

Authority Paper



Committee:	Authority
Meeting Date:	21 February 2007
Agenda Item:	2
Paper Number:	HFEA (10/01/07) 353
Paper Title:	Minutes of the non-confidential Authority meeting held on 10 January 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 12 members attending, 7 lay members and 5 professional members.

PRESENT

Shirley Harrison
(Chair)
Sam Abdalla
David Archard
Chris Barratt
Clare Brown
Anna Carragher

Walter Merricks
Susan Price
Ruth Fasht
Rebekah Dundas
Jennifer Hunt
Bill Ledger

APOLOGIES

Sally Cheshire
Roger Neuberg

IN ATTENDANCE

Tim Whitaker
Sally Townsend
Sarah Marsh (minute
taker)
Peter Mills
Helena Hird

John-Paul Maytum
Kerrie Waine
Helen Coath
Charles Lister
Paula Robinson

MEMBERS & EXECUTIVE WHO JOINED THE MEETING FOR ITEM 8:

Neva Haites
Lord Harries
Fran Clift

Emily Jackson
Maybeth Jamieson
David Tellis

Sharmila Nebhrajani
Angela McNab
Trish Davies

OBSERVERS

Ted Webb - Department of Health
Gareth Jones - Department of Health

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

- 1.0 The meeting was quorate with 7 lay members and 5 professional members in attendance.
- 1.1 Apologies were received from:

Roger Neuberg
Sally Cheshire
- 1.2 The Chair welcomed two new members Rebekah Dundas and Bill Ledger and they both introduced themselves to the Authority.
- 1.3 Rebekah Dundas is the new patient representative and Bill Ledger is Professor of Obstetrics and Gynaecology at the University of Sheffield and the Person Responsible for the Centre for Reproductive Medicine & Fertility, Sheffield.
- 1.4 There were no conflicts of interest.

Item 2. Minutes of the meeting held on 29 November 2006 HFEA (29/11/06) 344

- 2.0 The minutes were agreed as an accurate record of the 29 November meeting with the following amendments:
- 2.1 Front page - date to be changed to '10 January 2007'
- 2.2 Item 5.0 Last sentence should read - 'Sex selection, for social reasons, is illegal in both the UK and Cyprus'
- 2.3 Item 5.2 Last sentence should read - 'It was noted at this meeting that the HFEA was showing excellent progress on both performance and delivery, and had led the way in reporting arrangements.'
- 2.4 Item 6.2 Replace the word 'License' with 'Licence'
- 2.5 Item 6.8 Replace the word 'contract' with 'contracts'
- 2.6 Date of the next meeting should read '10 January 2007'

Item 3 Matters Arising & Previous Actions HFEA (29/11/06) 345

- 3.0 **10/05/06 8:8.10** The survey forms part of the Eggs for Research Consultation but INUK will publish some key findings on the HFEA website.

**Item 4. Chair's Report
(verbal)**

- 4.0 The new Chair introduced herself to the Authority. Shirley Harrison became a member of the HTA when it was founded and became interim Chair of the HTA when Baroness Hayman left the organisation in September 2006. Shirley Harrison is Chair of both the HTA and the HFEA and is looking forward to both roles.
- 4.1 The Chair thanked the Authority and the Executive for the warm welcome.

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

- 5.0 The Chief Executive informed the Authority that a report was launched at the Annual Meeting on 7th December 2006 presenting the overall picture of the compliance of clinics to the Code of Practice and the 1990 Act. Clinics were discussed in general and no one individual clinic was mentioned. There was found to be good compliance among clinics generally but a small number of clinics had a high non-compliance score.
- 5.1 Shortly afterwards, the HFEA received a 'Freedom of Information' request seeking individual clinic scores. The HFEA had no initial intention of publishing individual scores but were subject to 'Freedom of Information' rules and the information was provided.
- 5.2 The Chief Executive continued that the Executive had written to all clinics explaining why the information had been provided and warning clinics with high scores that they may be subject to media attention.

