. The committee noted that the HFEA Act 1990 (as amended) permits the Authority to issue directions to allow the export of gametes or embryos to countries outside the United Kingdom. Furthermore, the committee noted that if in relation to the export of gametes outside the EEA the conditions set out by schedule 2 of General Directions 0006, of which there are nine, are all satisfied, export is permitted without the need for a Special Direction.
- 1.3. The committee noted that this application for Special Directions is being made because the centre is unable to export the embryos under the auspices of General Directions 0006 because it is unable to meet the requirements of Schedule 2, Section 1:
 - (f) the gametes or embryos are not exported if they could not lawfully be used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre;
- 1.4. The committee noted that Special Directions should not be granted routinely, or where the purpose or dominant effect appears to be to circumvent these requirements.
- 1.5. The committee noted that the patient couple travelled to the Czech Republic for treatment where sperm procured from the male partner was mixed with donor eggs. An embryo transfer took place which was unsuccessful. Five embryos had be frozen at the time of treatment.
- 1.6. The committee noted that the embryos were imported into the United Kingdom by centre 0055 for treatment under the auspices of General Direction 0006 as at the time it was believed by that centre that the requirements under Schedule 1 were met. However, it is now known that these embryos cannot lawfully be used in the UK as they were created with the eggs of a donor who had not consented to their identity being known.
- 1.7. The committee noted that during a HFEA inspection of the centre the error was identified and the centre is taking action to correct this error and return the five embryos to Reprofit International in the Czech Republic for the continuation of treatment of the patient couple.
- 1.8. The committee noted that the application states the embryos represent the couple's only chance of having the family as the couple cannot afford to start any additional treatments in the UK.
- 1.9. The committee noted that the centre has offered the couple one or more free cycles of treatment but are unable to do so as they do not have an appropriate egg donor.
- 1.10. The committee noted that it is stated in the application that the couple have a great deal emotionally invested in these embryos, and denial of treatment might have serious effects on their health and wellbeing.

2. Decision

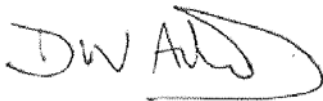
- 2.1. The committee weighed the receiving centre's inability to meet certain requirements set out in General Direction 0006 against the particular circumstances of the patient couple. The committee noted that General Directions existed for good reason, and were the footing on which the Authority sets out its policy for importing or exporting gametes or embryos. However, the committee also noted that evidence had been provided by the receiving centre that went some way to satisfying the requirements of General Direction 0006 that could not be fully satisfied.

- 2.2.** In light of the circumstances of the applicant couple the committee concluded that a refusal to issue Special Directions would interfere with the right to marry and found a family under Article 12 of the ECHR.
- 2.3.** The committee concluded that denying the application would be disproportionate as no significant level of concern has been raised which would make a refusal justified.
- 2.4.** The committee agreed to grant Special Directions in this case for centre 0055 (The James Cook University) to export 5 embryos to Reprofit International, Czech Republic.
- 2.5.** The committee concluded that the current case involves a highly exceptional set of circumstances. Accordingly, granting this application for Special Directions would not set an undesirable precedent which would undermine the imperative requirements identified.

3. Chair's signature

- 3.1.** I confirm this is a true and accurate record of the meeting.

Signature

A handwritten signature in black ink, appearing to read 'DWA', with a large, sweeping flourish underneath.

Name

David Archard

Date

10 February 2016