

Participant Information Sheet (Patients)

Version 2.0 15 May 2026

**Study title: Evaluation of Biomarkers in Menstrual Blood Compared with
Peripheral Blood (EBMBcPB-1)**

Invitation to take part

You are being invited 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 will involve. Please take time to read the following information carefully and discuss it with others, including your friends and family, and/or GP if you wish. Please ask a member of your clinical care team at **NAME SITE** during your appointment to clarify anything that is not clear.

Alternatively, you can contact your site outside of your visit time or you can contact Genie Fertility Limited if you would like more information or if you would like us to clarify anything that is not clear.

You can contact **NAME SITE** team via email:

You can contact the **NAME SITE** team via telephone:

Your study doctor is: **NAME & EMAIL ADDRESS & TELEPHONE NUMBER**

You can contact Genie Fertility Limited via email: **INSERT EMAIL**

You can contact Genie Fertility Limited via telephone: **INSERT TEL NUMBER**

Please note the use of the word 'we' throughout this document refers to Genie Fertility Limited, who are the Sponsor (responsible for all aspects of this research).

Do I have to take part?

No. Taking part is entirely voluntary. We would like to make sure you know what your involvement requires and suggest that you take at least 24 hours to decide whether to participate or not. There is no rush to decide whether you want to take part. If you wish to take longer than 24 hours to decide, you can. Taking part in the study will not affect your care nor affect your legal rights.

Who is organising and funding the research?

The study is organised and funded by **Genie Fertility Limited**. We are a UK-based biotech company developing non-invasive ways to obtain endometrium (lining of the womb) cells to learn about the health of the womb and reproductive system.

Genie Fertility Limited are the Sponsor of the study. This means we are responsible for all the legal and ethical responsible for the study and ensuring the proper conduct of the clinical study in line with the Medicines for Human Use (Clinical Trials) Regulations, and Good Clinical Practice.

What is the purpose of the study?

We are conducting a research study to evaluate whether biomarkers can be identified in menstrual blood. Biomarkers are found in blood, urine or biological tissue that can help researchers understand normal biological processes and disease. They act as a sign that can give us information about health or disease.

This study is exploratory and will not provide clinical diagnoses or individual health results. If you have any concerns please contact your clinical care team.

The study is being led by Genie Fertility Limited in London, with clinic sites in London, Oxford and Spain. It is anticipated that up to 250 women will participate.

The study will run from 1st May 2026 to 30th April 2029.

Why have I been invited?

You have been invited to join the study as you are receiving IVF treatment at a participating fertility clinic. Our study aims to help us better understand reproductive health using the samples you provide. In addition to this, you have been invited because you meet the inclusion criteria for the study.

Inclusion Criteria:

- you are aged 18 years or over
- you are biologically female
- you are willing and able to provide a menstrual blood sample collected using a menstrual cup
- you are willing to provide a vaginal swab
- You are willing and able to provide a peripheral blood sample
- You are willing to provide a uterine biopsy (**only if scheduled as part of routine care**)
- you are able to understand the study procedures and requirements
- you are able and willing to provide freely given written informed consent
- you are willing for your samples and associated data to be used for the research purposes described in this document

Exclusion Criteria:

- you are age 17 years or younger
- you are not biologically female
- you are currently pregnant
- you have an active vaginal, pelvic or systemic infection that may affect safe participation or sample integrity
- you have a known allergy, sensitivity or intolerance to the menstrual cup material
- you have any condition which, in the opinion of the Principal Investigator or delegated member of site staff, would make participation unsafe, inappropriate or unsuitable
- are unable or unwilling to provide freely given written informed consent

What if I change my mind?

If you decide not to take part, or if you withdraw later, this will not affect you in any way. You can withdraw at any time without giving a reason. If you decide not to take part, there is nothing you have to do. If you decide to take part and want to withdraw, please tell your study doctor in-person or via email or telephone. You do not have to give a reason. If you want to withdraw after giving your sample and would like to withdraw your sample, please contact your study doctor to request this as soon as possible. In the event that your sample may have been processed and used, your sample would no longer be able to be withdrawn. You may withdraw and request the disposal of your sample if it has not been fully processed.

What will happen if I take part?

