

Licence Committee Meeting

24 July 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Fisher Bioservices UK (0300) Initial licence application

Members of the Committee:

Anna Carragher, Lay Member – Chair
Ruth Fasht, Lay Member

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Present via conference telephone:
Chris Barratt, Head of the
Reproductive and Developmental
Biology research group, University of
Dundee

Providing Legal Advice to the
Committee:
Mary Timms, Field Fisher Waterhouse

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:

- papers for Licence Committee (32 pages)
- no papers were tabled.

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that this application is for a storage-only licence, to cover the storage of gametes and embryos. The centre is licensed by the Human Tissue Authority and currently stores other materials. Mr Lenton reported that the centre has been ISO accredited since February 2007. Mr Lenton also affirmed that a licence fee has been paid and the prospective Person Responsible has completed a Person Responsible Entry Programme (PREP) assessment to the satisfaction of the Executive.
2. Mr Lenton reported that a number of regulatory issues had been identified at the inspection visit to the centre on 18 December 2007. These were summarised on page 3 of the inspection report and are also discussed by the Person Responsible in his response to the findings of the inspection, appended at pages 15 to 17. Mr Lenton informed the Committee that the

matters raised in the report are (with the exception of one issue) all being addressed to the satisfaction of the Executive.

3. Mr Lenton explained that the only issue of some ongoing concern was the requirement for separation between the receipt and dispatch area. Mr Lenton described the temporary measures which had been put in place by the centre to reduce the possibility of mix ups.
4. In response to a question from the Committee, Mr Lenton affirmed that the centre was to be used as an overflow storage facility for licensed treatment centres.

The Committee's Decision

5. The Committee took into account the fact that the proposed Person Responsible had completed his PREP assessment to the satisfaction of the Executive. On this basis the Committee agreed that it was satisfied as to the suitability of the proposed Person Responsible.
6. The Committee took into account the comments at page 7 of the inspection report, which state that the centre premises are secure, clean and well presented and that servicing and maintenance of the cryovessels is documented. On this basis the Committee agreed that it was satisfied as to the suitability of the centre premises and the use of suitable practices at the centre. However, the Committee recommended that the measures put in place at the receipt and dispatch area are monitored carefully.
7. On the basis that the centre is already in operation and currently licensed by the HTA, and on the basis of the comments in the inspection report to the effect that the centre is well run, the Committee agreed that it was satisfied as to the use of suitable practices at the centre. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a determination and decided to grant a licence for a period of 12 months, which is the usual length of time for an initial licence.

Signed..... Date.....
Anna Carragher (Chair)