

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

MINUTES OF THE 135th OPEN AUTHORITY COMMITTEE MEETING (PART 2 - OPEN MEETING)

held at the Royal College of Physicians
on 24 March 2004

The Authority meeting was quorate with 12 Members attending, 7 lay members and 5 professional members.

PRESENT

Suzi Leather [*Chair*]
Tom Baldwin [*Deputy Chair*]
Peter Braude
Ivor Brecker
Jane Denton
Neva Haites

Jennifer Hunt
Emily Jackson
Maybeth Jamieson
Walter Merricks
Sara Nathan
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*]
Chris O'Toole [*Policy Manager*]
David Tellis [*Director of Information Management*]
Tim Whitaker [*Director of Policy & Communications*]
Heidi Homar [*Committee Secretary*]

OBSERVERS

Ted Webb [*Department of Health*]
Liz Woodeson [*Department of Health*]

Hilary Harris [*Human Genetics Commission*]

The Authority meeting began at 3:00 p.m.

Item 1 Apologies

1. Apologies for absence were received from David Barlow, Chris Barratt, Clare Brown, Iain Cameron, Richard Harries and Simon Jenkins. Trish Davies, Director of Regulation and Helena Hird, Head of Public Relations were both welcomed to the meeting.

Item 2 Minutes of the meeting held on 18 February 2004

[Paper HFEA (24/03/04) 139]

2. The minutes of the previous meeting held on 18 February were accepted subject to minor changes.

Item 3 Matters Arising & Previous Actions

[Paper HFEA (24/03/04) 140]

3. The Authority noted that actions taken have been included in the Matters arising.
4. Data Set Report will be discussed under item 7 of the agenda.
5. ***PGD/HLA Policy Review Research*** has been commissioned to undertake a public attitude survey as part of the review of the HLA/PGD. It was suggested that parent groups and specialist doctors could be included in this research. A briefing will be emailed to members with further details and the outcome will be reported to SCAG.

Item 4 Chair's Report

6. There was no report from the Chair.

Item 5 Chief Executive's Report

7. **Accommodation Update** The server and phone systems will be disconnected from Thursday 26 March and the offices will be packing up Friday for the move over the weekend. As there will be no phones on Friday, all calls will be diverted to a mobile number. All phones and servers will be reconnected on Monday 29 March.
8. **Paxton House Lease** HFEA is still negotiating the buy-out of the lease. A further update will be provided when information is available.
9. **Head of Policy** CL has been offered and accepted the permanent position of Head Of Policy. He is currently on secondment from the DH.

10. **Website** Starting in the next few months, details of research applications received at HFEA will be regularly included on the website.
11. **Head of Clinical Excellence** A candidate has been selected for this position.
12. **Directory of Clinics** Staff were thanked for the successful launch of the directory.

Item 6 Presentation of EU Directive & Accreditation

[Paper HFEA (24/03/04) 141]

13. The Head of Policy gave a presentation on the EU Directive and the action being taken by the Executive. A cross-organisation steering group has been set up, which members would join in May. The DH has met with the European Commission and member states to discuss the implementation of the Directive. 9 member states, including the UK will be meeting to draft the technical annexes and will present them to the full 25 member states in July. DH will involve the HFEA as a key stakeholder.
14. There were two opportunities to comment on the Annexes of the Tissue Directive, in May and in July. HFEA was aiming to comment in May as leaving it until July may be too late for any changes to be made.
15. Annex 4 shows a summary of the legal advice on how the directive affects HFEA, particularly licensable activities.
16. DH are working on identifying requirements already in the 1990 Act. Clinics may already be doing these but they may be made a legal requirement when applying for a license.
17. It was confirmed that the regulation of the Directive in ART is expected to be financed by fees from the clinics.
18. It was noted that implementing the Directive may have a financial impact on the clinics.
19. The Authority were advised that there were two options for implementing the extension of regulations:
 - The single track approach where the Directive is treated like an extension of the Act and the two are enforced together.
 - The twin track approach where the Directive is treated like a mandatory accreditation scheme backed by UK accreditation standards and enforced separately.

