

HFEA Licence Committee D Meeting

25 August 2009

Conference by Telephone

In respect of:

The Reproductive Genetics Institute (“RGI”) (Centre 0206)

IN RELATION TO THE SPECIAL DIRECTIONS IN FORCE IN RESPECT OF RGI

Members of the Committee: Gemma Hobcraft, Lay Member (Chair) Mair Crouch, Lay Member (Vice-Chair) Debbie Barber, Clinical Member Lillian Neville, Lay Member	Committee Secretary: Jonathan Lewis, Henderson Chambers Legal Adviser: Martin Forde Q.C., One Crown Office Row
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Quorate

1. The Chair declared the meeting to be quorate.
2. She confirmed that the committee had the following documents:
 - a. A document entitled “Executive Summary for Licence Committee August 2009” with ten appendices.
 - b. A document entitled “ Response to the Executive Summary for the Licence Committee on behalf of the Reproductive Genetics Institute (Centre 0206)” dated 20 August 2009.
 - c. As requested by the Chair on 18 August 2009, all further correspondence between the Executive and Mr Taranissi since the previous Licence Committee meeting on 4 June 2009.

Conflicts of Interest

3. The Chair confirmed that none of the Committee had any conflicts of interests in addition to those previously raised (see the minutes of the 4 June 2009 meeting).

Purpose Of Meeting

4. The Committee noted that the current special directions in place at RGI, dated 16 June 2009, are due to expire on 31 August 2009. At the previous Committee Meeting the Committee had decided that there was an extant application for a licence in respect of RGI and that it required an inspection report in order to decide that application.
5. The Committee had been informed by the Executive that an inspection scheduled for 4 August 2009 had been cancelled. It met to consider what action to take in respect of the Special Directions.

The Cancellation of the Scheduled Inspection

6. The Committee was concerned that the timetable set out at the previous hearing on 4 June 2009 had not been met, in particular an inspection of RGI had not taken place.
7. The Committee noted that 4 August Inspection had been cancelled by the Executive. The Person Responsible had urged the Executive to go ahead with it.
8. The Committee was concerned that the Person Responsible had failed to provide certain documents to the Executive which he had assured the Committee on 4 June 2009 that he could provide within 10 days of receipt of a request.

9. The Committee was uncertain as to why an inspection could not have taken place in the absence of these documents (with the necessary documents being provided on the day). It was also uncertain why communications as regards the inspection had not occurred between the Inspectorate and the Clinic's quality manager.
10. The Committee has some disquiet as regards the relationship between the Person Responsible and the Executive.

Next Steps

11. In order to assist with the progression of matters, the Committee considered that it would be useful to have a case management hearing on 2 September 2009 at 17:00. The Committee asked for the attendance of Will Lenton of the Inspectorate as well as the RGI's quality control manager.
12. At this hearing the Committee hopes to assist in resolving matters by obtaining information such as (but not limited to) when the next possible inspection could take place, what essential documents the Executive requires and why the Executive has asked for certain documentation in the present circumstances.
13. In order to allow for this meeting, the Committee decided to extend the special directions until 30 September 2009 or until its further direction.
14. The Committee considered that, in light of the gravity of the decisions that it might be called upon to make, it would need to meet in person to consider any further extension of the Special Directions. If it is necessary the Committee will meet in person on the afternoon of 28 September 2009 to consider what further steps are necessary to ensure the full regulation of Centre 0206 (this being the only date available to all the members of the Committee).

Decision

1. **The Special Directions issued by the Committee on 16 June 2009 be extended until 30 September 2009 or until further direction of the Licence Committee.**
2. **A case management meeting will take place at 17:00 on 2 September 2009 by telephone.**
3. **The Committee provisionally schedules a further meeting for 28 September 2009.**

Signed Gemma Hobcraft

Date 24/9/09

Gemma Hobcraft (Chair)