Participant Information Sheet

The Inflammatory Profile of Endometriosis

A research team at Swansea University Medical School (SUMS) and Swansea Bay University Health Board (SBU HB) is carrying out a research study. The purpose of this study is to determine the inflammatory profile of endometriosis to try and establish a blood-based biomarker to aid in diagnosis.

We would like to invite you to participate in this research study if you are having a laparoscopy as part of your normal medical care for the diagnosis or treatment of endometriosis.

Taking part in this research study is voluntary. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take your time to read the following information carefully and to decide if you do or do not wish to take part. If you would like more information or have any questions, please ask, or contact the research team whose details are provided at the end of this information sheet.

What is the purpose of the research?
In the UK, the average time between onset of symptoms and diagnosis is 7.5 years, with this rising to 9 years in Wales. The current gold standard for diagnosis of endometriosis is a type of keyhole surgery called a laparoscopy. A small camera is inserted into the abdomen via a small incision to allow the surgeon to assess for any ectopic tissue. If tissue is present and accessible, the surgeon will remove it in the same procedure. The tissue is typically sent for further testing to check if it's benign. We are developing what we hope will be a non-invasive, simpler, and quicker test that can be done in the blood. The purpose of this research study is to better understand how we might be able to diagnose endometriosis.

What will taking part involve?
During your pre-operative appointment, you will have to have blood tests from your arm as standard procedure. We would like to collect up to 60 ml of additional blood that we can use for our studies – this is the equivalent to less than 4 tablespoons. The blood sample would be taken at the same time as the blood sample being taken as part of your pre-operative tests, so there is no additional needle. In addition, during your laparoscopy, ectopic tissue may be removed as part of your clinical care. A portion of this removed tissue is sent to pathology for testing, and we would like to collect the rest of this tissue for our studies. Any samples provided will be donated as a "gift" to Swansea University. The sample(s) will be transferred to Swansea University for analysis and storage. We will use the blood sample to measure molecules and cells that circulate the blood, and the tissue sample to measure cells that contribute to the makeup of the tissue. In addition, we aim to test the ways in which the ectopic lesions grow and respond to treatment. We can do this by creating cell lines, which is when cells are taken from fresh tissue samples and can be grown under controlled conditions outside of the human body indefinitely. Some measurements will be looking at changes in thousands of genes in one test using biological genetic material such as RNA and mRNA, but not DNA. Some of these measurements might be made by researchers in other parts of the UK or the world. At the end

of our study, with your consent, we will store unused samples for further ethically approved investigations arising from our findings. These samples will be stored for up to 10 years. If you do not consent to the long-term storage of your samples for future studies, they will be disposed of appropriately at the end of this study.

We will also ask you some questions about your health and access your medical notes for information about you (e.g., the outcome of the laparoscopy, any treatment for endometriosis).

What happens if I do not want to take part or if I change my mind?
It is up to you to decide if you do or do not wish to take part. You do not need to take part in this study and not taking part would not affect your standard of care. 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 do decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself; please contact the chief investigator whose details are at the end of this information sheet. However, as your data and stored samples will have been anonymised it will not be possible to remove them from the research project, but we would not collect any further data about you. This does not affect your data protection rights. If you want to take part in this study but do not want your samples used for other research studies, you can still take part in this study. You can indicate on the consent form that you do not want your samples used for other research projects.

What information will be collected and will the information I provide remain confidential?
We will need to use information from your medical records for this research project. This information will include your name, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information at:

www.hra.nhs.uk/information-about-patients/

by sending an email to researchgovernance@swansea.ac.uk.

Will my data or samples be used for future research?
When you agree to take part in the research study, you have the option for short versus long-term storage of the data and samples. Should you consent for the long-term retention of data and samples, the information about your health and care as well as the samples you provide may be used in future research studies including being provided to researchers running other research studies in Swansea

University and in other organisations. These organisations may be universities, NHS organisations or companies involved in healthcare or commercial 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.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

What are the benefits from taking part?
There are no immediate benefits for you from taking part in this study.

What are the risks from taking part?
Taking the blood sample from you may cause bruising and some minor discomfort. The laparoscopy is associated with scarring and possibility of complications discussed with your consultants. There is no additional risk for this study.

What if something goes wrong?
If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, then you should contact:

Swansea Bay Community Health Council
First Floor, Cimla Hospital
Neath SA11 3SU
Phone: 01639 683490
Website: http://www.wales.nhs.uk/sitesplus/902/home

If you wish to complain about the management of your data, you should contact:

GDPR Information Commissioner's Office
Phone: 0303 123 1113
Website: https://ico.org.uk/make-a-complaint/

If you have any complaints about research project staff, then you should contact:

Head of Swansea University Medical School
email: meddean@swansea.ac.uk

What will happen to the results of the study?
The results of the study will determine if our new test might eventually be introduced as one of the first routes to diagnosis. This will require future larger studies. We will summarise our findings in a study report with will be available on the research team's webpage and social media (details at the end). The findings might also be published in a scientific journal or presented at a conference. Your identity will remain anonymous in all publications and presentations of the findings.

Who is organising the research?
The study is organised and carried out by a research team at Swansea University and SBU HB.

Who has reviewed the study?
This study also has been reviewed and given favourable opinion by Berkshire B Research Ethics Committee REC 23/SC/0332.

Where can I get more information?
You can get independent advice about taking part in research from the following website:

People in Research - http://www.peopleinresearch.org/

If you require further information about the study, you can contact a member of the research team via their email address:

Immunology-studies@swansea.ac.uk

Alternatively, you can contact the Chief Investigator directly:

Dr April Rees
Phone: 01792 987806
Email: april.rees@swansea.ac.uk

To keep up to date with our research, you can visit us on our research team webpage or follow us on social media.

Webpage: https://www.swansea-immunology.com/

Facebook: facebook.com/SUMSSWIM

Thank you for taking the time to read this information sheet!