

# Statutory Approvals Committee – minutes

## Centre 0162 (Queens Medical Centre Fertility Unit) – application for Special Directions to export sperm to Malpani Clinic, Mumbai, India

Friday, 5 August 2016

HFEA, 10 Spring Gardens, London, SW1A 2BU

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| Committee members        | Rebekah Dundas (Chair)<br>Anne Lampe<br>Margaret Gilmore |   |
| Members of the Executive | Ian Brown<br>Trent Fisher                                | Head of Corporate Governance<br>Secretary |
| Legal Adviser            | Sarah Ellson   | Fieldfisher LLP                           |
| Observers                | None   |   |

### 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
- consultation letter from Dr Malpani 27 June 2016
- letter from Malpani Clinic (undated)
- ART Certificate for Malpani Clinic
- Certificate of compliance (ASNH:2011) from Malpani Clinic

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## 1. Consideration of application

- 1.1. The committee noted that the centre has made an application for Special Directions (under section 24(4) of the Human Fertilisation and Embryology Act 1990 (as amended) ('the Act')) to export eight straws of patient's sperm to the Malpani Clinic, Mumbai, India for the patient's own use.
- 1.2. The committee has been advised that the patient underwent chemotherapy and has eight straws of sperm in storage at Queens Medical Centre Fertility Unit since July 2010. The patient is now a resident in India and has requested that his gametes be exported to be used in his partner's treatment.
- 1.3. 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 4 of General Directions 0006, of which there are nine, are all satisfied, export is permitted without the need for a Special Direction.
- 1.4. The committee noted that this application for Special Directions is being made because the centre is unable to export the sperm under the auspices of General Directions 0006 because it is unable to meet the requirements of Schedule 4, Section 1 as it cannot demonstrate that:
  - (b) the receiving centre has a quality management system in place which has been certified by an internationally recognised body;
  - (c) the receiving centre has a traceability system in place which ensures that all gametes and embryos are traceable from procurement of gametes to patient treatment and vice versa. The centre's traceability procedures should also encompass all materials or equipment that could have an impact on the quality or safety of the gametes and embryos;
- 1.5. 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.
- 1.6. The committee noted that within the application the Malpani Clinic has provided its ASNH:2011 certificate of quality. However, it has been determined by the executive that this standard is specific to clinical care. The exporting centre is unable to determine if the certifying body could be considered internationally recognised.
- 1.7. The committee noted also that the centre has provided certification stating that the Malpani Clinic is enrolled under the National Registry of ART Clinics and Banks in India.
- 1.8. The committee also noted that the Malpani Clinic have advised the exporting centre that there is a traceability system in place however no details have been provided prior to the application coming before the committee.
- 1.9. The committee noted that the receiving centre has given thought to the importance of the patient's gametes as, during discussions with the executive, it has suggested the export should be undertaken in two batches to minimise risk.

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## 2. Decision

- 2.1. The committee agreed that the receiving centre's ASNH:2011 certificate of quality would not normally constitute evidence that the centre has a quality management system in place which has been certified by an internationally recognised body, given that it was understood to assess clinical care.
- 2.2. However, the committee felt reassured by the additional information provided, including the letter from the receiving centre and the certification of enrolment under the National Registry of ART Clinics and Banks in India which indicates that the centre is enrolled with the Indian National Registry.

- 2.3.** The committee considered the potential impact of refusing to grant Special Directions and concluded that denying the application would be disproportionate. It was aware of the lists of tests (following the case of Blood) that it should consider when considering applications of this sort and were mindful that the application was being made to facilitate the treatment of the couple who now reside in India. The particular gametes are essential to the medical services the couple is seeking to have a child from their own gametes and as such a refusal would amount to an interference with their rights to found a family and family life. The committee did not think that there was an identifiable pressing social need to justify such interference or to require the couple to travel to the UK for treatment. The committee noted the nature of the concerns and did not consider that a 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 0162 (Queens Medical Centre Fertility Unit) to export eight straws of the patient sperm to, the Malpani Clinic Mumbai, India
- 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 in General Direction 0006.

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### **3. Chair's signature**

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

#### **Signature**



#### **Name**

Rebekah Dundas

#### **Date**

19 August 2016