

Pluripotency, reprogramming and mitochondrial biology during early human development

Information for potential research participants

We would like to invite you to take part in research. Before you decide it is important that you understand why the research is being done and what it will involve.

This information sheet is yours to keep. It tells you the purpose of the study and explains what will happen to you if you take part.

Please take time to read the following information carefully and discuss it with others if you wish.

Take time to decide whether or not you wish to take part. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

Research at the Newcastle Fertility Centre at LIFE is related to early human development. This research may be beneficial in helping us to improve clinical procedures in fertility treatment, but potentially also to develop cures for many serious diseases, to prevent children with serious disabilities from being born and to develop new research tools.

What am I asked to do?

We are asking if you would donate some of your eggs for research. We may also need a small blood sample (about 1 tablespoon) from you.

If you are happy to participate in this research, you will need to sign the consent form attached.

What are the possible benefits of taking part?

Taking part will have no direct benefit to you in the treatment that you donate eggs. If you are not pregnant after completing your 3 NHS funded treatments, you will receive a 4th free treatment paid by the research team if you want to continue with treatment. You would still be able to have a 4th treatment if you do not donate eggs now but you would need to fund this yourself as a private patient.

We are hoping that this research will lead to the development of new scientific insights and treatments that will be of general benefit.

The cells you donate or discoveries made from these cells could lead to the development of new treatments or tools that may be patented and may be used by commercial companies. You will not benefit financially from this.

What will happen to me if I take part?

Before you make your decision about egg sharing, you must have a meeting with the research nurse. If you decide to take part in egg sharing, your fertility treatment will be carried out as normal. After the eggs have been collected, they will be allocated randomly for either your treatment or for research. If there is an odd number of eggs, you will receive the extra one. The agreed number will be given immediately to the researchers.

What will happen to my cells/tissue if I take part?

We will grow your eggs and may freeze them for further laboratory studies.

We will study the mitochondria in your eggs. We may take the nucleus (the genetic material in your egg) and replace it with the genetic material from someone else's cell. The resulting cell may be then stimulated to divide so that we could make stem cells from it (therapeutic cloning).

Sometimes we stimulate the egg by injecting a sperm into it. The sperm might then be taken out within a few hours but if we are doing studies to find treatments that avoid the risk of mitochondrial disease, we may allow it to fertilise the egg so that we can study if the resulting embryo is normal.

What are the risks of taking part?

If you give eggs for research rather than use them for your treatment, there may be a reduced chance that the IVF will be successful. Our results so far indicate that overall this is not a problem but, for you individually, you may find it more difficult to accept if you are not pregnant. If you grow less than 10 eggs it would reduce your chance of pregnancy and we would recommend that you withdraw from the research project and keep all the eggs for yourself. Since you would no longer be in the project, you would then not be eligible for a free 4th treatment.

Will my taking part in research be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential to those involved in the research. Only members of the research team in the Fertility Clinic and some regulatory authorities (e.g. Human Fertilisation and Embryology Authority, Medical Research Council) may view any identifying information about you.

What will happen to the results of the study?

Whenever possible we will publish the results of our studies in scientific journals. We will also present data at scientific conferences. You will not be identified personally in any way in any publication or presentation

Will we get any results that you will need to know about?

It is unlikely that we will get any information from this research that we would need to give you. You will not be given any information about the outcome of your donation, or any information about any tests that may be done on your cells.

Some background on our research

Your donated cells would make an important contribution to a complex research programme at Research at the Newcastle Fertility Centre at LIFE and Newcastle University.

We would like you to understand what kind of research is going on at our unit and to give you an appreciation of the wider context where your cells would be useful.

Points that you should know about the research

- The cells we grow may be stored and cultured indefinitely. They could be studied by scientists all over the world for many years or even decades to come.
- Embryos may not be cultured in the laboratory for more than 14 days,
- You should be reassured that no cells we do research on will ever be used to establish a pregnancy.

- In addition to growing your cells, we will perform a range of biochemical and genetic studies to help us to understand their biological properties.
- Some of our research involves 'nuclear transfer'. This includes taking genetic material from one cell and transferring it to an egg which has had its own genetic material removed. This can result in the creation of a new embryo.
- Taking a cell such as a skin cell and putting it into an egg is similar to the first stages of cloning. You can be reassured that it is not our intention to make 'cloned babies'. This reproductive cloning is banned in most countries including the UK.
- Cells grown from your original cells may also be injected into animals e.g. cells may be put into mice to test how the cells grow.
- Cells grown from your original cells may be used for future treatment of others.
- Cells grown from your original cells may be used for other approved research studies as yet undetermined.
- Any stem cells lines derived as the result of this research will be deposited in the UK Stem Cell Bank. They may be made available to other research groups nationally and internationally.

