

The James Cook University Hospital
Department of Reproductive Medicine

DISCLOSING PATIENT-IDENTIFYING INFORMATION TO RESEARCHERS

On 1 October 2009 the law changed and there are new rules governing the information held by the HFEA that identifies patients.

The information held

HFEA licensed centres collect patient information, some of which goes to the HFEA and is recorded on their Register.

This information may include personal data such as:

- your date of birth
- the number of embryos transferred in treatment
- whether treatment led to pregnancy

What will change?

Before 1 October 2009, the HFEA used the Register to provide some researchers with anonymous information (information that cannot reveal your identity). This will not change.

However since 1 October 2009, researchers are also able to apply to access information from the Register that does identify patients.

This identifying information is a very valuable resource for researchers and could be used to carry out medical and social research. It could, for example, be used to investigate the safety and efficiency of fertility treatments, develop new treatment and storage techniques and study the effect of national policies, such as the HFEA multiple births policy.

The main use of identifying information is to link fertility treatment data with other healthcare records for example, to see whether IVF affects the health of women or their children. A minimum amount of identifying information (eg, one or two identifiers) would be needed to perform the linkage.

IF YOU REGISTERED AT A CLINIC BEFORE 1 OCTOBER 2009

Since 1 October 2009, under new legislation, the HFEA has been able to release patient-identifying information to researchers that was entered onto the Register before 1 October 2009.

The information below is to help you decide if you are content that your identifying information might be used in research or if you would prefer to opt-out.

What the identifying information might include

Your identifying information on the HFEA Register may include data such as your name or date and place of birth.

Donor information

The HFEA will not release donor-related information. The law does not allow the HFEA to release identifying information from their Register about:

- donors who have donated eggs, sperm or embryos for use in the treatment of others,
- those receiving treatment using donated eggs, sperm or embryos, or
- those born as a result of such treatment.

Who might be allowed to use the identifying information?

The HFEA would only provide identifying information if they think it really necessary, to allow important research to be done.

Patient-identifying information will only be available to researchers linked to a recognised research institution for projects which have received approval from a research ethics committee and it will not be disclosed to other parties.

How the identifying information would be used

Record linkage. The main use of identifying information is to link information held on different registers or databases.

Example: It is possible that researchers may want to link the HFEA Register on IVF with information on the [NHS Central Register](#) or data held by [Hospital Episode Statistics](#) and a minimum amount of identifying information (eg, one or two identifiers) could be released in order to do this.

Medical research. Researchers could use identifying information to carry out medical research.

Example: researchers could investigate the type of infertility patients have, their lifestyle in relation to their treatment outcome. Also, they could investigate the safety and efficacy of fertility treatments and develop new treatment and storage techniques.

Social science research. Researchers could use identifying information to carry out social science research.

Example: researchers could investigate the social characteristics (age, occupation, ethnic group) of those who seek fertility treatment, patients' treatment experience or the effect of national policies such as the HFEA multiple births policy.

Non-contact research. It is not the intention of the HFEA to approve research applications that would require your direct participation, only research applications for non-contact research.

Safeguarding your data and confidentiality

The HFEA is committed to safeguarding your confidential information. It will only be shared with researchers who are committed to the same standard.

- **Research project approval.** All applications by researchers to access patient-identifying information on the HFEA register will have to be approved by the HFEA.
- **Research institutions.** Patient-identifying information will only be available to researchers linked to a research institution on projects which have received approval from a research ethics committee and it will not be disclosed to other parties.
- **Published findings.** Where researchers publish their research findings, it will always be ensured that you cannot be identified from the published research.
- **Ethics committee approval.** The HFEA intends to ask the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care to review all medical research applications to ensure that releasing the information is in the public's interest.
- [National Information Governance Board for Health and Social Care website](#)

How to opt out

From 1 October 2009 researchers can access identifying information held on the HFEA register unless you opt out of this type of research.

If you would like to opt-out, complete the 'Opt out form' located on the HFEA website by following the link below –

<https://portal.hfea.gov.uk/OptOut/Default.aspx>

You must state that you wish to opt-out and include your full name, name at birth (if different), date of birth, place of birth and the centre(s) where you were treated and the year your, or your partner's, treatment(s) started.

IF YOU REGISTERED AT A CLINIC FROM 1 OCTOBER 2009

From 1 October 2009, under new legislation, the HFEA will be able to release patient-identifying information to researchers from the Register but only if you give them permission to do so.

If you are starting treatment or storage at an HFEA licensed fertility centre from 1 October 2009, you will be asked whether you would agree to your identifying information being used in research.

The information below is to help you decide whether or not you wish to consent to this.

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Contact research. Some research requires direct participation from patients and is known as contact research. Your centre will ask if you are willing to participate in this type of research.

If you agree to this, a member of staff from your centre will contact you if there is a particular research study you may be suitable for.

Your participation might range from minimal (such as a short questionnaire) to more extensive involvement (such as long-term longitudinal studies involving those born as a result of treatment).

You will always be asked to give consent and will be free to withdraw this at any time until your information is used in the study.

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Research project approval. All applications by researchers to access patient-identifying information on the HFEA register will have to be approved by the HFEA.

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How to get involved

Giving consent - If you are willing to allow researchers access your identifying information held on the HFEA Register, you must complete the HFEA consent form 'Disclosure of identifying information' (CD form). This will be provided by your clinic when you register.

The CD form allows you to consent to researchers using your identifying information on the HFEA register and allows you to specify whether this is for the purpose of non-contact and/or contact research.

Returning for treatment after 1 October 2009

If you have received treatment at an HFEA clinic before 1 October 2009 but are returning for further treatment after 1 October 2009 and complete the CD form then unless you indicate otherwise the consent you give on the CD form will be applied to all your information held on the HFEA Register, ie, including information collected during any treatment before 1 October 2009).

Withdrawing or varying consent - You will be able to make changes to or withdraw your consent at any time until your information is used in the research. If you wish to vary or withdraw your consent given on the CD form, you should instruct your centre of this in writing, preferably by completing another CD form. Your centre will be able to provide you with this.

Alternatively, if since your registration your centre has closed, and you wish to make any changes to your consent, please contact the HFEA at research.consent@hfea.gov.uk.