# Patient Information Sheet

## The OVARI Research Tissue Bank (OVRTB)

Version 4.0

You are being invited to consider donating a sample to the OVARI Research Tissue Bank. This information sheet provides details about the tissue bank and how your sample will be used for research. Please take your time to read it carefully and discuss any questions you have with a member of the OVARI team.

## What is OVARI?

OVARI (Organisation for Vital Advancements in Reproductive health and Infertility) is a registered charity dedicated to advancing reproductive science and women's health through education, research, and advocacy in the UK and Ireland. OVARI collaborates with but operates independently from Hertility Health Ltd. All research conducted by OVARI is done for **public benefit**.

## What is the OVARI Research Tissue Bank?

The OVRTB is a collection of ethically obtained and anonymised biological samples, primarily residual blood samples, donated by individuals who have undergone hormone testing with Hertility Health. These samples, along with associated de-identified diagnostic data, will be used exclusively for OVARI's independently approved, non-commercial research projects.

## Why are we setting up this Research Tissue Bank?

The purpose of the OVRTB is to **support scientific and clinical research into reproductive health, fertility, and menopause**. By collecting high-quality biological samples from diverse backgrounds, we aim to advance medical knowledge and innovation, highlight physical, medical, psychological, and social impacts of reproductive health issues, and ultimately improve the experiences of women and individuals assigned female at birth in the UK and Ireland.

## Why am I being asked to donate a sample?

You are being invited because OVARI is collaborating with Hertility Health Ltd. to collect samples relevant to reproductive health research. Our primary source of samples comes from individuals who have recently undergone serum hormone testing with Hertility. In this instance, you are being asked to donate a small, residual portion of the blood sample that was collected for your clinical tests, which would otherwise be discarded.

Additionally, in some cases where you may be referred to an external clinic or service, you may be asked at that time to consider donating any surplus biological tissue remaining after your clinical procedures are completed.

Individuals who have not undergone Hertility testing may also be invited to donate blood or tissue samples directly to the Research Tissue Bank; this is completely optional and entirely separate from any clinical testing, meaning no personal results will be provided.

Your participation in donating either blood or other tissue in any case is **entirely voluntary** and will not affect any medical care you receive.

## What does participation involve?

If you choose to take part, you will be donating a small leftover portion of your blood sample that was already collected as part of your Hertility Health hormone test. This sample would have otherwise been discarded. **No additional blood draw is required at this time**.

To allow us to use your blood sample for research, you simply need to read this Information Sheet and sign the accompanying **Consent Form**.

As part of this research, you may *optionally* be contacted in the future about taking part in other studies. These may involve providing additional samples (such as another blood sample), answering questionnaires, or sharing further information relevant to your health.

Taking part in any future research is **completely voluntary**, and you are under **no obligation** to agree. You can also choose **not to be contacted** for future studies at all - this will not affect your current participation in any way.

## What type of samples and data will be collected and stored?

The RTB will primarily store residual blood samples. We will also collect and store diagnostic data associated with your sample. This data will be **de-identified**, meaning that any information that could directly identify you (e.g. your name, date of birth, address) will be removed.

## How will my samples and data be used?

Your de-identified blood samples and data will be used for OVARI's research projects focused on reproductive health, fertility, and menopause. This research aims to **address gaps in knowledge, inform public health policy, clinical guidelines, and educational content**, particularly among historically underrepresented populations. All research projects undergo independent **ethical review**.

## How long will my samples and data be stored?

Your samples and data will be stored indefinitely within the OVRTB for future ethically approved research, unless you choose to withdraw your consent.

## Will my details be kept confidential?

Yes. Best ethical and legal practices will be followed to ensure that all information collected about you will be handled safely and securely. Your personal details will never be released to researchers without your consent. Researchers can apply to access your samples or data, and they have to explain how they will use it, e.g. the research question they wish to answer. This is referred to as '**managed access**'.