Management of this research

Who is funding the research?

This research is supported by the Wellcome Trust, Muscular Dystrophy Campaign and the University of Newcastle. Future funding is likely to include public funding agencies but could also include funding from private donors and companies.

How is the research overseen?

This research is jointly overseen by the Newcastle upon Tyne NHS Hospitals Foundation Trust and by Newcastle University.

All research is approved by the Local Research Ethics Committee.

Research in the fertility field is regulated by the Human Fertilisation and Embryology Authority. Information about this organisation can be found on www.HFEA.gov.uk.

This work is covered by Licence R1052.

What if something goes wrong?

In the event that something goes wrong and you are harmed during the research due to someone's negligence, then you may have grounds for a legal action for compensation against Newcastle upon Tyne Hospitals NHS Foundation Trust but you may have to pay your legal costs.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of the study, the normal NHS complaints mechanisms are available to you.

Can I control what happens in the research?

Once the cells that you donate have come under the control of research staff and are being cultured/ grown for use in research, they can no longer be withdrawn. Our research programme is monitored by the regulatory authorities and the ethics committee. Your donation is made without any restriction regarding the individual(s) who may receive medical benefit from the results of the research.

Contact for further information.

For further independent advice you can contact Sister Maria Nesbitt, Sister Linda Burgess or Professor Alison Murdoch at any time on 0191 213 8213.

Who is leading this research?

Professor Alison Murdoch,
Professor of Reproductive Medicine
Newcastle Fertility Centre at Life
International Centre for Life, NE1 4EP

Professor Mary Herbert
Professor of Reproductive Biology
Newcastle University

Professor Doug Turnbull
Professor of Neurology
Newcastle University

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CONSENT FORM

- I have read and understood the information sheet and the consent form about these studies; and have had the opportunity to discuss it.
- I understand that I am under no obligation to take part in this study and that a decision not to participate will not alter any treatment that I would normally receive.
- I understand that I have the right to withdraw from this study without giving any reason, at any stage up until the cells have been used for the purpose of any project of research. Any cell will be regarded as so used after it has come under the control of research staff and it is being cultured/ grown for use in research.
- I understand that any cell lines collected from this research will be deposited in the UK Stem Cell Bank and that a copy of the consent forms may be maintained securely in a restricted area by the Secretary to the Stem Cell Steering Committee. This will be secure and will not be revealed to any other staff at the Bank or anyone else who does further research on the cells.
- I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the NHS Trust and from regulatory authorities where it is relevant to my taking part in this research.
- I understand that there may be future research on those stem cell lines, as approved by the Stem Cell Steering Committee of the UK Stem Cell Bank.
- I understand that the cell lines could be used for treatment purposes (including cell replacement therapies) in the future.
- I understand that I will not benefit financially from this research and its outcomes.
- I understand that the research project may include genetic and other tests. I will not be informed of any of these results.

I consent to my participation in this study.

Woman's Name**Signature** **Date**

Signature of Witness **Date**
(from clinic)

AGREEMENT TO TREATMENT INVOLVING EGG SHARING

Full name of woman _____

Address _____

1. I have asked the Centre named above to provide treatment services to help me bear a child. In the course of this treatment I wish to donate half of my eggs to research.
2. I consent to an egg share with research on my 2nd NHS treatment. If I do not have a baby after this or a 3rd NHS funded treatment, I will be able to have a 4th treatment funded by the research team.
3. If more than ≥ 10 eggs are retrieved; I consent to donate half my eggs to research (where possible the eggs will be shared equally in number and quality regardless of the treatment type; if there are an odd number of eggs, I will receive the extra egg).
4. If there are ≤ 9 eggs retrieved, I will keep them for my own treatment. If this happens, I understand that I would have to pay for a 4th IVF treatment myself.
5. I understand that I am free to withdraw from treatment at any time.
6. If I withdraw my consent for egg sharing at any time the treatment will continue with no cost to myself.
7. I have read and understood the Information sheet about the research project.
8. I have been counselled about the implications of egg sharing and I am aware and understand the impact it may have on the outcome of my own treatment.
9. I have discussed in full with _____ the procedures outlined above and have been given information verbally and in writing about them.

Signed _____ Date _____

Witness Signature _____ Date _____

