

# Statutory Approvals Committee – minutes

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## Item 5

### Centre 0086 (BMI Chelsfield Park ACU)

### Special Directions application to export sperm to Northern Cyprus for patient couple's own use

Thursday, 29 November 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

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Committee members  
Margaret Gilmore (Chair)  
Bobbie Farsides (Deputy Chair)  
Anne Lampe  
Anthony Rutherford  
Ruth Wilde  
Emma Cave

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Members of the Executive	Dee Knoyle Catherine Burwood Paula Robinson Victoria Askew	Committee Secretary Senior Governance Manager (Observer) Head of Planning and Governance (Observer) Inspections & Logistics Officer (Observer)
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Specialist Adviser

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Legal Adviser	Ros Foster	Browne Jacobson LLP
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Observers	Rachel Cutting (New Member Induction - Observer)
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## Declarations of interest

- Members of the committee declared that they had no conflicts of interest in relation to this item.

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## The committee had before it:

- 8th 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)

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## The following papers were considered by the committee:

- Executive Summary
- Special Directions Application Form
- Further information form
- A letter and supporting evidence for exporting overseas (redacted)
- Evidence of licensing by the Ministry for Health in the receiving country (translated)
- Letter from the patient's partner providing further information (redacted)

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## 1. Background

- 1.1. The Person Responsible (PR) at Centre 0086 (the applicant) has applied for Special Directions to export five ampoules of patient sperm to Northern Cyprus IVF Centre, Kolan British Hospital. This centre is licensed by the Ministry of Health for the Turkish Republic of Northern Cyprus (TRNC) to act as a private hospital and has provided confirmation of this. However, this body is outside of the European Union (EU) and cannot demonstrate equivalence to EU standards of quality and safety. The proposed receiving centre has allowed its ISO accreditation for quality and safety to lapse on the basis that such accreditation is not required by local legislation.
- 1.2. The patients seeking consent to export is of African descent and reports to have had difficulty in sourcing a donor for egg donation from a similar ethnic background in the United Kingdom. The patient plans to use eggs from an anonymous donor in Northern Cyprus. The male said to providing the sperm is said to suffer from travel sickness and the female patient has said that she does not wish to have the stress of this prior to starting treatment in Northern Cyprus. The sperm has yet to be frozen; however appropriate HFEA consents have already been signed. The application seeks consent to export frozen sperm to the proposed receiving centre in Northern Cyprus.
- 1.3. The export cannot lawfully take place under General Direction 0006 because the following requirement is not satisfied:

### Schedule 4 - Export of gametes and embryos outside of the European Economic Area (EEA)

#### **Part 1**

- (b) *the receiving centre has a quality management system in place which has been certified by an internationally recognised body;*

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## 2. Consideration of application

### **Application**

- 2.1. The committee noted that the PR at centre 0086 has applied for Special Directions to export five ampoules of patient sperm to Northern Cyprus IVF Centre, Kolan British Hospital. The committee received a suitably completed application form and further information form.

### **Human Fertilisation and Embryology Act 1990 (as amended) Section 24**

#### **General Directions 0006**

- 2.2. The committee noted that Section 24(4) of the 1990 Act provides a power to make Directions and confers a broad power on the Authority to permit the export of a person's gametes. Pursuant to this power the Authority has issued General Direction 0006 ('the General Direction'). However, this application has arisen because the requirement of the General Direction listed below cannot be met and therefore the committee is asked to consider whether, in the particular circumstances of this case, there are grounds to exercise the power under Section 24(4) to issue Special Directions so as to permit the export to which the application relates.

### Schedule 4 - Export of gametes and embryos outside of the European Economic Area (EEA)

#### **Part 1**

- (b) *the receiving centre has a quality management system in place which has been certified by an internationally recognised body;*

## ISO 9001 – Accreditation expired

- 2.4. The committee noted that the proposed receiving centre forwarded ISO 9001 accreditation documents, however, this accreditation expired in August 2018.

## Legal Advice

- 2.3. The committee was reminded that the sperm was not yet procured. The committee was also made aware that there was no compelling need presented in the application to export the sperm to Northern Cyprus for treatment in this case as the male patient was able to travel for their treatment and already had plans to accompany the female patient to Northern Cyprus when she went there for treatment. The committee was advised that it should consider the particular set of circumstances relating to the application and decide whether there were grounds to exercise the power under Section 24(4) to issue Special Directions to permit the export of sperm to Northern Cyprus notwithstanding the fact that such export did not comply with part 1b of Schedule 4 of the General Directions.

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## 3. Decision

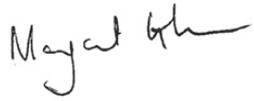
- 3.1. The committee had regard to:
- HFEA General Directions 0006
  - The Human Rights Act 1998:
  - Article 8 - respect for private and family life
  - Article 12 - right to marry and found a family
- 3.2. The committee had regard to the Authority's statutory duty to promote, in relation to activities governed by the Act, compliance with requirements imposed by or under the Act.
- 3.3. The committee had regard to the principles (tests) derived from the decision of the Court of Appeal in the Blood case and from rights arising under the Human Rights Act 1998. The committee considered whether a refusal to make Special Directions for the export of sperm, which has not yet been procured, would amount to an interference with the patients' rights under Articles 8 and/or 12 of the European Convention on Human Rights and if so, whether such interference would be justified and proportionate.
- 3.4. The application states that there is a shortage of egg donors matching African ethnicity in the United Kingdom (UK) and the patient couple have been unable to find a suitable egg donor. The patients wish to use eggs from an anonymous donor in Northern Cyprus, a country outside of the EU, for their treatment and the information provided indicates that the male patient intends to travel to accompany his partner when the relevant treatment takes place. The proposed receiving centre has confirmed that the couple are already patients of theirs.
- 3.5. The sperm is essential to the medical treatment services, to which this application refers, however the samples have not yet been procured and there is no requirement for procurement to take place in the UK. The committee agreed that there was no reason presented as to why the patient couple could not travel separately, allowing the male patient to arrive ahead of time to avoid causing stress to his female partner before the start of her treatment. The committee agreed that refusal of this application would not amount to interference with the individuals' right to obtain medical treatment services abroad.
- 3.6. The committee concluded that, taking all relevant factors into account, the current case does not involve an exceptional set of circumstances such that a departure from the requirement of General Directions 0006 for appropriate accreditation was justified and as such refused this application for Special Directions to export the (yet to be procured) sperm to Northern Cyprus.

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## 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

19 December 2018