Characterisation of Menstrual Fluid (COMF) - Participation Information Sheet

Sponsor and sample analysis laboratory:
Cyclana Bio Ltd, Babraham Research Campus

You are being invited to take part in a research study. Before you make your decision, 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. You may want to talk to others about the study before taking part. Take time to decide whether or not you wish to take part and do not hesitate to reach out if you have any further questions, via email at comf@cyclanabio.com.

What is the purpose of this study?

Many women's health conditions have limited treatments available and poor outcomes, in part due to the lack of understanding of the disease and lack of data available. This is particularly true for endometriosis, a condition that affects 1 in 10 women.

Menstrual fluid is more than just blood. It's the tissue lining your uterus shedding every month. Stem cells in there have even been used to treat diseases outside of the uterus in the lab. DNA and protein has been analysed to show differences between individuals. This tissue can be very informative of your health status, but has been very understudied.
We collect menstrual fluid to look for disease and health signals. We look at a lot of different metrics within the fluid and link it to both clinical and gynaecological history with three main goals:

1) Make better models of endometriosis and related conditions in the lab.
2) Better understand diseases that affect women.
3) Uncover early markers of disease and identify novel targets to cure them.

We hope to do this whilst developing personalised health insights that would more generally allow you to monitor your health through menstrual fluid!

Who are we?

We are a team of scientists using menstrual fluid to study endometriosis and other chronic diseases. You can learn more about each member of our team at https://www.cyclanabio.com/team-4

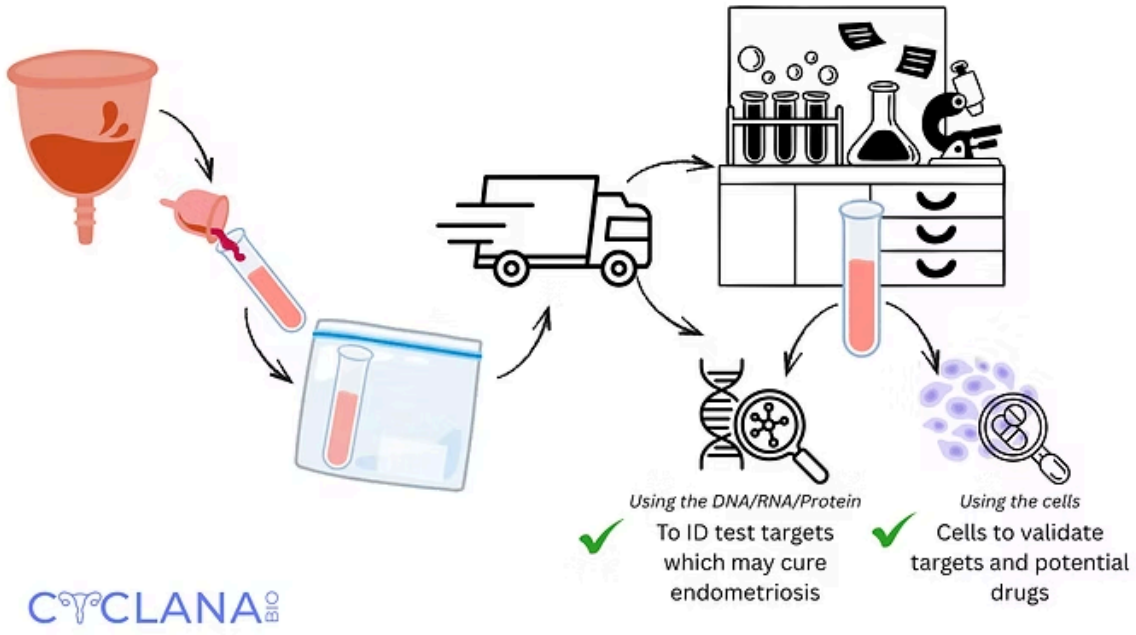
Do I have to take part?

No, participation is entirely voluntary. If you agree to take part, you will be asked to sign a consent form as confirmation of your decision. You are free to withdraw at any point without providing a reason. If you do withdraw your consent, we will destroy all remaining tissue we may still have in our laboratories.

What do I have to do?

To take part, you simply need to sign up on the Expression of Interest form and we will reach out with information and the consent form. Please note that as a small company with limited capacity, we will unfortunately be unable to take donations from everyone who registers interest. If selected to proceed, we will organise the collection kit and menstrual cup delivery and the sample pick up.

What would taking part look like?



