

# Statutory Approvals Committee - minutes

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## Centre 0293 (Andrology Solutions)

### Application for Special Directions to Export Sperm to South Africa

Monday, 23 January 2017

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

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Tony Rutherford	
Members of the Executive	Dee Knoyle Siobhain Kelly	Secretary Interim Head of Corporate Governance
External adviser		
Legal Adviser	Tom Rider	Field Fisher
Observers	Bobby Farsides Bernice Ash Anjeli Kara	Member (Induction) Committee Secretary Regulatory Policy Manager

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## Declarations of interest

- Members of the panel 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.

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## The following papers were considered by the committee:

### Papers Enclosed:

- Executive summary – 23 January 2017
- Annex 1
  - Application form
  - Further information form
  - Copy of the 'Embryo Protection Act, 1990' in force in applicants residing country
  - Response from the PR to address comments in the SAC minutes of October 2016 after a decision to decline special directions
  - Letter from the patient's therapist to the Committee
  - Supporting letter from the patient's egg donor coordinator
  - Supporting letter from the patients
  - Supporting letter from the importing clinic and evidence of an import permit
  - SAC minutes from October 2016
  
- Executive summary – 27 October 2016
- Annex 2
  - Application form
  - Further information form
  - Letter from the receiving centre required by General Directions 0008
  - Supporting letter from the receiving centre
  - Evidence of accreditation submitted in support of the application
  - Letter from the patients to the Committee

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## 1. Background

- 1.1. The committee reconsidered an application from Andrology Solutions, Centre 0293, for Special Directions to export sperm to Cape Fertility Clinic, South Africa.
- 1.2. The application previously came before the committee at its meeting on 27 October 2016, when the committee declined to grant Special Directions.
- 1.3. The PR at Centre 0293 resubmitted the application providing further information in response to the comments made by the committee in giving its reasons for its previous decision. The committee noted, in particular that, in contrast to the statement made in paragraph 2.10 of the minutes of their previous decision, the sperm is already in storage at Centre 0293.
- 1.4. The committee accepted the advice of its legal adviser that it was open to it to reconsider the application and that in doing so, the Committee should consider the matter entirely afresh on the basis of all the information now before it, without regard to its previous decision.

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## 2. Consideration of application

- 2.1. The committee noted that section 24(4) of 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.
- 2.2. The committee further noted that, in relation to the export of gametes outside of the European Economic Area and Gibraltar, export can be permitted without the need for directions if the conditions in schedule 4 to General Direction 0006 are satisfied.
- 2.3. The committee noted that this application concerns the proposed export of sperm to the receiving centre in South Africa for treatment using anonymous egg donation. The proposed use of an anonymous egg donor would be unlawful in the UK as Standard Licence Condition T54 requires that identifiable donors be used in licensed treatment. Accordingly, the Centre is unable to export the sperm under General Direction 0006 because the following condition (h) in paragraph 1 of schedule 4 has not been satisfied:
- 2.4. "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 in the receiving centre."
- 2.5. The committee agreed that Special Directions should not be routinely granted and not where the purpose or dominant effect appears to be to circumvent the requirements of the Act and/or those contained in General Directions 0006.
- 2.6. The committee noted that the female partner underwent premature menopause and is therefore unable to have a child using her own eggs.
- 2.7. The committee noted that the female partner lives in Germany, where egg donation is illegal, and her male partner (the gamete provider) lives in Ireland.
- 2.8. The committee noted the following information and submissions within the application:
  - (a) The couple are said to be unable to have treatment in Ireland as there is a limited supply of egg donors and this prevents them from finding a donor which matches their ethnic origins;
  - (b) The cost of treatment in both Ireland and the UK is said to exceed their budget: citing between £8,090 - £9,211 in Ireland and at least £7,950 in the UK. compared with £4,906 in South Africa;
  - (c) It is said the waiting list in the UK is long, with 9-12 months for an exclusive donor and 3 months for shared donors, whereas there is no waiting time in South Africa;

- (d) The couple have chosen to have egg donation in South Africa as it is said there is a wider selection of egg donors which match the female partner's Northern European background and there is more information available there about the donor;
- (e) The couple have already had one cycle of egg donation at the receiving centre in South Africa, for which the male partner flew to South Africa to provide a sperm sample, but the treatment was unsuccessful as the female partner miscarried;
- (f) It is said the male partner cannot handle long distance travel well: it took him weeks to recover from the stress and anxiety of the trip to South Africa. He has been seeing a therapist for CBT and has undergone hypnotherapy but this treatment is said to have been unsuccessful in allaying his fears of flying. He feels unable to make this trip again;
- (g) It was largely as a result of this that the male partner elected to freeze his sperm at Centre 0293, and also because there is no clinic in Ireland which has a licence to export sperm from Ireland to South Africa;
- (h) It is said that, having had one treatment cycle at their chosen clinic in South Africa, the couple have established a relationship with the doctor and other members of staff at that clinic; and
- (i) Centre 0293 say in the application that "the couple have no other choice but to attempt to export the sperm from the UK. The couple consider this to be their last chance to have a child and found a family. If the Special Direction is not approved and the patient's sperm cannot be exported, this would mean that the couple would be unable to proceed with fertility treatment at their chosen clinic".

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## **3. Decision**

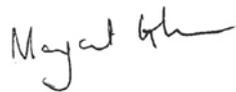
- 3.1.** The committee had regard to its decision tree.
- 3.2.** The committee agreed that all the requirements of schedule 4 to General Directions 0006 were not met.
- 3.3.** The committee considered whether a refusal to make Special Directions would be an interference with the patients' rights under Article 8 and/or 12 of the ECHR. The committee decided that refusal may amount to interference in that the couple wish to export the male partner's sperm to South Africa for treatment at a clinic of their choice using an egg donor in order to found a family.
- 3.4.** The committee went on to consider whether such interference would be justified and proportionate. 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. It recognised that, when setting the requirements in schedule 4 to General Directions 0006, the Authority attached considerable importance to identifiable egg donors being used in treatment.
- 3.5.** However, the committee decided that, on balance, refusal to make Special Directions would not be justified or proportionate in the exceptional circumstances of this case. Whilst the Committee was aware of UK clinics with Northern European donors and shorter waiting times for donors than asserted in the application, it did accept that the sperm was essential to the treatment, the male partner was unable for medical reasons to travel to South Africa to provide a further sample, the receiving clinic in South Africa was their chosen clinic, and the couple had already experienced one failed cycle of treatment.
- 3.6.** The committee therefore agreed to grant Special Directions to Andrology Solutions Centre 0293, to export sperm to Cape Fertility Clinic, South Africa.
- 3.7.** The committee considered that granting Special Directions for this application would not set an undesirable precedent which would undermine the imperative requirements identified.

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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

10 February 2017