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UR MEDICINE
MEDICINE of THE HIGHEST ORDER

# CONSENT FORM

## At-the-Breast vs. Expressed Human Milk: Genesis of Infant Nutrition (BEGIN)

**Principal Investigator:** Bridget E. Young, PhD

**This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.**

### Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you are breastfeeding or pumping for your infant.
- The purpose of this study is to learn about how breast milk differs in mothers that primarily nurse at the breast from mothers who primarily express (ie: pump) milk.
- Your participation in this study will last up to six months postpartum.
- Procedures will include collecting samples at home from you and your baby, as well as questionnaires.
- There are risks from participating.
    - The most common risk is invasion of privacy.
- Our study staff are Lactation Counselors, and are available to support you with breastfeeding and pumping.

### Purpose of Study

The purpose of this study is to learn about how breast milk, and other samples differ from two groups: 1.) mothers that mainly nurse at the breast, and 2.) mothers that mainly express breast milk. In addition to studying samples you collect from yourself, we will also be studying differences in samples collected from your baby.

### Description of Study Procedures

If you decide to take part in this study, you will be asked to collect samples in your home including:



RSRB Approval Date: 10/23/2025
Expiration Date: 5/13/2026

Breast milk from morning feed: we will ask that you collect a small amount (1 teaspoon = 5mL) of breast milk in the morning every day throughout your participation in the study.

Breast milk from each expression over 24 hours: *Express group:* we will ask that you save a small amount of breast milk (1 teaspoon) from each pumping session throughout an entire day. We will ask that these be collected once per month. *At-the-Breast group:* we will provide supplies for you to save a small amount of breast milk (1 teaspoon) from each pumping session throughout an entire day, if you are able.

Saliva: we will ask that you collect your saliva weekly, and that you perform a mouth swab for your baby monthly. These samples will be collected in the morning.

Stool: we ask that you collect a stool sample monthly, and that you collect a stool sample from your baby every week.

Fasting infant urine: we ask that you collect a urine sample using cotton balls from your baby from a diaper once per month. We ask for a fasted urine sample (collected once it has been at least 2 hours since baby last ate).

Very detailed collection instructions, and all required materials will be provided to you for all samples throughout the length of the study.

Samples will be stored in your freezer, and study staff will coordinate a pickup at least once per month.

We ask that you download one app to be used on a smartphone or tablet throughout the study. The app is completely free to download and use.

The app we will ask you to use is ‘Baby Tracker”. We will ask that information be entered such as pumping/ nursing times, pumping volume, feeding times, your baby’s measurements, your baby’s symptoms/ medications, daily notes, etc. We will ask you to use this app every day.

Data stored in this app can be downloaded, and we will then ask that you email this data to study staff.

We will also ask that you have your baby wear a watch (called a Micro Motionlogger®) which allows us to analyze their sleep. The watch is non-invasive and does not utilize Bluetooth technology. The watch fits around your baby’s calf or thigh and can be worn on top of clothes or a sock, or directly against the skin. We will have your baby wear the watch for 5 days at age 2 months, and again at 4 months. While they are wearing the watch, we will also ask some questions regarding their sleep.

Questionnaires will also be part of your participation. These will occur when you enroll in the study, as well as monthly throughout your participation. The questionnaires will ask you about your overall health, your moods/ stress levels, exercise, your baby's moods, etc. You may skip any question you do not wish to answer.

Participation in the study may last up until your baby is 6 months of age.

**Number of Subjects**

Approximately 240 subjects will take part in this study: 120 mothers primarily nursing at the breast, and 120 mothers primarily expressing milk.

**Risks of Participation**

Health information: there is minimal risk should you, and your baby participate in this study. You should be aware that there is a risk of breach of confidentiality. In order to protect all information, you and your baby will be assigned a study ID number. Therefore, no personal information will be tied to any samples in any way.

Infant Stool Collection: You will be provided with a stool collection tube that contains a preservative liquid, and a small spoon to scoop some of your baby's stool out of the diaper and place in the tube containing the preservative liquid. This preservative liquid can irritate the skin or eye if splashed onto the skin or eye. If you accidentally splash the liquid on your skin or in your eye you will need to wash the skin or eye for several minutes with water. To prevent such accidents, we will be provide you with gloves and safety goggles to wear when you are collecting the stool sample for us.

