HFEA Licence Committee Meeting
20 April 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 9

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 β-thalassaemia Major

Members of the Committee:	
Anna Carragher, Lay member – Chair Jennifer Hunt, Senior Fertility Counsellor, IVF Hammersmith Hossam Abdalla, Clinical Director, Lister Clinic	Committee Secretary: Kristen Veblen, assisted by Claudia Lally Legal Adviser: Sara Ellson, Field Fisher Waterhouse

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:

- tabled papers for Licence Committee (18 pages)
- 3 tabled pages: email from Andrew Doye to Kristen Veblen (20 April 2009); email from Karen Fordham to Wil Lenton (19 April 2009).

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 had been made had three children affected with β-thalassaemia. The Committee considered the tabled emails, which clarified that of the three affected children, there had been only one child (the subject of the application) for whom a suitable HLA match had not yet been found. The couple hope to use preimplantation diagnosis with HLA tissue typing to try for a child who would not be affected by β-thalassaemia and will be a tissue match for this particular child. This would enable a bone marrow transplant to the affected child to be performed at a future time.

2. The Committee noted that β-thalassaemia was a recessively inherited failure to produce the beta haemoglobin chains in red blood cells which carried oxygen around the body. This led to severe anaemia requiring lifelong blood transfusions beginning in infancy. The result of these transfusions was that too much iron built up in the body which could cause serious health problems and necessitated drug treatment to remove the unwanted iron. The Committee further noted that there was no simple cure for the condition, and nor was there likely to be one in the near future. However, bone marrow transplantation from an HLA matched donor could cure the condition, though the success rate was unpredictable. The Committee noted the statement by the peer reviewer that without transplantation there is a marked reduction in life expectancy.

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 had one of the largest PGD programmes of all UK licensed clinics and had considerable experience of carrying out PGD, including PGD HLA. Furthermore, this centre had been licensed on a number of previous occasions to carry out PGD HLA for patients with children affected with β-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 setting out the additional information to be given to patients considering preimplantation tissue typing. The Code stated that in any particular situation several factors were 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 type compatible with that of a very sick child was an activity necessary or desirable for the purposes of 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 was only a 50% chance that those affected with the condition will 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 required that PGD should be considered only where there was 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 were 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 was a one in four chance that any further child for these patients would be affected by β-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 any given

embryo. The Committee decided that, having regard to the information they had, they were entirely satisfied that PGD was therefore an appropriate treatment for the patients concerned.

11. The Committee agreed that they were satisfied that those seeking treatment and their family had been given 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 β-thalassaemia major with HLA typing, being a practice designed to secure that embryos were 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 was 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 had β-thalassaemia.

Signed..... Date.....5.5.2009
Anna Carragher (Chair)