Title: Reducing Disparity in Receipt of Mother's Own Milk in Very Low Birth Weight Infants Informed Consent Form

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RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Reducing Disparity in Receipt of Mother's Own Milk in Very Low Birth Weight Infants: An Economic Intervention to Improve Adherence to Sustained Maternal Breast Pump Use (ReDiMOM)

Sponsor(s): National Institute of Health (NIH)

Name of Participant: _____

Note: If you are a parent, guardian or legal representative of a minor, the terms "you" or "your" refer to the research participant, which for this study includes you and your infant or infants (if twins, triplets or higher multiples). The term "infant" in this document should be considered "infants" in the case of multiples.

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, and relationship with Rush University Medical Center (Rush) will not change nor be affected.

The purpose of this study is to test an intervention to support mothers of preterm infants in providing breastmilk or mothers own milk from birth of their infant through Neonatal Intensive Care Unit (NICU) discharge. This study may include an economic intervention in the form of financial support to you while providing milk to your infant in the NICU.

If you agree to participate in this study, your participation will begin after your infant is born and the study team confirms that you are eligible to participate. Your participation will last until your infant is discharged from the NICU. You will visit your infant in the NICU as you would normally and you will not be asked to complete any additional study visits outside your normal visitation hours. However, you will be contacted by research staff to collect data for the study by telephone, text, in writing or in person when you are not in the NICU.

During the study, you will be asked to , 1) provide small samples of your breastmilk once a month for study testing, 2) complete questionnaires about your health, current and past lactation (breast milk feeding) experience, maternal stress, and demographic information (such as age, education, and occupation) , and 3) allow the research team to collect feeding and health outcome information about your infant. You will be randomized (decided by chance like a coin toss) to receive either
(1) the NICU standard of care lactation support or (2) the NICU standard of care lactation support plus the economic intervention. For a detailed list of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

There are no foreseeable physical risks to either you or your infant by participation in this study because all study procedures are noninvasive. The probability or amount of harm or discomfort from this research study is not greater than that you would normally encounter in daily life or during routine hospital care.

There are theoretical emotional risks to you for participating in this study. There is a risk of external pressure from family or friends to continue to provide milk for the financial intervention even though you would like to stop. As with all research studies, there is a risk of breach of privacy associated with data collection. Several procedures are in place to minimize both of these risks. For a detailed list of risks you should know about and procedures that are in place to protect you from these risks please see the "*What are the risks and discomforts of participating in this study?*" section of this consent form.

Your participation in this study is voluntary; you have the option to not participate in this study. If you choose not to participate, you and your infant will continue to receive the same standard care by the Rush NICU medical and lactation team. Your choice to participate or not participate in this study will not affect you or your infant's medical care at Rush.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you have or may have an infant in the Rush NICU born earlier than 32 weeks gestational age, and you intend on pumping to provide breastmilk for your infant during the NICU hospitalization. Breastmilk has been shown to provide protection from some complications of prematurity (early birth) and is recommended by the American Academy of Pediatrics for at least the first 6 months of an infant's life. However, not all mothers pump or are able to pump for the entire NICU hospitalization, which is usually shorter than the first 6 months. This study will test the effectiveness and cost-effectiveness of an investigational economic intervention on mother's milk availability and duration of pumping.

How many people will take part in this study?

Approximately 284 mothers and their estimated 327 infants are expected to take part in this study.

What are the activities you will be doing if you participate in this study?

Randomization into one of two groups

If you agree to be in this study and sign this consent form, you will complete a brief Study Eligibility questionnaire for you and your infant after delivery. At the end of this questionnaire, you will be randomly assigned (by chance like flipping a coin) to one of two groups: a control group or an intervention group. This step must be completed before your baby is 6 days old (144 hours after delivery.) **Neither you nor the research team will be able to choose the group you are in.**

If you are assigned to the **control group**, you will receive the following standard lactation care provided by the Rush NICU, which is the same care you would receive if you were not in this study:

- Instruction in expressing breast milk with a breast pump, pump cleaning and milk storage by NICU breastfeeding peer counselors (BPCs). BPCs are former NICU mothers themselves.
- A hospital grade smart breast pump will be stored in your infant's room for use during your visits to the NICU.
- You will have the option to rent a hospital grade breast pump for use at your home. All NICU mothers who are eligible for WIC are also eligible for a subsidized rental fee. WIC is a national program that provides nutritional assistance for low income women, infants and children up to 5 years of age. You do not need to participate in this study to obtain support for which you are otherwise eligible.
- Sterile milk containers and bar code labels for pumping in the NICU and at home.
- Access to unlimited storage of milk in your infant's single room refrigerator and in the milk freezers in the NICU.
- Daily monitoring by the BPC team for the first 14 days after you deliver your infant followed by weekly contact by a BPC for the duration of your infant's stay in the NICU by text, telephone, or in person based on your preference to discuss lactation needs and feeding goals.
- Access to BPCs from 7:00 am to 8:30 pm 7 days a week for lactation care and support in the NICU.

