

HFEA Licence Committee Meeting

9 January 2014

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

Minutes – Item 5

Centre 0329 (Wales Fertility Institute – Neath) - Application to Remove Additional Licence Condition

Members of the Committee: Andy Greenfield (lay) (Chair) Bishop Lee Rayfield (lay) Debbie Barber (professional)	Legal Adviser: Sarah Ellson, Field Fisher Waterhouse
Committee Secretary: Lauren Crawford	Observing: Sam Hartley, Head of Governance and Licensing, HFEA

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee

- Executive Summary
- Application form for removal of condition
- Additional information provided by centre
- Initial licence inspection report
- Previous licensing minutes for the last three years:
 - 11 July 2013 – initial inspection report

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); and
- 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. The Committee noted that Wales Fertility institute was granted a two-year licence in July 2013.
2. The initial application for a full treatment (including embryo testing) and storage licence was considered by the Licence Committee on 11 July 2013. The Committee noted that such licences include the use of embryos for training as an activity, and that the centre intended to carry out this activity.
3. In having regard to its decision tree at the time, the Committee was not entirely satisfied that the information provided was sufficient to allow them to reach a decision on whether the use of embryos for training was necessary and should be licensed as an activity.
4. The Committee agreed to grant the centre a licence for a period of two years with the additional condition:

‘Use of embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques is not to be undertaken by this centre until it provides further information on the training techniques and methods to be used’.

The Committee noted that this information would be acceptable in the form of a standard SOP or QMS document.

5. The Committee noted that subsequent to the decision being made, legal advice was sought on whether it is necessary for a Committee to see evidence of whether the use of embryos for training is necessary before a decision can be made to grant a licence for this activity or whether the decision made by the Authority, at its meeting of 9 September 2009, which concluded then that use of embryos for the specific training purposes is necessary as required by paragraph 1(4A) of Schedule 2 of the HF&E Act 1990 (as amended) could be applied to all applications. Legal advice concluded that it is not necessary for individual applications/reports to provide evidence of why use of embryos for training is necessary.
6. The Committee noted that in light of the Authority’s decision in September 2009 and in consideration of the legal opinion obtained, the Licence Committee’s decision tree was amended and no longer directs the Committee to explicitly consider whether use of embryos for training purposes is necessary.

Discussion

7. The Committee noted it was in receipt of an application to vary the centre's licence to remove the additional condition:

'Use of embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques is not to be undertaken by this centre until it provides further information on the training techniques and methods to be used'.

8. The Committee was satisfied with the legal advice provided in regards to training using embryos and the revised decision tree.
9. The Committee also noted that in support of its application the centre had provided detailed information about the use of gametes and embryos in training.

Decision

10. The Committee agreed to remove the additional condition on the centre's licence.

Signed:

Date: 30/01/2014



Andy Greenfield (Chair)