HFEA Licence Committee Meeting

26 March 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 7

Assisted Conception Unit, UCH (0044), application to use human leukocyte antigen (HLA) tissue typing to select an embryo with the same tissue type as a child suffering from Acquired Aplastic Anaemia

Members of the Committee:	
Clare Lewis-Jones, Lay Member – Chair Ruth Fasht, Lay Member Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary Non-voting Specialist Adviser – present with the permission of the Chair: Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service	Committee Secretary: Claudia Lally Legal Adviser: Graham Miles, Morgan Cole HFEA Members Observing: Jane Dibblin Lillian Neville Debbie Barber

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 (19 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 21st January 2009.

1. The Committee noted that the couple on whose behalf the application had been made (SA and AAA) have a child affected with Acquired Aplastic Anaemia. The Specialist Adviser, who, as Peer Reviewer, had seen some additional paperwork submitted by the centre to accompany its application, advised the Committee that the affected child had been assessed as suitable for a cord blood stem cell transplant but no suitable HLA matches have been found. The couple hope to use HLA tissue typing to try for a child who will be a tissue match for their affected child. This would enable a tissue-matched cord blood transplant to the affected child at a future time. The Adviser added that a significant amount of information had been provided by the consultant treating the affected child, which had detailed the treatment being received and supported the option of a tissue matched cord blood transplant. This information had referred to the fact that the ethnic mix of the patients was partly responsible for the failure of the search for an alternative tissue-matched donor.

2. The Specialist Adviser informed the Committee that Acquired Aplastic Anaemia is a failure of the bone marrow to produce sufficient blood cells (red and white cells, and platelets) for the circulation. The condition is not passed on as a result of a genetic mutation but rather is developed during life, sometimes as a result of viral infection. The Adviser informed the Committee that this condition leads to a variety of symptoms, including repeated infections and fatigue. These symptoms are partially controlled with regular blood transfusion; however, susceptibility to infection often substantially reduces life expectancy. There is no simple cure for the condition, and nor is there likely to be one in the near future. However, cord blood transplantation from an HLA matched donor has an acceptable success rate.

3. 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, the Committee noted that the patients on behalf of whom the application had been made had been given access to appropriate counselling and advice and that the relevant patient information and consent forms had previously been submitted and approved by a Licence Committee.

4. 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 are 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. In particular, the Committee noted:

- the serious nature of the disease and the poor prognosis for the affected child
- the likely lack of available alternative sources of tissue for treatment of the affected child now and in the future
- the absence of evidence of adverse effects associated with embryo biopsy for the child who may be born; and
- the fact that the treatment of the affected child is likely to be accomplished by the use of cord blood without the requirement for invasive surgery for the child to be born.

5. The Legal Adviser advised that under 1(1) (d)of schedule 2 to the 1990 Act a licence may authorise, in the course of providing treatment services, a practice designed to secure that embryos are in a suitable condition to be implanted in a woman or to determine whether embryos are suitable for that purpose. In R (on the application of Josephine Quintavalle on behalf of Comment on Reproductive Ethics) v HFEA [2005] the House of Lords confirmed that the concept of suitability was broad enough to include suitability for the purposes of a particular mother. If testing would provide information that would enable a woman to determine whether to proceed with treatment services using a tested embryo then that might be regarded as treatment services for the purposes of assisting a woman to carry a child. However, before a licence could be granted, the Committee had to be satisfied that the proposed activity (i.e. the embryo biopsy and testing) was necessary or desirable for the purposes of treatment services.

6. The Committee took into account the fact that the parents have stated that any child born following the typing procedure would be wanted for its own sake, irrespective of the treatment that would be made possible for their sick child. However, the testing would facilitate the selection of an embryo for use in treatment services which would provide a tissue match with the existing child. The testing would, therefore, assist the parents in determining whether to proceed with IVF treatment services by transferring a selected embryo. The Committee further took into account that the cord blood transplant would not be an invasive treatment for the child born as a result of the HLA testing.

7. The Committee noted the suffering and shortened life expectancy associated with Acquired Aplastic Anaemia. The Committee agreed that they

had sufficient information and that they were satisfied that HLA typing was appropriate.

8. The Committee was satisfied that a licence should be granted to carry out HLA typing, being a practice designed to determine whether embryos are suitable 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).

9. The Committee decided to vary the centre's licence to add human leukocyte antigen (HLA) typing for named patients (SA and AAA) with a child who has Acquired Aplastic Anaemia.

Signed…… … Date……..
Clare Lewis-Jones (Chair)