

A research study to investigate factors supporting *in vitro* human embryo development

We would like to invite you to donate your frozen embryos for a research project that is focused on furthering our understanding of early human embryo development and healthy pregnancy.

Your donation would be extremely valuable and each embryo will have an important contribution to the research project. Before making a decision to donate, it is important that you understand the scope of the research undertaken and what it involves. Please read this Patient Information Document carefully. You should take as much time as needed before deciding on whether or not to participate in this research study. Should you have any questions regarding the information in this document please contact your clinic. The clinic is in direct contact with the research team who will also support in answering any questions. Please find the Consent Form to be signed at the end of this document (page 5).

1. What is the purpose of this study?

The research taking place at the Babraham Institute in Cambridge focuses on studying early human embryo development. We hope that the results of these studies will benefit medical knowledge in several important ways, such as:

- Improving our understanding of how human embryos develop. The first two weeks of embryo development are primarily concerned with forming the main cell types required to establish the future foetus and also to support the embryo as it implants into the womb. We aim to understand how these cell types are formed and how the activity of different genes is regulated at these stages to promote successful embryo development. We hope that ultimately these insights could lead to improvements in the treatment of infertility and benefit other patients trying to have a baby through IVF.
- This early stage of embryo development is associated with high rates of pregnancy loss. Our work aims to identify important indicators of healthy embryo development. Understanding what leads to successful development could provide new insights into some of the causes of early pre-clinical miscarriage. This knowledge will be important for designing rational therapeutics that could improve pregnancy rates and, in the longer-term, potentially overcome pre-clinical miscarriages occurring at this stage.

2. What are you being asked to do?

If you wish to contribute to this research, you may donate any of your embryos not required for your fertility treatment that were created as part of your treatment or that are currently kept in storage at your clinic. This includes embryos that are already frozen, and you decide you no longer wish to keep in storage or are no longer required. You can store your embryos for your treatment at your clinic for any period up to a maximum of 55 years from the date they were first placed in storage.

If you choose to donate your embryos to this study, we kindly ask you to read this information sheet and sign the consent form for research purposes at the end of this document (page 5). This will allow us to include those embryos into our research programme. Under the Human Fertilisation and Embryology Act 1990 (as amended), we are required to receive your written consent if you choose to donate your embryos to be used and stored for this research project.

The Human Fertilisation and Embryology Authority (HFEA) has issued new regulations for the storage of embryos which came into effect from 1st July 2022, and gives patients greater flexibility in relation to the storage of their embryos. If you decide to consent to the donation of your embryos for use in this research project, the storage period for research begins from the date on which you give consent. This is the date when you sign the Research Consent Form at the end of this Patient Information Document (page 5) and is different from the storage period you consented to as part of your treatment at your clinic.

The maximum period you are able to consent to your embryos being stored for research is 10 years. You may indicate in the Research Consent Form below the number of years you consent to your embryos being stored, up to a maximum of 10 years. Embryos can only be stored for research purposes if both gamete donors give their consent. If the period for storage for research purposes given by each gamete donor is different, the embryos will remain in storage for the lesser of the two storage periods. If each gamete donor gives consent on different days, the consented storage period will begin on the later of the two dates that consent was given.

It is important for you to know that once you have given your consent for donation to research, there may be a short period of time from the consent being given to when the embryos are transferred from your treatment clinic to the Babraham Institute.

You are under no obligation to take part in this study. Donating gametes or embryos to research during treatment services will not affect your treatment in any way. The decision whether to do so will have no repercussions for any treatment you may receive.

Only frozen gametes and embryos not required for treatment can be used for research. You may specify conditions for the use of embryos. Any individual who donates cells for creating embryos for research, consent to use these cells includes consent to do so after the individual's death, unless stated otherwise. By consenting to donate your embryos to this research project, you are also agreeing to the embryos being stored and used if you were to die or lose the ability to decide for yourself (become mentally incapacitated). After the research has been completed, all donated gametes and embryos will be allowed to perish.

3. What are the possible disadvantages and risks of taking part in the study?

There are no physical or medical risks or disadvantages to you. The research performed with your surplus frozen embryos will not affect you or your subsequent medical care in any way. You may experience uncertainty or anxiety when making decisions regarding any donation of your embryos, and independent counselling is available to support you and your partner. If you would like to receive counselling or discuss the possibility of donating embryo to this project, please contact your treatment clinic and they will be able to provide you with an independent counsellor.

4. Will you benefit from the research?

It is important for you to know that this research will not lead to any direct medical benefits to you. However, the information we get from this study may help to treat other patients in the future by improving infertility treatment. This research could also lead to the development of cures for many serious disorders, such as miscarriage and avoiding serious disabilities that may affect unborn children.

It is possible that the research discoveries could result in publications or patents being awarded to the researchers or commercial organisations. You will not receive any financial benefit from research discoveries arising from the embryos you donate.

5. What will happen to your embryos if you take part to this research study?

Below is a summary of the laboratory procedures that your embryos will be used for:

- Growing the embryos in a dish, for no longer than 14 days after fertilisation. This will allow us to study the way that the human embryo divides and grows.
- We will explore different methods and conditions to improve the growth and development of the embryos. This could be done by culturing the embryos on top of a layer of endometrial cells or by adding different growth factors and other compounds to stimulate growth.
- Using specialised microscopes to film the embryos as they develop. This will provide valuable information about the changes that happen over time.
- Biochemical studies will be performed to gain new information about how embryo cells communicate and signal during their development.
- Studying the genetic composition of embryos. This can be done by examining the DNA and gene changes that occur during development.