Questionnaires: You may skip any question you do not wish to answer.

There are no anticipated risks associated with the collection of your breast milk, saliva, or your baby's urine samples.

Use of E-mail in Research: You have the option to receive communications about this study via email messaging, by indicating your consent at the end of this form. Messages will be limited to study-related reminders.

Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email.

Email communications between you and the study team may be filed in your research record.

**Benefits of Participation**

You will not benefit from being in this research study.

**Costs**
There will be no cost to you to participate in this study.

**Payments**
You will be paid $100 for each month you participate in this study. You can earn up to $500 if you complete the entire study.

For this study we use a subject payment system called Participant Payments. The system allows three ways to provide payment. You can choose: a reloadable debit card; direct deposit; or mailed paper checks. The study team will help you create a "subject profile" in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile. Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have a Participant Payments account (because you are in another study that uses this system), your existing profile will be used to provide payment. See the 'Information Sheet for Participant Payments" for additional information.

Payment received for taking part in research is considered taxable income. If you receive payment for your taking part in studies at the University of Rochester of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. You may be asked to submit a W-9 form, which includes your Social Security Number. If you are asked to complete a W-9 form and we find that you are not a US citizen or permanent resident, we may need to withhold 30% of your payment for taxes consistent with tax requirements.

**Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes**

The University of Rochester will make every effort to keep the information collected from you private. In order to do so, we will assign you a study ID number to protect your information. Study personnel will be the only individuals that will have access to the samples that you provide. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

In order to collect study information, we have to get your permission to use and give out your personal health information. We will use your questionnaires, and samples to conduct the study.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

*What information may be used and given to others?*
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates

*Who may use and give out information about you?*

- The study doctor and the study staff
- URMC and Affiliates

*Your information may be given to:*

- The Department of Health and Human Services
- The University of Rochester
- The National Institutes of Health (NIH)
- Collaborators at NYU

*Why will this information be used and/or given to others?*

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

*What if I decide not to give permission to use and give out my health information?*
Then you will not be able to be in this research study.
*May I review or copy my information?*
Yes, but only after the research is over.

*How long will this permission be valid?*
This permission will last indefinitely.

*May I cancel my permission to use and disclose information?*
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

*May I withdraw from the study?*
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

*Is my health information protected after it has been given to others?*
No. There is a risk that your information will be given to others without your permission.

**Future Use of Information/Samples**
Your information / samples might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your information / samples are used or distributed. You will be given the option at the end of this consent form to decide if you would like your information / samples used for future research.

**Sponsor Support**
The University of Rochester is receiving payment from National Institute of Health conducting this research study.

**NIH Open-Access Data Sharing**
The National Institutes of Health (NIH) is funding this study and requests that we share the all the data collected in this study and from the samples we collect. As part of this study, we will collect information about your health and this information will also be sent to the NIH open access data repository. We will remove direct identifiers (such as your name) and assign a random code to your information before sending it to the repository. **The NIH will never get this code or the identifiers we removed.** Thus, the study data will be deidentified, meaning there will be no information in the data that can be traced back to you, your child or your family. The data will be stored and shared through an NIH open access database. This means the data will be publicly available. Anyone will be able to go to the website and download the information. We will not know what types of health-related research will be done with the shared data.

**Certificate of Confidentiality**
To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

**Contact Persons**

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Dr. Bridget Young: (585) 273-1733.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

**Voluntary Participation**

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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**USE OF EMAIL FOR COMMUNICATION IN RESEARCH**

I consent to the use of **email** in this study. If yes, enter email address:

_____

_____Yes _____No

**CONSENT TO FUTURE USE OF INFORMATION / SAMPLES**

May we share your samples (breast milk, stool, saliva, urine), and health information with other researchers to study breast milk composition and infant development?

_____Yes _____No

May we share your samples (breast milk, stool, saliva, urine), and health information with other researchers for future research projects related to other topics?

_____Yes _____No

**CONSENT TO RE-CONTACT**

May your study doctor, or someone from the study team, contact you in the future about using your samples [human milk, urine, saliva, stool] or information for research that is not described in this consent form?

_____Yes _____No

May your study doctor, or someone from the study team, contact you in the future to see if you would like to participate in other research?

_____Yes _____No

**SIGNATURES/DATES**

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

**Subject Consent**

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I agree to have my baby participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

**Person Obtaining Consent**

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date