Report from Cabinet Office

- 5.3 The Chief Executive informed the Authority that a report had been issued in November by the Cabinet Office and the Better Regulation Executive. It reported the performance of regulators over the past year, particularly in light of the Hampton Report which encouraged reducing the cost and bureaucracy of regulation. The HFEA featured highly in the report, under almost every heading.

- 5.4 There were two areas identified that the HFEA could improve upon; the time taken to complete forms and the lack of a range of different sanctions. The subject of sanctions has been raised with the Department of Health under the review of the Act.

International Stem Cell Society

- 5.5 The Chief Executive reported to the Authority that the International Stem Cell Society had held their first virtual meeting. Hybrids had featured highly on the list of issues to be discussed and the Society is currently working on identifying all the different issues associated with hybrid research. The timetable has still to be confirmed but it is likely that the first paper will feature the ethics of hybrids followed by a paper focussing on public awareness. The HFEA will be contributing to the public attitude paper.

Cyprus

- 5.6 The Chief Executive informed the Authority that she had spoken to the Ministry of Health in Cyprus about the report of sex selection treatment in Cyprus. The Ministry was aware of the issues raised but unable to inform the HFEA of what stage their investigations had reached but agreed to advise the Chief Executive when they had more information.
- 5.7 The Chief Executive continued that letters had been written to the individuals named in the report. One individual had a very misleading website suggesting that they worked in a licensed centre in the UK that carries out sex selection treatment in Cyprus. The individual has been asked to correct this misinformation. This has not been done to date despite persistent reminders from the HFEA.

European Commission

- 5.8 The Chief Executive reported to the Authority that as part of the EU Tissue Directive, the European Commission had made funds available and invited bids on certain aspects of implementing the directive. One of these areas was inspection and a group led by Italy, known as the EUSTITE project was awarded the funds. The project will be a three year study, looking at good practice in inspection.

- 5.9 The Chief Executive continued that the HFEA had joined the EUSTITE project and the first meeting had been held in Italy. The meeting set out the scope of the project and member states have been teamed up to share information on inspection practices and will then report back to the EUSTITE group as a whole.
- 5.10 A second strand of work being carried out by the project is to look at adverse incident reporting. The World Health Organisation representative is very keen to take this forward and has already looked at the way the HFEA report adverse incidents. It was thought that the HFEA incident reporting system would work well across the sectors.
- 5.11 The Chief Executive informed the Authority that it was important for the UK to be involved in the project but there were resource implications. When applying for EU funding it is understood that a maximum of 60% of the overall costs are recovered. There is also likely to be a time commitment over the three years but the Chief Executive agreed to provide the Authority will information on resources for this project.

AM

**Item 6. Regulation, Finance and HR Report
HFEA (10/01/07) 346**

- 6.0 Regulation Report

Trish Davies, Deputy Chief Executive and Director of Regulation, introduced the report.
- 6.1 The Authority heard that inspections were on target and report production exceeded all performance indicators. Also shown on Table 1 page 2 of the report are the high number of additional inspection visits.
- 6.2 Trish Davies continued that there had been a significant increase in the number of import/export applications in November which is expected to tail off as the HFEA deadline date for applications (27 February) draws closer.
- 6.3 The Authority was informed that new grading matrix for incidents had resulted in most being graded category 'B' although there were two serious incidents involving witnessing in November. There are 3 alerts currently in production.

- 6.4 Trish Davies, asked the Authority to note the tabled paper regarding PGD applications.
- 6.5 Members asked if the HFEA had any indication from clinics about sperm recruitment.
- 6.6 Trish Davies informed the Authority that sperm donor recruitment numbers were beginning to show an upturn. A rise in the number of registrations has been reported by most clinics and one clinic has stated to the HFEA that recruitment is becoming easier.
- 6.7 Trish Davies agreed to speak to the clinic to see if there is any learning to be shared. Authority members also requested waiting list information and a geographical breakdown of donors. **TD**

