PATIENT INFORMATION SHEET

ENDOMETRIAL SCRATCH TRIAL.

A Multicentre Randomised Controlled Trial of Induced Endometrial Scratch in Women Undergoing First Time in Vitro Fertilisation (IVF)

Protocol Number:	*V7 (28/01/2019)*
ISRCTN Number:	ISRCTN23800982
Sponsor:	Sheffield Teaching Hospitals NHS Foundation Trust Clinical Research Office Sheffield Royal Hallamshire Hospital D Floor Glossop Road Sheffield. S10 2JF
Chief Investigator:	Mostafa Metwally

Local Principal Investigator: Dr Sarah Martins Da Silva
Consultant Gynaecologist and Honorary Senior Lecturer
Medical Research Institute
Level 5
Ninewells Hospital and Medical School
Dundee
DD1 9SY

[insert contact details]

Introduction

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

What is our research about?

Taking a small amount of tissue from the lining of the womb (endometrium) can sometimes improve the chance of achieving a pregnancy in women who have previously had several unsuccessful attempts at In Vitro Fertilisation (IVF) or Intra-cytoplasmic sperm injection (ICSI). This procedure has been named “Endometrial Scratch” (ES). It is not known exactly why performing an Endometrial Scratch may be beneficial, but it is thought that the process of “scratching” the lining of the womb may release certain chemicals that are important in helping the fertilised egg (embryo) stick to the lining of the womb (implantation).

The use of Endometrial Scratch has not yet been fully tested in women who are about to have IVF/ICSI for the first time, but similar trials have used the same technique in women undergoing IVF/ICSI for the second or subsequent time, with beneficial results. If found to be beneficial then it could be used to improve the chance of achieving a pregnancy for a large group of women without the need for repeated IVF attempts.

Why have I been chosen and what are the possible benefits?

You have been invited to take part in this trial because you are having In Vitro Fertilisation (IVF) or Intra-cytoplasmic sperm injection (ICSI) for the first time. Taking part in this trial may or may not improve your chances of achieving a pregnancy. However, information from this trial may help doctors understand if there is any benefit to offering this procedure to women having first time IVF/ICSI on achieving a pregnancy in the future.

The trial plans to recruit a total of 1044 women over 2½ years having either IVF or ICSI for the first time across approximately 13 IVF units in the UK. Half of the women will receive the Endometrial Scratch procedure and half will not.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you withdraw from the trial, information already collected about you may be included in the final analysis after being anonymised. In the unlikely event of a loss of capacity, the research team will retain the data already collected about you and continue to use it confidentially in connection with the purposes of the research.

What will happen to me if I take part?

Women taking part in the trial will be randomly allocated by a computer to have either the Endometrial Scratch procedure or not. If you decide to take part this means that neither you nor your doctors can decide which treatment you will receive. There is an equal chance of being placed in either treatment group.
Those having the Endometrial Scratch will be known as the "Intervention group" and those who do not the "control group".

If you are randomised to have the Endometrial Scratch then you will require one additional visit to your IVF clinic to have the procedure performed. The procedure will be performed at a certain stage of your menstrual cycle, before you start IVF treatment.

Performing the Endometrial Scratch is a very simple routine outpatient procedure that does not require any anaesthetic. Women are advised to take simple painkillers beforehand such as paracetamol as this should lessen the chance of any discomfort as the procedure can sometimes cause period like cramps.

The procedure involves placing a small tube (about the size of a small drinking straw) through the neck of the womb and then the lining of the uterus (the endometrium) is gently 'scratched'. Performing the Endometrial Scratch has no clear risks although, in theory, inserting any instrument into the womb could carry a risk of infection. However all women having IVF are routinely screened for important vaginal infections before starting their IVF treatment.
The Endometrial Scratch procedure is performed about a week before starting IVF/ICSI treatment.

After the Endometrial Scratch procedure you will be able to leave the unit as soon as you are comfortable. Some women may feel discomfort after the procedure, so we recommend that you stay in the clinic until you feel well enough to leave. You will then be able to carry on with your IVF/ICSI treatment as usual.

If you are randomised to not have the Endometrial Scratch then you will receive no additional treatment and will continue with your IVF/ICSI treatment in the usual way.

