HFEA Executive Licence Panel Meeting

4 November 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0295 (Bristol Centre For Reproductive Medicine) - Renewal Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Mark Bennett, Director of Finance & Facilities	Joanne McAlpine

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

The Panel also 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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the centre was an amalgamation of Southmead Fertility Service and the Centre of Reproductive Medicine, University of Bristol that opened in January 2008.

2. The Panel noted that the Person Responsible (PR) is a consultant obstetrician & gynaecologist, who has successfully completed the PR Entry Programme and is registered with the General Medical Council.

3. The Panel noted that interim inspection reports were considered in October 2008 and October 2009 and, in both instances, the centre's licence was continued with no additional conditions. The Panel noted that the centre's current licence expires on 18 December 2010.

4. The Panel noted that the centre is large and has provided 1300 treatment cycles in total between 1 January and 31 December 2009.

5. The Panel noted that the renewal inspection took place back in July and that some unforeseen circumstances had delayed the report being presented to the Panel.

6. The Panel noted that there were a number of areas for improvement that the Inspectorate identified; one critical area of non-compliance, nine major areas and four other areas.

7. The Panel considered the report of the identified critical area of non-compliance. The Panel agreed that the potential risk of it being or becoming critical is real. However, after taking into account the evidence provided and the response of the Person Responsible, the Panel was satisfied that the centre was now actively managing the issue, having adopted a precautionary approach, and that, the issue is currently a major area of non-compliance rather than critical. The Panel considered the report due 12 November should provide an opportunity to reconsider this item.

8. The Panel noted the extended length of time it has taken the centre to deal with this issue.

9. The Panel referred to the decision tree for consideration of application to grant or renew a licence which, at stage 1 states the following "Is the application submitted in the form required and does it contain the supporting information, required by General Direction 0008"

10. The Panel noted that the supporting information required by General Direction 0008 had not been submitted, and, therefore, it could not continue with the decision tree.

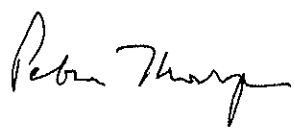
11. The Panel also noted that the centre is due to submit a final audit report of cryo-preserved gametes, relating to the critical area of non-compliance, by 12 November 2010.

12. The Panel referred to the protocol for "Conduct of Meetings of Executive Licensing Panel". The Panel noted in particular paragraph 8.7 (b) "Before the Panel makes its decision, the Chair may adjourn to-require further information from the applicant or Person Responsible for the centre to be licensed (as appropriate), or from the Authority's Inspector dealing with the matter."

Decision

13. The Panel agreed I to adjourn this item until the following information has been provided:

    - Supporting Information as required by General Direction 0008
    - Final audit report on cryo-preserved gametes from the Person Responsible due 12 November 2010 and any comments arising from the Inspectorate.

Signed:  Date: 17/11/10.

Peter Thompson (Chair)