Participant Information Sheet: Sample study

ERGO: the mEnstRual cycle and lonGer-term symptoms of cOvid-19

You are invited to take part in a research study. To help you decide whether or not to take part, 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. Talk to others about the study if you wish. Contact 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.

What is the purpose of the study?

We are studying the effects of long COVID-19 and the menstrual cycle. We wish to see if there are differences in female hormone levels and markers of inflammation in the blood and womb lining of those who have had long COVID-19 and those who have not.

Why have I been invited to take part?

You are being invited to take part in this research because you are experiencing long-term effects of COVID-19 and have regular periods.

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. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What happens if I decide to take part?

If you decide to take part in our research it will involve:

1. A short interview with a member of the clinical research team. You will be asked to sign a consent form and we will enquire about your past and recent health. This may take place via telephone or at an appointment at the hospital.

2. We will ask you to attend hospital on three occasions at different stages of your menstrual cycle. Once during your period and twice when you are not menstruating. At the first visit we will check a urine pregnancy test. At each

visit we wish to collect a blood sample (approximately one tablespoon) and an optional tissue sample from the lining of your womb. Taking a sample from the lining of the womb involves an examination similar to a smear test. A fine plastic sampler is passed through the neck of the womb to take a sample of the lining. This procedure is usually carried out in the out-patient department without the need for anaesthetic but you may wish to take painkillers (e.g. what you would take for a headache) 1 hour before the procedure. It can cause cramp-like period pain which quickly subsides. Each appointment would be expected to last approximately 1 hour. If you cannot come in for three visits in one month, these visits may be split over a few months if necessary.

We will reimburse you for reasonable travel expenses that you incur as a result of participating in this study. We will let your GP know if you agree to participate and let them know any information obtained from the study that may impact your health.

Is there anything I need to do or avoid?

We ask that you avoid getting pregnant during the study. We also ask that you let us know if you start using hormone-based medications (e.g. the contraceptive pill or hormone coil) during the study.

What are the possible benefits of taking part?

There are no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.

What are the possible disadvantages of taking part?

You will need to attend the hospital on three occasions at different times in your menstrual cycle. There is a small risk of discomfort and bruising associated with taking routine blood samples. There is also a risk of mild lower abdominal discomfort during obtaining an endometrial tissue sample, if this is something you decide to go ahead with. Most patients will also experience light bleeding following this procedure that can last a few days.

What if there are any problems?

If you have any concerns or questions about any aspect of this study please contact **Priscilla Fernandez** on **07788084807**9 who will do their best to answer your queries. If you wish to make a complaint at any stage during the study, you should ask to speak to the clinical researchers who will do their best to answer your concerns. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the NHS Lothian Patient Experience Team at Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG. Telephone number 0131 536 3370, email feedback@nhslothian.scot.nhs.uk.

In the event that something does go wrong and results in you being harmed during the research and this is due to someone's negligence, then you may have grounds for legal action for compensation against local NHS Boards but you may have to pay your legal costs. The standard National Health Service complaints mechanisms will still be available to you (if appropriate).

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

If you wish to withdraw from the study, you can stop participating at any point without giving a reason. In this case, we will assume that you are happy for us to use information you have already supplied. If you wish to withdraw all data and samples from the research you may do so at any time; you must contact the research team to inform us of this.

What happens when the study is finished?

For this study, the information and samples you provide will be used by researchers to investigate and understand how COVID-19 affect ovarian hormones and womb inflammation, comparing samples from women who have had COVID-19 with those from women who have not. Your anonymised information and samples will be stored in the Centre for Reproductive Health at The Queen's Medical Research Institute (University of Edinburgh).

If all of the samples are not used for this study, we will ask your consent to keep these anonymised samples to be used in other related studies. The samples are a valuable resource and could be used many times by researchers in several different studies using modern laboratory techniques. At present future studies cannot be specified in detail but may also involve collaboration with laboratories in other universities or commercial companies in the UK and overseas. Future studies may include DNA analysis of samples, and you will have the option to opt out of this aspect of the research if you wish. DNA research includes the examination of your genes, we can sometimes see patterns in people with similar medical conditions for example heavy bleeding. You also have the option to consent to researchers contacting you in the future about participation in future studies where your details would be revealed to researchers, you will not be contacted about future research using your anonymised samples. We will also ask your consent to look up your NHS records in the future via a system called "Data Linkage". Any data obtained from this will then be anonymised for analysis.

What will happen to the results of the study?

The results of this study may be presented at scientific conferences and published e.g. in medical journals, reports and textbooks. All results will be anonymous. The results may be used to inform future studies of new treatments for long-covid. You will be able to see the published results of the study on our website www.ed.ac.uk/hope.

Data Protection Information

The information below details what data will be held about you and who will hold or store this. The EU General Data Protection Regulation (GDPR), along with the UK Data Protection Act, governs the processing (holding or use) of personal data in the UK.

University of Edinburgh and NHS Lothian are the co-sponsors for this study based in the United Kingdom. We will use information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The co-sponsors will keep identifiable information about you for a minimum of 1 year after the study has finished.

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. 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.

Providing personal data directly e.g. verbally, in a questionnaire or from your care provider

NHS Lothian will use your name, Community Health Index (CHI) number and contact details (phone number, email address and address) to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and oversee the quality of the study. Certain individuals from the Sponsor (University of Edinburgh and NHS Lothian) and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS Lothian will pass these details to University of Edinburgh along with the information collected from you and your medical records. The only people at University of Edinburgh who will have access to information that identifies you will be people who need to contact you to arrange and carry out the study related visits or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, CHI number or contact details. The University of Edinburgh will keep identifiable information about you from this study for a minimum of 1 year after the study has finished.

Providing personal data indirectly e.g. from your medical records

The University of Edinburgh will collect information about you for this research study from NHS Lothian. This information will include your name, Community

Health Index (CHI) number, and contact details (email address, phone number and address) and health information, which is regarded as a special category of information. We will use this information to contact you regarding this study.

Use of data for future research

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research**.**

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of healthcare research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee and/ or the sponsor.

Who has reviewed this study?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee. A favourable opinion has been obtained from the East Midlands- Leicester South Ethics Committee, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. NHS management approval has also been given.

Contact for further information

This study has been organised by Dr Jackie Maybin (Consultant Gynaecologist) The study is co-sponsored by the University of Edinburgh and NHS Lothian.

For further information about this study, please contact Priscilla Fernandez on tel. 077880848079 or email priscilla.fernandez@nhslothian.scot.nhs.uk. If you wish to speak to a doctor not involved in this study you can contact Dr Karen Edgar at the Royal Infirmary of Edinburgh on 0131 242 1000.

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at www.accord.scot. For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website; https://www.hra.nhs.uk/information-about-patients/.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/.

Data Protection Officer contact information:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

NHS Lothian
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