If you agree to take part:

1. You will be asked to sign a consent form.

2. You will be given a study identifier (Study ID) which is used instead of your personal details.
3. You will be provided with a commercial menstrual cup and a vaginal swab both with instructions for use.
4. During your menstrual cycle, you will insert the menstrual cup as instructed.
5. After approximately 4–6 hours (depending on your flow), you will attend the clinic, where you will be guided to remove the cup and transfer the collected blood into a provided container. The amount of blood will typically be between 20-30 millilitres which is around 2 tablespoons.
6. During this visit, a peripheral blood sample will also be taken.
7. Your routine care uterine procedure may be scheduled for a different day (if applicable). Your doctor performs the endometrial biopsy (uterine procedure) by taking cells from the lining of the uterus. Much like during a gynaecological examination your doctor uses a speculum to open up your vagina and view the cervix (opening of the uterus). Your doctor then inserts a very thin, very small catheter directly into your uterine cavity, through the cervix, and using suction, draws out some of the endometrial tissue. (uterine biopsy). The procedure takes under 30 minutes and is part of your routine care. Although some women experience slight cramping and even some spotting after removal of the tissue many only feel mildly uncomfortable. There's no interruption to your normal routine when you have an endometrial biopsy. A small part of the sample will be shared with the research team as part of the study

and will not effect your routine care. The collection of the research sample will not add any additional discomfort or time to the procedure.

8. The study team will collect the sample/s from you or your site team for laboratory analysis.
9. Your sample will be transported to the Genie Fertility Limited laboratory in London where serum (liquid blood after is has clotted) and plasma (liquid blood which has not yet clotted) will be isolated and analysed for biomarkers. Samples will be kept for future research if you consent to use for this purpose, or you can choose for your samples to be destroyed upon study completion.
10. You will remain in the study until all of your samples have been taken, which can depend on your routine appointment schedule, but it is envisaged all samples should be collected within 3 months of entering the study.
11. You will be given a gift of thanks for your participation in the form of a voucher or bank transfer (if you agree to your personal details to be held for this purpose).

What are the possible benefits of taking part?

You will not receive any direct medical benefit from taking part. However, your participation will contribute to research that may help improve understanding of women's health in the future. We would like to gift you a £150 Amazon voucher or bank transfer as a thank you for your participation which will also

reimburse you your travel costs if your study visit occurs outside of your regular appointment.

What are the possible risks of taking part?

The risks associated with this study are minimal.

You may experience mild and temporary discomfort, irritation or inconvenience when inserting or removing the menstrual cup.

You may experience temporary discomfort, bruising, fainting or rarely infection or nerve damage associated with venepuncture. This is a routine part of your standard care. An additional sample will be obtained for this study.

You may experience temporary cramping (similar to period pains), light spotting or vaginal bleeding for a few days after your uterine procedure. Very rarely complications include uterine perforation (a small hole in the uterus), pelvic infection and/or severe bleeding. This is a routine part of your standard care. An additional sample will be obtained for this study.

If you feel unwell during your participation or within 24 hours of your participation please contact your study doctor.

What tests will be done on my samples?

Your samples will be separated into their component parts where molecular and biochemical analysis will be undertaken.

Will I receive the results of the study?

Please indicate on the consent form whether you would like to receive a copy of the summary of the study findings. If you choose not to receive a copy of the summary, but change your mind, tell a member of the study team or contact

Genie Fertility Limited. Alternatively, once the study has been published you may access the results on the Genie Fertility website.

Will my taking part be kept confidential?

Yes. We take your privacy seriously. Any information we collect about you will be kept securely at the site or if collected via the Genie Fertility Limited website, on our servers located at our headquarters in London, for the duration of the study and for 3 months afterwards, in line with research guidelines.

When information is shared with other sites, all details that could identify you are removed, so nobody can tell who it belongs to. We provide you a Study ID. The key that links your study ID to your name is kept securely at site and can only be accessed by members of the research team who have a need-to-know. Each site involved in the study must follow strict data protection rules which means they have legal obligations to keep your information safe and confidential.

How will we use information about you?

We will need to use information from you and your fertility records from **site** for this research project.

This information will include your:

- Initials
- Name
- Email address
- Date of Birth
- Telephone Number
- Postal Address
- Bank Account/Building Society Details (in case of thank you payment)

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 call this the Study ID.

Genie Fertility Limited is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Voucher companies to process your voucher in lieu of payment i.e Amazon this will be limited to name and email address

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

- Secure Server
- Need to know basis

How will we use information about you after the study ends?

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.

We will keep your study data for a maximum of 5 of years. The study data will then be fully anonymised and securely archived or destroyed.

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

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from **Site**. If you do not want this to happen, tell us and we will stop]
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. 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 do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.]

