

# Licence Committee - minutes

## Centre 0185 (CARE Manchester) – Executive update - Legal Parenthood anomalies

Thursday, 8 September 2016

HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

Committee members	Lee Rayfield (Chair) Margaret Gilmore Ruth Wilde Kate Brian Anita Bharucha	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
Legal Adviser	Graham Miles	Blake Morgan 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
- Licence Committee minutes 14 July 2016
- Interim inspection report (March 2016)
- Additional executive update (tabled)

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## 1. Background

- 1.1.** The committee noted that in July 2016 it considered two inspections reports which uncovered serious issues in relation to legal parenthood consent at centre 0185. The PR had accepted that these issues existed and indicated that the centre would voluntarily cease treatment involving donor sperm, or embryos that have been created with donor sperm, until a time that the committee was satisfied with the centre being able to effectively collect legal parenthood consent.
- 1.2.** The committee agreed to the centre's voluntary cessation of treatment involving donor sperm, or embryos that have been created with donor sperm and added that treatment would not be able to resume until:
- the centre has provided the newly devised corporate audit tool to the executive so that it can decide whether it is satisfactory; and
  - the executive has reviewed and is satisfied with the outcome of the new audit of January 2016 - June 2016 data; and
  - a satisfactory procedure for obtaining legal parenthood consent has been formulated and reviewed by the executive.
- 1.3.** The committee also requested that an update to be presented to its September 2016 Licence Committee meeting regarding the progress of the centre to comply with the recommendations.
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## 2. Consideration of application

- 2.1.** The committee noted from the paper work that the executive has now reviewed the newly devised corporate audit tool and considered it satisfactory and that the auditors had sufficient experience, insight and independence to ensure the robustness of the centre's repeat audits of consent to legal parenthood.
- 2.2.** The committee noted that the centre used the corporate management tool to audit relevant treatments between 1 January 2016 and 12 July. Another anomaly was identified, however, this was classified as a near miss and the patients involved had an unsuccessful treatment cycle. The audit report noted that the treatment took place after the interim inspections but before the actions identified in the centre's root cause analysis (RCA) as to the failings in taking proper consent to legal parenthood had been implemented.
- 2.3.** The committee noted that the executive discussed their concerns regarding the findings of the audit and requested:
- details of the training provided to relevant staff following the RCA completed in June 2016,
  - evidence of staff participation in that training, and
  - evidence of how staff have been assessed as competent following that training.
- 2.4.** The committee noted that the PR has provided the executive with the information on staff training and informed the executive that training had been provided to all centre staff involved in obtaining legal parenthood consent. Information regarding the centre's processes for obtaining legal parenthood have also been provided to the executive.
- 2.5.** The committee noted that the centre has conducted a re-audit of the historical data between 6 April 2009 and 31 December 2015. A further 10 anomalies were found and the PR states that immediate action was taken to contact and support the couples concerned. The PR also provided an update on previously identified cases where anomalies were found.
- 2.6.** The committee noted that the executive continue to liaise with the PR regarding all cases where anomalies in consent to legal parenthood have been identified.
- 2.7.** The committee noted that the executive recommend that monthly audits of records of patients undergoing treatment with donor sperm, or embryos created with donor sperm, are undertaken to

provide ongoing assurance of the effectiveness of the centre's procedures to obtain consent to legal parenthood.

- 2.8.** The committee noted that the executive has requested the centre to undertake another root cause analysis regarding the failings of the March 2016 audit.
- 2.9.** The committee also noted that since all staff at the centre who are involved in obtaining legal parenthood consent have been trained and that the centre is in a position to ensure that effective consent to legal parenthood consent can be obtained prior to treatment, the executive recommends that treatments for patients requiring donor sperm or embryos created with donor sperm may resume.
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### **3. Decision**

- 3.1.** The committee agreed with the executive and endorse the executive's recommendations that CARE Manchester could resume treatment using donor sperm or embryos created using donor sperm.
- 3.2.** The committee requires the centre to comply with all recommendations set out by the executive in relation to carrying out an additional root cause analysis and conducting monthly audits.
- 3.3.** The committee requests that it receives an executive update at its next meeting in November regarding:
- A summary of the monthly audits conducted by the centre
  - A summary of the outcome of the RCA investigating the failings of the March 2016 Audit
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### **4. Chair's signature**

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

#### **Signature**



#### **Name**

Lee Rayfield

#### **Date**

27 September 2016