1. Once you have signed up, we will be in touch with you to have you a collection kit and a menstrual cup (if you need one) delivered.
2. The day before your heaviest period, you can reach out to us to let us know your sample will be ready.
3. On your heaviest period day, you will wear the menstrual cup to collect as much fluid as possible (usually 4-6 hour collection period), before pouring the content into a tube and handing it over to us.
4. We will ask you to fill in a health questionnaire and a consent form and ask whether you are interested in donating again. We will organise the collection of your sample.
5. Your samples will be used directly by the research team to isolate non cellular material (like hormones) and cells to use for drug testing in the lab. We will also isolate some of your DNA to

look into marks that can help us find common biomarkers between women. None of the DNA that we receive will ever be shared externally without your consent.

6. The results from your samples will be stored securely and used for research aimed at understanding and treating women's health conditions.

Do I need a menstrual cup?

At the moment, we are using menstrual cups for blood collections. This is because we are using live cells and need fresh samples. We offer a menstrual cup to all those who wish to use one and we will ship this with your sample collection kit. We know not everyone can use them, so we are also working on ways to use other products too (eg. tampons).

What if I have regular infections, pelvic prolapse or known kidney problems?

Your safety is our primary concern. The main risks associated with taking part in this study are those related to the use of a menstrual cup. If a menstrual cup is not positioned properly, or if it is not thoroughly disinfected by boiling before use, it can carry risks of infection, pelvic organ prolapse, or kidney complications. The risk is very low.

Because of these specific risks, if you suffer from regular vaginal or pelvic infections, have an existing pelvic prolapse, or have known kidney problems, we strongly advise that you do not participate in the study at this time. Using a menstrual cup may aggravate these pre-existing conditions.

If you are unsure whether your medical history makes it safe for you to use a menstrual cup, please consult with your doctor or gynaecologist before registering your interest. We know that not everyone can use menstrual cups, which is why we are actively working on ways to use other sanitary products (such as tampons) in the future. We hope to be able to welcome you to participate in future phases of our research once these alternatives are available.

What do I get from this study?

You will have the chance to receive ongoing updates from us on how the field of women's health is progressing and how your samples may lead to scientific breakthroughs. This study will hopefully be part of a large initiative to promote women's health and close the gender health gap leading to better care and treatment of women with conditions like endometriosis. You will also receive a free menstrual cup. We hope that with more research thanks to these samples we will be able to develop tests that will then feedback onto your health.

What will happen to the samples I give?

The samples you give will be processed and analysed by Cyclana Bio. For each sample, we look into various biomarkers (eg. hormonal levels and including DNA) and isolate cells for our disease models, all with the aim of better understanding how these different pieces of data fit together in the context of health and disease. Results and data may be licensed out to third parties also looking to advance therapeutic development.

Will any genetic tests be performed?

Yes, we plan to use genetic data to address many questions involving better patient outcomes for endometriosis. It is impossible for us to list every genetic test we may perform, but as an example, we may carry out analyses aimed at developing new tests for diagnosis of endometriosis. By agreeing, you would be donating these samples as a "gift," meaning you give us permission to carry out any genetic analyses we consider helpful — for example, research aimed at developing new tests for diagnosis of endometriosis. We will not share your individual genetic data with anyone outside the research team. This includes insurance companies and employers. We may share results with other researchers and publish them, but only in aggregated form, meaning results are combined across many participants and do not include anyone's individual genetic data.

Given the exploratory nature of this work, it is unlikely that any of the tests that we perform will yield directly actionable findings related to your health. We may not run all of the listed tests on your sample either. Receiving results from genetic testing can significantly impact on quality of life and should be considered carefully with a genetic counsellor. Because of this, and because the types of analyses we run are unlikely to provide any direct actionable benefit, we will not be feeding back to you any direct results of genetic tests that we perform on your material.

Will my participation in this study be kept confidential? What will happen to my data?

Yes. We will follow ethical and legal guidelines, and your information will be kept confidential. Whilst we retain confidential information about your identity, we restrict this information to a very limited number of senior individuals. Everyone involved will keep your data safe and secure, following privacy rules. We will never share your personal identifiable information with any of our partners or anyone external to Cyclana.

We will share your non-identifiable information related to this research project with the following types of organisations:

- Organisations performing similar research, including for-profit companies looking to develop solutions for women's health.
- Organisations that help us look into a specific aspect of your sample (e.g. the University of Manchester will be looking at proteins, companies like Nordic Biosciences may work with us to develop new biomarkers for diagnosis).

We will keep all information about you safe and secure by:

- Operating from a pseudonymised online platform.
- Storing your personally identifiable information separately from your clinical data and experiment results.
- Pseudonymisation of your data to ensure separation from your personally identifiable information. This means the person handling your samples will not know they are yours.
- Providing access to your data on a strictly need-to-access basis.

