

Memorandum of Understanding (MoU) between the Human Fertilisation and Embryology Authority (HFEA) and the National Information Governance Board (NIGB)

1. The Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008) ('the HFE Act') and the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 ('the Regulations') will enhance the ability to share the information held on the HFEA Register with researchers. This is an important opportunity to improve our understanding of the efficacy and safety of assisted reproductive technologies and their immediate and long term outcomes for women and children.
 - 1.1. The HFEA is keen to enable good quality, ethically sound research, balancing the needs of researchers with the confidentiality of individuals.
 - 1.2. The HFEA acknowledges the expertise the NIGB's Ethics and Confidentiality Committee (ECC) has concerning access to patient identifiable information without consent where obtaining consent is impracticable.
 - 1.3. Both the NIGB and HFEA are convinced that it is of most benefit to researchers and users of fertility services if the HFEA delegate the assessment of applications for access to identifiable data for medical purposes on the HFEA Register to the NIGB because of its existing role in relation to section 251 of the National Health Service Act 2006 ('the NHS Act').
2. This MoU outlines this shared commitment to setting up a coherent, accessible and ethically sound system of administering requests for information from the HFEA Register.

Delegation of powers

3. Concerning pre-October 2009 data

- 3.1. The HFEA delegates the handling and assessment of all applications with a medical purpose under the HFE Act 1990 to the NIGB.
- 3.2. The NIGB will recommend to the HFEA whether to grant or refuse permission to use identifying register information (or to impose conditions on the use of such information).

- 3.3. Regarding the release of patient information not contained in the HFEA register (for linkage), the NIGB will make a final decision (see 1.4 and 2. below) under section 251 of the NHS Act.
- 3.4. The HFEA, both as data controller, and the body formally vested with powers under sections 33A-D of the HFE Act, will formally grant or refuse access, based on the NIGB's recommendation, and will then work with the researchers to enable them to use the HFEA Register dataset.
- 3.5. The respective decisions to grant access to both Register and other data will be communicated to applicants within 7 working days of the NIGB ECC meeting reviewing the application.
- 3.6. Access will only be granted without explicit consent, where it is impractical and/or not possible to contact former fertility patients for such consent.
- 3.7. It is not considered appropriate to contact patients who had treatment before 1 October 2009 to ask for their permission to use information (unless in exceptional circumstances: for example, where treatment stopped shortly before 1 October and the clinic might have reasons to contact the patient anyway). The use of patient identifiers will always be restricted to an absolute minimum.
- 3.8. In compliance with the Regulations, the HFEA will set up an Oversight Committee to regularly review this area of work.

4. Concerning data collected from 1 October 2009

- 4.1. Going forward, consents will be collected from fertility patients. However, these consents are not specific enough to sufficiently cover all types of research projects.
- 4.2. Where medical or health researchers want to link to HFEA Register information gathered from October 2009 onwards, the NIGB's ECC will therefore still assess the application in light of the more generic consent given by the patient and any specific research proposal. If the generic consent is not considered to cover the specific research project in question, then access to identifying information without more specific consent would only be granted where it would be impractical or not possible to contact patients directly to ask for their specific consent.
- 4.3. Patients who indicate that they are content to have their identifying information included in research studies, but do not want to take part in contact research, would not normally be approached to be asked whether their information can be included in non-contact research.
- 4.4. The NIGB will again recommend to the HFEA whether to grant or refuse access to patient identifying information. The process outlined above will apply here, too.

5. Research for a non-medical purpose

- 5.1. The HFEA will only delegate the handling of research proposals that relate to a medical purpose to the NIGB. The HFEA will run its own application process for research proposals which do not relate to a medical purpose.
- 5.2. In the medium-to-long term, the aim is to also join up this process with the IRAS system.
- 5.3. Applicants will be asked whether their proposal has a medical purpose or not.
- 5.4. Based on this self-assessment, the recipient body (either the HFEA or the NIGB) will review the proposal. In the rare circumstances where the recipient organisation does not agree with the applicant's assessment, this will be raised with the other organisation as soon as possible, so that a joint decision can be made as to where the application will be handled.

6. Four nations

- 6.1. The HFEA has power to release information from all four nations. The Regulations enable this authority to be delegated to the NIGB. However, in order to link to other datasets from outside England and Wales, separate approval from the Scottish and Northern Irish equivalent bodies is required.
- 6.2. This will be explained to researchers.
- 6.3. The HFEA will seek to establish a system for Northern Irish and Scottish linkage data, once the system for England and Wales is running.

Acknowledgement of each bodies' statutory powers

7. It is recognised that both the HFEA and NIGB are independent statutory bodies with responsibilities to advise the Secretary of State for Health. While this MoU establishes the delegation of authority by the HFEA to the NIGB in respect of its powers under sections 33A-D of the HFE Act, this should not be understood as undermining or limiting the authority of the NIGB with respect to its remit for oversight of the HFEA's information governance arrangements, nor with the administration of powers under section 251 of the NHS Act.
8. Where the ECC has refused an application under section 251 of the NHS Act, the HFEA will not subsequently overrule the ECC by granting access to Register data. Where section 251 approval has been granted, the HFEA, as data controller and under its authority in relation to sections 33A-D of the HFE Act, will retain the right to withhold permission for access to data, as the data.

9. Where applications require approval under both section 251 and sections 33A-D then the ECC will approve under section 251 and make a recommendation under sections 33A-D. However, the section 251 approval will be conditional on acceptance of its recommendation under sections 33A-D by the HFEA.

Operational coherence

10. The HFEA and the NIGB will provide as smooth and joined-up a process to the research community as possible.
11. To this end, all applications for medical research purposes will be managed by the NIGB, and all applications for non-medical research purposes will be managed by the HFEA.
12. Applications for either purpose will be processed in compliance with requirements set out in the Regulations.
13. The HFEA's process for handling research which does not relate to a medical purpose will be modelled on the NIGB's systems.
14. All applicants will be informed by the HFEA regarding the decision whether or not to grant them access to Register data. In the case of applications for medical purposes, such communication will be made within 7 working days of the ECC meeting.
15. The NIGB and the HFEA will inform each other of applications they may receive to carry out linkage studies.
16. The NIGB will share its ECC meeting dates with the HFEA as soon as possible, and the HFEA will arrange its own research committee meetings for the following day wherever possible.
17. The NIGB will let the HFEA know one month in advance whether a HFEA related research proposal will be discussed at ECC.
18. Appeals against any ECC decision will be heard by the NIGB's appeals panel.
19. Appeals against any decision of the HFEA as data controller or in respect of its consideration of applications for non-medical purposes will be heard by the Oversight Committee or an alternative committee with delegated responsibility.

Resources

20. The HFEA and the NIGB do not anticipate a volume of sections 33A-D research access applications that cannot be absorbed into the normal running costs of the NIGB.
21. Were the amount of work to exceed expectations, the question of financial support to the NIGB will be reviewed by both parties in consultation with the Department of Health.

Review

22. This MoU will be reviewed 12 months after implementation.