- An invitation to weekly Rush NICU Milk Café .
- One small cooler for milk transport between home and Rush.

If you are assigned to the **intervention group**, you will receive all the standard NICU lactation care the control group mothers receive listed above. In addition, you will receive the following interventions:

- A hospital grade smart breast pump for home use at no charge while your infant is in the NICU and you continue to pump and provide breastmilk. **This must be returned at the end of the study or when you stop pumping, whichever comes first.**
- Free pickup and transport of your expressed breastmilk by a Rush research team member from your home to the Rush NICU 2 to 3 times per week during weekdays, as needed.
- Payment for your time spent pumping milk at the rate of $30.00 for each day that you pump during your infant's NICU stay.

Study activities

All mothers – in both Control and Intervention groups – will participate in the following study activities:

1. Study Tablet
   - You will be given a cellular enabled tablet for the duration of your infant's NICU stay, which will be preloaded with study applications (apps such as REDCap) and used for data entry by you.
   - You will be responsible for making sure that the tablet is fully charged so that study data collection and data transmission can occur smoothly.
   - During the research study, the tablet will be limited to research functions only. Therefore, you cannot use the tablet for personal reasons or leisure during the study and while your baby is in the NICU.
   - **If the tablet is lost or stolen, please notify us as soon as possible since we will have to report this to the authorities.**
   - **At the end of the research study, when your baby is ready for discharge home, after all of the data and questionnaires have been collected from you and the breast pump has been returned (if this applies to you), you will be able to keep the tablet as appreciation for participating in this study, but cellular service will no longer be provided.**

2. You will be asked to do the following:
   - Provide current contact information including your email address, phone numbers, and home address so that the study team may contact you.
   - Complete a W-9 form including your Social Security Number so that you can be paid.

- Allow the research team to measure all of your pumped milk by bringing it (or sending it through the milk courier service, if you are in the intervention arm) to the NICU before storage or feeding your infant.
  - Very close to the end of your infant's stay in the NICU, and if you have a lot of milk stored in the NICU freezer, you will have the option to weigh your pumped milk at home with a study scale instead of bringing it in.
- Allow the research team to make note of any thoughts or comments you share about the study after you sign the consent form during the study.
- You will be asked to complete the following questionnaires. The estimated time it will take to complete each questionnaire is written in parentheses below.
  - The following questionnaires will be completed upon your enrollment to the study:
    - Randomization Group Identifier (less than 5 minutes)
    - Demographic Information (less than 15 minutes)
    - Health and Lactation History (20 minutes)
  - The following questionnaires will be completed during the study:
    - Weekly Questionnaire (less than 10 minutes every week). Study staff will contact you after you complete it to review your answers and ask some additional questions.
    - Discharge Questionnaire (10 minutes, once your infant is discharged)

3. Milk Sample Testing
   - You will be required to provide a 2 mL (less than ½ a teaspoon) milk sample while you are still hospitalized after delivering your infant or while in the NICU to serve as a BASELINE milk sample.
   - Over the course of your infant's NICU stay, the research team will take 2mL (less than ½ teaspoon) samples from the milk that you have brought to the NICU AT RANDOM. These samples will be taken approximately once a month.
   - The first 2mL sample, taken approximately one month after the BASELINE milk sample, is required as long as you continue to provide milk. Smaller amounts of milk may be taken from several pumping batches to reach the required sample volume of 2mL.
   - Milk samples from the second month of your infant's NICU stay through discharge will not be taken if there isn't enough for infant feedings. Smaller amounts of milk may be taken from several pumping batches to reach the required sample volume.
   - The milk samples will be sent to The Ohio State University for laboratory testing to verify that the milk that you provide during the study matches your BASELINE milk sample and is not from another woman nor contains any other liquids (water, cow's milk, etc.) to benefit from the intervention. **Note that you should not add anything to your milk since that may harm your infant.**
   - Milk samples will be coded with your study number and will not include your name or other identifying information.

