

# HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

## MINUTES OF THE 139<sup>th</sup> OPEN AUTHORITY COMMITTEE MEETING (PART 2 - OPEN MEETING)

held at the 21 Bloomsbury Street, London  
on 21 July 2004

The Authority meeting was quorate with 16 Members attending, 9 lay members and 7 professional members.

### PRESENT

Suzi Leather <i>[Chair]</i>	Jane Denton
Tom Baldwin <i>[Deputy Chair]</i>	Richard Harries
David Barlow	Jennifer Hunt
Chris Barratt	Emily Jackson
Peter Braude	Maybeth Jamieson
Ivor Brecker	Walter Merricks
Clare Brown	Sara Nathan
Iain Cameron	Sharmila Nebhrajani

### IN ATTENDANCE

Angela McNab *[Chief Executive]*  
Barry MacDonald *[Director of Resources & Corporate Development]*  
Trish Davies *[Director of Regulation]*  
Charles Lister *[Head of Policy]*  
Rita O'Brien *(Head of Corporate Development)*  
Chris O'Toole *[Head of Research Regulation]*  
David Tellis *[Director of Information Management]*  
Tim Whitaker *[Director of Policy & Communications]*  
Fran Clift *[Legal Advisor]*

### OBSERVERS

Liz Woodeson *[Department of Health]* Hilary Harris *[Human Genetics Commission]*  
Ted Webb *[Department of Health]*

The Authority meeting began at 2:00p.m.

Prior to the formal meeting there was a presentation from Sarah Carter and Nigel Jackson on the results of the research completed by Opinion Leader Research into Public attitudes to PGD/HLA..

### ACTION

#### Item 1 Apologies & Conflicts of Interest

1. Apologies for absence were received from Neva Haites and Simon Jenkins.

Ian Cameron, Chris Barrett, Peter Braude, Maybeth Jamieson and David Barlow declared conflicts of interest for item 8 Research Licence Fees. It was agreed they would leave the meeting for that item.

**Item 2 Minutes of the meeting held on 16 June 2004  
[Paper HFEA (21/07/04) 168]**

2. The minutes of the previous meeting held on 15 June were accepted subject to agreed changes.

**Item 3 Matters Arising & Previous Actions  
[Paper HFEA (21/07/04) 169]**

3. There were no matters arising to report.

**Item 4 Chair's Report**

4. **ESHRE Conference.** The Chair reported that HFEA contributions at ESHRE were well received. Information was presented on the Tissue Directive and Alert system. The HFEA's first Horizon Scanning meeting took place and the Expert Panel convened proposed to meet once a year at the ESHRE conference. Additional meetings can be held if needed, otherwise the group will work through email (as a virtual group). Currently Terms of Reference are being drafted. The next SCAG meeting will discuss the first questionnaire to be put to the horizon scanning panel.
5. Human Genetics Commission Consultation Paper – 'Choosing the Future: genetics and reproductive decision making'. This has been published and responses need to be with the HGC by 15 October. The September Authority meeting will agree a response.

**Item 5 Chief Executive's Report**

6. **Select Committee Hearing** 4 members of the HFEA appeared before the Select Committee this morning and answered a range of questions on policy, inspection, regulation and the Alert process. There is another meeting scheduled for later in the year when the Chair of the HFEA will attend.
7. **ESHRE** Following the presentation on the Alert system, the Chief Executive informed the Authority of the proposal to carry out research into incident reports from other countries. Countries that have agreed to take part are Netherlands, Sweden, Victoria State of Australia and possibly Canada. It is hoped to start the study in the Autumn.

8. **Healthcare Commission** HFEA have met with the Commission to discuss how we can work more closely together. Issues discussed included information sharing, the piloting of joint inspection and the development of an MOU.
9. **Patient Feedback Questionnaire** is now on the web and a number have been submitted.

