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PARTICIPANT INFORMATION SHEET

The NECTAR Study

Evaluation of laboratory methods for measuring the composition of breastmilk

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

Human milk is known to contain hormones, cells, antibodies and metabolites which may be passed to infants during breastfeeding. These components could play a role in improving the health and wellbeing of the breastfeeding infant. However, little is known about the types and quantities within human milk. The purpose of this study is to find out the suitability of laboratory methods for measuring the different breast milk hormones and other factors.

Why have I been invited?

You have been invited because you are providing breast milk to your infant(s) in the Oxford Newborn Care Unit and we would like you to ask you to donate a small sample of milk to our study. We are hoping to get 30 samples of breastmilk from healthy volunteers for this study.

Do I have to take part?

No. It is completely up to you to decide whether or not you wish to take part. If you do agree to participate, you may withdraw yourself from the study at any time, without giving a reason, by

advising the researchers of this decision. Withdrawal will not affect the clinical care of you or your infant(s)

What will happen to me if I decide to take part?

If you are happy to take part in the research, you will be asked to provide us with around 10mls (about 2 teaspoons) of breast milk. This will be collected in the same setting where you normally express milk for your baby e.g. in the Oxford Newborn Care Unit.

Initially, we will talk you through the procedure for collecting the milk sample and give you the chance to ask any questions. If you are still happy to take part, then you will be asked to sign a consent form.

We expect that discussing the study as well as providing the sample may take up to 45 minutes.

The Research Midwife or Nurse will provide you with a separate sterile bottle for you to express up to 10mls of your milk into. It is up to you at which point in your expressing session, you would like to do this. They will transfer the donated breast milk into another tube which will be given an anonymous study number and taken to our laboratory for processing. There, your donated breast milk sample will be tested straight away or frozen and kept securely in the laboratory until we are ready to use it to test the laboratory methods for measuring hormones and other factors. This will be within a 3 month period. Normally we would only ask you to provide a breast milk sample on a single occasion. However, if you are producing a substantial amount of breast milk, then we may ask if you would be willing to provide further samples when you next visit the Oxford Newborn Care Unit.

These tests will not generate any clinical information about you, it will only help us to develop suitable laboratory methods for the future. We will therefore not be able to contact you with any individual test results arising from these studies.

What should I consider?

You should also consider whether you feel like you are established in your milk production and whether you feel that donating a small amount of your breastmilk to this study will have any impact or cause disruption to you or your baby.

You can continue to take any medication that you are currently on and you can also take part in other research studies if you want to.

Are there any possible disadvantages or risks from taking part?

This study will involve you providing a small quantity of breast milk, and should not pose any risk to you or your baby/babies

What are the possible benefits of taking part?

There is no direct benefit to you or your baby for participating in this study. Information about the composition of your milk will not be provided to you. However, future mothers and infants may benefit from this research by having a better understanding about the hormones and other factors contained in breast milk.

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

No, as we will not be generating any clinical data, the results will not be fed back to you or to your GP. You can inform your GP of your participation in the study if you wish to.

Will my taking part in the study be kept confidential?

Yes, the study will comply with the General Data Protection Regulation (GDPR), which require data to be de-identified as soon as it is practical to do so. The researchers will refer to you using a unique participant study number. In addition, all the samples you provided will be identified by a unique sample number. The samples will not be labelled with any of your personal details. In addition, the study staff will safeguard the privacy of participants' personal data. Thus, all hardcopies of documents containing personal details will be stored in a locked filing cabinet in a locked office, which are only accessible to the research team. Furthermore, any electronic documents containing personal details will be stored on a secure university server. Once the study is over, we will keep your personal data for no more than 12 months before it is destroyed. Study documents related to the research data generated by the study will be archived in an off-site storage facility for 5 years.

Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

You will receive a one off £10 gift voucher for your overall participation in this study as compensation for your time and the inconvenience.

What will happen to the samples I give?

The sample you provide will be used to test the ability of laboratory methods to reliably measure hormones, cells, antibodies and metabolites in human milk. Your sample will be given a unique study code and will be anonymised. Your sample will be analysed in the laboratory of Dr Hannan, the Director of the Oxford Centre for the Endocrinology of Human Lactation or by one of his research collaborators within the University of Oxford or Oxford University Hospitals NHS Foundation Trust. Once the sample has been used it will be destroyed immediately. This means that if you decide to withdraw your sample from the study, we can only do so if it has not yet been destroyed.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. 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 in order to undertake this study and will use the minimum personally identifiable information possible. We will keep identifiable information about you for 12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study.

Third Party Processors:

The local NHS Trust or local study team will use your details, e.g. name, NHS number, to oversee the quality of the study. They will keep identifiable information about you from this study securely on the University of Oxford High Compliance server for 12 months after the study has finished. Consent forms or other personal details will be archived at an off-site facility, for up to 5 years.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, 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?

Participation is voluntary and you may change their mind at any stage. If you do agree to participate, you may withdraw yourself from the study at any time, without giving a reason, by advising the researchers of this decision. Withdrawal will not affect the clinical care of you or your infant(s). Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish.

What will happen to the results of this study?

A summary of the results from this study may be displayed on the Oxford Centre for the Endocrinology of Human Lactation (OCEHL) website, and also presented at scientific conferences. In addition, these results may be published in a peer-reviewed scientific journal. Any published data will be entirely anonymised, and not include any personal information.

What if we find something unexpected?

We do not anticipate finding anything unexpected as these tests are not clinical tests but purely for the aim of developing suitable laboratory methods for the future.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate 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, or how your information is handled during the course of this study, you should contact Dr Fadil Hannan who is the Chief Investigator of this study (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 may 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 patients and the public been involved in this study?

The Infant Feeding Team were consulted to ensure that the process for collecting milk samples would not interfere with the mother's ability to feed her baby with breast milk.

Mothers who were expressing or breastfeeding babies have also been shown the participant information sheet and invitation leaflets and asked to provide their feedback.

For more information about taking part in research please follow these links:

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
- www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Who is organising and funding the study?

This study is funded by the Family Larsson-Rosenquist Foundation (FLRF), which is an independent charitable organization supporting research into breast milk and breastfeeding.

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 favourable opinion by _____Research Ethics Committee.

Further information and contact details:

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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