Research site NHS logo

# CONSENT FORM. ENDOMETRIAL SCRATCH TRIAL

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

Local Principal Investigator: *Insert Local details*

Centre Number/ID

Participant Identification Number:

Please initial:

| | YES | NO |
|---|---|---|
| I confirm that I have read and understand the participant information sheet 20/07/2017 (version 4) for the Endometrial scratch trial and have had the opportunity to ask questions and these have been answered satisfactorily. | | |
| I understand that my participation in the trial is voluntary and I am free to withdraw at any time without my treatment or legal rights being affected. | | |
| I understand that my local research team will provide a copy of my consent form and personal information about my progress, in confidence via email or post, to the study organisers at the University of Sheffield for use in the Endometrial Scratch Trial. | | |
| I understand that the information collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. | | |
| I understand that even if I withdraw from the trial, information already collected about me may be included in the final analysis after being anonymised. | | |
| I understand that relevant sections of my medical notes and data collected during the trial may be looked at by members of the research team (at the University of Sheffield) or the NHS Trust of my participating trial centre, or by individuals from statutory regulators. I give permission for these individuals to have access to my records. | | |
| I understand that information held by the NHS may be used to keep in touch with me and follow up my pregnancy status for the purposes of the trial. | | |

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| I understand that researchers for the Endometrial Scratch trial based at my hospital or at the University of Sheffield will contact me by telephone, mobile telephone, post or e-mail to request information about my pregnancy or my baby's development. | | |
| I understand I may be contacted in the future to give my consent for future studies, and that I may be traced through the NHS databases and GP records ***(voluntary).*** | | |
| I agree to my General Practitioner being informed of my participation in the study. ***(voluntary)*** | | |
| I understand the information that I have been given about the Endometrial Scratch study and I agree to take part. | | |

_____ _____ _____

Name of Participant: Date: Signature:

_____ _____ _____

Name of Person Taking Consent: Date: Signature:

**CONSENT FORM. ENDOMETRIAL SCRATCH TRIAL (Sheffield and Southampton only)**

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

| |
|---|
| Local Principal Investigator: *Insert Local details* |
| Centre Number/ID |
| Participant Identification Number: |

Please initial:

| | YES | NO |
|---|---|---|
| I confirm that I have read and understand the participant information sheet dated 20/07/2017 (version 4) for the Endometrial scratch trial and have had the opportunity to ask questions and these have been answered satisfactorily. | | |
| I understand that my participation in the trial is voluntary and I am free to withdraw at any time without my treatment or legal rights being affected. | | |
| I understand that my local research team will provide a copy of my consent form and personal information about my progress, in confidence via email or post, to the study organisers at the University of Sheffield for use in the Endometrial Scratch Trial. | | |
| I understand that the information collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. | | |
| If randomised to receive the Endometrial Scratch procedure, I understand that the research team will retain a sample of the lining of my womb at Sheffield Hallam University/Southampton University, for a period of 10 years and use it alongside information collected about me for the purposes of future related research. I understand that the sample may be transferred to other institutions in the UK or abroad for analysis. ***(voluntary)*** | | |
| I understand that even if I withdraw from the trial, information already collected about me may be included in the final analysis after being anonymised. | | |
| I understand that relevant sections of my medical notes and data collected during the trial may be looked at by members of the research team (at The University of | | |

| | | |
|---|---|---|
| Sheffield) or the NHS Trust of my participating trial centre, or by individuals from statutory regulators. I give permission for these individuals to have access to my records. | | |
| I understand that information held by the NHS may be used to keep in touch with me and follow up my pregnancy status for the purposes of the trial. | | |
| I understand that researchers for the Endometrial Scratch trial based at my hospital or at the University of Sheffield will contact me by telephone, mobile telephone, post or e-mail to request information about my pregnancy or my baby's development. | | |
| I understand I may be contacted in the future to give my consent for future studies, and that I may be traced through the NHS databases and GP records***. (voluntary)*** | | |
| I agree to my General Practitioner being informed of my participation in the study. ***(voluntary)*** | | |
| I understand the information that I have been given about the Endometrial Scratch study and I agree to take part. | | |

_____ _____ _____

Name of Participant: Date: Signature:

_____ _____ _____

Name of Person Taking Consent: Date: Signature:

