

Authority Paper



Committee:	Authority
Meeting Date:	17 October 2007
Agenda Item:	2
Paper Number:	HFEA (05/09/07) 398
Paper Title:	Minutes of the non-confidential Authority meeting held on 5 September 2007
Author:	Committee Secretary
For Information or Decision?	Decision
Resource Implications:	None
Recommendation to the Committee:	The Authority is asked to confirm the minutes as a true and accurate record of the meeting

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY MINUTES OF THE NON-CONFIDENTIAL AUTHORITY MEETING (NON-CONFIDENTIAL - PART 2)

The meeting was quorate with 8 lay members and 6 professional members attending.

PRESENT

Shirley Harrison
(Chair)
Walter Merricks
(interim Dep. Chair)
Hossam Abdalla
David Archard
Christopher Barratt
Anna Carragher
Sally Cheshire
Rebekah Dundas
Neva Haites
Richard Harries

Jennifer Hunt
Susan Price
Emily Jackson
Maybeth Jamieson

APOLOGIES

Sharmila Nebhrajani
Ruth Fasht
William Ledger
Roger Neuberg
Clare Brown

IN ATTENDANCE

Angela McNab
Tim Whitaker
Sally Townsend
John-Paul Maytum
Charles Lister
Helen Coath
Chris O'Toole
Trish Davies
Kathryn Gray

OBSERVERS

Ted Webb - Department of Health
Gareth Jones - Department of Health
Helen Davies - Department of Health
Dinah Rose - Blackstone Chambers
Eve Piffaretti - Morgan Cole

Item 1. Apologies, Welcome & Conflicts of Interest **Action**

- 1.0 The Chair welcomed Catherine Drennan, the interim Legal Adviser and Department of Health observer, Helen Davies to the meeting.
- 1.1 Apologies received from :
 - Roger Neuberg
 - Clare Brown
 - Ruth Fasht
 - Sharmila Nebhrajani (on leave of absence until Jan 08)
 - Ros Gardner (HGC representative)
 - Bill Ledger
- 1.2 Walter Merricks declared a potential conflict of interest for matters arising item 10/01/07 6:6.7 and the tabled paper 'Geographical Breakdown of sperm donors ' as he has close links with the Donor Conception Network but the Chair deemed it unnecessary for him to leave the room.

Item 2. Minutes of the Authority meeting held on 25 July 2007

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- 2.0 The Authority approved the minutes of 25 July 2007 meeting with the following amendments:
- 2.1 Page 3, para 5.4 - should read 'the first Stage 3 Complaints Panel' and not 'her first Stage 3 Complaints Panel' as stated in the report.
- 2.2 Page 7, para 11.0 - should read 'embargoed until Wednesday 1 or Thursday 2 August 2007'
- 2.3 Page 10, Date of Next Meeting should read 5 September 2007 and not 17 October as stated in the minutes.

Item 3. Matters Arising & Previous Actions

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- 3.0 18/10/06 8:9.8 - Trish Davies, Director of Regulation and Deputy Chief Executive, informed the Authority that the HFEA does not currently have the means to collect data on the number of patient complaints received by clinic this data electronically and a new process is in development. The pre-inspection questionnaire has also been modified to collect this information.

- 3.1** 10/01/07 6:6.7 - David Tellis, Director of Information Management, directed the Authority to the tabled paper detailing the geographical breakdown of sperm donors and explained that the HFEA does not collect data regarding waiting lists.
- 3.2** A member stated that not all people who register subsequently become donors and that it would be useful to have information on the number of donors whose gametes were actually used in treatment services.
- 3.3** David Tellis, Director of Information Management, agreed the provision of the following information for a future Authority meeting:
- comparison of donors registered for the first time each year for the two years leading up to the change of law (1/04/05) for comparison to the subsequent two years
 - A comparison of where donors registered (i.e. centre location) for comparison to where the donors reside/live to examine whether high number of donors in a county correspond to areas with active sperm recruitment campaigns
 - A comparison of donors registered for the first time each year compared to those donors whose gametes were subsequently used (allowing us to separate out donors who were registered and then subsequently not used)
- 3.4** The Deputy Chair stated that it was important to include an analysis of future donor registrations to identify the outcomes of recent recruitment campaigns

Item 4. Chair's Report (verbal)

Changes to the Authority

- 4.0** The Chair thanked Walter Merricks for agreeing to take on the role of interim Deputy Chair of the Authority and Emily Jackson for agreeing to take on the role of interim Chair of the Regulation Committee while Sharmila Nebhrajani is on leave of absence.