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

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

- www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to **anoushka@geniefertility.com**, or
- by ringing us on **07772 112003**

The legal basis for processing the data under the general data protection regulation (GDPR) and the data protection act 2018 is that of Consent, the participants have consented to the use of their personal data as part of the study.

Who has reviewed the study?

This study has been reviewed by **NAME REC** to make sure that the study is scientifically and ethically acceptable.

What happens if something goes wrong?

Genie Fertility Limited hold insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Genie Fertility Limited is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you have any concerns or experience any problems related to the study, please contact the research team using the details on page 1 of this leaflet. If you wish to make a formal complaint, you can do so by contacting Genie Fertility Limited. (see below)

If you are harmed in any way due to your routine care at the fertility clinic, then the clinic holds appropriate insurance policies. You should contact the fertility clinic directly for further information.

What if I have a complaint?

If you have a complaint about the study this can be directed through the clinic independent complaints system:

Name and address of Clinic with email and contact number

Who can I contact for more information?

If you have any questions or would like further information, please contact:

Andreas Hadjimitsis

Chief Technology Officer (Chief Investigator)

Genie Fertility Limited

Email: andreas@geniefertility.com

Phone: 07780 440936

Thank you for considering taking part in this research.

Participant Informed Consent Form Version X.X DATE

Study Title	Evaluation of Biomarkers in Menstrual Blood Compared with Peripheral Blood (EBMBcPB-1)
IRAS ID	368739
REC REF	
Sponsor	Genie Fertility Limited 192 Drummond Street Fourth Floor London NW1 3HP
Study Doctor	<i>Name clinic consultant</i>
Address	<i>Of clinic</i>
Telephone	<i>Of clinic</i>

Please read each statement carefully and initial each box if you agree.

	Participant Initials
1. I confirm that I have read and understood the Participant Information Sheet Version X.X DATE	
2. I confirm that the study has been explained to me and that I have had the opportunity to ask questions. I have had enough time to decide whether to participate, and I know who to contact if I have further questions.	
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason without my medical care or legal rights being affected. I understand I can find details of how to withdraw in the section "Do I have to take part?" of the Participant Information Sheet Version X.X DATE	
4. I agree to provide menstrual, peripheral blood, vaginal swab and uterine biopsy* (*only if part of routine care) samples for the purposes	

described in the Participant Information Sheet Version X.X DATE	
5. I consent to my samples being analysed for biomarkers	
6. I consent to my samples being stored for the purpose of this study.	
7. <i>I understand that sections of my clinic records will be reviewed by the sponsor, and others including auditors and regulatory authorities. I give permission for these individuals to have access to my clinic records at the study doctor's site or through remote monitoring to ensure the study is being carried out safely.</i>	
8. I consent to the processing of my personal data, including health data for the purposes of the study as described in the Participant Information Sheet Version X.X DATE	
9. I understand that that anonymised or pseudonymised data from this study may be used in reports, publications, or presentations and that I will not be identified.	
10. I agree to take part in this study.	

Optional Consent – please only initial the box if you agree to the optional study activities. If you do not agree to the optional activities you can still participate in the study.

	Participant initials
1. I consent to Genie Fertility storing any unused samples for future research and understand that I will not receive any financial reward if any subsequent commercialisation of products or tests associated with my sample occurs.	
2. I consent to Genie Fertility Limited providing anonymised data (data that cannot identify me) or any of my unused samples to 3 rd parties including other	

private companies or academic institutions for research use.	
3. I agree to my personal details including my email address and telephone number, being retained by Genie Fertility Limited so I can be contacted about future research opportunities.	
4. I agree to provide my bank account / building society details for the purposes of receiving a bank transfer as a thank you from Genie Fertility Limited.	
5. I would like a copy of the study findings sent to me via (delete as appropriate) a. email or b. through the post. I agree to my contact details being used for this purpose.	

Your signature below means that you have read and understood the information within this form, as needed, to decide whether or not to participate in this study.

You will receive a copy of this signed and dated consent form and the Participant Information Sheet Version **X.X DATE** to keep for future reference.

Participant: Your signature below means that you are voluntarily choosing to take part in this study.

Person explaining the study: Your signature below means that you have been delegated to explain the research study and have explained the study to the participant. You have answered any questions the participant may have about the study.

Name of participant: _____

Signature: _____ **Date:** _____

Name of person taking consent: _____

Signature: _____ **Date:** _____

The original signed and dated (fully executed) copy of this ICF should be kept in the study site file, a fully executed copy should be kept in the clinic medical records and a fully executed copy should be provided to the participant.