

Research at Newcastle Fertility Centre at Life

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 eggs, sperm or embryos that are not needed for your treatment and that would otherwise be discarded 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. 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?

Taking part in research will not alter your treatment. If you consent to the research, the embryologist will give your cells to the researchers only after those needed for your treatment have been selected.

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

The main laboratory procedures that your cells will be used for include:

- Growing embryos for no more than 14 days to study the way that embryos divide and grow. We will look at different ways of growing and freezing embryos to find the best methods.
- Removing cells from early stage embryos to produce embryonic stem cells which could potentially be used to treat a variety of degenerative diseases.
- Taking genetic material from an egg cell and replacing it with genetic material from other sources including other eggs and cells such as skin cells. The resulting cell may be then stimulated to divide and can result in the production of stem cells.
- Study of the genetic composition of eggs, sperm and embryos

Will participating in research affect our treatment?

No. You can be reassured that your treatment always comes first and we would not do anything that would compromise your chance of achieving a pregnancy.

This is the main concern that patients tell us about. In particular, some are worried that we may not freeze remaining embryos so that they can be used for research. You can be reassured that your treatment comes first. Our advice about whether or not to freeze embryos is based on giving you the best possible chance of pregnancy whilst not giving you false hope by freezing poor quality embryos. We have already given you written information about our embryo freezing policy. If you still have any concerns about this, please talk to us.

Sister Maria Nesbitt and Sister Linda Burgess are employed to ensure that you are fully informed about the research. They have no role to play in your clinical treatment so they have no conflict of interest between your clinical needs and our research. They are funded by the Medical Research Council for this purpose.

Data and Results

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 are used in our research programme. These embryos (tiny clusters of cells not visible to the eye) would otherwise be discarded.
- 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?

Prof Mary Herbert
Reader of Reproductive Biology
Newcastle Fertility Centre at Life
International Centre for Life
NE1 4EP

Prof Alison Murdoch,
Head of Department

Prof Doug Turnbull
Dept of Neurology
Newcastle University

Pluripotency, reprogramming and mitochondrial biology during early human development

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**

Mans' Name **Signature** **Date**

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