Regardless of which group you are in, you will be followed up to see whether or not you get pregnant and have a healthy baby. If you achieve a pregnancy following your first IVF cycle, you will be contacted at three time points (approximately 3- and 6- months after your eggs are collected and then 6 weeks after delivery). You will also receive questionnaires at two time points (3 months into pregnancy and 6 weeks after delivery) which will ask you about your health and well-being and if you have attended hospital or visited you GP. If your eggs

are not transferred as part of your usual routine IVF treatment the Research Nurse or another member of the clinical research team will telephone you approximately two weeks after egg collection to find out how you are. Other than this, if you do not achieve a pregnancy following your first IVF cycle we will not send you any questionnaires or continue to follow you up.

Except for one extra visit when the scratch is performed, the study does not involve any other visits or treatments above normal routine care. Participation in this trial will be entirely voluntary and the choice not to participate would not have any impact on your care.

What are the side effects to having an endometrial scratch?
Taking a sample from the lining of the womb can sometimes cause period like cramps. You may also experience some spotting after the procedure. We suggest that you take simple painkillers like paracetamol before the procedure to reduce discomfort. There is also a potential risk of infection; however since you will have already been screened as part of your routine care for any relevant infection prior to commencing your IVF treatment, this risk of infection is very small.

What if new information becomes available?
If new information becomes available or known that might affect your choice to stay in the trial, we will tell you about it and discuss with you whether you want to continue.

If you decide to withdraw we will make arrangements for your care to continue. If you decide to continue in the trial you will be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the trial. He/she will explain the reasons and arrange for your care to continue.

Involvement of the GP
Your GP will be notified of your involvement in this trial if you give permission to do so.

Will my taking part in this study be kept confidential?
All the information collected in the Endometrial Scratch trial will be handled strictly in accordance with your consent and the Data Protection Act 1998. You will not be identified in any published results of the trial.

Sheffield Teaching Hospitals NHS Foundation Trust (STH) is the sponsor for this study, is based in the United Kingdom, and will act as the data controller for this study. The day to day running of the study is delegated to the Clinical Trials Research Unit (CTRU) in the School of Health and Related Research at The University of Sheffield. Together STH and CTRU will be using information from

you and your medical records in order to undertake this study. This means that we are responsible for looking after your information and using it properly. The University of Sheffield will keep paper copies of identifiable information about you for 5 years after the study has finished and securely store electronic data for a minimum of 10 years.

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. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information here: https://www.sheffieldclinicalresearch.org/for-patients-public/how-is-your-information-handled-in-research/

Ninewells Hospital, Dundee and the CTRU will keep your name and contact details confidential and will not pass this information to STH. Ninewells Hospital, Dundee and the CTRU will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from STH, CTRU and regulatory organisations may look at your medical and research records to check the accuracy of the research study. STH will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Ninewells Hospital, Dundee will keep identifiable information about you from this study for 15 years after the study has finished.

What will happen to the results of the research study?
We will publish the results of this trial and you will not be identified in any report or publication. If you would like a copy of the research report we will send this to you.

Who is sponsoring and funding the research?
This study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) and sponsored by Sheffield Teaching Hospitals NHS foundation Trust.

It is organised, managed and coordinated by the University of Sheffield, and data will be collected and stored by this institution.

Additionally, the trial will be supervised on a regular basis by a Data Monitoring Committee (DMC) and a Trial Steering Committee (TSC). The primary function of the DMC is to ensure the absolute safety of all participants in the project.

Who has reviewed the study?
Research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This trial has been reviewed and given a favourable opinion by the National Research Ethics Committee in South Central – Berkshire.

The trial has also been reviewed by the Reproductive Health Research Public Advisory Panel at the Jessop Wing, Sheffield. This is a lay group of members whose main purpose is to ensure that research carried out within the Directorate is patient focused. The role of the panel is to give a lay perspective on the research that is being carried out within Obstetrics, Gynaecology & Neonatology.

What if I wish to complain about the way in which this trial has been conducted?
Complaints
If you have a concern about any aspect of this trial you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure, by contacting the Patient Liaison Service (PALs).