Finance Report

- 6.8 The Authority was informed that the November fee income had fallen from the high figures reported in September and October. Early figures for December billing shows income has stabilised as expected.
- 6.9 A brokerage fee of 212K has been agreed with the Department of Health allowing the HFEA to hold these monies over for the 2007/08 financial year. The December accounts will be revised to reflect this amount and known billings for December with a forecast for the final 3 months of the year. The brokerage is incorporated in the Business Plan.
- 6.10 The Authority heard that there had been a small number of revisions to the November accounts, summarised in paragraph 2, page 11 of the report. Underspend on consultancy and central maternity fees has been vired to areas requiring additional budgetary support. These areas were identified as work on Multiple Births, the online Code of Practice and the production of standard operating procedures within Regulation.
- 6.11 The Authority was informed that the December Management accounts should indicate EU Tissue Directive fee income more accurately. Current expectation is that a £10K reduction in fee income may be necessary from new centres to be regulated under the Directive. It is anticipated that the end of year accounts will show a break even position.

HR Report

- 6.12 Sally Townsend, introduced this report.
- 6.13 The Authority heard that the headcount figures had dropped for November and the establishment figures remains within ALB projected limits for the year end. Turnover was high this month.
- 6.14 At the request of Authority members, reasons for leaving have been shown in more detail in this report on pages 20 and 21. There is no one clear trend. Band 1 shows a high percentage of leavers but includes members of staff who left their fixed term contract shortly before it expired if they had received a permanent job offer. Sally Townsend continued that had these members of staff not been included, the figure would have been 40%. It was also pointed out that there are only 5 members of staff in Band 1.
- 6.15 Last month the Authority requested more information on the 'other' category for reasons for leaving and the reasons recorded were as follows:
- 6.16 2 members of staff went travelling
1 member of staff left the HFEA with the previous Chair
2 members of staff left for personal reasons
1 member of staff wanted to move out of the sector
- 6.17 The Authority heard that the HR department is currently working on the Business Plan and in particular ensuring that HTA work is fully factored into the plan. Sally Townsend informed the Authority that feedback from the HTA indicates they are very satisfied with the services supplied by the HR department.
- 6.18 Work is continuing on the policy review and work will begin on a bullying policy in the New Year.

- Item 7. Code of Practice
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- 7.0 Pete Mills, Policy Development & Co-ordination Manager, introduced this paper.
- 7.1 The Authority was informed that the paper has now been revised to include comments and responses from the Consultation and legal advice. The Code of Practice will comprise of two parts; the HFEA Standards and supporting Guidance.
- 7.2 The text of the Standards was published in April and amendments made in the light of comments received have now been incorporated into the Code. The consultation on the full Code, including the guidance, ran from September to December 2006. The paper set out recommendations for amendments in the light of the consultation and in the light of legal advice obtained since the probable text of the transposition Regulations had become available. The Authority was asked to accept the amendments and approve the text of the Code for publication, subject to anticipated amendments to be agreed by the Regulation Committee in February (in particular, the licence conditions to be included at Appendix A, which were in preparation by the HFEA's legal advisors).
- 7.3 A member raised the issue G.1.4.2 (C) BICA should be consulted on recognised qualifications for counselling staff for a future release of the Code. **TD**
- 7.4 Pete Mills informed the Authority that the Code is currently available as a PDF download but this does not have a search function. The on-line version will be available from 7 April 2007.
- 7.5 Tim Whitaker stated that a mock-up of the interactive version of the Code would be made available at the February Authority meeting as stated in the paper. **TW**
- 7.6 Members approved the content of the Code subject to anticipated amendments and delegated final approval to the Regulation Committee. The Chair requested any further amendments are e-mailed to Pete Mills before the 29 January 2007.

