Patient Information Sheet

Research project to study meiosis in Unfertilised Human Oocytes (eggs)

NRES Ethics Reference Number: 11/EE/0346

Lead Investigator: Dr Melina Schuh (Max Planck Society)
Co-investigators: Dr Kay Elder and Martyn Blayney (Bourn Hall Clinic)

Introduction:
We would like to invite you to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it would involve. Please read the following information carefully and discuss it with friends and relatives if you wish.

Please ask if there is anything that is not clear or if you would like more information.

Take time to decide whether you wish to take part; thank you for reading this information.

What is the purpose of this study?
The purpose of this study is to investigate why some immature human egg cells (oocytes) develop into normal egg cells and some do not. This will provide information which will help us to understand why some women have problems conceiving and therefore might help to improve fertility treatments in the future.

Why have I been chosen?
You have been chosen to take part because you are receiving fertility treatment at Bourn Hall Clinic that will involve the collection of your eggs for your fertility treatment.
Some of these eggs are discarded because they are immature and thus not suitable for use in your treatment.
We would like to use eggs that would otherwise be discarded for use in this scientific research study.

Do I have to take part?
No.
Agreeing to allow us to use your immature eggs (that would normally be discarded) for this research study is entirely voluntary.
It is up to you to decide whether or not to take part and you can withdraw your consent at any time up until the eggs are used in research.
A decision not to take part or a decision to withdraw will in no way affect the care that you receive at Bourn Hall Clinic.

What do I have to do?
If you agree to participate, we will ask you to sign a consent form to indicate that you have agreed to take part.

What will happen to me if I take part?
All of the eggs collected from you that are suitable for use in your fertility treatment will be used for your fertility treatment.
Unfortunately not all of the eggs collected will have reached the correct stage of development and are therefore not suitable for use in your treatment, these eggs would normally be discarded.
If you agree to take part in the laboratory study, ONLY eggs that would otherwise be discarded will instead be used by Dr Melina Schuh's research team in her laboratory study.

What will happen to any samples I give?
The eggs which are unsuitable for your fertility treatment, will be analysed by Dr Schuh's team either directly in the laboratories at Bourn Hall Clinic, or may be frozen and transferred to the Max Planck Institute laboratories in Germany for further investigation by Dr Schuh and her researchers.
Your eggs will not be fertilised.
The eggs will be analysed primarily by light microscopy, some of the eggs may have their DNA status assessed together with the non-egg cells that usually surround them (called follicle cells. You are able to opt out from investigation of the DNA status of your immature eggs by ticking "No" to section 7 on the research consent form.
You can opt out of this investigation but still donate your eggs to the research project.

Will any genetic tests be done?
No testing for specific genes underlying human diseases will be performed. Please remember that all your mature eggs will be used for your fertility treatment.
Only immature eggs, that would have otherwise been discarded, will be investigated as part of our study.

What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks to your agreeing for your immature eggs (which would normally be discarded) to be used in the research study.

What are the possible benefits of taking part?
There are no direct clinical benefits to you in taking part in this study, but the information we obtain may help to improve fertility treatments in the future.

Will my taking part in the study be kept confidential?
Yes.

We follow best ethical and legal practice and all information about you will be handled in confidence.
In order to make best use of your eggs in the research study the research team will only need to know your age and the clinical reason for your fertility treatment all other information will be anonymised. This means that all information that could identify you will be removed and be replaced with a unique code. It would be impossible for anyone to be able to identify you from the code and the data supplied.

What will happen to data collected?
Bourn Hall Limited is the data controller for your personal data processed as a result of you requesting and/or receiving advice, assistance and/or treatment from Bourn Hall Clinic. Personal data will be processed in accordance with the privacy policy, published on our website www.Bournhall.co.uk.

Anonymised data that is supplied to the research team and any scientific data generated by the research team will be stored for a minimum of ten years. This is in accordance with scientific best practice.

What relevance will the data have to me?
No information will be generated from the research study that will directly affect your fertility treatment. This is because the research team cannot identify data relating to you since the samples have been anonymised before transport to the laboratory.

Responsibilities during treatment
The laboratory study will use eggs collected at Bourn Hall Clinic and, therefore, the study can be considered in two stages: (1) the collection of eggs; and (2) the laboratory study.

(1) Collection of eggs: The collection of eggs will be performed as discussed at your consultation consenting to this research study does not involve any additional procedures.
Bourn Hall Clinic continue to be responsible for your treatment.

Bourn Hall complaints procedure can be found here: www.bournhall.co.uk and any complaints will be handled in accordance with this procedure
(2) Laboratory study:
The Max Planck Society as the Sponsor of the laboratory study will provide an indemnity in the case of negligent harm and may consider, on a voluntary basis, an ex gratia payment in the case of non-negligent harm. This is extremely unlikely due to the anonymisation of your data before the samples are transferred to the research laboratory.

What will happen to the results of the research study?
The results of this study will be published in scientific and/or medical journals and may be presented at scientific and/or medical meetings. Please be assured it will not be possible to identify you from any report or publication.

Will my GP be informed?
As this study does not affect the care that you are receiving there are no plans to notify your GP of your involvement.

Who is funding the research?
The laboratory study is being funded by Dr Melina Schuh's Max Planck Society core research grant award.

Who has reviewed this study?
This study has been reviewed and given a favourable opinion by the East of England Research Ethics Committee.

Further information and contact details?
If you require any further information about the research study please do not hesitate to contact
Dr Kay Elder, Bourn Hall Clinic; kay.elder@bourn-hall.com; 07803 885237.

Further advice on research and conduct of studies can be obtained from Bourn Hall Clinic Patient Services on 01954 717210.

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Thank you for taking the time to read this Patient information Sheet.

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