

**HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY**  
**SCIENTIFIC AND CLINICAL ADVANCES GROUP**  
**ACCESS DATA FROM THE HFEA REGISTER FOR RESEARCH**  
**PURPOSES**

**Introduction**

1. The Authority, at its meeting in June 2003, agreed a procedure for disclosing anonymised data from the HFEA Register for research purposes.
2. It was agreed that future applications for data from the HFEA Register must be in writing and all applicants must show that they agree to / meet HFEA criteria (attached at Annex A).
3. The Authority also agreed to establish a Writing Group to manage articles of published using data from the HFEA Register. The purpose of the Writing Group is to ensure that any articles published, using data from the HFEA, are approved by the HFEA and acknowledge the HFEA and the clinics that provided the data.

**Processes for access to Data from the HFEA Register**

4. To facilitate the application process, the Executive has drafted a standard application form to be used by all researchers applying to have access to data from the HFEA Register. A copy of the application form is attached at Annex B.
5. A draft proposal for the operation of the HFEA Writing Group is attached at Annex C. The HFEA has received a letter from the Person Responsible at a Licensed Centre raising concerns about the HFEA having to agree publications that cite analysis of data from the HFEA Register. A copy of this correspondence is attached at Annex D. Members are asked to respond to these concerns and, if necessary, amend the draft proposal on the operation of the Writing Group,

**Conclusion**

6. Members are asked to:
  - Review the application form and agree, subject to amendments, its use in applications for access to data from the HFEA Register.
  - Review the draft proposal regarding the operation of the HFEA Writing Group.

**Chris O'Toole**  
**Policy Manager**  
**November 2003**

**HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY**

**ACCESS TO DATA FROM THE HFEA REGISTER**

**Criteria for Access to Anonymised Data from the HFEA Register**

- i. Proposed work / project must be an area of priority for the HFEA, as defined in the Business / Corporate Plan and must inform clinical practice.
- ii. Researchers must demonstrate through peer review or experience that the proposed study will be capable of withstanding scientific / academic scrutiny.
- iii. Researchers must accept that all publications that include data from the HFEA Register cannot be published without HFEA approval.
- iv. All media / press communications must be approved / co-ordinated by the HFEA.
- v. Access to data will be permitted for a specified project only and that further research projects using the data would need to be submitted to the HFEA for consideration.
- vi. Work required by the HFEA to provide the data in suitable form must be less than 2 days or the researcher must demonstrate willingness to meet / contribute to costs.

**HUMAN FERTILISATION AND EMBRYOLOGY  
AUTHORITY**

**APPLICATION FORM TO ACCESS DATA  
FROM THE HFEA REGISTER**

FOR OFFICE USE ONLY:

Date received : .....

Application number : .....

Centre number (if applicable) : .....

---

**INSTRUCTIONS :**

**It is important that the language used in this application is clear and understandable to non-specialist lay members. All abbreviations should be explained.**

**The completed form and all supporting documents should be returned to :**

**Human Fertilisation and Embryology  
Paxton House  
30 Artillery Lane  
London E1 7LS**

The following list is a record of the documents required in order for the application to be processed.

Researchers must demonstrate through peer review or through previously published research that the proposed study will be capable of withstanding scientific / academic scrutiny.

<b>APPLICANT'S CHECKLIST OF DOCUMENTS TO BE ATTACHED</b>		
	Please Tick	For Office use only
Application Form		
Full description of project to be undertaken with the requested data from the HFEA Register		
C.V. (s) of researcher(s) and collaborator(s)		
Up to three most recent relevant publications of lead researcher		
Details of funding for proposed project of research		

<b>SECTION 1</b>	<b>Details of applicant(s)</b>
------------------	--------------------------------

1.1 **Please provide details of the Principal Investigator**  
*(please attach a C.V.)*

**Surname:**

**Forename:**

**Title:**

**Present appointment:**

**Qualifications:**

**Address:**

**Telephone No:**

**Fax No:**

**E-mail:**

1.2 **Please provide names of all additional researchers who will be collaborating with you on work involving the use of data from the HFEA Register. Please attach a C.V. for each named person**  
*(please note, that you are obliged to inform the HFEA of the details of all researchers who join the project subsequent to this application)*

Names of researchers:


**1.3 Details of the institute undertaking the research**

Name of institution  
(including department)

Address:

Address for correspondence  
(if different):

Tel No:

Tel No:

Fax No:

Fax No:

E-mail:

Is the institute affiliated to a centre providing licensed IVF treatment and / or research on human embryos?

YES / NO

If yes, please indicate which by ticking the appropriate box below.

Treatment Centre     Research Centre     Both

Please give the HFEA centre number:

**1.4 Corporate information**

Is the application from an academic institution or NHS centre or a private operation? (Please tick appropriate box.)

Academic     NHS     Private

If the application is from an NHS centre or a private operation, is an academic institution involved?

YES / NO

If yes, please provide details:

**SECTION 2**

**Details of research project**

**2.1 Please provide the title of the project in full:**

**2.2 Summary of the data requested**

*(please list the data requested from the HFEA Register)*

**2.3 Abstract**

Please give a brief summary of the project in lay terms, which may be disclosed to the UK licensed centres. Please provide a short paragraph that we may use for this purpose. N.B. all other information provided in the application remains confidential.