**Item 6 HLA/PGD Review  
[Paper HFEA (21/0704) 170]**

10. The Authority were asked to consider the following:
  1. To endorse the findings in Annex A1. The main proposal is that tissue typing should be available in the absence of indications for preimplantation genetic diagnosis and that HFEA should not restrict tissue typing to cord blood donation but should leave the matter of bone marrow donation up to judgements made between doctors and patients.
  2. To agree the guideline in Annex 2
  3. To discuss three points:
    - a) 'Insurance siblings'
    - b) Donations for patients
    - c) Solid organ donation
  4. Agreement on what should go on the website
11. It was clarified that HGC would be looking at the wider screening issues and the HFEA will focus on PGD/HLA.
12. The legal powers regarding PGD have now been clarified in the court of appeal in May 2003.
13. The Authority agreed with the main proposal. The Authority reviewed Annex A1. The following points were made:
14. **3 Risk of blastomere biopsy** Finding (i) It was noted that there appears to be no substantial evidence to show any increase in risk. Ongoing monitoring and assessment should continue however. It was agreed to accept the Ethic & Law Committees' findings subject to ongoing follow up work. It was also agreed that a clause be added under 'Patient Information' on page 24 14.27/8 (ii) to the effect that at present there is no evidence from long term follow up studies that demonstrates that there is any increased risk from this procedures.

15. **5 Psychological Welfare of the Child** Finding (ii). The evidence considered by the Ethics and Law Committee was that families with donor siblings feel 'special' and the experience of having a sick child and a donor child causes bonding in a different way from other families. The Authority endorsed the Ethics & Law Committees' findings subject to changes to the wording.
16. **6 Additional considerations to be taken into account** Finding (iii) the HFEA intends to move the emphasis to the clinician treating the child and family to put the case to HFEA for treatment. The Authority agreed to these findings but wished to include on page 23 14.27/2 a statement that all efforts have been made to explore other treatments with information on why they were not suitable or successful. The Regulation Committee will look at the specifics of how this information is gathered.
17. **7 Cord blood and bone marrow** Finding (iv) The Authority endorsed the Ethics & Law Committees' findings subject to the change at the end of the last sentence to '*use of bone marrow can not be ruled out*'.
18. **Legal Issues** Finding (v) The Authority endorsed the findings subject to the inclusion of the following sentence to be included after 'non-therapeutic'. 'Although parents usually give consent to a child's medical treatment, the courts always have the power to overrule their consent where the procedure would not be in the child's best interests'. The word 'arrangement' in the last sentence is to be changed to 'law'.
19. **8 Ethical Issues** Finding (vi) The Authority endorsed the findings.
20. **9 Public Opinion Finding** (vii) A presentation was given to the committee before the meeting on public opinion.
21. **Annex A2**  
The guidelines amend Section 14 on preimplantation testing of the 6<sup>th</sup> code of Practice. After discussion the guidelines were approved subject to the following changes:  
**14.27/3** 'Preimplantation tissue typing service' – remove the word 'service'  
**14.27/6** This paragraph to be removed  
**14.27/7** Should read 'Primary care and counselling'  
**14.27/12** Should read 'The decision to use preimplantation tissue typing should be made *based upon the individual circumstances of each case*'  
**14.27/13** Remove 'or at significant risk of'.

It was felt that information should be in writing for patients. Information on counselling and where it can be accessed should be included in the guidelines.

Points (vi) financial costs and (vii) emotional burden under **14.26** should be included in **14.27/9**.

It was agreed that the guidelines note that it would be the clinics responsibility to provide information to the patients in different languages.

**14.27/15** Follow Up. Centres to report to Licence Committee the detailed arrangements for following up. It was also suggested that statutory Health visitor records would provide a good source of information.

3.30 At this point Iain Cameron left the meeting

22. **Insurance siblings.** It was agreed that the current guidelines for the use of preimplantation tissue typing would in principle permit applications for the use of this technique in cases for example, where there is a child with leukaemia.

The Ethics and Law committee have also discussed the ethical issues raised by the use of this technique to select a child whose cord blood would be available as a source of stem cells to treat an adult, e.g. a parent. The committee takes the view that the situation in a case of this kind is ethically more problematic than that in a 'saviour sibling' case, and recommends that the matter be set aside for further discussion. The Authority accepted this recommendation.

23. **Press Release** A press release was circulated to the Authority for comments. As a result of the changes discussed in the meeting, the release was amended and reviewed before approval was given.

4.00pm Suzi Leather left the meeting and Tom Baldwin took over the Chair.

**Item 7 May Management Accounts  
[Paper HFEA (21/07/04) 171]**

24. The Authority was advised that the annual accounts had been approved by NAO and laid before Parliament without any problems. The May management accounts for the current year showed a small variance from budget but it is too early to see if this will continue in the future. This will be reviewed again at the end of the 1<sup>st</sup> quarter (at the end of June) to see if there are any systematic overspends emerging.

