

Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at
Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF
on
27 February 2015

Minutes – item no. 7

Centre 0076 (NURTURE) – Change of Premises, Change of Name & Special Directions

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Paula Robinson Head of Business Planning Ian Peacock Analyst Programmer
Observing:	Sam Hartley Head of Governance & Licensing
Committee Secretary:	Dee Knogle

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. NURTURE is currently located within the Queens Medical Centre campus, Nottingham University Hospitals NHS Trust and is now part of the Academic Reproductive Partnership. The centre has been licensed by the HFEA since 1992 and provides a full range of fertility services. In relation to activity levels this is a medium-sized centre.

Consideration of Applications

2. The centre had applied to vary the current licence to reflect a change of name and change of premises and for Special Directions to permit storage of gametes and embryos outside the licensed premises.
3. The Panel considered the papers, which included a report, an application form, floor plans and licensing minutes for the past three years.
4. The Panel noted the application to vary the centre's current licence to change the name from 'NURTURE to 'NURTURE Fertility'.
5. The Panel noted the application to vary the centre's current licence to reflect a change of premises and that the Person Responsible (PR) submitted this application on 4 November 2014, however there was some delay to the building work. The centre proposed to relocate to new, larger premises on the outskirts of the city. The new premises had been designed to accommodate a maximum of 200 IUI/DI and 1500 IVF/ICSI treatment cycles per year and to provide better patient facilities. All patient areas were fully accessible to those with restricted mobility and wheelchair users.

The new premises covers three floors:

- Ground floor - laboratory and patient treatment areas;
- First floor - staff offices, consultation and scanning rooms;
- Third floor – this floor is not currently in use by the centre but is secure.

The new premises comprises:

- five consultation rooms;
- one egg collection/theatre procedure room;
- one embryo transfer/IUI/DI procedure room;
- one embryology laboratory;
- one andrology laboratory;
- cryostore;
- five bed recovery area;
- nurse's station;
- two male production rooms;
- secure medical records store;
- dedicated counselling room;
- staff facilities and rest areas.

6. The Panel noted that all existing staff would move with the centre. The PR had provided assurance that activity would be managed commensurate with resources and any expansion would be gradual as staffing increases.
7. 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 were 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 final site visit was conducted on 19 February 2015. On the basis of these assessments and documented information set out in the report relating to health and safety, equipment, deep cleaning, air quality, privacy, standard operating procedures (SOPs), it was concluded that the centre's proposed new premises were suitable for the conduct of licensed activities.
8. The Panel noted that a full set of critical clinical and laboratory equipment sufficient to be able to perform licensed treatment was already available and was considered to be suitable at the time of the centre's licence renewal inspection on 21 January 2015. This equipment would be relocated to the new premises and would be re-validated prior to licensed activity commencing. Some additional equipment was planned to accommodate increased activity and would be validated prior to use.
9. The Panel noted that testing and re-validation of the dewars and related monitoring alarms would be undertaken by the centre staff when the dewars have been transferred to the new premises. A comprehensive risk assessment and plan for the safe movement of cryo-preserved gametes and embryos had been provided by the centre and was considered suitable. The move would be conducted by specialist contractors.
10. The Panel noted that the centre's critical processes and procedures were in practice unchanged and were considered appropriate at the time of the centre's licence renewal inspection on 21 January 2015. The centre did not intend to change any activities or the type of licence. The relevant SOPs had been updated to reflect physical differences in the premises.
11. Patient information had been amended to reflect the change of premises and patients with gametes and embryos stored at the centre had been informed of the relocation.
12. The Panel noted that at the time of the inspection there were two major areas of non-compliance which had resulted in the following recommendations:
 - The PR should ensure that a final deep clean of the premises was undertaken before licensed treatment commences.
 - The PR should ensure that any new or re-commissioned critical equipment was tested and validated before licensed treatment commences.
13. The Panel noted that the PR had agreed to confirm that these recommendations had been completed, following the move, and prior to licensed activity commencing at the new premises.

14. The Panel noted that the PR had requested for the variation of the licence to reflect a change of premises to be active from 12 March 2015. The centre wished to resume licensed activities at the new premises in mid-March 2015. The centre proposed to store gametes and embryos at the new premises for a short period of time ahead of the licence variation to allow for the staged move of stored gametes and embryos to the new premises. The Panel noted that Special Directions had been requested to be in force from 1 March 2015 to 12 March 2015 to facilitate the staged relocation of the dewars and revalidation of accompanying monitoring systems. The Panel noted that the Inspectorate recommended that the Panel issues the requested Special Directions under delegated power of Section 24 5A of the Act to allow storage of gametes and embryos at the new site. The Panel noted that the new premises were secure and suitable for these activities as confirmed by documentation provided to the Inspectorate and during the site visit.
15. The Panel noted the Inspectorate's recommendation to approve the variation of licence application to reflect a change of centre name and change of premises subject to the recommendations made in this report being implemented to:
- NURTURE Fertility
The East Midlands Fertility Centre
Bostock's Lane
Sandiacre
Nottingham
NG10 5QG
16. The Panel noted the Inspectorate's recommendation to approve the Special Directions to allow storage of gametes and embryos at the new site ahead of the licence variation to allow for the staged move of stored gametes and embryos to the new premises.

Decision

17. 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.
18. The Panel endorsed the Inspectorate's recommendations and agreed to vary the centre's licence to reflect a change of name to 'NURTURE Fertility' and change of premises.
19. The Panel endorsed the Inspectorate's recommendation to issue Special Directions under delegated power of Section 24(5A) of the Act to allow storage of gametes and embryos at the new site to be in force until 12 March 2015 to facilitate the staged relocation of the dewars and revalidation of accompanying monitoring systems.



Signed:
Juliet Tizzard (Chair)

Date: 2 March 2015