

# Statutory Approvals Committee – minutes

## Centre 0185 (CARE Manchester)

## Special Directions application to Import Sperm from Israel for patients' own use in treatment in the United Kingdom (UK)

Thursday, 27 April 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Anthony Rutherford Bobbie Farsides	
Members of the Executive	Dee Knoyle Paula Robinson Bernice Ash	Secretary Head of Planning and Governance Committee Officer
External adviser		
Legal Adviser	Graham Miles	Blake Morgan
Observers		

## Declarations of interest

- Members of the panel 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
- Special Directions Application Form
- Further Information form

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## 1. Background

- 1.1. CARE Manchester, centre 0185 has applied for Special Directions to import six straws of sperm from Hadassah Ein Kerem Hospital, Israel on behalf of a couple now residing in the UK.
- 1.2. Sperm of the male partner were stored at the clinic in Israel following surgical retrieval. The couple wish to import the sperm for use in treatment services using donor eggs.
- 1.3. At the time that the sperm were stored, blood tests were carried out for HIV, but not Hepatitis B or C. The sperm were then stored at the clinic in Israel along with samples for other patients for whom HIV testing was carried out, but for whom Hepatitis B and C testing was not carried out. If the application is granted, Care Manchester propose to store the sperm in an 'un-screened' tank.
- 1.4. Both partners have subsequently been screened in the UK for HIV and Hepatitis B and C and all of these tests are negative.

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## 2. Consideration of application

- 2.1. The committee considered the application, which included an executive summary, Special Directions 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 imports of gametes or embryos from countries outside of the United Kingdom. Furthermore, the committee noted that if a licensed centre meets all ten requirements set out in section 1 of Schedule 3 to General Directions 0006, import is permitted without the need for Special Directions.
- 2.3. In considering the application, the committee had regard to the principles (tests) derived from the decision of the Court of Appeal in *Blood* and from rights arising under the Human Rights Act 1998.

### Principle 1

- 2.4. The committee noted that the centre is unable to import the gametes under General Directions 0006 because requirements of part 1(j) of Schedule 3 cannot be met:
  - j) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice that is currently in force.
- 2.5. The committee noted that the requirements of part1(j) could not be met because of the absence of test result for Hepatitis B and C prior to the sperm being stored at the clinic in Israel.

### Principle 2

- 2.6. The committee accepted advice from the Legal Adviser that Articles 49 and 50 of the EC Treaty are concerned with the prohibition of restrictions on the obtaining of services by a national of one member state from another member state within the European Community.
- 2.7. The committee noted that it is proposed that the gametes be imported to the UK from a clinic outside of the European Community. Accordingly, Articles 49 and 50 are not engaged and Principle 2 is not relevant in this case.

### Principles 3, 4 and 5

- 2.8. The committee recognised that the couple's rights under the European Convention of Human Rights (ECHR) are separate and distinct from those arising under the EC Treaty. The committee accepted that a refusal to allow the sperm to be imported could amount to an interference with the couple's rights under Articles 8 and/or 12 of the ECHR.

- 2.9.** The committee was satisfied that, if it is not possible for another sample of sperm to be procured from the male partner, a refusal to allow the sperm to be imported would amount to an interference with the couple's right to found a family and/or their right to respect for their private and family life. The committee noted that the application submitted by CARE Manchester does not confirm whether a further sample of sperm could be procured within the UK. Accordingly, the committee was not able to determine whether Articles 8 and/or 12 are engaged. Without such a determination, the committee could not apply principles 3, 4 or 5.
- 2.10.** Nevertheless, the committee accepted advice from the legal adviser that, even if rights under the ECHR do not apply, the committee had to determine the application on its merits, taking into account all relevant considerations.
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### **3. Decision**

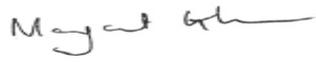
- 3.1.** The committee regarded as significant that, even if it is possible to procure further sperm from the male partner, this would require surgical retrieval. The committee considered that the invasive and complicated nature of this procedure were factors that should be weighed against any risks that might arise.
- 3.2.** Although tests for Hepatitis B and C were not undertaken prior to the sperm being stored, the committee took into consideration that testing for HIV was carried out and that the couple have subsequently been tested for HIV and Hepatitis B and C, with negative results. The committee also noted that the person responsible at CARE Manchester does not believe that use of the stored sperm to treat the female partner would pose any additional risk to her compared to normal married life given that she has an intimate relationship with the male partner.
- 3.3.** The committee also considered any risks arising from the fact that the sperm have been stored in the clinic in Israel in a tank with other samples tested for HIV, but not Hepatitis B and C. The committee regarded any risks arising from this as negligible. The committee also had regard to the fact that the couple have been made aware of any risks arising from the intended storage of the sperm in an 'un-screened' tank at CARE Manchester.
- 3.4.** After careful consideration, taking all factors into account, the committee concluded that a refusal to issue Special Directions and the consequential need for further surgical intervention (if possible), would be disproportionate to the identified risks.
- 3.5.** The committee, therefore, agreed to issue Special Directions in the case for CARE Manchester, centre 0185 to import six straws of sperm from Hadassah Ein Kerem Hospital, Israel to the UK for use in providing treatment services to the gamete provider and his partner.
- 3.6.** The committee concluded that this case involves a highly exceptional set of circumstances. Accordingly, granting the application for Special Directions would not set any precedent and was not intended to undermine the important requirements of Schedule 3 to General Directions 0006.

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#### **4. Chair's 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**

15 May 2017