### What is a 'managed access' process?

"Managed access" is a really important part of how a research tissue bank like OVARI ensures that your donated samples and data are used responsibly and ethically. It's essentially a controlled process for allowing approved researchers to use the valuable resources in the tissue bank.

- **Who can access the samples?**
    - Managed access requests could come from researchers from the public and charitable sector (Universities, Research Institutes) or from commercial and pharmaceutical companies. These can be based either in the UK or overseas.
    - Only legitimate researchers with approved projects can gain access. They can't just take samples whenever they want.
    - All research proposals must undergo **rigorous ethical review and approval** by an independent Biobank Access Research Committee (**BARC**). This ensures the research is scientifically sound, ethical, and aligns with OVARI's charitable purposes, focusing on public benefit.
    - Data may be accessed in a number of ways, for example, by logging in to secure data analysis environments. Researchers will be reminded of their obligation to keep your data safe and secure by accepting the terms of a data transfer/access agreement. Researchers who analyse the information will not be able to identify you, and promise not to do so as a condition of data access.
- **How is my privacy protected?**
    - Before any samples or data are shared with researchers, all direct identifiers like your name, address, and date of birth are replaced with a unique code (**pseudo-anonymised**) before being transferred to the laboratory for testing, so researchers cannot identify you.
    - Data about you (e.g. personal details and health information) will be stored in secure electronic databases.
    - Any information from genetic and other tests or analyses will be stored **separately** from your personal details, and access to your personal details will only be available to authorised members of OVARI (e.g. to invite you to take part in other research studies).
    - Your samples and data can only be accessed by researchers once they've been de-personalised (i.e. with all identifying information removed).

  - Researchers can share the results of their studies in reports or publications, which are published on the internet and in press articles, etc. Under no circumstances will information that identifies you personally be disclosed in any of these documents.
- **Independent Oversight:**
  - OVARI has a dedicated **Trustee Research Subcommittee** that provides governance and oversight for all research activities. This committee, along with the full Board of Trustees, reviews and approves research partnerships and data-sharing arrangements, ensuring compliance with ethical standards and regulations like **General Data Protection Regulation** (**GDPR)** and the **Human Tissue Act 2004 (HTA)**.
    - GDPR is an EU regulation that harmonises data privacy laws across Europe and applies to how personal data of individuals is processed and transferred. In the UK, it is retained in domestic law as the UK GDPR and requires organisations, such as OVARI, to protect personal data by following principles like **lawfulness, purpose limitation, and security**. The regulation grants individuals rights regarding their data, such as the right to be informed, access, and erase their personal data.
    - The HTA is UK legislation that created a legal framework for the **ethical use** of human organs and tissue in purposes such as research. It established the Human Tissue Authority (HTA) to regulate the removal, storage, and use of human tissue, with a focus on ensuring proper **consent** is obtained.
- **Conflict of Interest Management:**
  - A key part of managed access is addressing any potential conflicts of interest. All researchers and OVARI trustees involved must declare any personal, professional, or financial interests that could influence the research. If a conflict exists, the individual is excluded from decision-making related to that research.
- **Transparency:**
  - The process is designed to be transparent. OVARI publishes information about its research framework and policies, including how it manages conflicts of interest and partnerships. Research findings are also published and made publicly available.

In short, "managed access" means that while your sample contributes to important research, its use is carefully controlled, ethically reviewed, and your privacy is protected at all times. It's about ensuring your generous donation is used wisely and responsibly for the greater public good.

## Will I benefit from my participation?

You may not directly benefit from donating your sample. However, your contribution will be invaluable in advancing reproductive health research for the public benefit.

## Can I know the results obtained from my study samples?

Unfortunately, we will not be able to provide you with individual reports or feedback about any genetic or laboratory results from your sample, as it is collected solely for research purposes. This means you will not receive any personal health information from the analyses carried out on your sample.

However, in **rare cases**, research may uncover an **incidental finding** - that is, an unexpected result that may have **serious implications for your health** and for which **treatment or prevention is available** (i.e. it is clinically actionable). In such cases, we may offer to share this information with you and, with your permission, your GP or healthcare provider.

