Impact of Maternal Sugar Intake on Breast Milk Composition and Breast Milk Variation over 24 hours.

Short title: **MATSUB: The Maternal Sugar and Breast Milk Study**

INFORMATION SHEET

HUMAN RESEARCH ETHICS COMMITTEE NUMBER:

INTRODUCTION

Each year CSIRO perform a number of research projects involving human participants. We examine the effect of different diets on health, disease and other related outcomes. This study is an investigation into the effect of diet on breast milk composition.

Nutrition in early life has lasting impacts on health, hence it has become a major focus of scientific research. It is important to recognise that the nutritional environment we expose infants to at an early age will have an impact on their development. Breast milk is an immensely beneficial food source which gives infants optimal nutrition, however a mother's diet can change the nutrient content of breast milk. We hope to develop a better understanding of this relationship through this study.

WHAT IS THE AIM OF THIS STUDY?

This study has been designed based on an almost identical 'pilot' study which was conducted in the UK in 2019. The aim of this study is to build on the findings of this study to further develop our understanding of how sugar consumption changes the content of breast milk over a 24-hour period.

If you would like to read the details of the pilot study please contact us on the details listed below.

HOW WILL THE STUDY BE CARRIED OUT?

Screening Call

- A chance to ask questions and discuss any concerns about the study before confirming participation, informed consent will be taken verbally until the first visit for the purposes of completing screening.
- A questionnaire regarding you and your baby's health and baby's feeding patterns will be completed.
- Diet diaries along with instructions on how to fill these out will be provided.

↓

Following confirmation of suitability mothers will be contacted and asked to complete the diet diary for 3 days.

Study visits/days

- There will be **two study days** in total over which you will consume two different diets (**control** and **higher sugar**).
- On visit 1 an informed consent form will be signed by you and the student investigator to confirm your intent to participate in the study and your baby will be weighed.
- The student investigator will visit your house twice per study day; to deliver food and sampling supplies before the intervention commences and again to collect samples and used supplies.
- **Three main meals** as well as **two** snacks will be provided following each specific diet. The meals may be tailored to personal preferences within reason. Consumption at each meal will be recorded as well as snacks and fluid intake.
- Breakfast will be eaten when you wake up, this will start the **12 hour sampling period**. Lunch and dinner will be consumed at 5 and 10 hours from breakfast respectively. Snacks can be consumed at any time between meals.
- You will be asked to collect a **5ml** sample of breast milk by **manual expression** before beginning the controlled diet in the morning and then **every hour** until 12 samples have been collected. Privacy will be given during this time if the student investigator is present.
- There will be a week washout period between each diet, overall the study will take up two full days over ~10 days plus 1-2 phone calls at the beginning for screening purposes.

Please contact us if you wish to see an itemised copy of all foods which will be provided, you will have a chance to discuss the option for personal tailoring during the screening call with the student investigator.

ARE THERE ANY RISKS INVOLVED?

You may find the hourly sampling protocol difficult. If some samples are missed this is fine as long as the exact time is recorded for the missed sample, you can then resume at the next sampling time. The requirement for frequent sample collection may also limit your ability to work or undertake activities outside the home for the 2-day study period, so we encourage you to arrange in advance for study days to take place when suits you.
There is the possibility that delayed or interruption to infants' feeds may cause stress to you or your baby, however, we ask for only a small amount of milk per sample so it should not delay feeding for more than 5 minutes. If your baby is distressed, you can opt to miss that sample and simply record the reason. Again, it is possible that expression of breast milk may cause irritation or discomfort at the breast. If this occurs please miss the next sampling and record the reason.
There is the potential risk of allergy to foods provided and/or risks associated with food such as contamination. To minimise this risk, we will ask you to provide us with information on any allergies or intolerances so we can adjust the diets if required. Food will be prepared in a controlled clinical environment in line with food safety regulations and all precautions will be followed to avoid contamination or incorrect cooking of foods.

WHAT ARE THE REQUIREMENTS FOR PARTICIPATING IN THIS STUDY?