- These samples must be provided and may not be withdrawn after collection.

4. Health information
   - Health information such as diagnoses and treatment related to your pregnancy and delivery will be collected from your medical record for this study.

   Demographic and health information about your infant such as birth weight, gender, diagnoses and treatments received at birth and in the NICU will be collected from your infant's medical record for this study.

5. Hospital and Out-of-Pocket Costs
   - You will be asked to complete questions at study enrollment and weekly while your infant is in the NICU about costs you are paying related to having a baby in the NICU.
   - Costs of hospitalization for your infants will be collected from RUSH financial records.

Mothers in the Intervention group only will participate in these activities:

1. Smart Breast Pump
   - The smart hospital-grade breast pumps will record pumping data that will be downloaded to a flash drive that will be provided to you.

2. Milk Pickup
   - Milk pickup will be performed by a security-cleared research team member (milk courier) who has been trained on safe handling and transport of milk.
   - You will arrange times for milk pick up that are convenient to you and also fit in with the milk courier's driving plan and destinations.
   - You will need to be at your home at the planned time and also be reachable by phone or text, in case changes are necessary due to traffic or unforeseen circumstances.
   - The milk courier may wear a mask and gloves to handle your milk.

3. Payment
   - You will receive payment for the number of days that you pump breast milk.
   - You will receive payment each week, based on the number of days pumping was recorded with the smart pump.
   - You will be required to fill out a W-9 form to receive this payment.

Does this study involve genetic testing?
Yes, this study involves testing of your milk samples to identify a DNA pattern that is specific to you, to be used for matching with other milk samples that we receive from you. The cells of your body contain a molecule called deoxyribonucleic acid (DNA). DNA is received from your parents and carries a code in the form of genes, which determine your physical characteristics such as the color of your hair and eyes.

What do you need to know regarding the collection of biospecimens?
Biospecimens may include blood, tissue, urine, bone marrow, saliva, cells, etc. In this study, we will collect **milk samples** which will be labeled with your study number and will not include your name or other identifying information. Milk samples may not be withdrawn after collection. The samples will be transferred to Dr. Jesse Kweik at The Ohio State University for laboratory analysis, as described above.

Jesse Kweik, PhD
The Ohio State University
Department of Microbiology
476 Biological Sciences Building
484 West 12th Avenue
Columbus, OH 43210

Will your information or biospecimens be used for research in the future?
Information or biospecimens collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will not be included with any information or biospecimens that are shared. Since identifying information will be removed, you will not be asked for additional consent.

What are the risks and discomforts of participating in this study?
There is no foreseeable physical risk to either you or your infant in this study, because all study procedures are noninvasive. The discomfort anticipated in the research is not greater than those ordinarily encountered in daily life or during routine medical care.

There are theoretical emotional risks to participating in this study; however, several procedures are in place to minimize these risks. You may feel external pressure from family or friends to continue to provide milk and to continue to receive the benefits of the Intervention group, even though you would like to stop. If you are unable or unwilling to continue to pump or wish to terminate/stop your participation in the study, there will be no adverse impact on the care of you or your infant Your relationship with Rush University Medical Center and the health providers in the NICU will not be affected.

As with all research studies, there is a risk of breach of privacy associated with the data collection. Your data and your infant's data will be coded with unique study ID numbers. All research data will be stored on secure databases on locked computers. Your name, addresses, and contact information will be recorded and required for arranging pickup of milk. This contact information will only be accessible to the research team. Data taken from your or your infant's

medical record will be maintained securely on the Rush Network, which is protected from cybersecurity breaches.

There is a risk that your tablet may be lost or stolen during the study. However, the information you enter into the tablet for this study will transferred directly to the researchers and will not be stored on the tablet itself. Additionally, you will not be entering any identifiable information on the tablet. Instead, all of your information will be associated with your unique study ID. Only the researchers will have access to your study ID and associated contact information, which will be kept safe by the above-mentioned protocol. If your tablet is lost or stolen during the study, the research team will report this to the authorities. There are a limited number of tablets for this study so it may be difficult to replace it if it is lost or stolen. An encrypted data management tool used for research and quality improvement studies will be used in this study for the questionnaires. You will receive your own personal username and password to this database to enter information on the questionnaires. These procedures along with trained research staff will minimize any risk of breach of privacy.

There may be other risks that may happen that we cannot predict.