Scrutiny Committee

- 4.1** The Chair reminded the Authority that she and the Chief Executive had provided evidence to the Scrutiny Committee who are examining the draft of the Human Tissue and Embryos Bill. The Scrutiny Committee report was published on 1st August and a formal response from Ministers is expected in October. The Committee

recognised the international profile of the HFEA, which was mentioned in the report.

- 4.2** The Chair stated that as a further example of its international standing the HFEA has recently provided advice and information on how fertility clinics are regulated in the UK to two new regulators in Canada and Portugal.

European Tissue and Cells Directive

- 4.3** The Chair informed the Authority that the HFEA had now fully implemented the EUTCD and had licensed all IUI and GIFT centres. The Authority was among the first regulators in Europe to have done so.

**Item 5. Chief Executive's Report
(verbal)**

5.0 Staffing Issues

The Chief Executive informed the Authority of the following staff changes:

- 5.1** Richard Cullen, the Interim Director of Information Management, is due to start at end of September.
- 5.2** The new Legal Advisor, David Gomez, begins his role on 8th October 2007 and Catherine Drennan is covering for him in the interim.
- 5.3** The Head of Inspection, Marion Witton, is leaving and Stephanie Sullivan will be taking her place in the interim. The Authority expressed their thanks to Marion Witton for all her hard work.
- 5.4** The Chief Executive informed the Authority that this was David Tellis's last Authority meeting. The Authority expressed their thanks for all the hard work he has done for the HFEA and stated that he will be sadly missed.

**Item 6. Regulation, Finance and HR Report
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Regulation**

- 6.1** Trish Davies, Deputy CE and Director of Regulation, informed the Authority that the Regulation Department has completed statutory inspections for the year and that inspections of all the newly regulated clinics had started.

- 6.2** The Authority was informed that report production had still met performance indicators but had slipped from the 100% achievement in June 2007. This fall was due to IT problems with inspectors' laptops.
- 6.3** The Authority was informed that there had been no serious adverse incidents in July and the first patient safety notice (001) was published in the 'HFEA Update' reminding clinics of the importance of adhering to Section 33 of the Human Fertilisation and Embryology Act regarding the disclosure of information and confidentiality.

Finance

- 6.4** Sally Townsend, Dir of Resources, introduced this report.
- 6.5** The Authority was informed that the report contains the July management accounts. The income forecast has been increased by £115K to reflect the higher levels of reported treatments compared to the budget and income levels will continue to be monitored.
- 6.6** Ms Townsend continued that the report highlighted various cost pressures that may impact on the forecast. These cost pressures include the resource requirements of inspecting centres newly regulated under the EUTCD, which may be more resource intensive than planned and also legal fees. The budget continues to show a break-even position for the financial year.

HR

- 6.7** Sally Townsend, Dir of Resources, introduced this report.
- 6.8** Ms Townsend informed the Authority that staff turnover has stabilised since last month although the annual rate is still high.
- 6.9** The Authority heard that the pay award had been implemented according to timeline in the August 2007 salaries.
- 6.10** The HFEA has also met with the local Disability Employment Adviser (DEA) to progress the HFEA's application for the ✓✓ 'Positive about Disabled People' national disability symbol award.

Item 7. Delegated Decision Making for the Code of Practice HFEA (05/09/07) 395

7.0 Charles Lister, Head of Policy, introduced the report and asked the Authority to approve the new decision making process for the Code of Practice and to delegate decision making powers for minor amendments.

The proposed approval process would be as follows:

7.1 The Authority: signs off (i) new or amended standards/guidance that introduce new policy requirements (these will normally have been preceded by a policy review) and (ii) completely new editions of the Code (the next new edition - the 8th - will follow enactment of the Human Tissue and Embryos Bill).

7.2 Regulation Committee: signs off all amendments not involving a change in policy, for example points of clarification or correction of typographical errors. This would include:- re-writes, additional paragraphs, deleted paragraphs, external links and typographical errors
The Authority was informed that any new editions of the Code of Practice would primarily have both Ministerial and Department of Health approval.

7.3 The Authority approved the new decision making process for the Code of Practice updates and granted delegated authority to the Regulation Committee. The Regulation Committee terms of reference will be amended accordingly and circulated to the Authority.

TD

Item 8. Hybrids and Chimeras: Findings of the Consultation [HFEA (05/09/07) 396]

8.0 Helen Coath, Policy Manager, introduced the report.

8.1 The Authority was informed that hybrids and chimeras had first been discussed at the January 10 2007 meeting and that in light of current scientific opinion it concluded that the regulation of research using human-animal embryos was probably within its scope and so it needed to consider HFEA policy in this area. In addition, the Authority decided that a full public consultation should be held on the ethical and social implications of creating such entities. The findings of the consultation are presented within the paper.

