

PARTICIPANT INFORMATION SHEET

Harnessing menstrual fluid for innovative diagnostic insights

Before consenting to take part in this research, please read the following information.

What is the purpose of the research?

We are conducting research trying to determine the feasibility of using menstrual fluid as a diagnostic tool. Conditions such as endometriosis currently take an average of 7.5 years to diagnose in the UK, and only with an invasive type of keyhole surgery called a laparoscopy. Menstrual fluid is a novel sampling type, which would be easy to collect and non-invasive. The aim of this study is to see if there are any detectable differences with reproductive disorders, which would provide us with new opportunities to understand the condition and lead to novel therapeutic and diagnostic techniques.

Who is carrying out the research?

The study is organised and carried out by a research team at Swansea University. The data is being collected by Dr April Rees of Swansea University Medical School. *This research has been given a favourable ethical opinion by Swansea University Medical School (SUMS) Research Ethics committee (RESC), project reference 2 2024 9064 8225.*

What happens if I agree to take part?

After you read this participant information sheet, we will record your consent to taking part in this study. Taking part in this study first involves answering a few questions about yourself (e.g., your age and ethnicity), your health (e.g., smoking and any chronic disease), and your menstrual cycle (e.g., average length of cycle, contraception).

You will then be provided with a brand new mooncup® menstrual cup, with your choice of size: Size A (appropriate for those over 30 and/or with a history of giving birth) or Size B (appropriate for those under 30 with no history of giving birth), with instructions on its proper use. You will then be asked to use the mooncup© when you have a heavy flow (day 1 or 2 typically), collecting the flow for at least 4 hours or overnight. You will then move the flow into a sterile tube provided (you should have collected a minimum of 7 ml) and keep refrigerated (a bag will be provided) until you can bring the sample back to the research team as soon as possible (within 4 hours).

On the same day as the collection of the menstrual flow, you will be asked to book in with the research team to donate up to 10 ml (equivalent to 2 teaspoons) of blood taken by a certified phlebotomist, and up to 1 ml of blood via finger-prick.

As an option, we would also like repeat menstrual blood samples from future months after the first collection. You can opt out of this, and still take part in the first collection. Only the first menstrual cup will be provided. New sterile tubes and bags for the collection will be provide each time.

Samples will be kept at Swansea University for analysis and storage (note: only cell-free plasma and serum will be stored). We will use this sample to measure molecules and cells that are in the blood. We will not study your DNA. At the end of the study, we will dispose of unused material.

Are there any risks associated with taking part?

The research has been approved by Swansea University Medical School Research Ethics Committee. There are no significant risks associated with participation. There are minimal risks involved with the use of menstrual cups, provided they are used as recommended. Infections are a rare complication and is usually mitigated by washing your hands thoroughly with water and antibacterial soap, as well as the cup itself between uses. Irritation may happen but this can be prevented with the manufacturer's recommendations on the product packaging.

Data Protection and Confidentiality

Your data will be processed in accordance with the Data Protection Act 2018 and the General Data Protection Regulation 2016 (GDPR). All personal information collected will be kept strictly confidential. You will be assigned a unique study number that will be used to label your samples and link to the laboratory data gathered using your samples. The personal information provided by you will only be viewed by Dr April Rees. All collected identifiable data will be destroyed on or before 3 months have progressed when it is no longer required for the research endeavours.

What will happen to the information I provide?

An analysis of the information will form part of our report at the end of the study and may be presented to interested parties and published in scientific journals and related media. All information presented in any reports or publications will be anonymous and unidentifiable.

Is participation voluntary and what if I wish to later withdraw?

Your participation is entirely voluntary – you do not have to participate if you do not want to. If you decide to participate, but later wish to withdraw from the study, then you are free to withdraw, without giving a reason and without penalty. However, as we destroy all collectable data after 3 months, after this time your data will not be able to be identified and we cannot withdraw your samples from the study. We would ask that you return your unopened and unused mooncup®. You can withdraw by contacting Dr April Rees via the contact information at the end of this document.

Data Protection Privacy Notice

The data controller for this project will be Swansea University. The University Data Protection Officer provides oversight of university activities involving the processing of personal data and can be contacted at the Vice Chancellor's Office.

Your personal data will be processed for the purposes outlined in this information sheet.

Standard ethical procedures will involve you providing your consent to participate in this study by completing the consent form that has been provided to you.

The legal basis that we will rely on to process your personal data will be processing is necessary for the performance of a task carried out in the public interest. This public interest justification is approved by Swansea University Medical School Research Ethics Committee.

The legal basis that we will rely on to process special categories of data will be processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

How long will your information be held?

Any identifiable data held about you such as your name will be destroyed 3 months after consent, when it is no longer required. The laboratory data that we generate using your blood samples will be held for 10 years after the study has finished. This is so that we can ensure all our findings from the study are published in scientific journals and comply with the regulations relating to this.

What are your rights?

You have a right to access your personal information, to object to the processing of your personal information, to rectify, to erase, to restrict and to port your personal information. To safeguard your rights, we will use the minimum personally identifiable information possible. Please visit the University Data Protection webpages for further information in relation to your rights.

Any requests or objections should be made in writing to the University Data Protection Officer:

University Compliance Officer (FOI/DP)
Vice-Chancellor's Office
Swansea University
Singleton Park
Swansea
SA2 8PP
Email: dataprotection@swansea.ac.uk

How to make a complaint

If you are unhappy with the way in which your personal data has been processed, you may in the first instance contact the University Data Protection Officer using the contact details above.

If you remain dissatisfied, then you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
www.ico.org.uk

What if I have other questions?

If you have further questions about this study, please do not hesitate to contact us:

immunology-studies@swansea.ac.uk

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