HFEA Licence Committee Meeting

26 August 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0250 (Glasgow Centre for Reproductive Medicine) –Application for Variation for the use of unquarantined sperm

Members of the Committee: Anna Carragher (lay) – (Chair) Jane Dibblin (lay) Sally Cheshire (lay) Sue Price (Professional) Debbie Barber (lay) Mair Crouch (lay) Apologies: Rebekah Dundas (lay)	Committee Secretary: Joanne McAlpine Legal Advisers: Sarah Ellson – Field Fisher

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item, Debbie Barber noted that she works in a licensed centre.

The following papers were considered by the Committee:

- Executive summary
- Application for the variation of licence
- Previous Minutes where similar applications have been accepted

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)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- 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.

1. The Committee noted from the executive summary that centres are required to comply with the donor selection and screening requirements set out in standard licence conditions T52 and T53. Standard licence condition T53c requires that "donor sperm must be quarantined for a minimum of 180 days, after which repeat testing is required." However T53c goes on to explain that if the donor's blood sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV repeat testing is not required.

2. The Committee noted that this centre has applied to vary the condition to T53c to permit embryos created from non quarantined sperm to be transferred to a gestational surrogate.

3. The Committee noted that previous applications for this centre have been approved by the Licence Committee in the past on 27 May 2010 and on 17 September 2009. The Committee discussed that this was the third such application that the centre has submitted.

4. The Committee noted that, according to the executive summary, the commissioning couple and surrogate, had been through the normal pathway of medical assessment and counselling, and appropriate advice given in relation to surrogacy in accordance with the Code of Practice, and there were no concerns regarding the welfare of the unborn child.

5. The Committee noted that the commissioning couple have commissioned treatment with a surrogate in two previous unsuccessful cycles and a further transfer of frozen embryos was unsuccessful with their current surrogate.

6. The Committee noted that both the surrogate and the commissioning couple wish to proceed immediately. .They have applied to vary the licence condition as the surrogate has domestic commitments in 2011 and wishes to complete the pregnancy as soon as possible.

7. The Legal Adviser to the Committee drew the Committee's attention to the Code of Practice Section 11 Donation and Surrogacy, and to the wording of T53. She highlighted that the requirement for a 180 day quarantine period was not mandatory if the centre tested blood samples using NAT testing (Nucleic Acid Testing). The Legal Adviser referred the Committee to the Code of Practice 11.16 that recommends that the centre should quarantine donated gametes and eggs in line with guidance from the relevant professional bodies.

8. The Committee noted the executive summary paragraph 7 which states that discussions with the PR and the inspector have confirmed that the centre intend to implement NAT testing in the future but is unable to do this for this case as a new third party agreement and validation have not yet been completed. The Legal Adviser indicated that the Committee had to focus on the application made which was to waive quarantine provisions.

9. The Committee acknowledged the reasons outlined in the executive summary and application for the request. It noted the recommendation by the Executive that the centre should be allowed to vary the centre's licence condition T53(c) for the treatment of the patients.

10. The Committee noted that the quarantine provisions existed to protect the health of the surrogate and the child. They noted that the surrogate had apparently consented to the use of non quarantined embryos.

The Committee's Decision

11. The Committee accepted the application to vary licence condition T53c of the Centre's for the specified patients so that non quarantined embryos could be used.

12. The Committee did however express their concern that this is the third application that they have seen in the past year from this centre, despite the use of NAT testing being included in the 8th Code of Practice from the 1 October 2010.

13. The Committee would strongly recommend that if there continues to be a demand to use non quarantined embryos the Centre obtain access to NAT testing to avoid further applications coming before the Licence Committee in the future, and would encourage the centre to expedite the third party agreements for such NAT testing.

Signed: Date:

A Carragher 8.9.2010

Anna Carragher (Chair)