**Item 8. Hybrids
HFEA (10/01/07) 348**

8.0 A further 5 members joined the meeting at this point. The meeting was quorate with 10 lay members and 7 professional members in attendance (see front sheet for names)

Introduction

8.1 Angela McNab, Chief Executive, introduced this paper to the Authority.

8.2 The HFEA began policy work on Hybrids in anticipation of receiving applications from clinics for this type of research. The Authority agreed the scope at the November meeting noting that the project was constrained by both time and resources. This paper considers broadly the potential benefits and risks of this type of research, ethical issues and legal status. Requested international comparisons are also included within the paper.

8.3 The Chief Executive continued that while this is a wide ranging paper it is limited by the following issues:

8.4

- the HFEA has not consulted widely with scientists worldwide although a small expert group has contributed to this piece of work

8.5

- no distinction has been made between the different types of hybrid research and the Authority may wish to consider different policy and controls for each type of hybrid research

8.6

- the HFEA has not consulted widely with members of the public

8.7 The Chief Executive explained that the Authority needs to consider if hybrids fall under the scope of the HFEA. Following that determination, if it concludes they do, there are three options:

8.8 The potentially permissive approach - the HFEA would treat applications for hybrid research in the same way as any other research licence application

8.9 The restrictive approach - the HFEA would determine that the decision as to whether to permit novel research of this kind should be left to Parliament

- 8.10 To carry out a full public consultation alongside a consultation with the wider scientific community

Advice from Dinah Rose, QC

- 8.11 Ms Rose explained to the Authority that the first point to be considered is whether an embryo created from a mixture of human and non-human components falls within the HFEA's remit as hybrid research was not contemplated by Parliament when the HF & E Act 1990 ('The Act') was passed.
- 8.12 Ms Rose advised that if the embryo contains a complete human genome and it cannot be shown definitively that the embryo does not have the normal potential to develop it is most likely that a Court would find that this constitutes a live human embryo for the purposes of the Act. The Courts are likely to see the 'hybrid' embryo in this way to ensure that this type of research falls under the scope of regulation rather than to allow it to be unregulated.
- 8.13 The Authority was informed however that the legal situation is unclear. The Government has now produced a White Paper calling for the creation of such embryos to be banned, whilst allowing the Secretary of State power to make regulations permitting the creation of 'hybrid' embryos in certain (unspecified) circumstances.
- 8.14 However, the White Paper has no legal significance and there has been no timetable set for legislation. There had been some public consultation by the Department but some have criticised this as being limited.
- 8.15 Ms Rose explained that if the Authority believes that 'hybrid' embryos fall within the scope of the HFE Act, then they must deal with the applications received but it would be unfair for the Authority to take an in-principle decision at present. A policy decision now would leave the HFEA open to legal challenge on the basis that full and proper consultation of the public and scientific view had not taken place.

Information from the Department of Health

- 8.16 Gareth Jones, Acting Director of Scientific Development & Bioethics, Department of Health informed the Authority that the White Paper is a proposal for a Draft Bill which will be scrutinised by a Parliamentary Committee. The White Paper originated from a consultation carried out in

2005 in which the general view had been that this type of research should be prohibited.

- 8.17 Mr Jones continued that the recent consultation was intended to help draft the White Paper but Ministers had deliberately chosen a very open process with the intention of it being debated fully. If the Authority decided to hold a detailed consultation, the results would probably be considered by the Parliamentary Committee undertaking the proposed pre-legislative scrutiny of the Bill.

Discussion

- 8.18 One member requested clarification of what was meant by 'fairness' in page 2, para 7 (of the Tabled Paper - The Human Fertilisation & Embryology Authority and The Status of Embryos Created from Human and Non-Human Components - Summary of Advice). Ms Rose explained that one of the classic grounds for a Judicial Review would be when a public body makes a decision by an unfair process. If parties with an interest had not been given the opportunity to make representations or been consulted (such as the two applicants and interest groups) this would constitute an unfair decision which could be quashed, in which case the decision would have to be taken again following a fair procedure.
- 8.19 A member raised the issue of the difficulty of balancing the legal obligation of licence committees to deal with applications such as these in a timely manner and the importance of holding a full consultation. It is important that the HFEA is not seen as deliberately delaying the decision.
- 8.20 Ms Rose responded that it is lawful and appropriate for the Authority to wait for a consultation to be carried out to prevent inconsistency between the decisions of individual Licence Committees and a general policy decision. As this is a completely new type of licence, one of the questions to be put to the Authority is whether it should be granting this type of licence at all. The Authority has the power under section 9(4) of the Act to direct Licence Committees to refrain from making a decision pending the result of the consultation.
- 8.21 A member requested clarification on the role of the Licence Committee as it was thought that these Committees must make applications decisions without having their decision-making process fettered by the

Authority.

