

Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
26 June 2015

Minutes – item no. 8

Centre 0044 (The Centre for Reproductive and Genetic Health) – Variation
Change of Premises & Special Directions

Members of the Panel:

Juliet Tizzard
Director of Strategy & Corporate Affairs (Chair)
Joanne Anton
Policy Manager
Rachel Hopkins
Head of Human Resources

Members of the Executive in attendance:

Sam Hartley
Head of Governance & Licensing
Dee Knoyle
Committee Secretary

Declarations of interest: members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Background

1. The Centre for Reproductive and Genetic Health is a large centre located in central London. The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing.
2. On 10 December 2014 the Person Responsible (PR) submitted a variation of licensed premises application to change the centre's address to 230-232 Great Portland Street, London, W1W 5QS.
3. On 13 May 2015 the centre was inspected to assess the suitability of the new premises. However, due to unforeseen delays with the build, the new premises were completed later than anticipated, hence the delay between the submission of the application and the inspection visit on 13 May 2015.

Consideration of application

4. The panel considered the papers, which included a completed variation of licensed premises application form, a Special Directions application, a change of premises report and licensing minutes for the past three years.
5. The panel noted that key documents were requested from the centre in support of the change of premises application, to provide assurance that the proposed new premises, and equipment therein, are suitable. On the basis of the assessment of the submitted information and documented findings, it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities.
6. The panel noted that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda.
7. The panel noted that a building works completion certification/sign off has been issued by the contractor to the centre.
8. The panel noted that a fire safety inspection has been performed and has confirmed the premises to be safe.
9. The panel noted that security measures at the new premises, including those relating to storage of gametes and embryos and confidential records were considered to be suitable.
10. The panel noted that the air cleaning system has been validated and gametes and embryos will be processed in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality.
11. The panel noted that privacy, comfort and confidentiality for patients have been considered in the planning of the new premises and designated counselling, scanning, consulting and male production rooms were seen to be available and appeared to be fit for purpose.
12. The panel noted that confirmation of the completion of an effective deep clean of laboratory and clinical areas has been provided. A final deep clean is planned prior to the commencement of licensed activity. A full infection control audit throughout the new premises has also been performed and found no significant failings.

13. The panel noted that the centre already has suitable equipment to provide licensed activity. Validation documentation for relevant items of equipment was reviewed and was compliant with requirements. The centre plans to move additional equipment from the current premises to the new premises as activity levels increase once the variation of licensed premises application is approved. The laboratory manager confirmed that any equipment moved will be revalidated before being used in licensed activity.
14. The panel noted that some dewars and a validated monitoring system are already present at the new centre. Re-validation of further dewars and related monitoring devices will be undertaken when they have been transferred to the new premises.
15. The panel noted that the centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection in October 2012. Relevant standard operating procedures have been reviewed and updated where necessary.
16. The panel noted that the Inspectorate recommends the approval of the variation of licensed premises application to reflect a change of premises and the PR is to provide evidence that a final deep clean has been undertaken and that air quality still meets the required standard.
17. The panel noted that the PR has requested that the variation to the licence comes into effect on Saturday 18 July 2015.
18. The panel noted that should the variation of licensed premises be approved, there would be a period of time after 18 July 2015 when the centre will need to store gametes and embryos at the centre's 'old' premises at The New Wing, University College Hospital, 256 Gray's Inn Road, London, WC1X 8LD. Special Directions have therefore been requested by the PR to be in force from 18 July 2015 for three months, to allow storage of gametes and embryos at the 'old' premises. The Inspectorate considered the storage facilities at the 'old' premises to be suitable at the last inspection and note that satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the Special Direction. The Inspectorate therefore recommends that the panel approves the application for Special Directions, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended).

Decision

19. The panel noted that the centre has complied with the requirements of General Directions 0008 (section H 13).
20. The panel endorsed the Inspectorate's recommendations and agreed to vary the centre's licence to reflect a change of premises from 18 July 2015. The new premises will be located at:

230-232 Great Portland Street
London
W1W 5QS
21. The panel also endorsed the Inspectorate's recommendation that the PR is to provide evidence that a final deep clean has been undertaken and that air quality still meets the required standard before licensed activities begin.

22. The panel agreed to issue Special Directions to allow storage of gametes and embryos at the 'old' premises, The New Wing, University College Hospital, 256 Gray's Inn Road, London, WC1X 8LD for a period of three months to facilitate the move. These Special Directions will be in force for three months from 18 July 2015.

A handwritten signature in black ink, appearing to read 'Juliet Tizzard', with a period at the end.

Signed:
Juliet Tizzard (Chair)

Date: 8 July 2015