We follow a clear and carefully governed **Incidental Findings Policy** to decide **if, when**, and **how** such findings may be shared.

## Will my genetic information be used?

Research conducted on your sample may involve genetic analysis. This information will be anonymised and used for research purposes only. It will not be linked back to you or used to provide you with any personal health information.

## Will any of the results obtained with my sample predict the risk of disease?

Some studies which OVARI might support aim to discover variations in the genetic code (‘genetic markers’) that might predict the risk of certain diseases. However, it may be years before researchers can confirm how important or accurate these markers are and determine the associated risk.

If your samples/data are used for a study which involves predicting disease risk, this does not mean that your health is at risk. Genetic variation between individuals can both protect and put individuals at risk of disease. We are a long way from understanding how they balance each other and what combination of markers, combined with other factors such as age, gender, smoking and drinking habits, increases the risk of disease.

## Are there any risks involved?

As the blood sample has already been collected for your Hertility Health test, the primary risk is the potential for a breach of confidentiality, which we mitigate through robust anonymisation procedures and strict data protection protocols in line with UK GDPR and the Data Protection Act.

If you are invited to take part in future studies that involve providing an additional sample, any risks (such as minor discomfort or bruising from a blood draw) will be explained to you at the time. Again, there is **no obligation to give any additional samples**, and you can decline without affecting your current participation.

## What if I change my mind?

Your participation is entirely voluntary, and you have the right to withdraw your consent at any time without giving a reason. If you withdraw your consent, your residual sample will be destroyed, and your associated de-identified data will be removed from the tissue bank for future research use. This will not affect your relationship with Hertility Health or any medical care you receive.

### Withdrawal process

If you choose to withdraw from the Research Tissue bank, you have two options:

1. You can allow us to continue accessing your data but not contact you for any further studies. This is a 'no further contact' withdrawal.
2. You can ask us to stop further use of your data and to destroy your remaining samples. Any research that has used your data or sample(s) cannot be undone. This is 'no further use' withdrawal.

Your personal information will be retained in an archive so that a record remains of your initial consent and the withdrawal process. If we are unable to confirm your decision, your sample(s) and data will be retained for future use, and you will not be contacted again.

## How will the results of the research be used and shared?

All research findings will be published in peer-reviewed scientific journals or in open-access formats to ensure transparency and broad dissemination. Findings will be made available to healthcare professionals, the public, and relevant policymakers to encourage application in clinical practice, advocacy, and informed decision-making. OVARI does not seek commercial return from its research.

## What happens if an invention is made using my sample?

Your donated samples and related information are given as a gift, which may help researchers in the public and commercial sectors make an invention that could improve the future healthcare of patients and blood/organ donors, such as a new product to diagnose or treat a condition. If an invention results from the research undertaken with your sample, you will not receive any compensation, recognition or payment. OVARI will not share your sample to make a profit.

## Who has reviewed this study?

The OVARI Research Tissue Bank has approval by a UK Health Research Authority-accredited Research Ethics Committee (REC). All researchers wishing to use samples from OVARI will apply to and gain approval from the OVARI Research Ethics Committee before they are given access to samples or data.

## Further Information and Contact Details

If you have any questions, concerns, or feedback about the OVARI Research Tissue Bank or your participation in it, please don't hesitate to get in touch.

You can contact the OVARI Research Tissue Bank team to:

- Ask questions about the purpose of the research, how your samples or data are used, or how they are stored and protected
- Request additional information or clarification about your consent or your rights as a participant
- Provide feedback or suggestions about your experience
- Make a formal comment or complaint

We take all enquiries, comments, and complaints seriously and will respond as promptly as possible. If your concern cannot be resolved by the research team, you will be provided with information on how to escalate your complaint through the appropriate institutional or regulatory channels.

Email: [info@ovari.me](mailto:info@ovari.me)
Website: [www.ovari.me](http://www.ovari.me)