What are the risks involving genetic information?

While we believe that the risks to you and your family are very low, we are not able to know all of the risks from taking part in genetic research. Your privacy will be protected to the fullest extent possible. The genetic testing of your milk will not be able to identify any diseases or inherited traits. Even though your genes are unique, you share some of the same genes with your blood relatives. Genetic information is considered health information and is protected under the Health Insurance Portability and Accountability Act (HIPAA) as is your other health information. While very rare, information could be misused by employers, insurance companies and others. For example, life insurance companies may charge a higher rate based on this information. A federal law called the Genetic Information Non-Discrimination Act (GINA) should help lower the risk from unfair health insurance or employment policies. To learn more about the GINA Law, please go to http://www.ginahelp.org/GINAhelp.pdf or ask the research team.

What if there is new information that may affect my decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this study?

You have the right to leave the study at any time without penalty. If you decide to not participate in this study or leave the study at any time, you and your infant healthcare, benefits, or relationship with Rush University Medical Center will not be affected.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;

- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study.

By signing this document, you voluntarily authorize (give permission to) Dr. Aloka Patel and Dr. Tricia Johnson, their research team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the research study described in this document.

During the study, Dr. Aloka Patel and Dr. Tricia Johnson and their research team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Information about your age, gender, race/ethnicity, education, employment, and household.
- Health and Lactation History
- Healthcare Cost data
- Information from your medical chart, such as reason for preterm delivery, and your infant's medical chart, such as information on feedings and growth.

Dr. Aloka Patel and Dr. Tricia Johnson and their research team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of the research study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- The study Sponsor, National Institutes of Health (NIH), its representatives, and the Data Safety Monitoring Board.
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).
- To the Researchers outside of Rush who are collaborating on this study with Drs. Patel and Johnson, including

  Jesse Kwiek, PhD
  The Ohio State University
  Department of Microbiology
  476 Biological Sciences Building
  484 West 12th Avenue
  Columbus, OH 43210

Sarah Keim, PhD, MA, MS
The Ohio State University
The Research Institute at Nationwide Children's Hospital
700 Children's Drive,
Columbus, OH 43205

John A. F. Zupancic, MD, MS, ScD
Harvard Medical School
Department of Neonatology
330 Brookline Avenue
Boston, Massachusetts 02215

While you participate in the study you will have access to your medical record, but Dr. Aloka Patel and Dr. Tricia Johnson are not required to release to you research information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any research information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the Rush medical records office.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Aloka Patel or Dr. Tricia Johnson at the provided addresses at the top of this document. If the authorization is revoked, you will no longer be allowed to participate in the research and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current research.

This authorization is valid for the entirety of this research study. It will expire upon your completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data and samples already collected from you may not be removed from the study records. The study doctor and/or research team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Your data and your infant's data will be coded with linked study ID numbers. All research data will be maintained on secure databases on locked computers. Your name, addresses, and contact information will be recorded and required for arranging pickup of milk. This contact information will only be accessible to the research team. Data taken from your or your infant medical record will be maintained securely. An encrypted data management tool used for

research and quality improvement studies will be used in this study for the questionnaires. You will receive your own personal username and password to this database to enter information on the questionnaires. These procedures along with trained research staff will minimize any risk of breach of privacy.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is an ethics committee that reviews new and ongoing human research studies to check that every study is conducted in an ethical manner and that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov Identifier: NCT04540575, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality

To help us protect you and the information we will be collecting from you, this study has obtained a Certificate of Confidentiality by the U.S. government. This certificate means that researchers cannot be forced, even by courts or the police, to disclose any information about you.

The Certificate does not stop you from disclosing, or agreeing in writing to allow researchers to disclose, information about you. For example, if you would like an employer or insurer to know something about you that is documented in this study, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) If you consent to the disclosure, including for your medical treatment;
(3) If it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants;
(4) For the purpose of auditing or program evaluation by the government or funding agency
(5) If required by the United States Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. Please contact the investigator for more information on how to provide this consent.

What are the costs to participate in this study?
There are no additional costs to you for participating in this research. You are or your insurer is responsible for paying the cost of your and your infant's hospital stay, just as you would be if you did not participate in this study.

Will you be paid for your participation in this study?
Regardless of which group you are randomly assigned to, you will receive:

- $100 after completion of randomization within 144 hours after delivery. If your infant is still in the NICU 4 weeks after delivery, you will receive an additional $50 after completion of the fourth Weekly Questionnaire.
- When your infant is discharged from the NICU, you will receive an additional $100 after completion of the final Weekly Questionnaire and the Discharge Questionnaire.

