

## **The Breastmilk Epigenetics Cohort Study: Participant Information Sheet**

### Investigating breast cancer risk: what can we learn from breast milk?

You are being invited to take part in a research study. Before you decide whether or not 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 if you wish. The study overview tells you the purpose of this study and the overall aims of collecting information and samples from you. The Participant Information Sheet will explain more detail information about the conduct of the study. You can find out more about the study [here](#) and in the BECS Participant Study Overview (15.01.2021 v3).

Ask us if there is anything that is not clear, or if you would like more information. Contact information can be found at the end of this information sheet. Please take time to decide whether or not you wish to take part. Thank you for reading this information.

### **What is the purpose of the study?**

This study aims to investigate the causes of breast cancer, as well as help us to understand and develop ways to predict who will develop the disease. We know that breastfeeding protects women from getting breast cancer, and to some extent ovarian cancer. Also, the longer a woman produces milk over her lifetime, the more her risk is reduced. However, we do not understand how this happens.

Furthermore, many of the markers of breast cancer risk that we already know about have been found in blood. We do not know whether these markers are relevant to what happens in the breasts themselves, as such markers can be very different in different cell types.

Therefore, this study has three broad purposes:

- i) To understand how variations between milk samples from different women indicates risk of cancer
- ii) To understand how breastfeeding reduces cancer risk.
- iii) To understand how milk varies over a full term of lactation.

### **Why am I being asked to take part in this study?**

We are asking as many breastfeeding women nationwide as possible to join our study. We are asking women to complete a questionnaire about their general health as well as risk factors for cancer. We will then ask for samples of milk from a large number of healthy volunteers from all backgrounds so that we can look for differences in the milk based on breast cancer risk factors, such as family history. Some women may be asked for blood samples, or for repeat milk samples later on.

### **Who will be carrying out the research?**

The primary research projects will be conducted by researchers at Imperial College London, but other researchers will also be allowed access to use this resource. Your sample may be used by researchers based in academic institutions, the NHS or collaborating commercial companies (excluding the infant formula industry or companies commercialising human milk) worldwide. All project applications will be reviewed independently by the [Imperial College NHS Tissue Bank \(ICHTB\) Access Committee](#) before being allowed to use your sample.

Queries about the study or consent forms should be directed to:

**The BECS study team**

c/o Epigenetics Unit, 4<sup>th</sup> Floor IRDB, Hammersmith Hospital Campus  
Imperial College London, UK, W12 0NN

Email: [becs@milk-research.com](mailto:becs@milk-research.com)

**What will I have to do if I take part?**

By joining the study, you will be part of a cohort or group of women who are followed up for many years, perhaps even decades. By being able to find out which women go on to develop cancer, and be able to understand changes in their milk samples, it will help to develop new screening tools to identify women at higher risk of cancer. You can choose to stay in touch with the research team, and take part in future studies that come out of this initial work, or simply to take part in the first part of the study by completing the questionnaire and providing a sample of milk.

To take part in the study:

- 1) Firstly you can find out more about the study at [www.milk-research.com](http://www.milk-research.com) and then email [becs@milk-research.com](mailto:becs@milk-research.com) to receive your unique study identifier ID.
- 2) By going to <https://www.milk-research.com/participants> you can read and electronically sign the online consent form. You will not be able to continue without a Study ID.
- 3) Continue to the questionnaire link on the website and complete the questionnaire online. Please be assured that any information about you that leaves the Imperial College database will have your name and address removed so that you cannot be recognised from it. The questionnaire will take between 20-40 minutes to complete. You will need your NHS number, and it would be helpful if you could measure your waist and hips, and have a recent weight measurement.
- 4) The study team will either send you a pack to express milk for the research, or you can provide samples at a study recruitment day. Milk donors will also be able to take part in the research.
  - You will need to provide a sample of 100-200 ml expressed milk in a container provided, labelled with your study ID number. To make up this volume, it would be best if the milk was from the same breast at a single sitting, but you can combine milk from different times during the same day. If expressing from both breasts, please place into two containers labelled with the side from which it was expressed. If the research team have asked you to freeze your milk, please do this as soon as possible after expressing.
  - The study team can give you more guidance about expressing milk, and lactation support if needed.
  - Please keep all milk in the fridge as soon as possible after expressing if you are combining samples or before collection or postage. The bottle(s) should be enclosed in the padded envelope for postage immediately after expressing, and posted the same day to arrive in the lab the next day.
  - If a member of the research team is visiting to collect your sample, please express and refrigerate the milk as close to their arrival as possible.
  - If you have been asked to provide a blood sample, they will take your blood during their visit. If you are attending a BECS Recruitment Day, a sample of your blood will be taken then. If you are a milk donor, we will send a blood kit along with your donor recruitment pack.

