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PATIENT INFORMATION SHEET (FOR MEN PROVIDING SPERM FOR RESEARCH USE)

Indicators of oocyte and embryo development

IRAS ID: 65414
HFEA: R0155

Dear Sir

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. If you are undertaking fertility treatment, your decision in respect of the research 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. Such withdrawal of consent will have no effect on your treatment or care.

Thank you for reading this.

Yours faithfully



Prof Geraldine Hartshorne (Chief Investigator)
Scientific Director
Centre for Reproductive Medicine

Who is organising and funding the research?

This study is organised by Professor Geraldine Hartshorne, Scientific Director of the Centre for Reproductive Medicine at University Hospitals Coventry and Warwickshire NHS Trust (UHCW NHS Trust), who is also a Professor at Warwick Medical School, University of Warwick. The study involves research teams at the University of Warwick (Professor Andrew McAinsh and Professor Jan Brosens) and other Universities and fertility treatment centres, particularly the University of Edinburgh, where Professor Adele Marston and Professor Richard Anderson are the Principal Investigators (researchers leading the project).

A large part of this study is being funded by the charity Wellcome however, funding changes from time to time. The funding is paid to the organisations involved in the research. No inducement or financial reward is given to any of the staff involved in recruiting patients for this study.

What is the purpose of the study?

We are doing research to understand better how human eggs and embryos are formed and grow. This is an ongoing study that has been in progress since 2004 and will continue until at least 2026.

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 egg or embryo is growing well. Egg quality declines as women get older, so we are studying the reasons for this, such as why some eggs end up with the wrong amount of genetic material (DNA). DNA is packaged into chromosomes and incorrect chromosome movements may cause problems with embryo development and miscarriage. Development could also 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 eggs and embryos in our clinical laboratory are growing well and can implant in the womb, or whether any problems have arisen for any reason, so we will also study how the embryo interacts with different cell types in the womb lining.

To do this, we need to study eggs and embryos in great detail and using a variety of different scientific methods at different stages from the unfertilised egg through to the implantation of an embryo in the womb.

The tests we intend to do may include analysis of the chromosomes (long thin structures) which carry the genetic material (DNA) in the eggs and embryos, and studying other parts of the cells such as RNA (a product of DNA) and proteins. We would like to use some of the latest laboratory methods which can target individual molecules (parts of the cell) allowing us to understand which of them are the most important and what effect modifying them has on the egg or embryo's function.

The study may include analysis of the egg and embryo genetic material to understand whether the expected numbers of chromosomes are present, to show whether there are

any chromosomal rearrangements (genetic variations) and to understand how the chromosomes are organised. As each egg, sperm and embryo is distinct, and most embryos include cells that have differing genetic material, this would not have any relevance to your own or your children's health. We may also introduce specific chemicals into sperm, eggs and embryos to make key markers visible under the microscope, or to alter their function. In some eggs and embryos, techniques to remove particular proteins or alter sections of the genetic material will help us to understand how eggs and embryos develop without them. In all cases, embryos will only be studied for a maximum of 14 days and usually much less.

These methods allow us to target key genes, chromosomes and molecules and track subsequent events, for example, using imaging. This will tell us, for example, whether certain specialised molecules are behaving normally inside the eggs and embryos and which molecules are the most important.

We hope that in future, it may be possible to test embryos for features that reflect 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 and to develop new educational resources.

What will happen to the results of the research study?

We aim to make the findings available as widely as possible. The results will be published in medical journals and presented at conferences, but you would not be identified in any publication. The information that we gain will be of no use to you personally and will not provide any information about your or your embryos' health so we do not plan to tell you about it. If you would like a copy of the final publication, please contact 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 lead to financial benefit in the future, for some of the researchers if they create something of value.

Why have I been chosen?

You are currently either a sperm donor or you are a patient considering or undergoing fertility treatment. We would like to ask if you would be willing to let us use some of your sperm for our research.

If you are undergoing treatment, providing sperm to research would not affect your treatment at all as we would only use any that would normally be discarded.

If you are a sperm donor, if possible, we would use the same sperm samples that you provide for donation so you would not normally be asked to provide any extra samples. We would only use your sperm in research if you agree and sign your consent on the form.

If you agree, we would like to use your sperm to try to fertilise eggs that have been donated for research use, in order to make embryos for use in research. We would keep a stock

of your sperm frozen for research use, but it would not be available to you or anyone else for clinical use. Your sperm would be stored in HFEA-licensed premises at the Centre for Reproductive Medicine or Warwick Medical School and would be used for research within the time limits allowed by the HFEA's regulations.

Consenting to the frozen storage of gametes (sperm or eggs) and embryos

This project includes the use of frozen sperm, eggs or embryos. The Human Fertilisation and Embryology law about frozen storage changed in July 2022. This means that we need to ask you for consent to store your sperm or embryos frozen for the purposes of research. There is a special section for this on the consent form.

