

Patient Information Sheet

Meiosis in Unfertilised Human Oocytes

NRES Ethics Reference Number: 11/EE/0346

Chief 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 or not 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 will receive 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 in vitro fertilisation. We would like to use eggs that would otherwise be discarded for use in a scientific research study.

Do I have to take part?

No. Your 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 at any time up to the eggs being 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.

If you agree to participate, we will describe the study to you as detailed in this information sheet (and you will be given a copy of this information to keep) and 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? What do I have to do?

All of the eggs collected from you that are suitable for use in your fertility treatment will be used for your fertility treatment. However, at the time of egg collection, some eggs will not 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, any unfertilised eggs that would otherwise be discarded will instead be used by Dr Melina Schuh's research team in her laboratory study. These eggs, which are unsuitable for fertility treatment, will be analysed by Dr Schuh's team either directly in the laboratories at Bourn Hall Clinic, or may be cryopreserved and transferred to the Max Planck Institute laboratories in Germany for further investigation by Dr Schuh and her researchers.

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 immediate 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 need to know your age and the clinical reason for your fertility treatment. All eggs and this information will be anonymised before they are provided to Dr Melina Schuh and her research team. 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 that relates to my participation?

Bourn Hall Clinic as a matter of standard practice retains your clinical records in confidence indefinitely. 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 new information will be generated from the research study that will influence 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.

What will happen to any samples I give? Will any genetic tests be done?

Some of your eggs may not be mature and hence will not be suitable for fertility procedures. These immature unfertilised samples are normally discarded. Alternatively, they can be kept and a proportion of them may resume maturation in vitro. However, such eggs are still regarded as being of sub-standard quality and are not desirable for use in fertility treatments. They are however suitable for investigation by researchers to help them understand the factors that dictate the quality of an egg. If you decide to donate your immature eggs to research, instead of being discarded these samples will be anonymised by the clinical team before they are passed to the laboratory research team. The research team will then use your samples to investigate why some immature human egg cells develop into normal egg cells and some do not. The immature eggs will be analysed either on the day of collection, or, when this is not possible, they will be cryopreserved for analysis at the earliest possible date. 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) in order to help us better understand why a particular egg is faulty and would not have resulted in a successful pregnancy. You are entitled to opt out from investigation of the DNA status of your immature eggs as part of the analysis, while still donating your eggs to research. 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 happens if something goes wrong?

The laboratory study will use eggs collected from 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: Care organisations (in this case Bourn Hall Clinic) continue to be responsible for any breaches of the duty of care they owe their patients. The collection of eggs does not involve any additional procedure to those that you will be having as part of your standard clinical care. If you wish to complain about any aspect of the way you have been approached or treated, the normal complaints procedures at Bourn Hall Clinic will be available to you. In the event that something does go wrong and you are harmed there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against Bourn Hall Clinic.

(2) Laboratory study: The laboratory study is extremely unlikely to cause you any harm because the samples will be fully anonymised before they are transferred to the research laboratory. However, should this occur 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.

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 Melina Schuh, contact details below. Further advice on research and conduct of studies can be obtained from Bourn Hall Clinic Patient Services on 01954 717210.

Dr Melina Schuh

Max Planck Institute for Biophysical Chemistry
Department of Meiosis
Am Fassberg 11
37077 Göttingen
Germany
Tel.: +49-(0)551 201-2881
Email: melina.schuh@mpibpc.mpg.de

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

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