

## HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

### MINUTES OF THE 138<sup>th</sup> OPEN AUTHORITY COMMITTEE MEETING (PART 2 - OPEN MEETING)

held at the 21 Bloomsbury Street, London  
on 16 June 2004

The Authority meeting was quorate with 16 Members attending, 9 lay members and 6 professional members.

#### PRESENT

Suzi Leather <i>[Chair]</i>	Jennifer Hunt
Tom Baldwin <i>[Deputy Chair]</i>	Emily Jackson
David Barlow	Maybeth Jamieson
Peter Braude	Simon Jenkins
Ivor Brecker	Walter Merricks
Jane Denton	Sara Nathan
Neva Haites	Sharmila Nebhrajani
Richard Harries	

#### 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 12:45p.m.

#### Note:

Suzi Leather, Angela McNab and Simon Jenkins left at 2.30pm.  
Tom Baldwin took over the chair from 2.30pm.

**Item 1 Apologies**

1. Apologies for absence were received from Chris Barratt, Clare Brown, and Iain Cameron.

**Item 2 Minutes of the meeting held on 12 May 2004**

[Paper HFEA (16/06/04) 156]

2. **Para 14** This should be amended to read 'It was agreed that any measures relating to patient safety (e.g. alarms on dewars) should be implemented immediately. Any issues relating to staff safety were the remit of HSE, and we should seek clarification from them before giving advice to clinics.

The minutes of the previous meeting held on 24 March were accepted subject to this and other agreed changes.

**Item 3 Matters Arising & Previous Actions**

[Paper HFEA (16/06/04) 157]

3. The Director of Regulation reported that Nurse and Counsellor Inspector posts were being recruited. The job description and protocols were being discussed with the relevant professional bodies, and there would be a further report to Regulation Committee and the Authority in the Autumn.

**Item 4 Chair's Report**

4. There was nothing to report.

**Item 5 Chief Executive's Report**

5. The statutory accounts for 2003/4 would normally come to the July meeting for sign-off by the Authority. However the meeting would be too late to allow the accounts to be laid before Parliament, which was rising early on 22 July.
6. The Authority agreed that on this occasion final approval of the accounts should be delegated to the Audit Committee.

**Item 6 Report on Quality Improvement Project for License Committees**  
[Paper HFEA (16/06/04) 158]

7. Sarah Ellson of Field Fisher Waterhouse gave a presentation of the findings of the project, which had been presented to the Regulation Committee. The paper included the Committee's comments and recommendations. The Chair of the Regulation Committee reported that although the recommendations in the report had not been accepted in total, they welcomed the principles underpinning the report, and supported the majority of its recommendations.
8. The Director of Regulation reported that some of the changes recommended in the report were already being implemented:-
  - A dedicated licence committee Secretary was being recruited
  - The format for inspection reports was being standardised
  - Factors in the Risk Assessment Matrix are beginning to be used as part of evidence.
  - Dedicated IT staff had been identified to support Regulation, including developing an IT system for the Risk Matrix.
  - Licence Committees are starting to use the decision-making tools.
9. The Authority welcomed the report, and supported the overall objectives of improving the operation of Licence Committees, and the emphasis on ensuring evidence based process. However there were concerns about specific issues and recommendations.
10. **Recommendation 3.4.** The Regulation Committee had expressed concern about the proposal that Licence Committees could determine that in specific cases interim inspections were not necessary; it was felt this might run counter to the Toft Report. It was noted, however, that increasingly decisions on inspections would be driven by risk assessments and these would be the decisive factors. The Authority therefore accepted this recommendation, but agreed interim inspections would continue until the risk tool was considered to be fully tested and reliable.
11. **Recommendation 3.6.** It was not felt that annual change in membership was appropriate at this time. The new Licence Committee system had only just recently been established; it was agreed that the changes would be 'periodic'.

