Executive Licensing Panel - minutes

Centre 0185 (CARE Manchester) Variation Change of Licensed Premises

Friday, 4 November 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) David Moysen Anjeli Kara	Director of Strategy & Corporate Affairs Head of IT Regulatory Policy Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers		

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. CARE Manchester, centre 0185 is a treatment (including embryo testing) and storage centre which provides a full range of fertility services. In relation to activity levels this is a large centre.

1.2. The centre has submitted a variation of licensed premises application. Licensed activity currently takes place on the ground floor (laboratory, theatre suite and male production rooms). The variation of premises is occurring over two floors. The overall footprint of the centre has been increased to include a major development of the lower ground floor which now houses a new laboratory, cryo-store, male production rooms, theatre suite, recovery and patient rooms.

1.3. The current training laboratory is to be relocated from the second floor to the first floor. The Person Responsible (PR) has advised that even though this area is not going to be used for treatment purposes, in consideration that gametes and embryos will be used for training in this area, it has been refurbished to the same standards as the main laboratory.

1.4. A phased relocation of licensed treatment activity from the ground floor to the refurbished premises on the lower ground floor is planned, subject to the variation of licensed premises being approved. The ground floor laboratory, theatre suite and male production rooms will then be decommissioned and reconfigured into consultation and scanning rooms.

2. Consideration of application

2.1. The panel considered the papers, which included a completed application form, report and licensing minutes for the past three years.

2.2. The panel noted that key documents were requested from the centre in support of the change of premises application to provide assurance that the premises and equipment in the proposed refurbished facilities are 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)). On completion of the desk based assessment, a site visit was conducted on 17 October 2016.

2.3. The panel noted that, on the basis of the assessment of the submitted information and findings documented below, it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities.

2.4. The panel noted that confirmation that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes has been provided by the project manager.

2.5. The panel noted that a building works completion certification/sign off has been issued by the contractor to the centre.

2.6. The panel noted that a fire safety risk assessment has been performed and has confirmed the premises to be safe.

2.7. The panel noted that security measures at the premises, including those relating to storage of gametes and embryos and confidential records were considered to be suitable.

2.8. The panel noted that privacy, comfort and confidentiality for patients have been considered in the planning of the new premises. Designated patient rooms, a recovery room and male production rooms are available and appeared to be fit for purpose.

2.9. The panel noted that an infection control audit throughout the refurbished premises has also been performed and found no significant failings.

2.10. The panel noted that the air supply unit has been installed and commissioned, however an air quality test has yet to be undertaken. This is planned once the deep clean has been completed, and the PR has confirmed that the air quality report will be submitted to the inspectorate as soon as this has been completed.

2.11. The panel noted that the centre has suitable equipment. A full set of critical laboratory equipment sufficient to be able to perform licensed treatment has been installed in the new laboratory and evidence of validation has been provided. The remaining equipment will be moved from the currently licensed areas to the new laboratory once the variation of licensed premises has been approved. The PR confirmed that any equipment moved will be revalidated before being used for licensed activity.

2.12. The panel noted that the centre's cryo-storage dewars will be moved to the new laboratories once the variation of licensed premises has been approved. The PR has conducted a risk assessment for the movement of the dewars and re-validation of the dewars and monitoring devices will be undertaken after re-location.

2.13. 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 March 2014. Relevant standard operating procedures have been reviewed and updated where necessary.

2.14. The panel noted that, on completion of the relocation of licensed activity, the Executive will seek confirmation from the PR that licensed activities will no longer be performed on the ground and second floors.

2.15. The panel noted that the centre has complied with the requirements of General Direction 0008 (Section H 14) in submitting:

- a relevant on-line application form;
- a floor plan of the premises to be referenced on the licence.

2.16. The panel noted that at the time of the inspection on 17 October 2016 there were two major areas of non-compliance identified. The panel noted that since the inspection the PR has given a commitment to fully implement the following recommendations:

- The PR should ensure that a final deep clean is completed and that air quality and microbiological testing demonstrates that the areas meets the required standards of air quality before licensed activity commences.
- The PR should ensure that any outstanding validation for new or relocated critical equipment is completed before it is used for licensed activity.

2.17. The panel noted that the inspectorate recommends the variation of the centre's licence to reflect a change of premises.

3. Decision

3.1. The panel noted that the centre has complied with the requirements of General Directions 0008 (section H 13).

3.2. The panel endorsed the inspectorate's recommendation to vary the centre's licence to reflect a change of premises with immediate effect.

4. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

14 November 2016