**A trial of egg recovery rates for IVF using a collection chamber that provides environmental control: Eggcell Trial.**

**Participant Information Sheet**

**Version 2.0, 05/01/17**

**Invitation**

You are being invited to take part in a research study. Please read the following information to help you decide if you want to take part. We would like you to understand why we are doing this research and what it means for you. You do not need to make a decision straight away, so please feel free to talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you want to know more.

Please remember that you do not have to take part and your normal healthcare will not be affected in any way, whatever you decide.

**Part 1**

**What is the purpose of this study?**

We have developed a new device (Eggcell) for use during the egg collection procedure. Currently the fluid that is taken from the ovary during egg collection goes into a test tube and can be exposed to the air. The new device is an airtight container that is filled with fluid so that the eggs never come in contact with the air. We hope that this will keep the eggs more protected. We need to do this study to test this new method and we will measure the number of eggs recovered using both methods.

**What would taking part involve?**

We are asking if you would be willing to be randomly allocated to have your eggs collected using the standard test tube method or using the Eggcell method. You will be told which method you have been randomised to receive if you wish to be given this information. We would also like to collect information from your medical notes about your treatment and its outcome. If you are happy to participate in this research, you will need to sign a consent form.

**What are the possible benefits of taking part?**

There is no evidence at present that there will be any benefit from participation in the study. It might improve the potential of the eggs to be fertilised but we do not have any evidence about this yet. Initially we want to confirm that the number of eggs collected is not reduced using Eggcell.

**What are the possible risks of taking part?**

The aim of the study is to assess the egg recovery rate. Our initial study in research patients indicated that the number of eggs collected will not be reduced or damaged. We need to confirm this in this larger clinical study but, until then, there remains a very small risk that the number of eggs collected may be reduced.

To minimise the risk that this will affect your chance of pregnancy, we will only include you in the study if you grow 10-20 follicles (larger than 16mm in diameter) before the egg collection.

**What will happen to me if I take part?**

When you have your final scan we will count the number of follicles in your ovary. If you have 10-20 follicles you will be asked if you want to join the study. If you agree you will sign the consent form and will then be randomly allocated to have the eggs collected using the standard test tube or Eggcell method.

We would also like to collect information from your medical notes about your medical and fertility history and to record the outcome of your fertility treatment.

**Will participating in research affect our treatment?**

Apart from the egg collection method, your treatment will not be affected by the study both before and after the egg collection. The method of fertilising the egg and looking after any embryos will be as normal.

**What will happen if I don't want to carry on with the study?**

You may withdraw from the study at any time without giving a reason. If you decide to withdraw after the procedure we would not collect any further information about you from your medical notes. However, we would like to use the information previously provided. If you decide that you don’t want this information used in the study please contact a member of the study team so it can be removed.

**Will I be paid for taking part?**

As this will part of your routine clinic visit you travel expenses will not be reimbursed and you will not be paid for taking part in this study.

**Part 2**

**Will my GP be told about my involvement in this study?**

If you decide to take part in this study and consent to have your GP informed then we will inform your GP. Your participation in the study will also be noted in your medical records.

**Will my taking part in research be kept confidential?**

All personal details will be kept confidential. The study data in your medical notes will be looked at by people directly involved in the study, as well as by people who are monitoring and auditing the study to make sure the study is being run correctly. This may include the Newcastle Clinical Trials Unit, the Human Fertilisation and Embryology Authority (HFEA), the Medicines and Healthcare products Regulatory Agency (MHRA) or the NHS department who manage research in your Trust.

**What will happen to the results of the research study?**

Whenever possible we will publish the results of our studies in scientific journals. We also plan to present data at scientific conferences. You will not be named in any publication or presentation of the study results. We would also like to send you a newsletter with a summary of our results. Please let the research team know if you want to receive the newsletter.

**Who is organising and funding the research?**

This study is funded by a National Institute for Health Research (NIHR) i4i Development Award. The study is sponsored and indemnified by the Newcastle Upon Tyne NHS Foundation Trust and Newcastle University. The Newcastle Clinical Trials Unit is managing the study.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a NHS Research Ethics Committee (REC). This is to protect your interests. This study has been reviewed and given a favourable opinion by Newcastle and North Tyneside Research Ethics Committee and been approved by the NHS Health Research Authority (HRA). The study has also been given a notice of no objection by the Medicines and Healthcare products Regulatory Agency (MHRA).

Research in the fertility field is regulated by the Human Fertilisation and Embryology Authority (HFEA). Information about this organisation can be found on [www.HFEA.gov.uk](http://www.HFEA.gov.uk). This work is covered under the HFEA Treatment License 0017.

**What if relevant new information becomes available?**

The study team will ensure the patients are receiving the most appropriate and up to date medical care they require.

**What if something goes wrong?**

If you have a concern about any aspect of the study please contact your local doctor (see contact details below). Alternatively you can contact one of the researchers running this study, Nilendran Prathalingam (0191 2138213) and Professor Alison Murdoch (0191 213 8213) to discuss your concerns.

**Your local contact people for the study are:**

Contact details of local Research Nurse:

Name:

Address:

Phone:

Email:

Contact Details of local PI:

Name:

Address:

Phone:

Email:

If you are still unhappy and wish to complain formally and confidentially you can do this through the NHS complaints procedure by speaking to a member of the PALS (Patient Advise and Liaison Service) on 0800 0320 202 or by visiting [www.PALS.nhs.uk](http://www.PALS.nhs.uk).

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.

**How have patients and the public been involved in this study?**

We carried out interviews with five individuals who were undertaking IVF treatment at the Newcastle clinic to understand their views about the IVF process and their embryos.

We have set up a patient focus groups made up of patients that are not participating in the study. Both male and female partners were recruited. These groups have helped to design the study and study documents.

The group will meet when the trial is near completion to have input into the interpretation of the results. Their views of Eggcell on egg and embryo quality will be evaluated. This will inform the publication of results. Patient views about the dissemination of results and ethical marketing of Eggcell will be discussed.

**Thank you for taking time to read this information sheet**