<u>Inclusion Criteria</u>

- Healthy mothers and singleton infants born at full term (>38 weeks gestation)
- Mothers between the ages of 21-35 years
- Mothers with a Body Mass Index (BMI) between 20 and 30 kg/m^2
- Infants between 6 and 20 weeks of age at the time of recruitment
- Mother and infants have no self-reported underlying medical conditions/special dietary requirements which result in restriction of any major food groups (e.g. vegan/dairy allergy)
- Mothers able to give informed consent for themselves and their infants
- Mothers have been exclusively breastfeeding (with the exception of additional water or medication such as paracetamol suspensions) their infant since birth

Exclusion Criteria

- Infants who were born by caesarean section
- Infants who are fed formula milk or fed a mixture of breast milk and formula
- Mothers who are struggling with breast feeding and/or are unable to manually express milk.
- Mother and/or baby who has an allergy/intolerance/aversion to the study diet (e.g. lactose intolerance).

WHAT ARE THE BENEFITS OF PARTICIPATING IN THE STUDY?

As a thank you for contributing to this study you will be provided with a $75 gift card. By participating in this study you will also be providing a valuable contribution to the scientific knowledge in this field. Your personal results will be mailed out to you at the completion of the study, and the overall group results will also be provided.

HOW WILL MY PRIVACY BE PROTECTED?

CSIRO is governed under the *Privacy Act 1988* (Cth). CSIRO is collecting your personal information for the purposes of conducting the study and related scientific research. CSIRO will only use and disclose your personal information in accordance with the Privacy Act 1988 and the *NH&MRC National Statement on Ethical Conduct in Human Research* (2007, Updated 2018) as amended from time to time, and as otherwise required by law.

CSIRO will collect your personal information, including your name, email address, residential address, weight and details surrounding your pregnancy and birth for the purposes of undertaking this study.

CSIRO may also collect your sensitive information, including health information for the purposes of undertaking this study. The telephone screening may be hosted by CSIRO using the Cisco Webex platform and/or Microsoft Teams. While most of the information collected via Webex/Teams is stored on servers in Australia, there may be limited circumstances where information is transferred to Webex/Teams servers based overseas. This means that your personal information may be transferred to Webex/Teams servers located outside Australia. By giving consent to participate in the focus group, you consent to the potential transfer of your personal information to Webex/Teams servers located outside of Australia, and you acknowledge that this information may not be subject to the requirements of the *Privacy Act 1988* (Cth).

You and, with your permission, your doctor will be notified of any medical condition deemed significant by the Clinical Research Unit Medical Officer. We will not use or disclose your information for direct marketing purposes.
CSIRO may publish study results and data in research publications and press releases, however, CSIRO will de-identify any personal information contained in the data and results so that you cannot be identified.
For further information on how CSIRO handles your personal information and our complaints process please read our privacy policy available on our website or contact us at privacy@csiro.au.

WHAT IF I WISH TO WITHDRAW?
You are free to withdraw at any time during the study. However, you will note in the consent form a request to maintain any data collected prior to your withdrawal from the study. Your data up until your withdrawal are an important part of the data set for analytical purposes. Your personal information will be kept with those of continuing participants until the end of the study.
It is also important to understand that we can choose to end your participation, too. That decision would be made if we decided that the study is not in your best interest, if you are unable to follow the protocol of the study, or if the study is discontinued. If we ever have to end your participation, we will make sure you understand the reasons why.

YOUR OBLIGATIONS AS A PARTICIPANT.
You will need to inform a study staff member of any changes in your health as some changes could have an effect on your participation in the study and the study findings. You must also be able to attend all visits and undertake all relevant procedures during the study period.

IF YOU HAVE FURTHER QUESTIONS
Please contact Ellen at ellen.ward@csiro.au.

This study has been approved by the CSIRO Human Research Ethics Committee. If you would like to speak with someone with respect to ethical matters or wish to register a formal complaint about the conduct of this research, please contact the Secretary of the Committee via email at chmhrec@csiro.au .

Print Name: .....

Signature: ..... Date: / /