12. **Recommendation 4.6.** Ensuring the PR saw all documentation prior to a Licence Committee was welcomed. It was felt this would focus the discussion on these issues on which there was disagreement. The Director of Regulation confirmed that there would be a reasonable cut-off point, to avoid protracted correspondence with centres.
13. **Recommendation 5.4.** The handling of conflict of interest raised concerns about how relevant clinical expertise could be provided in such a small field, whilst avoiding even the appearance of conflict of interest. It was questioned whether it was appropriate for clinicians to bring particular knowledge of a clinic to discussions.
14. The Chair of Regulation Committee acknowledged that they had been concerned about this, but the fundamental principle to be observed was that decision-making should be evidence-based. Sarah Ellson suggested that the test of whether there was a conflict of interest would be the view of 'a reasonable person', not the perception of the PR. The key factor was the objectivity of the decision-making process. It might not necessarily be appropriate to use the wider knowledge of a member in a decision; but if it was used it must be recorded.
15. **Recommendation 5.5.** There was some concern that recording detailed legal advice would leave the Authority open to challenge. The Regulation Committee had felt that if legal advice affected the decision, it must be recorded. The GMC caselaw supported this.
16. **Recommendation 6.5.** It was felt that there would be value in the SRM/RO remaining in the room during the decision making process. Members might need technical advice or clarification.
17. **Recommendation 6.7.** Members did not accept the recommendation that a vote should be registered after each case. Whilst accepting that an approval or removal decision has to be unanimous, it was not felt that this required a formal vote.
18. **Recommendation 7.7.** Some members felt concern that not commending centres might damage the HFEA's relationship with centres. The Regulation Committee felt this was not the role of a regulator, which was strongly supported by a majority of members. The Regulation Committee's view was accepted, but the Director of Regulation was asked to consider the HFEA's wider relationships with clinics.
19. The recommendations of the Regulation Committee were accepted, subject to the amendments agreed by the Authority.

**Item 7 ICSI Inspections Review**  
[Paper HFEA (16/06/04) 159]

- 20. This paper recommended that inspections of ICSI practitioners and approval by Licence Committees should no longer be required. The Code of Practice required PRs to ensure appropriate qualifications of the centre staff, and ensuring ICSI practitioners had appropriate training and qualifications as part of this role. Centres would still be required to submit reports on ICSI, and new Directives would strengthen this. The HFEA would still inspect embryo biopsy practitioners. These recommendations had been accepted by the Regulation Committee.
- 21. There was a question raised about the uniformity of standards which would be applied in clinics. It was proposed to work with ACE to agree assessment criteria, which would be sent to PR's.
- 22. The proposals were welcomed by the Authority. There were questions raised over whether we should continue to inspect embryo biopsy. But it was recognised that there were fewer clinics doing embryo biopsies, and hence fewer opportunities to learn its use.
- 23. The Authority agreed the recommendations of the Regulation Committee. It was also agreed that embryo biopsy practitioners would continue to be inspected, but that this would be reviewed in the future.

**Item 8 Complaints Leaflet**  
[Paper HFEA (16/06/04) 160]

- 24. The revised draft was felt to be an improvement. Agreement of the final wording was delegated to the Director of Communications, who would work with JH on redrafting. Any comments should be sent to TW.

**TW/JH**

**Item 9 Regulatory Activity Report**  
[Paper HFEA (16/06/04) 161]

- 25. The Director of Regulation presented the paper, which included the draft patient questionnaire which will be sent to patients by clinics. This was an edited version of the draft seen by the Authority in 2003. The information produced would be fed into the pre-inspection analysis.  
  
The questionnaire was welcomed by the Authority.
- 26. Members commended the Regulation team for the promptness of production of inspection reports.

**Item 10 April Management Accounts**  
[Paper HFEA (16/06/04) 162]

27. The Director of Resources and Corporate Development reported that no trends were yet apparent. The reported under spends reflected timing of expenditure.

**Item 11 IMPB Summary Progress Report**  
[Paper HFEA (16/06/04)163]

28. It was emphasised that it is important to reach an early decision on the format of the next Patients' Guide. The Clinical Information Working Group would have a final discussion, and the proposed format would be submitted to the Authority in September. The Authority will have to decide a format if no agreement is reached at CIWG. The format should be tested with patients in parallel with the work on verifying the figures.

**Item 12 Update on Tissue Directive**  
[Paper HFEA (16/06/04) 164]

29. The Authority noted the report.

**Item 13 Regulation Committee Minutes**  
[Paper HFEA (16/06/04) 165]

30. The Authority noted the minutes.

**Item 14 Audit Committee Report**  
[Paper HFEA (16/06/04) 166]

31. The Authority noted the report.

**Item 15 Communications Update**  
[Paper HFEA (16/06/04) 167]

32. The Authority noted the report.

**Item 16 Any Other Business**

33. No other business was reported.

**Item 17 Date of the Next Meeting**

The next meeting of the Authority will be 21 July and will be held at the HFEA offices at 21 Bloomsbury Street.

The regular Authority meeting closed at 4.30p.m.