

Information Sheet HFEA Research Project R0214

Validation of stem cell models for investigation of early human embryology

You are invited you to donate frozen human embryos that are no longer needed for your own treatment to a research project on early embryo development and obtaining stem cells. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

Background

In the two weeks after fertilisation the human embryo develops to the stage where it is ready to form the tissues that will make up our body. Scientists are now making progress in growing embryos up to this stage in the laboratory. This is important for understanding why many pregnancies fail at these early stages. In addition, some of the cells that make up the early human embryo are very special because they have the potential to form all of the cell types in the body. Scientists have found that these early embryo cells can be taken out of the embryo and multiplied in the laboratory as so-called stem cells. Such stem cells may be maintained and used for research in the laboratory for many years.

Study of embryo stem cells may benefit medical knowledge in a number of important ways. These include:

1. Studying the requirements for helping such cells grow in a dish in the laboratory will be a valuable way of trying to work out the ideal conditions for looking after human embryos in culture. This sort of work could have important benefits for assisted conception treatments.
2. Stem cells in the laboratory can develop into different types of cells found in the human embryo and form structures that are similar to the early embryo. These stem cell-based embryo models can yield new information about how the human embryo develops and how this may sometimes go wrong during early pregnancy.
3. There are also similarities between the development of stem cells and the development of certain very particular types of malignant disease (cancer). Once again, studying the behaviour of these cells could produce new and valuable insights into factors which regulate or fail to regulate the growth of cancers.
4. Just as the cells in an early embryo have the potential to develop into any cell type in the body, so may the derived stem cells. It is therefore possible that stem cells could be used to develop future treatments to degenerative diseases such as Parkinson's disease or juvenile diabetes. Such treatments may be developed by using the stem cells to develop new drugs or could be by transplantation of the stem cells themselves, similar to bone marrow transplantation.

What is required of us?

You will have been given this Information Sheet after you have decided that you no longer require your stored frozen embryos. In the normal course of events, these embryos would be allowed to perish with your written consent. As an alternative, you could decide to donate to this study to allow research on these embryos. If you would like counselling on this decision, details are available at the end of this form.

What are the possible risks of taking part in the study?

There are no risks to you. Embryos will be sent to the Living Systems Institute at the University of Exeter, where the research team will not record your identity.

What would happen to the embryos?

If you do consent, the donated embryos would be thawed and grown in culture for up to 8 days. The embryos will be fixed to stop development at different timepoints and then stained to detect markers of early embryonic cell lineages and visualise how they are arranged. Some embryos will be separated into single cells, which will be profiled for gene expression using state of the art technology and computational analysis. In some embryos gene modification technology will be used to investigate the function of specific genes. These studies will provide new information on the development of the human embryo, in particular during the second week where there is currently little information. In addition, some of the embryos will be used to attempt to obtain stem cells. These embryos would be treated to separate the cells making up the embryo, so it is no longer intact. The separated cells may die naturally, or they may survive and multiply indefinitely as stem cells. If they do survive as stem cells, then they would be contributed to a publicly funded stem cell 'bank' which has been established by the UK Medical Research Council as a resource for doctors and scientists. The stem cell bank may make the stem cells available to research teams in the UK and internationally.

Stem cells may be combined with embryos and cultured together for up to 8 days to understand how similar they are to cells in the embryo. Stem cells can be used to make models of early human development or disease, and as the basis for the development of new treatments. It is thus possible that these stem cell lines could be used in a variety of research projects, essentially indefinitely, and it is not possible at this time to specify the exact nature of all of this potential research.

Will I benefit personally?

It is important that you appreciate that this research will not lead to any direct medical benefits to you.

In addition, it is important that you understand that there is the possibility that stem cell lines derived from donated embryos could, in future, be used for research or for the development of new treatments. This might include discoveries and patents, or work by commercial organisations. You would not receive any financial reward relating to research discoveries or use of the embryos or derived cell lines.

Will my confidentiality be protected?

Yes, of course. This research is being undertaken under the terms of a licence granted by the Human Fertilisation and Embryology Authority and with approval of a Multi-Centre Research Ethics Committee, both of which impose strict requirements about the maintenance of your confidentiality. The embryos will be coded and your identity will remain confidential to your clinic. Your name may be visible to a member of the research team during collection of the embryos but will not be recorded by them. If a stem cell line is derived, it may be necessary for the clinic to provide a copy of your consent form in confidence to the Secretary of the UK Stem Cell Steering Committee. Your identity will not be disclosed to staff of the Bank or to anyone else.

Am I entitled to information on the outcome of the research?

Yes, you may request and be provided with feedback from **Lyndon Miles** at CRGW/CARE on the development of your embryos and whether stem cells are derived. You will not receive information on any subsequent research because your identity will be anonymous to the researchers.

How do I give my consent to this research?

You will be asked to sign a consent form which is specific to this project, and which has been approved by the HFEA and by a Multi-Centre Research Ethics Committee. The consent form also records your consent to the storage of your embryos for subsequent use in this project. This storage period can be for up to 10 years. You must specify in the consent form the maximum length of the embryo storage period you consent to.

Can I change my mind and withdraw my consent?

You are of course entitled to refuse to participate in this research, and to withdraw from participation after you have consented to do so, without in any way affecting your subsequent medical care.

You can withdraw or vary your consent to research at any time up until any of the methods, techniques or processes particular to project R0214 have been applied to the embryo in question. In order to withdraw consent, you must contact **Lyndon Miles**, CRGW/CARE Cardiff: Ely Meadows Medi-Science Park, Rhodfa Marics, Llantrisant, CF72 8XL; Tel 01443 443999. It is important that you understand that your embryos will be stored under the HFEA research licence provided to project R0214 and can be used for research at any time after we receive your consent.

How is this research funded?

This research is funded by the Medical Research Council and the Biotechnology and Biological Sciences Research Council. The research work is carried out in the Living Systems Institute at the University of Exeter.

Counselling

Counselling and further information is available from:

Lyndon Miles

Consultant Clinical Embryologist

CRGW/CARE Cardiff: Ely Meadows Medi-Science Park, Rhodfa Marics, Llantrisant, CF72 8XL

Tel: 01443 443999

Email: Lyndon.Miles@carefertility.com

If you would like to discuss this study with an independent person who is not involved in this research, you may contact:

Amanda O'Leary

Medical Consultant and CRGW/CARE Director

CRGW/CARE Cardiff: Ely Meadows Medi-Science Park, Rhodfa Marics, Llantrisant, CF72 8XL

Tel: 01443 443999

Email: amandaoleary@CRGW.co.uk