

HFEA Licence Committee Meeting

12 August 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 8

Edinburgh ACU (0201) – Variation to include PGD for Cystic Fibrosis

Members of the Committee:	Committee Secretary:
Anna Carragher (lay) -- Chair	Kristen Veblen
Rebekah Dundas (lay) – by videolink	Legal Adviser:
Richard Harries (lay)	Stephen Hocking, Beachcroft LLP
Emily Jackson (lay)	
Apologies:	
William Ledger (clinician)	

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 (67 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th 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; and
- 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 considered the papers, which included an Executive Summary, application form, peer review, patient information about PGD and cystic fibrosis, patient consent form, various laboratory protocols and an email response from the Centre to questions from the Inspector.
2. The Committee noted that this application was the Centre's initial application to provide PGD as a licensed treatment and had been made to treat couples with cystic fibrosis.
3. The Committee noted that cystic fibrosis (CF) was recessively inherited and was the most common life-shortening Mendelian disorder found in children and young adults of Caucasian descent. CF presents a number of clinical features including disruption of exocrine function in the pancreas, liver disease, chronic bronchopulmonary infection with emphysema, high sweat electrolyte with depletion in a hot environment and infertility in males and females.
4. The Committee noted that treatment of CF remained purely symptomatic; however, treatment had significantly improved life expectancy, from under 5 years in the 1960s, to 19-21 in the late 1970s-early 1980s, to c.40 years of age in the present day, if the patient undertook a great deal of medical intervention and daily routine management.
5. The Committee noted that this condition had been previously approved by the HFEA for PGD and that the peer reviewer had judged CF to be a severe condition and judged PGD as a supportable intervention.
6. The Committee noted that the genetics laboratory the Centre would use was well established, NHS funded and CPA accredited.
7. The Committee noted that the Centre had a multidisciplinary team having suitable expertise and that the supplied protocols and email communication from the PR demonstrated suitable practices. Additionally, the peer reviewer in their evaluation had indicated that the Centre's staff were suitably qualified.

The Committee's Decision

8. The Committee considered the guidance given in the 7th Code of Practice at G.12.3.3 (c) and (d) and agreed that there was a high degree of suffering associated with this condition and that, as discussed above, there was currently no effective cure available.
9. The Committee agreed that based on the information before it, it considered CF to be a serious genetic condition, as described by the 7th Code of Practice

section G.12.3.2, which posed a significant risk of being present in the embryo.

10. The Committee was satisfied from the documentation provided and from the peer reviewer's evaluation that those seeking treatment had proper information and would have access to proper counselling.
11. The Committee was satisfied that a licence should be granted to carry out PGD selection for the purpose of avoiding cystic fibrosis, being a practice designed to secure that embryos were in a suitable condition to be placed in a woman as indicated by Schedule 2, paragraph 1(1)(d) of the HFE Act 1990 (as amended). Further, the Committee agreed that, taking into account all the matters set out above, this practice was necessary and desirable for the purpose of providing treatment services, as required by Schedule 2, paragraph 1(3) of the HFE Act (as amended).
12. The Committee decided to vary the Centre's licence to add PGD for avoidance of cystic fibrosis (OMIM219700).

Signed... *Anna Carragher* Date *25.8.2009*
Anna Carragher (Chair)