

HFEA Executive Licensing Panel Meeting

12 December 2014

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

Minutes – Item 4

Centre 0198 – (St Jude’s Women’s Hospital) – Consideration of Special Directions

Members of the Panel: Paula Robinson (Chair) Head of Business Planning Hannah Verdin – Head of Regulatory Policy 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 following papers were considered by the Panel:

- Executive Summary

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. St Jude's Women's Hospital ('the Clinic') has been licensed by the HFEA since 2002. A renewal inspection took place in June 2013, the report of which was subsequently presented to a Licence Committee (LC).
2. Following its meeting on 8 May 2014, the LC reached a proposed decision to refuse the application for the renewal of the licence of St Jude's Women's Hospital.
3. The Person Responsible (PR), Mr Jude Harris Adeghe made representations against this proposed decision and the determination of the HFEA LC in relation to these representations was made on 10 November 2014.
4. The LC considered the representations and concluded that it was not persuaded that Mr Adeghe is a suitable person to act as Person Responsible and accordingly refused the application for a licence.
5. The PR had 28 days from the date of the LC's determination to appeal the decision. On 3 December 2014, the PR notified the HFEA of his intention to appeal.
6. The clinic's licence expired on 31 January 2014 and since then it has been operating under successive Special Directions. The current Directions were in force until the earliest of:
 - a. 12 December 2014; or
 - b. the conclusion of the statutory representations and reconsideration processes.
7. The Inspectorate recommended that Special Directions on the same terms as those currently in place are issued, with an expiry term linked to the conclusion of the statutory appeals process.

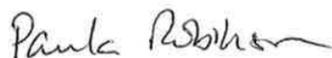
Discussion

8. The Panel noted that the Inspectorate's original recommendation to the LC of 8 May 2014 related, inter alia, to the practice of patients consenting to egg-sharing whilst recovering from the influence of sedative drugs.
9. The HFEA had considered at that time whether it was required in law to use its powers to protect patients by suspending the licence (under section 19C of the Act). The Inspectorate had required from the PR, and had received, an undertaking that the activities would cease and not be repeated. In the light of this assurance, the Inspectorate did not believe it was proportionate to restrain the PR from operating his clinic forthwith on the grounds of an on-going risk to the safety of patients.
10. The Panel further noted that following receipt of the LC's determination on 10 November 2014, following representations, a management review meeting was held in accordance with the HFEA's Compliance and Enforcement Policy. The review considered whether the recent LC findings were such that the risk to the safety of patients, their gametes and/or embryos should be reappraised, and whether any other materials suggested further steps were required to be taken, including consideration of whether evidence now showed that the clinic should not be permitted to continue to operate.
11. The Panel had regard to the clarity and force of the LC's determination which decided that Mr Adeghe is not a suitable person to act as a Person Responsible. The Panel noted the Inspectorate's ongoing view that this is a correct conclusion on the facts of the case, and their concern that the PR may indeed continue to exercise poor judgement - particularly in relation to regulatory expectations.
12. However, the Panel also noted that the PR has repeated his intention never to repeat the relevant activities which were at the centre of the Inspectorate's and the LC's concern. The Panel agreed with the Inspectorate's conclusion that it does not believe there is evidence of a serious measurable risk to patients from this, nor any change in

circumstances that would make any further steps at this point necessary or proportionate.

Decision

13. The Panel endorsed the Inspectorate's recommendation that Special Directions on the same terms as those currently in place are issued for the continuation of the Clinic's activities under its last licence (L0198-7-B), with an expiry term linked to the conclusion of the statutory appeals process. The Panel was not minded to add any restrictions to the Special Directions at this time.
14. The Special Directions will be effective from 13 December 2014, and shall remain in force until the conclusion of the statutory appeal and reconsideration process.
15. The Panel also requested that, should the circumstances change during the statutory appeal and reconsideration process, the Inspectorate should inform either the Panel or a Licensing Committee, as appropriate.



Signed
Paula Robinson (Chair)

Date 12 December 2014