

**HFEA Research Register Panel Meeting  
8 June 2010**

21 Bloomsbury Street London WC1B 3HF

**MINUTES**

Members of the Panel:

Panel Secretary:

Peter Thompson, Director of Strategy and Information  
(Chair)  
Richard Martin, Information Governance Projects  
Manager  
David Moysen, Head of IT  
Charlotte Augst, Acting Head of Policy (observing)

Lauren Crawford

**Item 1**

**Do Hormonal Treatments for assisted reproduction increase risks of cancer or mortality in women ? A national cohort study. Dr Alastair Sutcliffe, Institute of Child Health, London**

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Panel:

- 1 NIGB Ethics and Confidentiality Committee (ECC) draft recommendation letter
- 2 Paper in support of application (12 pages)
- 3 NIGB application form

The Panel also had before it:

- The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010
- Memorandum of Understanding (MoU) between the Human Fertilisation and Embryology Authority (HFEA) and the National Information Governance Board (NIGB)
- Decision trees for use by Register Research Panel & Register Research Review Panel for the consideration of applications for the disclosure of information for research purposes – s.33D
- Terms of reference for Register Research Panel
- HFEA Data Capture Sheet

1. The Panel considered the papers, which included the NIGB application

form and supporting paper and the NIGB draft recommendation letter.

2. The Panel noted the recommendation of the ECC in its draft letter: that the application should be provisionally approved subject to a number of conditions. These were:
  - I. A favourable opinion to be received from a Research Ethics Committee (REC);
  - II. A data sharing agreement to be in place to ensure that there is no onward disclosure of identifiers by the NHS Information Centre other than back to the HFEA/ researcher;
  - III. Formal confirmation from the HFEA if they approve access to the HFEA register dataset;
  - IV. Confirmation of satisfactory security arrangements.
3. The Panel noted that the application did not contain a favourable opinion from a REC for the proposed research project. The Regulations covering the disclosure of HFEA information for research require that such approval be supplied by the applicant within 14 days of the date of notification of the recommendation from the HFEA. Otherwise the application will have to be re-submitted for decision when REC approval is received.
4. The Panel raised concerns over the location of the linkage study in light of the stringent confidentiality provisions in the HFE Act 2008. The Panel were also mindful of the views of the Authority, which had previously determined that all dataset linkage work involving protected information held in its Register should usually take place on the premises of the HFEA, unless there were exceptional circumstances (Authority Meeting 24 March 2010).
5. The Panel agreed that on the basis of the information before it, such exceptional circumstances did not apply and therefore the linkage work for this project should be conducted on HFEA premises.
6. The Panel noted that the project was estimated to last 3 years.
7. The Panel were satisfied that a three year period of authorisation was acceptable, subject to annual reports from the applicant within the period. Once the period of authorisation had passed the data, and any linkage information held externally to the HFEA, should be destroyed.
8. The Panel were satisfied that it had sufficient information to make a decision.

#### The Panel's Decision

9. The Panel agreed with the ECC that this was an application that addressed a subject of real public interest. The Panel accepted the recommendation from the ECC and approved *in principle* the

application to access Register data, *subject to a number of conditions* being met; these are:

- **Missing Information**  
The applicant must supply REC approval for the project, within 14 days of date of notification of approval from the NIGB/HFEA.
- **Location for linkage study**  
The proposed linkage work should be carried out on HFEA premises, taking into account the Authority's view on the disclosure of protected information held in its Register of treatments and outcomes.
- **Period of authorisation**  
The Panel decided that a period of 3 years was appropriate and that any further follow up study would require an additional application.

## Item 2

### **Are children born after assisted reproduction at increased risk of cancer? A population based linkage study. Dr Alastair Sutcliffe, Institute of Child Health, London**

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Panel:

- 1 NIGB Ethics and Confidentiality Committee (ECC) Draft recommendation letter
- 2 Paper in support of application (8 pages) – Childhood cancer after ART
- 3 NIGB application form

The Panel also had before it:

- The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010
- Memorandum of Understanding (MoU) between the Human Fertilisation and Embryology Authority (HFEA) and the National Information Governance Board (NIGB)
- Decision trees for use by Register Research Panel & Register Research Review Panel for the consideration of applications for the disclosure of information for research purposes – s.33D
- Terms of reference for Register Research Panel
- HFEA Data Capture Sheet

