



Leicester Fertility Centre
Caring at its best

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HFEA Centre Number 0068



PATIENT INFORMATION SHEET

Indicators of oocyte and embryo development

Dear Patient

You are being invited to take part in a research study.

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. Your decision in this respect will not affect your treatment at all.

If you do choose to participate in the research, you still remain free to withdraw your consent at any time before your material has been used in the research.

Thank you for reading this.

Yours faithfully

Prof Geraldine Hartshorne
Scientific Director
Centre for Reproductive Medicine
UHCW NHS Trust, Coventry, CV2 2DX

WHAT IS THE PURPOSE OF THE STUDY?

We are doing research to understand better how eggs and embryos are formed and grow. This is an ongoing study that has been in progress since 1996 and will continue until at least 2014

At present, it is very difficult to identify the embryos that are most likely to implant when placed into the womb during fertility treatments. There are few markers that show clearly whether an embryo is growing well. Moreover, it is possible that development could be affected by the laboratory environment because it is different to the environment in the body. For the future, we want to be able to tell whether embryos in our laboratory are growing well and whether any problems have arisen for any reason. To do this, we need to study embryos in great detail and using a variety of different scientific methods. This will tell us, for example, whether certain genes on the chromosomes are being programmed properly. This is important because they should behave differently according to whether they come from the mother or the father. We will also be able to see if the specialised ends of the chromosomes (these control ageing) are of a normal length. We hope that in future, it may be possible to test embryos for these features to monitor normal development, and to check the risks of any new methods of fertility treatment that might be invented. We shall also collect digital images of embryos in order to construct virtual reality models for use in further research to develop new educational resources.

We would like to ask if you would be willing to let us use your embryos for our research. We would only use any embryos that you no longer need for your own treatment. Embryos that are used in research would never be used to make a pregnancy for you or anyone else. We would only use your embryos in research if you agree and sign your consent on the form.

During the course of our research, it may be necessary for embryos to be taken to other research centres for study, such as the Universities of Warwick, Nottingham or Paris, as the specialised equipment that we need to use is based there. Please be assured that any samples moved to other centres would be treated there with the same respect as if they remained here. All the samples will be anonymised so that your personal details would only be accessible under strictly controlled conditions and then only to Trust personnel who are already authorised to access your medical records.

Do I have to take part?

Participation is entirely voluntary and your decision in this respect will not affect any aspect of your treatment or its outcome.

What will happen to me if I take part?

If you choose to participate, the embryologists in the laboratory will identify the frozen embryos that you wish to donate and make them available to researchers working on this project. If you wish to pursue further fresh treatment in the future, your treatment will proceed in exactly the same way, whether or not you choose to take part.

What do I have to do?

Please take time to read the information and discuss with a member of staff any questions that you may have. If you wish to take part, please complete and sign the three copies of the consent form (both partners need to sign).

What are the possible benefits of taking part?

There are no benefits to you personally of taking part. In future we hope that this research may bring benefits to other people going through fertility treatment.

What happens when the research study stops?

At the end of this study, any embryos that have been used for research are normally disposed of. However, if you agree, it is possible that they can be kept in case they could be useful for other research projects in future. We would like to keep them for this purpose, however, you are under no obligation to agree to this, regardless of whether you agree to participate in the present study. Please indicate on the consent form whether you agree for this to be done. Rest assured that any such future research would be approved in advance by a Research Ethics Committee.

What if something goes wrong?

We do not envisage any problems arising during the course of this research. However, if an untoward event were to occur, please be assured that we will do everything we can to put matters right. You have a right to complain to the hospital through the normal NHS complaints procedure. If you wish to complain, please write to the hospital complaints officer at the address of the hospital where the problem occurred. In addition, you are also welcome to contact the Human Fertilisation and Embryology Authority which regulates research such as this. Their address is: 21 Bloomsbury Street, London, WC1B 3HF.

Will my taking part in this study be kept confidential?

Yes, your participation will be confidential. Any samples you provide and non-identifying information from your medical history will be stored in an anonymous form. Please note that such anonymised information may be stored on a computer database.

What will happen to the results of the research study?

The results will be published in a medical journal and presented to learned societies at conferences, but you would not be identified in any publication. The information that we gain will be of no use to you personally so we do not plan to tell you about it. But if you would like a copy of the final publication, please write to the principal investigator at the address above. Please note, it usually takes several years for results to be fully analysed and published.

It is possible that some of the results could be used to develop a virtual reality tool which might result in intellectual property rights, and possible financial benefit in the future, for some of the researchers.

Who is organising and funding the research?

This study is currently not receiving any specially allocated financial support or sponsorship. A small amount of general research funding is available through the Centre for Reproductive Medicine, University Hospitals Coventry and Warwickshire NHS Trust, allowing us to make some progress. No inducement or financial reward will be given to any of the staff involved in recruiting patients for this study.

If you would like to take part, please complete all three copies of the consent form and return two to Leicester Fertility Centre (keep the other for your own records).

If you have any questions or queries, or decide to change your mind, please ask one of the staff at Leicester Fertility Centre, or contact:

Prof Geraldine Hartshorne
Scientific Director
Centre for Reproductive Medicine
UHCW NHS Trust, Coventry, CV2 2DX
Tel: 02476 968879.

You are also very welcome to contact Leicester Fertility Centre's independent counsellor for any reason. Making decisions about the use, donation or disposal of embryos can be difficult. The counsellor is experienced in helping people with various queries and personal questions. Please phone the clinic on 0116 258 5922 for an appointment.

Thank you for your help.

The Trust has access to interpreting and translation services. If you need this information in another language, please contact the Quality Manager on (024) 76968864, and we will do our best to accommodate your needs. The Trust operates a smoke free policy.