**POSTAL CONSENT FORM [DUNDEE Only]. ENDOMETRIAL SCRATCH TRIAL**

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

Local Principal Investigator: *Insert Local details*

Centre Number/ID: 06

Participant Identification Number:

Please initial:

| | YES | NO |
|---|---|---|
| I confirm that I have read and understand the participant information sheet dated 13/11/2017 (version 5) for the Endometrial scratch trial and have had the opportunity to ask questions and these have been answered satisfactorily. | | |
| I understand that my participation in the trial is voluntary and I am free to withdraw at any time without my treatment or legal rights being affected. | | |
| I understand that my local research team will provide a copy of my consent form and personal information about my progress, in confidence via email or post, to the study organisers at the University of Sheffield for use in the Endometrial Scratch Trial. | | |
| I understand that the information collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. | | |
| I understand that even if I withdraw from the trial, information already collected about me may be included in the final analysis after being anonymised. | | |
| I understand that relevant sections of my medical notes and data collected during the trial may be looked at by members of the research team (at the University of Sheffield) or the NHS Trust of my participating trial centre, or by individuals from statutory regulators. I give permission for these individuals to have access to my records. | | |
| I understand that information held by the NHS may be used to keep in touch with me and follow up my pregnancy status for the purposes of the trial. | | |

| | | |
|---|---|---|
| I understand that researchers for the Endometrial Scratch trial based at my hospital or at the University of Sheffield will contact me by telephone, mobile telephone, post or e-mail to request information about my pregnancy or my baby's development. | | |
| I understand I may be contacted in the future to give my consent for future studies, and that I may be traced through the NHS databases and GP records ***(voluntary).*** | | |
| I agree to my General Practitioner being informed of my participation in the study. ***(voluntary)*** | | |
| I understand that I will be randomised to receive either the Endometrial Scratch, followed by usual IVF treatment, or usual IVF treatment without the Endometrial Scratch. I will complete the main trial consent form in the presence of the site research staff when I next attend the Fertility Unit. | | |
| I understand the information that I have been given about the Endometrial Scratch study and I agree to take part. | | |

_____ _____ _____

Name of Participant: Date: Signature:

The University Of Sheffield. Clinical Trials Research Unit.

endometrial scratch

# Participant Telephone Interview Consent Form

**Title of Project:** Endometrial Scratch Trial – Qualitative sub-study

Participant Identification Number: E S | | / | | |

Name of Researcher:

**Note:** Prior to the consent process, the researcher will have confirmed that the Participant has received a copy of the Invitation and Information Sheet (if not, this can be read to them including allowing time to consider the information) and answered any questions raised. *Instructions for the researcher are highlighted.*

Before we start the interview, I need to confirm with you that you understand what is involved and whether or not you agree to take part. I will be recording this process. Is that all right with you? *(If **yes,** start recording and proceed as follows)*

I am going to read some statements to you. After each one, please answer 'yes' if you agree with the statement; or, 'no' if you do not agree with the statement.

| | ***Enter response*** |
|---|---|
| 1. I confirm that I have read and understand the Invitation and Information document dated ……..... (version ……..). I have had the opportunity to consider the information relating to the interview, ask questions and have had these answered satisfactorily. (*Wait for response*) | Y/N |
| 2. I confirm that I understand that my participation in the interview is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. (*Wait for response*) | Y/N |
| 3. I understand that the interview will be audio taped, transcribed and used in the research process. I understand that the sound recording will be destroyed at the end of the study; and, any quotations in reports about the research will be anonymous. I agree to the audio-taping of the interview. (*Wait for response*) | Y/N |
| 4. I understand that the information collected during the interview may be used to support other research in the future, and may be shared anonymously with other researchers. (*Wait for response*) | Y/N |
| 5. I agree to take part in the interview. (*Wait for response*) | Y/N |

*(If all responses are '**yes**' proceed as follows)*

Thank you. Now I need you to state your name for me so that it is recorded with this consent information *(wait for response and print name)* Name of Participant. The date today is: Date of call

Please can you confirm that this is the date on which you have given your permission *(wait for response and complete the section below)*.

| Name of person taking audio consent | Date (d d / m m / y y y y) | Signature |
|---|---|---|
| | | |

**When completed: 1 copy for participant; 1 copy for Site File; 1 (original) to be kept in Trial Master File.**