Taking pART

Participant Information Leaflet

Taking pART: How people decide to consent to fertility research

We are writing to invite you to take part in a research study based at the University of Oxford. This sheet explains why we are doing this study and what we are inviting you to do.

What is the purpose of the study?

Under UK law the Human Fertilisation and Embryology Authority (HFEA) must keep a record of all cycles of fertility treatment such as IVF. This includes details about the patient (name, date of birth, place of birth), about their fertility diagnosis and subsequent treatment. Information is also kept on the outcome of any pregnancy resulting from fertility treatment. This data is used for monitoring success rates and safety. In certain circumstances it can also be used for research to learn more about fertility treatment.

Since 2009, the HFEA has asked patients for consent to allow this data to be used in research – this includes consent for their data to be used for linkage to other records, and for their details to be available for future contact for research. To be a really useful resource for research, it is important that many people agree to this, but at the moment only about half the people undergoing treatment in the UK say yes to allow their HFEA data to be used for research. We want to find out why.

The aims of this study are to:

i. Find out why people accept or refuse to allow their data to be used in infertility research;
ii. to see if there are different reasons why people decide to allow the use of data on a child born after infertility treatment for infertility research;
iii. and to describe how staff find the consent process, to see whether their own feelings about the use of personal data or the importance of research affects the way they interact with patients.

Why have I been asked to help?

You have been asked to help because you have experience of fertility treatment and the consent procedures that the HFEA requires for all those undergoing treatment. This may be because you are going through fertility treatment (or have done so in the last 5 years), you are the partner of someone who is going through fertility treatment (or has done so in the last five years) or because you are a member of clinic staff who is involved in talking to patients about consent.

Do I have to take part?

No, you can choose whether you want to take part in this study. If you decide to take part and then change your mind, you are free to withdraw at any time and you will not be asked why. The level of medical care and/or your legal rights will not be affected by your decision to take part or not.

If I do agree to take part, what will happen next?

If you would like to take part, please get in touch. Information on how to do that is at the end of the leaflet. We will then arrange an interview at a time and place to suit you. If this is not your home (or place of work for clinic staff) you will be paid for the cost of your travel. If you have any questions about the study or the interview, you will be able to discuss these with the researcher.

What would the interview be like?

First, the interviewer will go through the participant information sheet (this leaflet) to make sure you fully understand what the study is about. You will then be asked to sign a consent form – we will store this in our records at the University of Oxford and you will also be given a copy to keep.

The interview will be a bit like a conversation. If you are a patient or the partner of someone having fertility treatment then you will be asked to describe in your own words your experience and how you made the decision about whether your data held by the HFEA would be made available for research. You will be asked some questions about

what happened to you, how you got your information, and what your thoughts and feelings were at that time. If you are a staff member, you will be asked your thoughts on the consent process, the use of data and the decision that patients are asked to make. The interviews will be audio recorded.

You may find it useful to talk about your story with a researcher, but this is not the same as counselling. If through the interview, you realise that you would find it helpful to speak to someone about your experiences we will be able to provide you with a list of useful contacts.

How long will it take?

This depends on how much you have to say! In general, we would expect the interview to last between 1 and 2 hours. Should you wish to pause or stop the interview during this time, you can do so.

What happens after the interview?

After the interview, what you and the interviewer have said will be typed out (transcribed). The interview recording and transcript will not include your name or identifying information, from this point on everything will be labelled with a code so that you cannot be identified. A record of the codes and names will be kept in a secure place at the University of Oxford.

If you wish, we can send you a copy of the interview transcript to allow you to review what you said and to give you the opportunity to remove or alter any sections. We will delete anything that you do not want us to use. If you choose to review your transcript, we would give you 21 days to look through it and accept or make changes.

How will the researchers use my interview?

Your interview would be analysed alongside about 30 other interviews from people who have also undergone fertility treatment or are staff at a fertility clinic. The results of the study will be published in reports, academic journals and presented at conferences. Quotations from the interviews may be used in any publication, but they will be anonymous and you will never be identified in any publication. All the data that you give us for analysis will be confidential, and have no personal information with it so you cannot be traced. It will be used strictly within the terms of the Data Protection Act. The results from the study will be available to read on the study website.

How will my data be kept confidential?

All collected data will be stored securely. Paper transcripts will be stored in locked filing cabinets in locked offices which only the researchers can access. Electronic files will be stored in a restricted area of the university computer network. Responsible members of the University of Oxford, and your NHS Trust (if you have found out about the study through and NHS clinic), may be given access to the data for monitoring and/or audit of the study to ensure we are complying with regulations.

What if I change my mind? Can I withdraw after the interview has taken place? How do I tell you?

You can decide to withdraw from the study at any time. If your interview has already taken place then all recordings and transcripts will be destroyed and your data will not be used. If you change your mind please contact us using the telephone number or email address at the end of this leaflet.

Are there any benefits or risks in taking part?

Participants may feel that by taking part they may influence how researchers or clinics speak to new patients about the consent process. People who have taken part in studies have said that they valued the opportunity to talk about their experiences, and have found the experience a positive one.

Although the focus of the interviews will be about consent and participation in research, you will need to talk about your fertility problems. You will have control over what we talk about, and will be able to stop the interview if you wish to. You can withdraw from the study at any point, if you want to do so.

What will happen if there is a problem?

Given the nature of this study, which is using only interviews to collect information, it is very unlikely that you will suffer harm by taking part. However, the University of Oxford has insurance in place to provide for harm arising from participation in a study for which the university is the Research Sponsor. If you are unhappy about the way that you have been approached or treated during this study, you should contact Dr Claire Carson on (01865) 289755 or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the Head of the Clinical Trials and Research Governance, email ctrg@admin.ox.ac.uk.

Expenses and payments

We will pay your travel expenses on the day of interview, if they have been incurred.

Who has reviewed this study?

This study has been reviewed by the NRES Committee London - City & East on 16 July 2015.

Who is organising and funding the study?

This research is based at the National Perinatal Epidemiology Unit, which is part of the Nuffield Department of Population Health at the University of Oxford. This study has been funded by the Medical Research Council as part of a fellowship grant to Dr Claire Carson.

Who are the research team?

The study team at the University of Oxford comprises: Dr Claire Carson, Prof Jennifer Kurinczuk and Prof Maria Quigley at the National Perinatal Epidemiology Unit, and Dr Lisa Hinton in the Health Experiences Research Group. If you choose to participate in the study, Claire will be the person you speak to in your interview.

For further information –

We hope that this information sheet has told you what you need to know before you decide whether to take part in this study. If you do have any questions or wish to talk to someone about this study, please contact Claire Carson at the National Perinatal Epidemiology Unit on (01865) 289755.

Many thanks for reading this leaflet.

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National Perinatal Epidemiology Unit
Nuffield Department of Population Health
University of Oxford
Richard Doll Building
Old Road Campus
Headington
Oxford
OX3 7LF
T: (01865) 289755
E: claire.carson@npeu.ox.ac.uk

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npeu National Perinatal Epidemiology Unit

MRC Medical Research Council