**Will the milk or blood be tested for (genetic) inherited disorders?**

It is now possible to assess tissue for genetic factors that affect many diseases. Samples of your milk will be kept at Imperial College and analysed for the purposes of this study. These analyses may include looking into your genetic code and the genes that are expressed. All samples are strictly pseudonymised, and the information we will gain following genetic analysis is

unlikely to have any implications for you or your family. No information about your genetic makeup that could affect you or your family will be disclosed in any way.

Any genetic information generated as part of this study is for research purposes only. It does not get shared with the police or other government organisation.

If you have questions about how your genetic information might be used please ask a member of our research team and we will be happy to answer any of your questions.

### **Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you decide to take part you will be asked to sign a consent form to confirm that you understand what is involved when taking part in this study.

### **What happens if I change my mind?**

You are free to change your mind at any time and do not need to give a reason. To withdraw consent, please write to the Tissue Bank Manager at the address at the end of this document.

A decision to withdraw at any time, or indeed a decision not to take part, will not affect your relationship with the Milk Bank if you are already a donor there, or planning to become one. In the event of you deciding to withdraw from the study, all samples taken from you for research will be destroyed, and any information about you will be removed from the study database. However, some of your sample may already have been used in completed research studies.

### **Does this affect my future medical care?**

Participation in this study is unlikely to have direct benefits for you, although it may be of benefit to women in the future. Giving this sample would not in any way affect any future medical treatment that you may require. If you do develop breast cancer in the future, the study would be notified automatically by accessing the nationally held information in the UK Cancer Registries (<http://www.ukiacr.org/about/membership>). We have requested that small amounts of surplus tumour tissue could be accessible after your care is completed, which would not affect your care in any way. This is important so that we can understand how breast cancer develops, and whether changes seen in cells from breast milk could help to explain this.

### **Are there any possible disadvantages or risks of taking part?**

There should be no side effects from providing the breast milk sample. There may be a risk of bruising if you agree to give a blood sample. Risk of infection during the blood taking will be minimised according to standard Imperial College Risk Assessment and training. You do not have to undergo any other extra procedures apart from answering the questions on the questionnaire as part of the study. We will not disclose any information about you to any third party, such as insurance companies, and will keep all the information we have about you strictly confidential at all times. Under the Data Protection Act, you are entitled to see what is recorded about you by applying to the Manager of the Imperial College Healthcare Tissue Bank.

### **What are the possible benefits of taking part?**

We cannot promise that the study will help you, but the information we get might help to improve the prevention and treatment of breast cancer in the future. We also aim for the information to improve our society's understanding of human milk, and how it changes over time. We will not be able to provide you with your individual results from any of the analyses in the study.

### **What will happen to the results of studies using my sample?**

Research studies usually take several years to complete. The results from these studies will be used to improve the screening of women in the future. Results will be published as appropriate in scientific papers and magazines and regular updates of research in progress, research results and other relevant information will be published on [www.milk-research.com](http://www.milk-research.com). Study information will be available via a newsletter yearly, which will be emailed or posted according to your preference, and available on the BECS website.

All information will be pseudonymised (your name replaced with a study code) and therefore you will not be identified in any publication. Pseudonymised data from published studies will be made available for other scientists to use in future research.

If you went on to breastfeed again in the future, it would be highly useful if we could have another sample of milk, to understand how markers we identify change over time. We will not actively contact you, but this would be very helpful to bear in mind in case you would like to contact the team again in this instance.

### **What if something goes wrong?**

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr James Flanagan, [j.flanagan@imperial.ac.uk](mailto:j.flanagan@imperial.ac.uk) or Dr Natalie Shenker, [natalie.shenker@imperial.ac.uk](mailto:natalie.shenker@imperial.ac.uk)).

Imperial College London holds 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 Imperial College 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 wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team

### **Who funds this study?**

This is a research project run by the Imperial College Academic Health Science Centre, and supported by funds from UK Research and Innovation, provided by the UK government through the Medical Research Council. The Hearts Milk Bank is assisting with the recruitment and collection of participants, and is part of a charity, The Human Milk Foundation.

### **Who has approved this study?**

The Multi Centre Research Ethics Committee for Research in Wales has approved, and will regularly review, this study. Their contact details are as follows:

REC for Wales Churchill House  
6th Floor, 17 Churchill Way  
Cardiff CF10 2TW

Website: [www.nres.nhs.uk](http://www.nres.nhs.uk)

If you have any further questions, please contact:

The Manager  
Imperial College Healthcare Tissue Bank  
11th Floor, Charing Cross Hospital, Fulham Palace Road,  
London W6 8RF

Email: [tissuebank@imperial.ac.uk](mailto:tissuebank@imperial.ac.uk)

Or, contact the Imperial study team directly on [becs@milk-research.com](mailto:becs@milk-research.com).

**Thank you for reading this, and if you decide to, for taking part in the study.**