- 8.22 Ms Rose responded that Section 9 (1) of the Act states 'the Authority shall maintain one or more committees to discharge the Authority's functions relating to the grant, variation, suspension and revocation of licences, and a committee discharging those functions is referred to in this Act as a 'licence committee' This means that the Authority has an obligation to discharge its licensing functions through one or more Committees. However, section 9 (4) states: ' Persons, committees or sub-committees discharging functions of the Authority shall do so in accordance with any general directions of the Authority'. This means that the Authority has the general power to give directions to any such Committees, maintaining overall control.
- 8.23 One member asked what the shortest possible timescale for a consultation would be.
- 8.24 Ms Rose responded that general Government guidance is 12 - 14 weeks. This is guidance only and in urgent circumstances a public body can put forward a case for an 8 - 10 week consultation with good reason. However, it is crucial that the period is long enough for the consultation to set out clearly what the issues are, for interested parties to respond and for analysis of the data. Angela McNab, Chief Executive, added that if the Authority decided to consult, the Executive were confident that the full consultation could be carried out in a 12 week period
- 8.26 A member asked what weight that consultation would have in policy making as the responses have the potential to be from lobbyists and people who have a particular interest.
- 8.27 Ms Rose responded that a consultation has to be undertaken before a decision is made. The decision must take into account responses to the consultation, but does not have to follow the majority view.
- 8.28 One member asked whether the Authority would be legally vulnerable for allowing Licence Committees to make application decisions in the past, before a policy had been formulated, but requesting that a full consultation takes place in this case.
- 8.29 Ms Rose responded that it would theoretically be possible for the applicants to seek a Judicial Review but

it would be very difficult to persuade the High Court that the Authority had made an irrational decision by requesting a consultation and issuing such a direction to Licence Committees. This would be particularly difficult in this case as this is a completely new type of research and the issues are extremely complex.

- 8.30 A member asked whether the Authority felt obliged to consult because of the moral objections of pro-life groups as this type of research was not very different from the types of research already licensed on a case-by-case basis by HFEA Licence Committees. The question was raised: how different does a new type of research have to be to warrant a consultation? The Authority discussed the point that although having a consultation might be said to be fair to the opponents of such research, it was also important to be fair to the applicants.
- 8.31 Ms Rose responded that a claim for judicial review was commenced against the HFEA, but later withdrawn, which cited non-consultation as one of the reasons for taking the case to Court. In this case, it is very clear, given the novel process raising complex ethical questions, the two outstanding applications, the White Paper, media attention and the views of the scientific community, that fairness requires consultation. Members raised the issue that a consultation would have a very important educative function for the HFEA, members of the public and scientific groups.
- 8.32 A member felt strongly that it would be important not to ask amateur scientists to answer complex scientific questions in the consultation but to seek detailed expert advice in this area. The point was also made that it is important to involve scientists very early on in the consultation so that it may benefit from their expertise.
- 8.33 Ms Rose responded that if a wide-ranging consultation is put forward at this stage and the views of all groups are sought on all subjects it ensures the Authority is in the safest position because all views have been considered.
- 8.34 Members asked how the consultation would fit with the parliamentary process which is currently underway. They were informed that the Department of Health had been informed of the possibility of the HFEA consulting on this issue and that the results could be fed into the parliamentary process and debating stage in Parliament. Members felt it was important that, as part of the consultation, the HFEA issue a statement acknowledging

that the previous view of the Authority expressed in its advice to the Department of Health on the Review of the Act, was that the creation of the hybrid embryos for research purposes should be permitted. But that because 'hybrid' embryos are a sensitive subject on which people hold widely differing views it is fair to have a full consultation. It was also stated that it should be made clear that at the end of the consultation process the HFEA will be making a decision on whether to license this type of research, and the implementation of that decision, will not wait until the legislation is in place.