[insert contact details]

Harm
We do not expect any harm to come to you by taking part in this trial. The endometrial scratch technique is already being used in the NHS. Your participation in this trial is therefore to help us find out if performing this procedure in women having IVF/ICSI for the first time increases the chances of a pregnancy and should not involve any additional risk to you.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Further information and contact details
You may freely ask questions about this information sheet or the trial now or at any time during the trial. If you experience any side effects, or if you have any questions about this research during this trial you may contact:

Dr Sarah Martins da Silva
Consultant Gynaecologist and Honorary Senior Lecturer
Medical Research Institute
Level 5
Ninewells Hospital and Medical School
Dundee
DD1 9SY

[insert contact details]

The trial website contains information that may be helpful, including a video that explains what taking part in the trial involves. The website is located at www.shef.ac.uk/scratchtrial/patients.

If you agree to participate in this study, you will receive a signed and dated copy of the consent form and this patient information sheet for your records.

Whether or not you wish to participate in our study, we would like to thank you for taking the time to read the information sheet.

PATIENT INFORMATION SHEET (*Sheffield and Southampton Only*)

ENDOMETRIAL SCRATCH TRIAL

A Multicentre Randomised Controlled Trial of Induced Endometrial Scratch in Women Undergoing First Time in Vitro Fertilisation (IVF)

Protocol Number:	V5 (20/07/2017)
ISRCTN Number:	ISRCTN23800982
Sponsor:	Sheffield Teaching Hospitals NHS Foundation Trust Clinical Research Office Sheffield Royal Hallamshire Hospital D Floor Glossop Road Sheffield. S10 2JF
Chief Investigator:	Mostafa Metwally
Local Principal Investigator:	Vidya Tamhankar
Address:	Jessop Fertility The Jessop Wing Tree Root Walk Sheffield S10 2SF
Contact details:	[insert contact details]

Introduction

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

What is our research about?

Taking a small amount of tissue from the lining of the womb (endometrium) can sometimes improve the chance of achieving a pregnancy in women who have previously had several unsuccessful attempts at In Vitro Fertilisation (IVF) or Intra-cytoplasmic sperm injection (ICSI). This procedure has been named “Endometrial Scratch” (ES). It is not known exactly why performing an Endometrial Scratch may

be beneficial, but it is thought that the process of “scratching” the lining of the womb may release certain chemicals that are important in helping the fertilised egg (embryo) stick to the lining of the womb (implantation).
The use of Endometrial Scratch has not yet been fully tested in women who are about to have IVF/ICSI for the first time but similar trials have used the same technique in women undergoing IVF/ICSI for the second or subsequent time, with beneficial results. If found to be beneficial then it could be used to improve the chance of achieving a pregnancy for a large group of women without the need for repeated IVF attempts.

Why have I been chosen and what are the possible benefits?
You have been invited to take part in this trial because you are having In Vitro Fertilisation (IVF) or Intra-cytoplasmic sperm injection (ICSI) for the first time. Taking part in this trial may or may not improve your chances of achieving a pregnancy. However, information from this trial may help doctors understand if there is any benefit to offering this procedure to women having first time IVF/ICSI on achieving a pregnancy in the future.

The trial plans to recruit a total of 1044 women over 2½ years having either IVF or ICSI for the first time across approximately 13 IVF units in the UK. Half of the women will receive the Endometrial Scratch procedure and half will not.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.
A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you withdraw from the trial, information already collected about you may be included in the final analysis after being anonymised. In the unlikely event of a loss of capacity, the research team will retain the data already collected about you and continue to use it confidentially in connection with the purposes of the research.

What will happen to me if I take part?
Women taking part in the trial will be randomly allocated by a computer to have either the Endometrial Scratch procedure or not. If you decide to take part this means that neither you nor your doctors can decide which treatment you will receive. There is an equal chance of being placed in either treatment group.
Those having the Endometrial Scratch will be known as the “Intervention group” and those who do not the “control group”.
If you are randomised to have the Endometrial Scratch then you will require one additional visit to your IVF clinic to have the procedure performed. The procedure

will be performed at a certain stage of your menstrual cycle, before you start your IVF treatment.

The Endometrial scratch procedure involves placing a small tube (about the size of a small drinking straw) through the neck of the womb and then the lining of the uterus (the endometrium) is gently 'scratched'. Performing the Endometrial Scratch has no clear risks although, in theory, inserting any instrument into the womb could carry a risk of infection. However all women having IVF are routinely screened for important vaginal infections before starting their IVF treatment.
The Endometrial Scratch procedure is performed about a week before starting IVF/ICSI treatment.

