We invite you and your baby to take part in our research study. Please take time to read this information. If there is anything that is not clear, or you would like further details, please ask us.

# What is the purpose of the study?

To develop hormone tests for mothers who have problems producing milk when breastfeeding.

To achieve this aim, the INSIGHT Study will establish normal ranges for the hormones that stimulate breast milk production in the first few days after giving birth. INSIGHT will also investigate if hormones influence breast milk composition.

The first phase of INSIGHT consists of a pilot study to investigate the feasibility of collecting blood samples soon after giving birth, and also to provide us with an initial understanding of hormone levels around the time your milk has come in (day 4 after child birth).

# Why have I been invited?

You are planning to breastfeed, and we would like to ask you to donate some blood, breast milk and urine samples for this study. We plan to recruit a total of 100 volunteers to this initial pilot, with another 968 volunteers for the main study.

You will not be able to take part in this study if you do not reside in Oxfordshire, if you or your baby become seriously unwell, if you are separated from your baby for a prolonged period, if you have COVID-19 symptoms or if there is any reason that it would be unsafe for the study team or you to visit your home.

# Do I have to take part?

No. It is up to you to decide whether you wish to participate. You can also withdraw from the study at any time, without giving a reason. Withdrawal would not affect your clinical care or your baby’s care.

# What wOULD happen to me if I decide to take part?

We will talk you through the study and give you the chance to ask any questions. If you are still happy to take part, then you will be asked to complete a consent form.

The INSIGHT study involves the following procedures during the first 4 days after giving birth:

**1. Completion of a breast-fullness diary:**

You will be asked to record when your milk is coming in, by documenting how full your breasts are feeling on a daily basis.

**2. Single visit to collect a blood sample before and after a breastfeed:**

A research midwife, nurse or assistant will visit you at home or at the maternity unit on day 4 after giving birth. This is to collect a blood sample just prior to a breast feed, and also at 45 minutes after the feeding session has started.

**3. Collection of a breast milk and urine sample:**

This will be undertaken during the study visit. We will collect around 10 ml of breast milk (two teaspoons) and a urine sample (around 20 ml).

**4. Collect information about you and your pregnancy:**

We will collect information such as your age, ethnicity, and medical conditions from your medical records. We will also note whether you experienced any complications during your pregnancy, labour and birth.

# What should I consider?

We will only recruit women who plan to breastfeed. Although hospital policy is to encourage breastfeeding, we understand that some women decide not to, in which case it is not possible to take part in this study. Remember that you do not need to make a decision now about feeding your baby. You can also change your mind at any time without affecting the care that you or your baby receive.

You can continue to take medication that you are currently on. You can also take part in other research studies, as long as these do not involve you taking medication for research purposes.

# Are there any possible risks from taking part?

This study involves taking two blood samples, which could inconvenience you, or cause a small amount of discomfort, bruising, or irritation to the vein (known as ‘phlebitis’). To minimise any discomfort, we shall not make more than two attempts to take blood at any one time.

To minimise the risk of COVID transmission, we will check prior to any home visit that no one in your household has COVID symptoms. The research team will follow up to date COVID guidelines when conducting study visits and use appropriate personal protective equpiment (PPE), as well as undertaking regular lateral flow testing as per government guidelines.

# What are the possible benefits of taking part?

A member of the research team will offer advice and guidance on breastfeeding your baby during the study visit. We also hope that this research leads to the development of blood tests, which can be used to help mothers with limited breast milk supply.

# WOULD my General Practitioner/family doctor (GP) be informed of my participation?

There will be no need to inform your GP about your participation in this study.

# Will my taking part in the study be kept confidential?

Yes, the study will comply with the UK General Data Protection Regulation (UK GDPR), which requires data to be anonymised as soon as it is practical to do so.

The researchers would take the following steps to ensure your taking part is kept confidential:

* Minimise the use of your personal details by using unique study numbers to refer to you and your samples.
* Store hardcopies of documents containing your personal details in a locked filing cabinet in a locked office, which are only accessible to the research team.
* Store electronic documents containing your personal details on a secure University of Oxford server.

Outside of the care team, the study team will have access to your medical records. The only other parties that may access your medical records would be monitors and/or auditors from the University of Oxford and the Oxford University Hospitals NHS Foundation Trust (OUHFT) for governance and compliance purposes.

# WOULD I be reimbursed for taking part?

You would receive the following reimbursements for your time and inconvienience:

1. £10 for the study visit after your baby is born, where you donate a blood sample before and after a breast feed

2. A further £25 for completing and returning the breast fullness diary.

Payments will be in the form of a gift voucher.