- 8.35 A member wanted to register concern at the comments made in The Times newspaper on Monday 8th January stating that the Authority was likely to ban this type of research. Angela McNab, Chief Executive, explained that the Executive had also been distressed at the assumptions made in the article.

Decisions

- 8.36 The Authority concluded that in the light of current scientific opinion it believes it is probable that hybrid embryos are within its scope
- 8.37 The Authority decided on a full consultation on 'hybrid' embryos
- 8.38 The scientific consultation should begin the process so that it may inform the public consultation
- 8.39 The consultation should have as short a timescale as possible without compromising the quality of the consultation
- 8.40 The consultation should be in keeping with the definition of fairness as defined in public law
- 8.41 The consultation should ask for a view of whether 'hybrid' embryos could be potentially regarded as 'human embryos' for the purposes of the Act
- 8.42 The Authority will formally direct the Research Licence Committee under Section 9 (4) of the Act to wait until the consultation has taken place and a general policy has been developed before making decisions on the current applications. It is particularly appropriate for the licence committee to postpone decisions since the consultation concerns the ethical implications of an entirely new practice, which has not hitherto been

licensed

- 8.43 Angela McNab informed the Authority that a project plan will be circulated to the Authority via e-mail early w/c 15th January setting out the range of activities to be looked at, a project plan and timescale to be agreed remotely.
- 8.44 The Chief Executive stated that a paper would be ready to go to the Authority by August and an extraordinary meeting may need to be convened.

**Item 9. White Paper
HFEA (10/01/07) 349**

- 9.0 Charles Lister introduced the report.
- 9.1 It was explained to the Authority that In December 2006, the Government had published a White Paper with proposals for revision to the HFE Act 1990 and the establishment of the Regulatory Authority for Tissues and Embryos. This followed a public consultation, launched by Department of Health in August 2005.
- 9.2 The HFEA has been providing advice to DH on the review of the Act for the past two years. This included preliminary recommendations on areas of the Act the Authority would like to see reviewed (in May 2005) and a formal response to the DH consultation in November 2005. This paper summarises the proposals in the White Paper and identifies areas where HFEA recommendations have either not been picked up or have been addressed differently.
- 9.3 Ted Webb, Department of Health, explained to the Authority that the items in Paragraph 5 Page 2 of the report needed more discussion as to whether they should be included in the legislation, particularly in light of the Government's drive to reduce bureaucracy. Some of these issues can be covered by the Code of Practice and they need to be looked at in more detail.
- 9.4 Ted Webb requested the Authority's comments on the White Paper be given to the Executive who will report to the Department of Health.
- 9.5 A member asked the Department of Health to explore whether the proposed extension of storage periods from 5-10 years should be retrospective or not. **DH**

- 9.6 The Chair asked the Department for a timescale for the new Bill.
- 9.7 Ted Webb explained to the Authority that the Department is currently drafting the clauses of the Bill and a draft should be available by the late Spring. A Parliamentary Committee will be established to gather evidence on the draft and the Department will then reconsider the Bill in light of these recommendations.

Item 10. PGD update & Presentation

- 10.0 The Authority noted the PGD applications on the tabled paper.