We will also ask you if you would like to participate in a sub-study where your consent will be sought to remove a small amount of tissue from the lining of your womb at the same time as performing the Endometrial Scratch procedure. This tissue will be stored in a way in which you will not be identifiable and later examined in the laboratory which could provide helpful information to tell us why some women may respond better than others to the scratch procedure. The tissue will be stored for up to 10 years at Sheffield Hallam University and will be used for future related research after which it will be disposed of in a secure manner. Professor Susan Laird of Sheffield Hallam University will be the custodians of the samples. The sample and custody of it may be transferred to another individual/institution either in the UK or abroad at a later date if appropriate for analysis to take place.

If you consent to participate in this study and you are randomised to receive the Endometrial Scratch procedure you will be provided with an ovulation kit and asked to contact your fertility unit when the test is positive. Your research nurse will show you how to use the kit. The ovulation kit is not required if you don't participate in the sub-study or are randomised to the control arm.

After the Endometrial Scratch procedure you will be able to leave the unit as soon as you are comfortable. Some women may feel discomfort after the procedure, so we recommend that you stay in the clinic until you feel well enough to leave. You will then be able to carry on with your IVF/ICSI treatment as usual.

If you are randomised to not have the Endometrial Scratch then you will receive no additional treatment and we will not be collecting the tissue from the lining of your womb as mentioned above. You will continue with your IVF/ICSI treatment in the usual way.

Regardless of which group you are in, you will be followed up to see whether or not you get pregnant and have a healthy baby. If you achieve a pregnancy following your first IVF cycle, you will be contacted at three time points

(approximately 3 and, 6 months after your eggs are collected- and then 6 weeks after delivery). You will also receive questionnaires at two time points (3 months into pregnancy and 6 weeks after delivery) which will ask you about your health and well-being and if you have attended hospital or visited your GP. If your eggs are not transferred as part of your usual routine IVF treatment the Research Nurse or another member of the clinical research team will telephone you approximately two weeks after egg collection to find out how you are. Other than this, if you do not achieve a pregnancy following your first IVF cycle we will not send you any questionnaires or continue to follow you up.

Except for one extra visit when the scratch is performed, the study does not involve any other visits or treatments above normal routine care. Participation in this trial will be entirely voluntary and the choice not to participate would not have any impact on your care.

What are the side effects to having an endometrial scratch?

Taking a sample from the lining of the womb can sometimes cause period like cramps. You may also experience some spotting after the procedure. We suggest that you take simple painkillers like paracetamol before the procedure to reduce discomfort. There is also a potential risk of infection; however since you will have already been screened as part of your routine care for any relevant infection prior to commencing your IVF treatment, this risk of infection is very small.

What if new information becomes available?

If new information becomes available or known that might affect your choice to stay in the trial, we will tell you about it and discuss with you whether you want to continue.

If you decide to withdraw we will make arrangements for your care to continue. If you decide to continue in the trial you will be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the trial. He/she will explain the reasons and arrange for your care to continue.

Involvement of the GP

Your GP will be notified of your involvement in this trial if you give permission to do so.

Will my taking part in this study be kept confidential?

All the information collected in the Endometrial Scratch trial will be handled strictly in accordance with your consent and the Data Protection Act 1998. If you decide to participate in the project, your fertility team will send the data we collect about you during the study to the trial organisers at the University of Sheffield. All the information will be held securely and in strictest confidence, and used only for research purposes. You will not be identified in any published results of the trial.

Occasionally, inspections of clinical study data are undertaken by statutory regulators, to verify the quality of the research. But otherwise, only authorised members of the research team will have access to any information collected from you. At the end of the study your data will be archived in accordance with Research Governance Framework guidelines and the NHS Trust policy of your participating centre. Any information about you will have your name and address removed so that you cannot be recognised.

What will happen to the results of the research study?
We will publish the results of this trial and you will not be identified in any report or publication. If you would like a copy of the research report we will send this to you.