This study will not involve the derivation of any stem cell line.

This study will not involve genetic modification of embryos.

No embryos in this study will be used to establish a pregnancy.

Embryos will not be donated to another research institute.

No embryos will be used for animal research.

6. Will your participation in the research be kept confidential?

Yes. We have put in place careful procedures to protect your identity and confidentiality. This is a key requirement that is specified in the research licence issued to us by the HFEA and by the NHS Research Ethics Committee. All of the consent forms will be fully anonymised before being received at the research laboratory: including names, date of birth, addresses, phone number, and passport or NHS numbers. In some cases, the researchers may have access to some identifying information that is used to label the device containing the embryos, such as the patient name, date of birth or patient number. This information identifying your embryo will be visible to a member of the research team during the thawing procedure, but your identity will not be recorded and any information on the label will be made unreadable and safely disposed as soon as the embryo is used. The embryos will be coded and your identity and participation in the research will be kept strictly anonymous. Furthermore, due to the anonymisation, it is not possible to provide you with any information that could be gained regarding your health and welfare as a result of this research.

7. Will you be informed of the progress of the research project?

You will not receive any information from either this study or on the results of genetic analysis on the embryos that you donate. The information collected will be studied scientifically and the information gained may be published in appropriate medical and scientific journals, however no references to your individual donation or identity will be made.

8. Can you change your mind later and vary or withdraw your consent?

Yes, you can choose to vary your consent or withdraw from the study at any point. This does not affect your medical care in any way. In order to vary or withdraw your consent, please contact your treatment clinic which, in turn, will inform the research centre. If you withdraw your consent after the transfer of embryos to the Babraham Institute, any unused embryos will be allowed to respectfully perish and will be destroyed. These embryos cannot be returned to the treatment clinic or used for

your own treatment in the future. The consent cannot be withdrawn once the embryo that you donate becomes part of the research programme and is being used in research.

9. How is this research authorised and funded?

The research will be performed under a license issued by the HFEA and approved by an NHS Research Ethics Committee. The research will be funded by several independent research bodies including the Wellcome Trust, Medical Research Council (MRC) and the Biotechnology and Biological Sciences Research Council (BBSRC), among other public or private funding or philanthropic organisations. Your treatment clinic has no financial incentives in this research project.

10. Contact details

More information about the research project can be found on the following web page:

<https://www.babraham.ac.uk/our-research/epigenetics/peter-rugg-gunn/human-embryo-research>

Please refer to the HFEA website for information about licensed human embryo research:

<https://www.hfea.gov.uk/donation/donors/donating-to-research/embryo-research-project-summaries/>

If you would like to receive counselling or discuss the possibility of donating embryo to this project, please contact your treatment clinic and they will be able to provide you with an independent counsellor.

Contact details of the principal investigator of the research study:

Dr. Peter Rugg-Gunn
Babraham Institute
Babraham Research Campus
Cambridge,
CB22 3AT

Telephone: 01223 496385

Email: peter.rugg-gunn@babraham.ac.uk

Research Consent Form

**Project Title: a research study to investigate factors supporting
in vitro human embryo implantation and development**



Clinic Name and Number: Patient Medical Number: Research Identification Number: R0209-1-a. Centre reference: 0370 (The Babraham Institute)		
Please initial to confirm Patient Partner		
We have read this Consent Form (page 5) and the Patient Information Document (pages 1-4), and have had the opportunity to ask questions and receive counselling.		
We agree for our cryopreserved embryos to be used for the research studies outlined in this Patient Information Document and we understand that our donated embryos will not be stored for longer than the period for which we have given consent. We agree to donate our embryos for this research study which will be covered by an HFEA Research Licence.		
In the box below, please specify the number of years you consent to your cryopreserved embryos being stored. You can consent to your embryos being stored for use in this research study for any period up to 10 years. We agree for our cryopreserved embryos to be stored for the research study for a period of <input type="text"/> years.		
We understand that we are also agreeing to our cryopreserved embryos being stored and used if we were to die or lose the ability to decide for ourselves (incapacitated).		
We understand that our cryopreserved embryos may continue to be stored at our treatment clinic for a short time before they are transferred to the research centre.		
We understand that we are under no obligation to take part in this study and that our decision whether or not to participate will not alter our medical treatment in any way.		
We understand that all measures have been taken to protect our identity and confidentiality, but we accept that that a member of the research team may have access temporarily to some identifying information.		
We understand that the research project may include genetic and other tests. We understand that we will not receive any information about the outcome of the study on embryos that we donate.		
We understand that we will not benefit financially or otherwise from the research discoveries, which could be published or patented by the researchers.		
We confirm that we will be taking part in this research by our own free will, and that we may withdraw from it at any time and for any reason up to the time our embryos are used in the research project. Any embryo will be regarded as being used after becoming part of the research program and being cultured/grown for use in research.		
Patient full name (printed)		
Signature		Date
Partner full name (printed)		
Signature		Date
Witness full name (printed)		
Signature		Date