For information about our data policies relating to international transfer, please refer to the information on https://www.cyclanabio.com/data-information.

Can I request that my information is erased?

We plan to **hold your identifiable data for 10 years, and the anonymised results from it indefinitely**, so that it may benefit future research in the field. You have the right to ask us to delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot.

What about my menstrual fluid sample if I am not bleeding much/do not bleed?

We require a minimum of 5mL (a full teaspoon's worth) of menstrual fluid for a successful test. If you do not menstruate or cannot provide a menstrual fluid sample of large enough volume, you are not at present eligible to participate in this study.

What are the possible disadvantages and risks of taking part?

There are no additional risks to you, beyond the risks associated with the use of a menstrual cup, which is one of the major tools for menstrual health and is widely used. Risks can include infection, prolapse or kidney complications is the cup is not positioned properly or disinfected (boiling) before use. We have a flyer explaining how best to use the menstrual cup attached on our website.

What if there is a problem or I want to make a complaint?

If you have any concerns or questions about any part of this study, please contact the research team, who will do their best to assist you.

To ensure robust independent scrutiny of the study and our recruitment procedures, both an independent Quality Assurance (QA) manager and a Study Steering Committee—including an independent statistician—have been appointed:

- The **independent QA manager** ensures that Cyclana Bio maintains appropriate operational and Quality Management System (QMS) standards to safeguard the safety, handling, and dignity of all collected samples.
- The **independent Study Steering Committee** ensures that all study procedures are conducted in participants' best interests and is responsible for independently evaluating and resolving any complaints raised throughout the project.

If you wish to make a formal complaint regarding the study, the conduct of the research team, or the handling of your data and samples, please email comfcomplaints@cyclanabio.com. Any complaints submitted through this channel will be formally escalated directly to the independent Study Steering Committee for objective review.

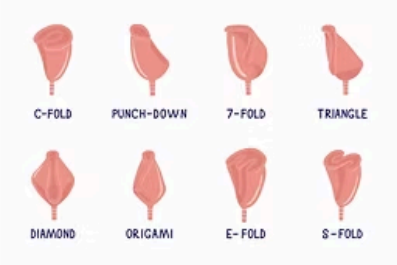
Name: Cyclana Bio Research Team
Email: comfcomplaints@cyclanabio.com

Your guide to using a menstrual cup for the first time

Simple. Safe. Sustainable.

🌸 What Is a Menstrual Cup?

A menstrual cup is a small, soft, flexible cup made of medical-grade silicone or rubber. It's inserted into the vagina to collect (not absorb) your menstrual flow. Once full, you empty it, rinse it, and reuse it.



cyclanabio.com /donate-menstrual-blood

Why Use One?

- Reusable & eco-friendly
- Can be worn for up to 8–12 hours
- No fibers, bleaches, or drying effects
- Less odor and leakage than pads or tampons
- Cost-effective over time
- For us, it allows the collection of high quality samples for our research

🩹 1. Wash Your Hands and the Cup

- Always wash your hands with soap and water before insertion or removal.
- If it's your first time using the cup, boil it for 5 minutes to sterilize.

✨ 2. Fold the Cup for Insertion

- Choose a fold that feels easiest (see diagram above!)
- Hold it firmly between your fingers.

💧 3. Relax and Insert

- Sit on the toilet, squat, or lift one leg on the bathtub.
- Gently guide the folded cup into the vagina. Aim horizontally, not straight up.
- Let it pop open fully. It should sit low in the vagina, not deep like a tampon.

🔄 4. Check the Seal

- Gently rotate or tug the stem to ensure it has opened fully and created a seal.
- You shouldn't feel it if placed correctly.

⏰ 5. Wear for around 6 Hours

- Empty earlier if your flow is particularly heavy

💧 6. Removing the Cup (Without the Mess!)

- Wash your hands.
- Sit on the toilet and relax your pelvic floor.
- Pinch the base (not the stem!) to break the seal.
- Gently pull it out upright to avoid spilling.

➡️ *Tip: Remove it over the toilet or in the shower at first, until you're confident.*

🩹 7. Empty, Rinse, Reinsert

- Empty into the tube we will give you.
- Rinse with clean water (mild, unscented soap optional).
- Reinsert if you wish to use it further!

🧼 Cleaning After Your Period

- Boil the cup for 5 minutes to sterilize.
- Store it in a breathable cotton pouch (not airtight plastic).