Who is sponsoring and funding the research?
This study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) and sponsored by Sheffield Teaching Hospitals NHS foundation Trust.
It is organised, managed and coordinated by the University of Sheffield, and data will be collected and stored by this institution.
Additionally, the trial will be supervised on a regular basis by a Data Monitoring Committee (DMC) and a Trial Steering Committee (TSC). The primary function of the DMC is to ensure the absolute safety of all participants in the project.

Who has reviewed the study?
Research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This trial has been reviewed and given a favourable opinion by the National Research Ethics Committee in South Central-Berkshire.
The trial has also been reviewed by the Reproductive Health Research Public Advisory Panel at the Jessop Wing, Sheffield. This is a lay group of members whose main purpose is to ensure that research carried out within the Directorate is patient focused. The role of the panel is to give a lay perspective on the research that is being carried out within Obstetrics, Gynaecology & Neonatology.

What if I wish to complain about the way in which this trial has been conducted?
Complaints
If you have a concern about any aspect of this trial you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure, by contacting the Patient Liaison Service (PALs)

Patient Partnership Department on B Floor, Royal Hallamshire Hospital, telephone on 0114 271 2400, via email on PST@sth.nhs.uk

Harm
We do not expect any harm to come to you by taking part in this trial. The endometrial scratch technique is already being used in the NHS. Your participation in this trial is therefore to help us find out if performing this procedure in women having IVF/ICSI for the first time increases the chances of a pregnancy and should not involve any additional risk to you.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Further information and contact details
You may freely ask questions about this information sheet or the trial now or at any time during the trial. If you experience any side effects, or if you have any questions about this research during this trial you may contact:

[insert contact details]

The trial website contains information that may be helpful, including a video that explains what taking part in the trial involves. The website is located at www.shef.ac.uk/scratchtrial/patients.

If you agree to participate in this study, you will receive a signed and dated copy of the consent form and this patient information sheet for your records.

Whether or not you wish to participate in our study, we would like to thank you for taking the time to read the information sheet.

Participant Information Sheet

Endometrial Scratch Trial Participant Interviews

Invitation

We would like to invite you to participate in an interview about your involvement in the Endometrial Scratch Trial, which was a randomised trial that assessed the effectiveness of the endometrial scratch procedure prior to IVF/ICSI. Before you decide whether you want to take part, we need you to understand what the research is for and what you would be expected to do. Please read the following information carefully. If you do not understand anything or have any questions, please contact us. Please take time to decide whether you wish to take part.

What is the study about?

This extra component of the study aims to find out [any reasons behind why individuals allocated to receive the endometrial scratch did not receive it/your thoughts about the endometrial scratch procedure that you received, and DELETE AS APPROPRAITE/DELETE IF NOT APPLICABLE] your perspective of the recruitment procedures and questionnaires/text messages used during the study.

Why have I been invited?

You have been invited to participate as you were involved in the main trial to find out the effectiveness of the endometrial scratch procedure prior to IVF/ICSI and therefore are able to answer questions about your participation. Also, you consented to being contacted about further studies involving this trial.

Do I have to take part?

No. It is up to you to decide whether you would like to take part in this extra interview. If you decide to take part you are still free to withdraw at any time without giving a reason. Your future care will not be affected if you choose not to take part. If you withdraw during the course of the study any data we've collected from you will be retained and may be used for reports and publications.

How do I give my permission to take part in the study?

If you agree to take part after reading this information sheet, we will arrange with you a time to either meet with you in person to undertake the interview or to undertake the interview over the telephone. Before the interview you will be asked to sign a consent form, or we may ask you to confirm your

consent over the phone, which will be audio recorded and kept separately to your interview recording. The consent form is a form you sign to say that you understand why the study is being done, that you understand what you are expected to do and what the researchers will do with the information they will collect. If you change your mind between arranging the interview and the interview itself, you are free to withdraw from the interview – just use the contact details below to inform us.

Who will see the information that I give to you?

The information we will collect from you will be seen by a number of different people and organisations. These are listed below:

The Research Team

The information you give us and any data collected will be seen by authorised individuals from the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust.

Other individuals

Quotes from the interview may be published in academic journals or other printed materials (for example, leaflets), but we will ensure that you cannot be identified in any way.