20. There were still concerns in the field about implications of the Directive for clinics, particularly around issues such as air quality requirements, The UK was arguing for centres to be able to demonstrate they were operating within standards appropriate to their specific needs, rather than a single standard covering all.
21. There were also concerns about the timetables for full implementation; 2006 was felt to be challenging.
22. The HFEA would need to ensure it had the skills to provide the professional regulation required by the Directive. The Regulation Committee would be considering this.

Item 7 Access to Data
[Paper HFEA (24/03/04)142]

23. The paper sets out guidance on the information that the HFEA is going to give to Primary Care Trusts and Health Boards who request data. This is the solution proposed before the publication of the next Patient Guide. If information is requested, HFEA will circulate the same CD Rom we sent out earlier this year to licensed centres containing a copy of our previous Patient Guide and the data published by ESHRE.
24. This was agreed, subject to agreement to publish this information and the caveat that the information is from 2 years ago.
25. Paper EP24/03/04x2 entitled Future Donor Information was tabled. The Authority's forms for donors' information had been compared to the information requested under the Assisted Conception and Legislation in the State of Victoria, Australia.
26. The members discussed the additional information that had not been included on the Authority's forms and the following was agreed:
 - 1.5 It was felt that it was important for offspring to be able to gain knowledge of their identity and if we cannot get access to the NHS number tracking system, the name of the donor should be included.
 - 1.6 the marital status of the donor should be included but not the spouse's name
 - 1.7 If the HFEA does not get access the NHS tracking system, then the current address details of the donor should be included.
27.
 - 1.15 The donor and the donor's parents' ethnicity should be collected. If the donor is adopted, this should be included on the form.
 - 1.18 The donor's blood group should automatically be collected and this information should appear on the clinics records.

- 1.21 The number of donor's children is already on the form
- 1.22 All information on the form is fact based. The reason for the donor making a donation should come under the pen portrait. However, it was felt that there should be some guidance notes for the donor.

- 28. The members were asked to contact the Director of Information Management directly with any further amendments to the donor form.

Item 8 Risk Register
[Paper HFEA (24/03/04) 143]

- 29. The paper described the work that had been done on risk management in 2003. The Register reflected the comments of standing committees.
- 30. Some discussion on mitigation of risks took place and it was agreed the register be reviewed again in September.
- 31. **Corporate and Business Plans** The Authority noted the very full agenda set out in the plan. SMT have looked at identifying contingencies or work that can be left to the latter part of the year should additional issues divert resources. It was agreed that the contingencies be discussed at OFC along with ongoing monitoring of the plan.
- 32. **Staff Turnover** The Authority was concerned over the staff turnover. This will be passed back to the OFC for review.

Item 9 GMC (NMC) Memorandum of Understanding Update
[Paper HFEA (24/03/04) 144]

- 33. The Authority approved the MOU with the GMC. It was noted that the MOU does not change any statutory functions of the GMC or the HFEA.
- 34. MOUs are currently being draft with MRHA and NPSA. The MRH MOU should be ready in May or June.

Item 10 Regulatory Activity Report
[Paper HFEA (24/03/04) 145]

- 35. The Authority noted the report of activities over the last three months and they were advised that it was planned that future reports would contain more information.

Item 11 Communication Update
[Paper HFEA (24/03/04) 146]

- 36. The Authority was advised that the Directory of Clinics had been launched. The staff involved was congratulated on their work.
- 37. The corporate calendar continues to expand and information on conferences and members' presentations will also be included.

Item 12 Any Other Business

- 38. Remote Access for Authority members Paper EP (24/03/04) x1 was circulated to the Authority. IT had noted comments from the Authority on problems on accessing emails. A CD had been circulated to members with instructions to help speed up access to HFEA data.

It is planned to introduce special email groups to send out sensitive information to members via the secure connection. Staff will be able to send out non-sensitive information to ordinary non-secure mail boxes. The members approved these suggestions.

Item 13 Date of the Next Meeting

The next 'open' meeting of the Authority will be 12 May and will be in Central London.

The regular Authority meeting closed at 5.30p.m.