# What would happen to the samples I give?

The samples provided would be used to measure hormone changes in your blood, urine and breast milk during the first 4 days after birth, as this period is essential for the initiation and maintenance of breast milk production.

You would be asked to give consent to the use of any remaining samples for future ethically approved research. Your anonymised samples would be used mainly by local researchers (if applicable), but ethically approved research projects may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide. At the end of this study your samples could be transferred to an ethically approved Biobank/Research Tissue Bank. This is optional and whether or not you agree does not influence your participation in this study. If you do not wish for your samples to be used in further studies, they will be destroyed at the end of this study.

# What wOULD happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you and your baby. In the case of research, this is ‘a task in the public interest.’ The University of Oxford is the data controller and is responsible for looking after your information and using it properly. We will be using information from you and your medical records and would use the minimum personally-identifiable information possible. Once the study is over, we would keep your personal data for 5 years. Study documents would be held securely at the University of Oxford and archived in an off-site storage facility.

It would also be necessary to keep the consent form (personal data) until the sample has been depleted or destroyed, in order to meet the traceability requirements of the Human Tissue Act. If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed.

The OUH NHS Trustor local INSIGHT study team will use your name and contact details to arrage study visits following your recrutiment to the study. They will keep identifiable information about you from this study in line with the Trust’s policy on medical record retention after the study has finished.

Data protection regulation provides you with control over your personal data and how it is used. However, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>

You can find out more about how we use your information by contacting fadil.hannan@wrh.ox.ac.uk

# [What will happen if I don't want to carry on with the study?](http://hra-decisiontools.org.uk/consent/content-sheet-support.html#two)

Participation is voluntary and you may change your mind at any stage, or withdraw from the study at any time. Withdrawal will not affect the clinical care of you or your baby. If you withdraw from the study, any samples which have already been collected will be used for research as detailed in this information sheet. You are free to request that your samples are disposed of at any time during or after the study. You can also request for your data to be destroyed and removed from the final analysis. However, this will not be possible once the study has undergone publication.

# What will happen to the results of this study?

A summary of the results from this study will be displayed on the LRF Oxford Centre for the Endocrinology of Human Lactation (LRF OCEHL) website, and also presented at scientific conferences. The results may also be published in a scientific journal. Published data will be anonymised and not include any personal information. Some of the research may also contribute to an educational requirement (e.g. a doctoral thesis).

# What if we find something unexpected?

We do not anticipate finding anything to report back to you or your doctor, as the hormone measurements are not yet used as clinical tests.

# What if there is a problem?

The University of Oxford, as Sponsor, has insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during this study, you should contact Dr Fadil Hannan who is the Chief Investigator (email:fadil.hannan@wrh.ox.ac.uk; tel:01865 222937); or Helen Price, Research Midwife (tel: 01865 221074; email:helen.price@wrh.ox.ac.uk).

Or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email: ctrg@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact Tel. No: 01865 221473 or Email: PALS@ouh.nhs.uk

# How have MOTHERS and the public been involved in this study?

Members of the public were involved in reviewing the Participant Information Sheet. In designing this study, we have taken into account their opinions on the frequency of participant visits and the tests we will carry out

# Who is organising and funding the study?

This study is funded by the Family Larsson-Rosenquist Foundation (FLRF), which is an independent charitable organisation supporting research into breast milk and breastfeeding to help women around the world.

# Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants’ interests. This study has been reviewed and given a favourable opinion by Cambridgeshire and Hertfordshire Research Ethics Committee.

# Participation in future research

Any future contact would come from your research team in the first instance. Agreeing to allow your contact details to be held does not oblige you to take part in future research. Your contact details would be stored securely on the University of Oxford High Compliance server. You can be removed from this database at any time you wish.

# Further information and contact details

If you would like to discuss the research, please contact:

**Helen Price, Research Midwife**, LRF Oxford Centre for the Endocrinology of Human Lactation,Level 3, Women’s Centre, John Radcliffe Hospital, Headington, Oxford, OX3 9DU, Direct Line: 01865 221074 / E-Mail: helen.price@wrh.ox.ac.uk

**Dr Fadil Hannan, Director of the LRF Oxford Centre for the Endocrinology of Human Lactation** Direct Line: 01865 222937 / E-Mail: fadil.hannan@wrh.ox.ac.uk

Thank you for reading this information and for considering taking part.