**Item 12 Regulatory Activity Report – May 2004  
[Paper HFEA (21/07/04) 176]**

25. The Authority was informed that in future the regulatory report and the Finance Report will be presented together.

The planned inspections vary from month to month and the reports are going out on time. There was a rise in incidents in March but there was no apparent consistent reason for this. Regulation continues to scrutinise centres that have a high number of incidents. They have done a root cause analysis on centres where a cluster of incidents have occurred.

26. Licensing activities are listed on the report. On a quarterly basis there will be an analysis of the activities of research licences.
27. A scientific advisor is being recruited who will comment on the issues of high risk in laboratories and risk management strategies.

**Item 9 Agree Changes to HFEA Signatories of Licenses  
[Paper HFEA (21/07/04) 173]**

28. The Authority ratified the Regulation Committee's decision to change the signatories for licences to include the Director of Regulation, Chief Executive or any other Director.

**Item 10 Submissions of Papers to Licence Committees by pressure groups  
& interested parties  
[Paper HFEA (21/07/04) 174]**

29. As a result of a research application put on the website, HFEA received submissions from pressure groups and outside parties.

The Authority considered the options on whether the Licence Committee should (1) not consider this material or (2) consider only material relevant to statutory tests or (3) consider all the submissions, on the understanding that these would be sorted in advance by a member of the Executive.

30. The Regulation Committee recommend Option 3 to the Authority but wish to review in 6 months time. This was approved.

4.30 At this point Peter Braude left the meeting

At this point Maybeth Jamieson, Chris Barratt and David Barlow were asked to leave the meeting whilst the next agenda item was discussed.

**Item 8 Results of HFEA Consultation on Human Embryo Research Fees and proposed changes in the Application Process [Paper HFEA (21/07/04) 172]**

31. The Authority discussed the two options suggested for the licence fee to be introduced: (1) A flat rate Licence Fee or (2) Differential Fee related to workload. The DH agreed this work should be included in the list of items funded by their grant in aid.
32. The Authority agreed to propose an increased fee of £500 for all small projects and a fee of £750 for large, complex projects. A watch would be kept on the impact of resources available for regulating treatment and patient safety. Treasury and Ministerial approval for this will now be sought.

**Item 11 The Next Patients' Guide – A single comparator and reporting congenital abnormalities [Paper HFEA (21/07/04) 175]**

33. It was agreed that this item would be deferred to the next meeting of the Authority in September. In the meantime, the Authority were asked that if they have any comments on the paper to contact DT.

**Item 13 Report on Regulation Committee Activity 03/04 and planned activity 04/05 [Paper HFEA (21/07/04) 177]**

34. The Authority noted the paper. The objectives of the committee are to help the Authority to set regulatory strategy for the next three years and to focus on modernising regulatory processes and professionalising inspection and improving efficiency and effectiveness. The Committee is looking at finalising the risk matrix and the practical implementation of it. Additional issues from meetings are putting pressure on the Committee. It was noted that the workload had risen beyond that in the business plan, this will need to be reviewed.

**Item 14 SCAG Summary Report [Paper HFEA (21/07/04) 178]**

35. The Authority noted the report.

**Item 15 Regulation Committee Minutes [Paper HFEA (21/07/04) 179]**

36. The Authority noted the report.

**Item 16 Any Other Business**

37. **Progress on SEED Review** (WM). This will come to the Authority in September when a consultation paper will be issued.

A meeting will be held with some stakeholders e.g. professional bodies, interested patient organisations and some major recruiters of egg and sperm donors. The Working Group has done a factual survey of current availability of recruitment practice amongst the recruiting and receiving clinics. Major issues that will be consulted on are money or benefits paid to gamete donors, age limits for gamete donors, limit of life births, restrictions on live transfer between UK clinics. A paper was circulated which sets out the options and the Authority are invited to feedback to WM any comments.

**Item 17 Date of the Next Meeting**

The next meeting of the Authority will be **Wednesday 15 September 2004** and will be held at the HFEA offices at 21 Bloomsbury Street.

The regular Authority meeting closed at 5.00p.m.

I confirm this to be a true and accurate record of the meeting.

Signed .....

Chair

Date .....