You will be given a cellular enabled tablet for the duration of your infant's NICU stay, which will be used for data entry. You will be able to keep the tablet (without cellular service) at the end of the study. Each tablet with its case is valued at approximately $200.

If you are randomly assigned to the **Intervention group**, you will receive a payment for each calendar day that you pump and provide breastmilk for your infant in the NICU. The daily payment is $30.00 per day. If assigned to the **Intervention group**, you will receive this payment every week in order to minimize the delay between the time the NICU receives your pumped breastmilk and when you receive payment.

If you are randomly assigned to the **Control group**, you will **NOT** receive the weekly payment.

Regardless of which group you are assigned to, you will be required to complete a W-9 tax form which includes your Social Security Number, name, and address. According to the U.S. Internal Revenue Service (IRS) regulations, payment received as compensation for participation in research is considered taxable income to the research participant. If payment exceeds $600 in any one calendar year for participation in any number of research studies, Rush will file a 1099 tax form. Reimbursement for travel or other study-related expenses is not considered compensation for tax purposes.

If you do not complete randomization within 144 hours after delivery, you will be removed from the study. You will not receive any money and you will not receive the tablet.

What other information should you know about?
Investigator Dual-Role: Your health care provider (Dr. Aloka Patel) is an investigator on this

research study, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from a clinician who is not associated with this project. You are not obligated to participate in any research project offered by your clinician. The decision to not participate will not affect your clinical care now or in the future.

Conflict of Interest Disclosure: This research study is supported by a product manufactured by Medela, Inc. Drs. Aloka Patel, Paula Meier, Michael Schoeny, Tricia Johnson (the investigators on this study) and Ms. Judy Janes stand to receive extra money from Medela, Inc. for work involving Medela products. It was determined that these potential future payments to Drs. Patel, Meier, Schoeny, Johnson and Ms. Janes are considered unlikely to affect your safety and/or the scientific quality of the study. This recommendation was given to the IRB for its review and approval of this study. If you would like more information, please contact Dr. Patel.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Aloka Patel at 312-947-8800 or email her at Aloka_Patel@rush.edu. You may also call Dr. Tricia Johnson at 312-942-5402 or email her at Tricia_J_Johnson@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Aloka Patel or Dr. Tricia Johnson in writing at the address on the first page. Dr. Aloka Patel and Dr. Tricia Johnson may still use your information that was collected prior to your written notice.

What if your infant is transferred to another hospital?
In rare circumstances, infants may be transferred to another hospital for long-term care or to be closer to family. This is a decision made with the medical team, with your consent. In the unlikely case that your infant is transferred to another NICU before being discharged, we would like to obtain information from the other hospital about your infant's hospital course, healthcare received, growth and nutrition to complete the data collection for this research. Please initial and date one of the following options:

Yes, I agree to release information about my infant's hospital course from another hospital if my infant is transferred prior to discharge from the Rush NICU.

_____ _____
Initials Date

No, I do **NOT** agree to release information about my infant's hospital course from another hospital if my infant is transferred prior to discharge from the Rush NICU.

_____ _____
Initials Date

Will you be contacted about participating in future research?
We may contact you during your participation in this study about participating in an optional sub-study, where we would collect additional weekly samples from your breastmilk to be used for future research. If you are interested in participating in this sub-study, you will be provided with more information and asked to sign a separate sub-study consent form.

SIGNATURE BY THE PARTICIPANT [OR THE PARTICIPANT'S LEGAL REPRESENTATIVE]:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the research team. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

_____ _____ _____
Name of Participant (mother) Signature of Participant (mother) Date of Signature

_____ _____
Name of Participant (infant 1) Name of Participant (infant 2)

_____ _____
Name of Participant (infant 3) Name of Participant (infant 4)

_____ _____
Parent, Guardian or Legal Representative's Signature (for infant(s)) Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant [or the participant's legally authorized representative]. I further attest that all questions asked by the participant [or the participant's legal representative] were answered to the best of my knowledge.

_____ _____
Signature of Individual Obtaining Consent Date of Signature

SIGNATURE BY WITNESS/TRANSLATOR:
I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant [or the participant's legally authorized representative] and the person signing the form has done so voluntarily.

Name of Witness/Translator

Signature of Witness/Translator Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator Date of Signature