1. The Panel considered the papers, which included the NIGB application form and supporting paper and the NIGB draft recommendation letter.
2. The Panel noted the recommendation of the ECC in its draft letter: that the application should be provisionally approved subject to a number of conditions. These were:
  - I. A favourable opinion to be received from a Research Ethics Committee (REC)
  - II. Once appropriate HFEA staff have been trained in the probabilistic methodology, it was expected that HFEA will carry out any further linkages;
  - III. Flag not to be placed on HFEA dataset;
  - IV. Donor information is excluded from this approval;
  - V. Permission must be obtained from the HFEA in order to permit the linkages;
  - VI. Confirmation of satisfactory security arrangements.
3. The Panel noted that the application did not contain a favourable opinion from a REC for the proposed research project. The Regulations covering the disclosure of HFEA information for research require that such approval be supplied by the applicant within 14 days of the date of notification of the recommendation from the HFEA. Otherwise the application will have to be re-submitted for decision when REC approval is received.
4. The Panel noted that the application requested that the HFEA work up donor related information and provide anonymised data from this information to add to the research register project. This would involve the use of 'probabilistic matching techniques'.
5. The Panel agreed that the HFEA would need to assess the costs involved before making a decision as to whether resources should be made available to assist in this aspect of the project. The Panel felt, however, that the research study would be worthwhile either way, even if donation related information would have to be excluded.
6. The Panel noted that the data linkage work involved in this study would be conducted on HFEA premises. This was consistent with the view expressed by the Authority at its meeting on 24 March 2010.
7. The Panel noted that the project was estimated to last 2 Years.
8. The Panel were satisfied that two years was an acceptable authorisation period, subject to annual reports from the applicant within the period. Once the period of authorisation had passed the data, and any linkage information held externally to the HFEA, should be destroyed.

9. The Panel was satisfied that it had sufficient information to make a decision.

### The Panel's Decision

10. The Panel agreed with the ECC that the proposed work was important and in the public interest. The Panel accepted the recommendation from the ECC and approved *in principle* the application to access Register data, *subject to a number of conditions* being met; these are:

- **Missing Information**

The applicant must supply the favourable opinion of a REC for their research project, this must be done within 14 days of date of notification of approval from the HFEA.

- **Exclusion of data**

Donor-related information is expressly excluded from disclosure by virtue of Regulations 2(3)(a)-(e) and 2(4)(e)-(f).

The proposal that the HFEA carry out 'probabilistic matching techniques' on behalf of the researchers will need to be discussed with the researchers to see whether such assistance is possible within the cost limitations set out in the Regulations and the wider resources available to the HFEA.

- **Location for linkage study**

The Panel concluded that the proposed linkage work should be carried out on HFEA premises taking into account the Authority's view on the disclosure of protected information held in its Register of treatments and outcomes.

- **Period of authorisation**

The Panel decided that a period of 2 years was appropriate and any further follow up study would require an additional application.

### **Item 3**

#### **Access to an expanded anonymised HFEA data set from 1991 to 2008. Mr Hossam Abdalla, The Lister Clinic, London**

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item, though it noted that Mr Abdalla was a member of the Authority.


The following papers were considered by the Panel:

- 1 Email request from Mr Hossam Abdalla
  - 2 Email from HFEA staff commenting on proposal
- 
1. The Panel agreed that this application was not for access to disclosable protected information held by the HFEA. Nonetheless, the Authority had taken a decision to establish the Register Research Panel and it was in keeping with that decision that the Panel should consider this and similar applications in future. Further, the membership of the Panel includes those who have responsibilities as the Information Asset Owner for the HFEA Register and the Caldicott Guardian. Such individuals would have oversight of the use of any Register information held by the HFEA or its disclosure to a third party.
  2. In respect of the application from Mr Abdalla, the Panel were agreed that the proposal as drafted could possibly, taken together with other published datasets, and given plans to publish more information in the future, compromise anonymity. However, if the primary identifier was the patient these concerns could be met through the implementation of the HFEA ID. This unique, but anonymous identifier is expected to be implemented for the vast majority of treatment cycles (more than 90%) by the end of July and will be published as part of the now public anonymised register.
  3. The Panel therefore concluded that the proposal could be dealt with in one of two ways. Either by access to the Anonymised Register, once the HFEA ID had been added to patient records, or by means of a formal application to the ECC NIGB which would enable the applicant to access identifiable information under the safeguards imposed by the statutory and regulatory regime.

#### The Panel's Decision

4. The Panel agreed that the Chair should write to Mr Abdalla, setting out the two options.

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

Signed..........Date.....*18/06/10*.....  
Peter Thompson (Chair)