

HFEA Executive Licensing Panel Meeting

16 January 2015

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 3

Centre 0055 – (The James Cook University Hospital) – Variation of Licence – Change of Premises

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| Members of the Panel: Juliet Tizzard (Chair) Director of Strategy & Corporate Affairs David Moysen – Head of IT Ian Peacock – Analyst Programmer | Committee Secretary: Dee Knoyle Observing: Sam Hartley – Head of Governance & Licensing |
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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 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 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 Publication of Authority and Committee Papers

Background

1. The James Cook University Hospital is a small centre located in Middlesbrough and has been licensed by the HFEA since July 1992. The centre provides a full range of fertility services.
2. The centre's premises are currently located on two floors in the James Cook Hospital. The proposed new premises will be larger and offer patients improved comfort and privacy and all the treatment and consultation rooms will be together on one floor.

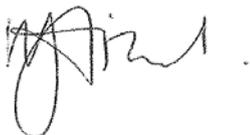
Consideration of Application

3. The Panel considered the papers, which included a report, a completed application form and licensing minutes for the past three years.
4. The Panel noted that key documents were requested from the centre in support of the change of premises application assessment, to provide assurance that the premises and equipment in the proposed new facilities would be suitable and satisfy the requirements of the Act in relation to the granting of a licence (HF&E Act 1990 (as amended) S16 (2)(d) and (e)).
5. The Panel noted that on completion of the desk based assessment, a site visit was conducted on 16 December 2014. On the basis of these assessments, and key information documented in the report, the Inspectorate concluded that, on completion of the recommendations, the centre's proposed new premises would be suitable for the conduct of licensed activities.
6. The Panel noted that the existing office and consultation space would be retained.
7. The Panel noted that the proposed new area of the premises would comprise:
 - a treatment room;
 - embryology laboratory;
 - andrology laboratory;
 - cryostore;
 - recovery area;
 - nurse's station;
 - male production room.
8. The Panel noted that the address of the new premises would be unchanged.
9. The Panel noted that the existing and new premises were within the James Cook Hospital and are subject to the overarching hospital governance.
10. The Panel noted that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes had been provided by the building contractor.

11. The Panel noted that confirmation of a fire safety inspection was provided.
12. The Panel noted that the centre had suitable equipment. A full set of critical laboratory equipment sufficient to be able to perform licensed treatment was available. This equipment will be re-validated in the new premises during January 2015.
13. The Panel noted that the centre's critical processes and procedures were, in practice, unchanged and were considered appropriate at the time of the last renewal inspection in July 2011. The centre did not intend to change any activities or the type of licence. Relevant standard operating procedures had been updated to reflect physical differences in the premises.
14. The Panel noted the Inspectorate's recommendation to vary the centre's licence to reflect a change of existing premises.. The Panel noted that at the time of the inspection there were three major areas of non-compliance and that the PR must provide confirmation and evidence to the Inspectorate that the following recommendations are completed before licensed activity can begin:
 - a final deep clean of the premises is undertaken
 - air quality testing of the premises is undertaken
 - re-commissioned critical equipment is tested and re-validated

Decision

15. The Panel noted that the centre had complied with the requirements of General Directions 0008 (section H 13) by submitting a relevant application form and a floor plan of the premises to be referenced on the licence.
16. The Panel endorsed the Inspectorate's recommendations and agreed to vary the centre's licence to reflect a change of premises from 30 January 2015.
17. The Panel reminded the PR that all recommendations must be completed within the prescribed timescales and to the satisfaction of the Inspectorate. The Panel asked that the Inspectorate provide a report to the Executive Licensing Panel by the end of March 2015 if all requirements are not met.



Signed:
Juliet Tizzard (Chair)

Date: 19 January 2015