2.4 **Summary of research project including aims, objectives and rationale**

2.5 **Background**

Please state how the project fits in to the current state of knowledge on this subject.

**2.6 Methodology / experimental design**

Please state how this work is to be carried out. Please provide information on how the data is to be analysed.

2.7 Please provide the period of time that the project will last:

2.8 Has the research project been subjected to conventional peer review in the case of academics or in-house review in the case of companies or academics funded by companies?

YES / NO

If conventional peer review, please specify; the funding body, the grant reference number and start / end dates:

If in-house review, please provide details of the review process:

<b>SECTION 3</b>	<b>Declaration</b>
------------------	--------------------

**Principle Investigator**

- 3.1 **The information in this form is to the best of my knowledge and belief accurate and I take full responsibility for it.**
  
- 3.2 **I accept that should the application be approved by the HFEA, I will be required to sign a separate Agreement in which I will agree that:**
  - **Access to data will be permitted for a specified project only and that further research projects using the data would need to be submitted to the HFEA for consideration.**
  - **The data can only be used by a specified person or persons to whom the information has been given and not passed to any third party.**
  - **All publications that include data from the HFEA Register cannot be published without HFEA approval.**
  - **The HFEA must be notified prior to all media / press communications.**

Signed: ----- Date: -----

**PLEASE ENSURE THAT YOU HAVE COMPLETED THE CHECKLIST ON THE FIRST PAGE OF THIS APPLICATION FORM AND ENCLOSED ALL RELEVANT ADDITIONAL DOCUMENTS.**

## Development of the HFEA Writing Group

The idea of the Writing Group was to create a formulation which could mediate the involvement of the UK IVF clinics whose hard work generated the data.

### Draft proposal regarding the operation of the HFEA Writing Group

- i. The researchers (Drs A, B and C) apply for and, after due process, get permission to do their study and access the database.
- ii. The application includes a summary of the project – this summary is sent to the Person Responsible at all licensed Centres, once the project has been approved by the HFEA.
- iii. The researchers do the analysis.
- iv. The researchers compile a draft paper which is submitted to HFEA to go to the Writing Group.  
(The Writing Group comprises the lead researchers and HFEA nominees who will not necessarily be the same nominees each time.)
- v. The Writing Group reach a draft that is "near final" and this is disseminated (in confidence) to the Persons Responsible (PR) at all Licensed Centres with a time-limited request for comment. (The PR may have chosen to nominate a different member of the team if they are not the appropriate person to receive the draft paper.)
- vi. The Writing Team receives the comments, which may be few. They may or may not incorporate the comments into the paper. It could be that the comments are mainly processed by the researchers who did the research.
- vii. The final version of the paper can be sent to a journal under the authorship of "Dr A, Dr B, Dr C and the HFEA Writing Group on behalf of the UK HFEA Licensed Clinics." Within the paper will be a list of the Members of the Writing Group and a list of the Persons Responsible or their nominees.

This process has the advantage that it -

- is inclusive of everyone
- leaves the lead researchers with the main work and the main glory
- provides sufficient opportunity for input by the Persons Responsible at Licensed Centres and enables them to be named in a list within the paper. (Publication rules and ethics demand that they have some input if they are to be named).

LONDON

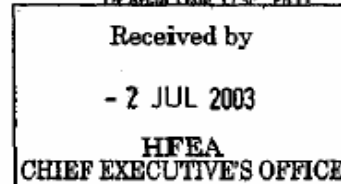


Medical Director:  
**Dr Robert Forman, MD FRCOG.**

Scientific Directors : **Dr Jacques Cohen, Ph.D.**  
**Dr Brian Dale, D.Sc., Ph.D.**

30 June 2003

Ms Angela McNab  
Interim Chief Executive  
Human Fertilisation & Embryology Authority  
30 Artillery Lane  
London E1 7LS



Dear Ms McNab

**HFEA REGISTER OF INFORMATION**

Thank you for sending me a copy of the conditions for accessing data from the register. Most of this seems straightforward although I do have concerns that researchers cannot publish data from the register without approval from the HFEA. I think this condition is a cause for concern because it would lead to the suspicion that results and conclusions which do not conform to the HFEA agenda could be refused permission for publication and hence lead to publication bias in HFEA data.

I think the HFEA should accept that all data that is to be published will be subject to peer review in the journals and it would also be appropriate for the HFEA to insist that the HFEA is given an opportunity to comment on any data which is submitted for publication but it would be in my opinion a form of scientific censorship for the HFEA to need to approve this data for publication. If you could think of a parallel context, do you think it is appropriate that a pharmaceutical company that is financing a clinical trial should have approval about whether the data can be published?

I would appreciate your comments.

Kind regards,

Yours sincerely

**Robert Forman MD, FRCOG**  
**Medical Director**

cc

Ms Alison Murdoch  
Chairman of the British Fertility Society  
British Fertility Society Secretariat  
22 Apex Court  
Woodlands  
Bradley Stoke  
Bristol BS32 4JT

Park Lorne, 111 Park Road, London NW8 7JL. Tel:44 (0) 20 7616 6767 Fax:44 (0) 20 7616 6789  
Website: [www.crmlondon.co.uk](http://www.crmlondon.co.uk)