The information that we need to give you about this is included in the consent form, as required by the Human Fertilisation and Embryology Authority (HFEA). The law requires us to provide you with this information and document your consent in writing.

The legal maximum time for sperm storage is 55 years in total from the date when they were frozen. For embryo storage, the maximum time is 10 years from the date of consent to storage specifically for use in research. If you wish to consent to a shorter time, please write your preferred amount of time on the consent form.

We will only be able to use your sperm or embryos in research if you also consent to frozen storage for research purposes.

None of the sperm, or embryos derived from your sperm, would ever be used to treat anyone else or to make a pregnancy. Please note that eggs or embryos in a non-viable state may be taken to other research centres for study, such as the Universities of Edinburgh, Cambridge, London or Nottingham. 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 are coded so that your personal details would only be accessible under strictly controlled conditions and then only to NHS Trust personnel who are already authorised to access your medical records.

Do I have to take part?

Participation is entirely voluntary and your decision about this will not affect any aspect of your treatment or its outcome. You can also choose to withdraw your participation at any time, without giving a reason by contacting a member of the research team. Further details about withdrawing from the study are provided later on in this document.

What would taking part involve?

Any treatment that you are undertaking will proceed in exactly the same way, whether or not you choose to take part. However, if you choose to participate, the embryologists in the laboratory will identify your sample and store it for research use under a unique code number. Your sample would then be made available to researchers working on this project.

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. You are welcome to consult the counsellor if you wish. If you wish to take part, please complete and sign the consent form.

What are the possible benefits and risks of taking part in this study?

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 or having problems with miscarriages.

What are the possible disadvantages, side effects or risks, of taking part in this study?

There are no disadvantages, side effects or risks of this study over and above those of any treatment that you are already undergoing.

Expenses and payments

There are no expenses or payments provided for participation in this study.

What happens when the research study stops?

At the end of this study, any sperm and embryos that have been used for research are normally disposed of. However, if you agree, it may be 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 would you 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 the Research Ethics Committee.

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 using a non-identifying code. Please note that such non-identifying information may be stored on a computer database.

What will happen to the data collected about me?

We are committed to protecting the rights of individuals in line with data protection legislation. Publicly-funded organisations have to ensure that it is in the public interest to use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, such as this, we will use your data in the ways needed to conduct and analyse the research study.

For this study, your personal identifying details will only be accessible to NHS Trust personnel who are already authorised to access your medical records and your NHS

Trust will act as the data controller for the identifiable data involved in this study. However, the University of Warwick, as co-sponsor of this project, requires access to the non-identifying data for auditing to ensure that the research has been conducted properly.

Research data will be **pseudonymised** as quickly as possible after data collection. This means all direct and indirect identifiers will be removed from the research data and will be replaced with a participant number. The key to identification will be stored separately and securely to the research data to safeguard your identity. For this study, UHCW NHS Trust will hold personally identifiable data and will provide the University of Warwick with non-identifiable data only.

In the event that you participate in the study, it will not be possible to withdraw your data once your sperm has been used in the research programme.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. The University of Warwick has in place policies and procedures to keep your data safe.

Your material and data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

For further information, about the University of Warwick's data procedures, please refer to the University of Warwick Research Privacy Notice which is available here: <https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice> or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?

Your participation is entirely voluntary. You may withdraw participation from the study at any time and without giving a reason. Such withdrawal will not affect your treatment or legal rights in any way. If you wish to withdraw from participation, please contact any member of the clinic staff or write to the Chief Investigator whose details are above. Withdrawal will mean that no further use will be made of your sperm in research and any remaining sperm samples will be disposed of.

If you also wish to withdraw your data from the study, this is a separate process. Please write to the Chief Investigator to request withdrawal of your data. This can only be done if your sperm has not already been used in research.

Who has reviewed the study?

This study has been approved by Coventry and Warwickshire NHS Research Ethics Committee (04/Q2802/26) and the Human Fertilisation and Embryology Authority (R0155).

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. Please contact Professor Geraldine Hartshorne as the Chief Investigator of this project and Person Responsible to the HFEA for the research, if you wish to discuss any problems.

If you remain concerned, please contact 'PALS', the Patient Advice and Liaison Service at University Hospitals Coventry and Warwickshire NHS Trust. PALS can be reached at feedback@uhcw.nhs.uk, or by writing to PALS at UHCW, using the address at the top of this information sheet.

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 above. In addition, you are also welcome to contact the Human Fertilisation and Embryology Authority which regulates research such as this. Their address is: 10 Spring Gardens, London, SW1A 2BU.

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 024 76 575733

Who should I contact if I want further information?

If you would like to take part, please complete the consent form. You will be given the information sheet and a copy of the signed consent form to keep.

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

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

You are also very welcome to contact the centre's independent counsellor for any reason. Making decisions about the use, donation or disposal of eggs or embryos can be difficult.

The counsellor is experienced in helping people with various queries and personal questions. She can be contacted directly on telephone number 02476968886.

Thank you for taking the time to read this participant information leaflet.

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.