**Item 11. Draft Business Plan 2007/08
HFEA (10/01/07) 350**

- 11.0 Trish Davies, Deputy Chief Executive and Director of Regulation, introduced this report.
- 11.1 The Authority was asked to note Page 4 and the list of achievements from 2006/07. The year has been very demanding for the HFEA and the Business Plan for 2007/08 has already been amended to take into account the resource implications of recent events.
- 11.2 Ms Davies informed the Authority that the Hybrids Consultation would be added to the Business Plan following this meeting.
- 11.3 The Authority heard that the draft Business Plan has been extensively discussed with staff, and considered by the Organisation and Finance Committee. The draft has been submitted to the Department of Health and will be finalised following this meeting.
- 11.4 The Authority requested the following changes:
- 11.5 Page 4, first bullet point - remove the figure 750
- 11.6 Page 10, Objective 4, 4th bullet point - should read 'Develop and implement revised policy on witnessing in the laboratory'
- 11.7 Page 11, Objective 5 - Agreed the final bullet point should be amended to reflect the continuing need to respond to register requests in a timely and sensitive manner, while ensuring the data held is accurate.
- 11.8 The Authority approved the Business Plan with the above amendments.

**Item 12. EU Tissue and Cells Directive Regulations
HFEA (10/01/07) 351**

- 12.0 Helen Coath introduced this paper.
- 12.1 The Department of Health are close to finalising the regulations that transpose the EU Tissue and Cells Directive into UK law.
- 12.2 The Authority was informed that some significant changes will be made as a result of the Regulation, in particular:
- 12.3
- The extension of the Authority's remit to include the regulation of internet sperm providers and Intra Uterine Insemination
- 12.4
- New requirements relating to third parties (which have been incorporated into the Code of Practice)
- 12.5
- The movement of embryos within the EEA (the EU countries plus Norway, Iceland and Lichtenstein) will be treated as transfer between premises as opposed to imports
- 12.6 These new changes and others listed in the paper (page 2 Key changes to the HFE Act 1990) will be enforced by 7 April 2007.
- 12.7 A member raised the issue of the legal father in paragraph 3.11 on page 3 of the report:
- 12.8 'Those providing non-medical fertility services must provide identifiable donors. However, Section 28 of the HFE Act 1990 has not been extended to non-medical fertility services, therefore donors of any resulting children will be the legal father'
- 12.9 The Authority was informed by Ted Webb of the Department of Health that this issue would be assessed under the Review of the Act.
- 12.10 The Authority noted the report.

**Item 13.0 ITT Introduction
HFEA (10/01/07) 352**

- 13.0 David Tellis introduced this report.

- 13.1 The Authority heard that the 'Intention to Treat' (ITT) forms are to be introduced from 1st April 2007 to ensure that all cycles are reported to the HFEA and changes to treatment can be fully tracked. The Authority is asked to consider the amount of time allowed in submitting treatment forms to the HFEA. This will ensure that all cycles and changes to treatment are reported to the HFEA and statistics cannot be changed to make success rates look higher.
- 13.2 The Authority heard that the British Fertility Society had discussed reporting treatment within 5 working days but in Authority discussions at previous meetings, members felt strongly that this was too long. Members decided that 3 calendar days was a sufficient timescale for cycles to be reported to the HFEA and would provide more accurate figures.
- 13.3 Members felt it was important to have sanctions to deal with non-compliance ensuring that ITT forms are returned within the appropriate timescale. IMPB and Regulation Committee will be asked to consider appropriate sanctions. Frances Clift, Legal Advisor, informed the Authority that ITT will be implemented through Directions and to breach Directions would be a breach of licence. The members still thought sanctions were necessary to reiterate the importance of reporting all cycles to the HFEA, whether they were cancelled or treatment was changed.

Decision:

- 13.4 The Authority agreed to implement the ITT forms by 1st April 2007. Clinics using a third party electronic patient record system which is integrated with the HFEA EDI system will be granted an exemption up to the 30th of June 2007 to allow the development and installation work to take place.
- 13.5 The Authority agreed that 3 calendar days are sufficient time for cycles to be reported to the HFEA
- 13.6 Sanctions for non-compliance will be considered by Regulation Committee with advice from the Information Management Programme Board (IMPB).

**Item
14.0**

Date of Next Meeting

The next Authority meeting will be held on 21 February 2007

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

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Chair

Date