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

If you agree to take part in the study, you will be invited to undertake the interview either face to face, Skype or Facetime, or over the telephone. If face to face, we will arrange a time and place that is convenient for you to undertake the interview. Prior to the interview the researcher will remind you about what will be involved, and ask you to complete a consent form (either using the paper form or over the telephone). The interview itself will last approximately twenty minutes. The researcher will ask you questions about [the reasons behind you not receiving the endometrial scratch procedure/your thoughts of the endometrial scratch procedure, and DELETE IF NOT APPLICABLE] the trial recruitment process and your thoughts about the trial questionnaires and text messages. The interview will be audio recorded.

Are there any expenses or payments involved?

At the end of the interview you will receive a £20 shopping voucher. If your interview is undertaken over the phone, this will be posted to you after the interview.

Will my taking part in the study be kept confidential?

Yes. All information about you will be handled in confidence. The information you give us will be 'anonymised'; this means that we won't use any recognisable information such as your name or any other personal information in reports or publications. Identifiable data collected for the study will only be looked at by authorised persons from the research team; the information you provide during the interview will not be shared with your Fertility Unit/Team.

What if there is a problem?

If you have any cause to complain about how you have been approached or treated during this study you can contact either the Trial Manager *Robin Chatters*, in Sheffield on (0114) 222 2969 or, you can use PALS (Patient Advice and Liaison Service) at Sheffield Teaching Hospitals NHS Foundation Trust.

[insert PALs contact details]

You will not be compromised in any way because you have taken part in a research study.

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

There are no risks to taking part in this extra component of the study.

What will happen to the results of the study?

[The results will be used to inform how the endometrial scratch procedure is undertaken in practice] DELETE IF NOT ASKING ABOUT THIS. Information you provide regarding the trial procedures (recruitment and questionnaires/text messages) will be used to inform future studies, to ensure recruitment to studies and the collection of data are undertaken in ways that are acceptable to participants. Results will be presented at appropriate conferences and published as reports in scientific journals. You will not be identified in any presentation, report or publication. You will be able to access the results of the study on the University of Sheffield website at: *www.shef.ac.uk/scratchtrial*.

Who is organising and funding the study?

The study is organised by the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust. The study has been funded by the Health Technology Assessment (HTA) programme, which is administered by the National Institute for Health Research (NIHR).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by South Berkshire Research Ethics Committee.

Will my taking part in this study be kept confidential?

Sheffield Teaching Hospitals NHS Foundation Trust (STH) is the sponsor for this study, is based in the United Kingdom, and will act as the data controller for this study. The day to day running of the study is delegated to the Clinical Trials Research Unit (CTRU) in the School of Health and Related Research at The University of Sheffield. Together STH and CTRU will be using information from you and your medical records in order to undertake this study. This means that we are responsible for looking after your information and using it properly. The University of Sheffield will keep paper copies of

identifiable information about you for 5 years after the study has finished and securely store electronic data for a minimum of 10 years.

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. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information here: https://www.sheffieldclinicalresearch.org/for-patients-public/how-is-your-information-handled-in-research/

[site name] and the CTRU will keep your name and contact details (add other identifiers) confidential and will not pass this information to STH. [site name] and the CTRU will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from STH, CTRU and regulatory organisations may look at your medical and research records to check the accuracy of the research study. STH will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

[site name] will keep identifiable information about you from this study for 15 years after the study has finished.

Contacts for further information:

You can contact the Endometrial Scratch research team using any of the following methods:

☎ Tel: [telephone number of researcher] Calls and answerphone messages will be monitored between [times/days researcher is in office]

[email address]. Emails will be monitored between [times/days researcher is in office]

Robin Chatters, Clinical Trials Unit, c/o ScHARR, The University of Sheffield, Regent Street, Sheffield, S1 4DA

This information sheet is for you to keep.

Thank you for your time and help.

Participant Information Sheet

Endometrial Scratch Trial - Staff Interviews

Invitation

We would like to invite you to participate in an interview about the Endometrial Scratch Trial, which was a randomised trial that assessed the effectiveness of the endometrial scratch procedure prior to IVF/ICSI. Before you decide whether you want to take part, we need you to understand what the research is for and what you would be expected to do. Please read the following information carefully. If you do not understand anything or have any questions, please contact us. Please take time to decide whether you wish to take part.

What is the study about?

