HFEA Licence Committee Meeting

26 August 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 7

Centre 0070 (The Bridge Centre)–Application for Variation of licence to include embryo testing for Dominant Dystrophic Epidermolysis Bullosa (OMIM 131750)

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
- Redacted correspondence with peer reviewer
- Redacted peer reviewer
- Genetic Alliance UK opinion

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.
- 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

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the Centre has been licensed to perform PGD for a number of years and has appropriately trained and experienced staff to deliver the service.

2. The Committee noted that the centre's proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of schedule 2 of the Act, i.e ' Where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality'.

3. The Committee noted that the request is for the dominantly inherited form of Epidermolysis Bullosa, and there is therefore a 50% chance of the embryo being affected in a family where one parent is affected and the other is unaffected.

4. The Committee noted that there is a significant risk that a person with the abnormality will develop a serious medical condition because it is close to 100% penetrant.

5. The Committee considered that the condition is serious. The condition Dominant Dystrophic Epidermolysis Bullosa is a clinically heterogeneous disorder characterised by blistering and scarring of the skin and mucous membranes in response to mechanical force. The onset of the disease usually is at birth or during infancy, with generalised blistering as a common presentation. With advancing age, blistering is often limited to hands, feet, knees, elbows and is associated with scarring. Treatment for this condition includes lancing, draining, and dressing all new blisters. Secondary infection following blisters is common.

6. The Committee noted that the hallmark feature of Dominant Dystrophic Epidermolysis Bullosa is the formation of large, fluid-filled blisters that develop in response to minor trauma. Some infants may have large blisters at birth, others start shortly after birth. Chafing of the skin, rubbing, or even increased room temperature may cause blisters to form. Some children have delays or difficulty walking because of blistering. Overall, virtually all individuals affected with this condition have a serious physical disability, though the degree of severity will depend on each individual case.

7. The Committee noted the Peer Reviewer's comments on page 13 of the application that there is no treatment for the condition other than supportive care when blisters occur – dressings, fluid and blood

replacement, treatment/prevention of infection, and psychological help when needed. The physical aspects may give rise to psychological morbidity.

The Committee's Decision

8. The Committee agreed that on the basis of the information presented, the Committee was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. Accordingly, it was appropriate to grant the application under 1ZA(1)(b) of Schedule 2 of the Act.

9. The Committee wished to remind centres of paragraph 10.5 of the Code of Practice (8th edition)/ HFEA guidance for Centres: 'The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. When deciding if it is appropriate to provide PGD in particular cases, the seriousness of the condition in that case should be discussed between the people seeking treatment and the clinical team. The perception of the level of risk for those seeking treatment will also be an important factor for the centre to consider.'

10. The Committee agreed that the licence should be varied to authorise the testing of embryos for Dominant Dystrophic Epidermolysis Bullosa – OMIM# 131750, and that no conditions should be put on the licence in relation to this variation. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date:

Anna Carragher 8.9.2010

As approved by Anna Carragher (Chair)