HFEA Licence Committee Meeting
8 April 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 6

Assisted Conception Unit, UCH (0044) application to conduct human leukocyte antigen tissue (HLA) typing with PGD to select an embryo with the same tissue type as a child with beta Thalassaemia Major (case 2)

Members of the Committee:	
Anna Carragher, Lay Member (Chair) Emily Jackson, Lay Member William Ledger, Professor of Obstetrics and Gynaecology at the University of Sheffield	Committee Secretary: Claudia Lally Legal Adviser: Sarah Ellson, Field Fisher Waterhouse Solicitors
Attending via video conference link: Rebekah Dundas, Lay Member	Observing: Lillian Neville

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 (18 pages)
- 10 tabled pages: correspondence submitted with the application.

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 21st January 2009.

1. The Committee noted that the couple on whose behalf the application has been made have a child affected with beta thalassaemia. This child has been assessed as suitable for a bone marrow transplant but no suitable HLA matches have been found. The couple hope to use preimplantation diagnosis with HLA tissue typing to try for a child who will not be affected by beta thalassaemia and will be a tissue match for their affected child. This would enable a bone marrow transplant to the affected child to be performed at a future time.

2. The Committee noted that beta thalassaemia is a recessively inherited failure to produce the beta haemoglobin chains in red blood cells which carry oxygen around the body. This leads to severe anaemia requiring lifelong blood transfusions beginning in infancy. The result of these transfusions is that too much iron builds up in the body which can cause serious health problems and necessitates drug treatment to remove the unwanted iron. The Committee further noted that there is no simple cure for the condition, and nor is there likely to be one in the near future. However, bone marrow transplantation from an HLA matched donor can cure the condition, though the success rate is unpredictable.

3. The Committee noted the correspondence submitted with the application from a number of Consultants involved in the treatment of the family.

4. The Committee noted that this centre has one of the largest PGD programmes of all UK licensed clinics and has considerable experience of carrying out PGD, including PGD with HLA typing. Furthermore, this centre has been licensed on a number of previous occasions to carry out PGD with HLA for patients with children affected with beta thalassaemia.

5. The Committee considered the peer review and noted that the reviewer recommended that the application be granted.

6. The Committee considered G.5.9.1 of the Code of Practice, which sets out the additional information to be given to patients considering preimplantation tissue typing. The Code states that in any particular situation several factors are expected to be considered when deciding the appropriateness of tissue typing, including the overall likelihood of a successful outcome for the affected child. The Committee also considered the factors set out at G12.5.6 of the Code (and the matters at G12.5.7 and G12.5.8) which were relevant when deciding the appropriateness of preimplantation tissue typing including the possible consequences for any child born as a result and the family circumstances of the people seeking treatment.

7. The Legal Adviser indicated that case law had confirmed that it was open to the HFEA to conclude that biopsy for the purpose of selecting an embryo with a tissue compatible with that of a very sick child was an activity necessary or desirable for the purpose of providing treatment services. When considering whether the activity was necessary or desirable for the purpose of providing treatment services the Court had also said tissue typing for compatibility was capable of constituting a treatment service for the purpose of assisting a woman to carry a child. She reminded the Committee that the decision whether to grant such an application was discretionary and required consideration of the particular circumstances of each case.

8. The Committee noted the high degree of suffering associated with beta thalassaemia and that there is a significant risk that those affected with the condition will not live beyond 35 years of age. The Committee agreed that they had sufficient information and that they were satisfied that HLA typing was an appropriate treatment for the patients concerned.

9. The Committee considered G12.3.2 of the Code of Practice, which requires that PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo, and G12.3.3 of the Code of Practice, which states that in any particular situation the following factors are expected to be considered when deciding the appropriateness of preimplantation genetic diagnosis:

- the view of the people seeking treatment of the condition to be avoided
- their previous reproductive experience
- the likely degree of suffering associated with the condition
- the availability of effective therapy, now and in the future
- the speed of degeneration in progressive disorders
- the extent of any intellectual impairment
- the extent of social support available
- the family circumstances of the people seeking treatment.

10. The Committee noted that there is a one in four chance that any further child for these patients would be affected by beta thalassaemia. The Committee therefore agreed that this was a case in which there was a significant risk of a serious genetic condition being present in the embryo. The Committee decided that, having regard to the information they had, they were entirely satisfied that PGD was an appropriate treatment for the patients concerned.

11. The Committee agreed that they were satisfied that those seeking treatment and their families have had access to proper counselling about the implications of the procedure.

12. The Committee was satisfied that a licence should be granted to carry out PGD for beta thalassaemia major with HLA typing, being a practice designed to secure that embryos are in a suitable condition to be placed in a woman (Schedule 2 paragraph 1(1)(d) of the Human Fertilisation and Embryology Act 1990) and agreed that, taking into account all the matters set out above, this is necessary or desirable for the purpose of providing treatment services (Schedule 2 paragraph 1(3) of the Human Fertilisation and Embryology Act 1990).

13. The Committee decided to vary the centre's licence to add PGD with human leukocyte antigen (HLA) typing for named patients with a child who has beta thalassaemia.

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