This extra component of the study aims to find out your perspective of the trial screening and recruitment procedures.

Why have I been invited?

You have been identified as you were involved in recruiting and managing patients in the main trial.

Do I have to take part?

No. It is up to you to decide whether you would like to take part in this interview. If you decide to take part you are still free to withdraw at any time without giving a reason. Your future care will not be affected if you choose not to take part. If you withdraw during the course of the study any data collected from you will be retained and may be used for reports and publications.

How do I give my permission to take part in the study?

If you agree to take part after reading this information sheet, we will arrange with you a mutually convenient time to visit you or contact you by telephone to undertake the interview. Before the interview, you will be asked to sign (or audibly agree, if the interview is undertaken over the telephone) a 'Consent Form'. This is a form you sign to say that you understand why the study is being done, that you understand what you are expected to do and what the researchers will do with the information they collect. If you change your mind between arranging the interview and the interview itself, you are free to withdraw from the interview – just use the contact details below to inform us.

Who will see the information that I give to you?

The information we will collect from you will be seen by a number of different people and organisations. These are listed below:

The Research Team

The information you give us and any data collected will be seen by authorised individuals from the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust.

Other individuals

Quotes from the interview may be published in academic journals or other printed materials (for example, leaflets), but we will ensure that you cannot be identified in any way.

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

If you agree to take part we will arrange a convenient time to undertake the interview either face to face or over the telephone. The interview itself will last approximately twenty minutes. The researcher will ask you questions about the trial recruitment process. The interview will be audio recorded.

Are there any expenses or payments involved?

Upon completion of the interview you will receive a £20 voucher to thank you for taking part; this will be posted to you after the interview.

Will my taking part in the study be kept confidential?

Yes. All information about you will be handled in confidence. The information you give us will be 'anonymised'; this means that we won't use any recognisable information such as your name or any other personal information in reports or publications. Identifiable data collected for the study will only be looked at by authorised persons from the research team; the information you provide during the interview will not be shared with your Fertility Unit/Team.

What if there is a problem?

If you have any cause to complain about how you have been approached or treated during this study you can contact either the Trial Manager *Robin Chatters*, in Sheffield on (0114) 222 2969.

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

There are no risks to taking part in this extra component of the study.

What will happen to the results of the study?

Information you provide regarding the trial procedures (recruitment and questionnaires/text messages) will be used to inform future studies, to ensure recruitment to studies and the collection of data are undertaken in ways that are acceptable to participants and NHS staff. Results will be presented at appropriate conferences and published as reports in scientific journals. You will not be identified in any presentation, report or publication. You will be able to access the results of the study on the University of Sheffield website at: *www.shef.ac.uk/scratchtrial*.

Who is organising and funding the study?

The study is organised by the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust. The study has been funded by the Health Technology Assessment (HTA) programme, which is administered by the National Institute for Health Research (NIHR).

Will my taking part in this study be kept confidential?

Sheffield Teaching Hospitals NHS Foundation Trust (STH) is the sponsor for this study, is based in the United Kingdom, and will act as the data controller for this study. The day to day running of the study is delegated to the Clinical Trials Research Unit (CTRU) in the School of Health and Related Research at The University of Sheffield. Together STH and CTRU will be using information from you and your medical records in order to undertake this study. This means that we are responsible for looking after your information and using it properly. The University of Sheffield will keep paper copies of identifiable information about you for 5 years after the study has finished and securely store electronic data for a minimum of 10 years.

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. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information here: https://www.sheffieldclinicalresearch.org/for-patients-public/how-is-your-information-handled-in-research/

[site name] and the CTRU will keep your name and contact details (add other identifiers) confidential and will not pass this information to STH. [site name] and the CTRU will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from STH, CTRU and regulatory organisations may look at your medical and research records to check the accuracy of the research study. STH will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

[site name] will keep identifiable information about you from this study for 15 years after the study has finished.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by South Berkshire Research Ethics Committee.

Contacts for further information:

You can contact the Endometrial Scratch research team using any of the following methods:

- ☎ Tel: [telephone number of researcher] Calls and answerphone messages will be monitored between [times/days researcher is in office]
- [email address]. Emails will be monitored between [times/days researcher is in office]

This information sheet is for you to keep.

Thank you for your time and help.