- 8.2** The Authority was reminded that the discussion at this meeting is with regards to cytoplasmic hybrids only. A member felt it useful to point out that there have been two applications for cytoplasmic hybrid embryo research but no applications for true hybrid research at this time. The HFEA is anticipating that the draft Tissues and Embryos Bill will cover the regulation of true hybrids and that this matter is not for the Authority.
- 8.3** A further member referred to the deliberative public dialogue work which was done as part of the Consultation and how public opinion regarding cytoplasmic embryo research changed as they became more aware of the enormous potential benefits of the research. It was also pointed out that the vast majority of those who are against this type of research are against any type of embryo research. Members also stated that 'shock' and inaccurate reporting in the media was unhelpful.
- 8.4** An Authority member welcomed the report from the Academy of Medical Science, cited within the paper, which provided a broad view from medical scientists stating the potential benefits of this type of research.
- 8.5** The point was made that it is better to use cytoplasmic hybrid embryos for research rather than use human embryos which are in short supply.
- 8.6** In accordance with the Human Fertilisation and Embryology Act 1990 any such embryos would never be transferred and must be destroyed after 14 days.
- 8.7** The Authority concluded that cytoplasmic hybrid embryo research falls within the HFEA's remit and that the creation of such embryos is prohibited except in pursuance of a licence granted by the Authority. After considering the detailed findings of the consultation, the Authority also concluded there was no fundamental reason in principle to prevent cytoplasmic hybrid research.
- 8.8** Members discussed the fact that this decision is an in principle decision and that each application would be considered on a case-by-case basis by the Research Licence Committee. The Licence Committee scrutinises each application to ensure that it satisfies all of the statutory tests, and is assisted by reports from two independent Peer Reviewers.

8.9 The Authority noted the conclusions of the Academy of Medical Sciences that there was currently no reason why researchers would want to create human transgenic embryos, true hybrids or human chimera embryos, although it was difficult to predict how scientific research may develop in future. Without a rationale for such research, it had not been possible to gather evidence through the consultation process on the desirability of creating human-animal embryos, other than cytoplasmic hybrids.

8.10 The Authority concluded that it would be wrong to make a decision on broader hybrid and chimera research without an adequate evidence base but that the HFEA should continue to monitor the potential for this wider research and any emerging evidence through its 'horizon scanning' programme. The Authority also requested a discussion on the need for ongoing public dialogue on issues of science and research as part of its November agenda once the report, from the independent evaluator had been received.

**Item 9. Report on Licensing of IUI Clinics
[HFEA (05/09/07) 397]**

9.0 Trish Davies, Deputy Chair and Director of Regulation, introduced this report.

9.1 The Authority was informed that the implementation of the EUTD into UK law requires the licensing of all services involved in donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. This means that treatments using fresh partner gametes such as IUI and GIFT now fall under the HFEA remit and require a licence. Services providing IVF, DI and storage need to be re-licensed to include the requirements of the EUTD.

9.2 The Authority was informed that the legislation had come into force on 5th July 2007 and all the applications had been processed within the deadline and the HFEA is now dealing with late or contentious applications.

9.3 Ms Davies informed the Authority that two applications had been received for sperm sorting for social reasons and were subject to a proposal to refuse licence, confirmed at a Representations hearing. An early Appeal has been scheduled for July but then cancelled by the appellant and the HFEA have been unable to contact them since.

9.4 The HFEA is working closely with centres to provide them with a high level of support and advice which is proving more time consuming than first thought. This may have resource implications and is being monitored closely.

Item 10. Committee Update (verbal)

- ICC Meeting 25 July 2007

10.0 The Chair of the Committee updated the Authority with the business of the Information & Communications Committee from the 25 July 2007 meeting.

10.1 The Committee has agreed to publish the 2005 data in November 2007 as usual alongside the 2007 pregnancy rates/early outcome data (Jan-Jun 2007) subject to any feedback received.

Item 11. Minutes of Standing Committees for approval by the Authority

OFC minutes 14 March 2007

11.0 The Authority approved the Organisation & Finance Committee minutes from 14 March 2007.

Item 12 Any Other Business

12.0 There was no other business to discuss.

Date of Next Meeting

The next Authority meeting will be held on 17 October 2007 at Lion Court Conference Centre, 25 Proctor Street, London, WC1B 3HF.

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

Chair

Date