

# HFEA Executive Licensing Panel Meeting

31 October 2014

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

## Minutes – Item 4

### Centre 0293 – (Andrology Solutions) – Change of Premises & Special Directions

Members of the Panel: Paula Robinson – Head of Business Planning (Chair) David Moysen – Head of IT Matthew Watts – Regulatory Policy Manager	Committee Secretary: Dee Knoyle
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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

## Consideration of Application

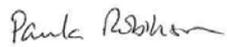
1. The Panel considered the papers, which included an executive summary, executive update, a completed application form and licensing minutes for the past three years.
2. The Panel noted that Andrology Solutions was a small centre located in London. The centre had been licensed by the HFEA since 2007 and provided insemination, using partner/donor sperm and storage services.
3. The Panel noted that an interim inspection was performed at the centre on 11 February 2014 and two non-compliances were identified. The Panel noted that the centre had promptly addressed the recommendations within the specified timescales.
4. The Panel noted that the Person Responsible (PR) had submitted an application to vary the centre's licence to reflect a change in premises, on 30 May 2014, to move all functions to larger premises at 76 Wimpole Street, London, W1G 9RT. However, due to unforeseen delays with the build, the move into the new premises had been delayed.
5. The Panel noted that the building of the new premises would primarily be leased by The Doctors Laboratory (TDL) who would have overall responsibility for maintaining the premises and practices, including health and safety and fire, in line with clinical pathology accreditation (CPA) standards. Andrology Solutions planned to lease their premises from TDL. The new premises to be licensed will comprise the following:
  - one consulting room;
  - one treatment room;
  - three male production rooms;
  - one laboratory;
  - one cryostore;
  - one administration office;
  - waiting room;
  - staff room.
6. The male production rooms, waiting room and staff room will be shared with TDL and appropriate security arrangements are in place to ensure privacy and confidentiality for patients attending Andrology Solutions.
7. The Panel noted that key documents and information were provided by the PR to support a desk-based assessment. This information provided assurance that the premises and equipment in respect of which the licence was to be varied were suitable for the activities and satisfied all other requirements of the Act in relation to the granting of a licence (1990 Act (as amended) S. 16 (2) (d) and (e)). On the basis of these activities it was concluded that the centre's proposed new premises were suitable for the conduct of licensed activities.

8. The Panel noted that the centre's critical processes and procedures, which were considered to be appropriate at the time of the last inspection in February 2014, had been updated to reflect physical differences in the premises. The centre does not intend to change any activities or the type of licence.
9. The Panel noted that the centre was considered to have suitable equipment at the last inspection in February 2014. This equipment, including alarmed dewars, would be moved from the current to the new premises by a specialist company on 28 November 2014, with continuous monitoring during the move. Revalidation of the dewars and alarms after the move would be performed on 1 December 2014.
10. The Panel noted that following the move, and prior to licensed activity commencing at the new premises, the PR had agreed to confirm the following with the Inspectorate;
  - a) the laboratory and clinical procedure room areas had been subject to a final deep clean;
  - b) environmental air quality testing had been conducted and meets at least Grade C air quality in the critical work areas, with a background environment of at least Grade D air quality;
  - c) relocated critical equipment in the laboratory and clinical areas had been commissioned, calibrated and validated or revalidated as required.
11. The Panel noted that the Inspectorate recommended that the application to vary the licence to reflect a change of premises is approved and the licence would become active from 28 November 2014.
12. The Panel noted that in order to allow the transfer of cryopreserved gametes from the old to the new premises, and to allow for any further changes to the proposed movement schedule, Special Directions for storage were required to be in force at the old premises from 28 November 2014 to 12 December 2014.

## **Decision**

13. The Panel noted that the centre has complied with the requirements of General Directions 0008 (section H 13) in submitting a relevant application form and a floor plan of the premises to be referenced on the licence.

14. The Panel endorsed the Inspectorate's recommendations and agreed to vary the centre's licence to reflect a change of premises from 28 November 2014. The Panel also agreed to issue Special Directions for storage at the old premises to be in force from 28 November 2014 to 12 December 2014 so as to allow for the transfer of cryopreserved gametes from the old to the new premises.



Signed:  
Paula Robinson (Chair)

Date: 31 October 2014