Participant's Name: _____
Participant's Medical Record Number: _____

Augusta University
Research informed Consent Document

"Human Milk in Preterm Infants"

Principal Investigator: Zanna Wynter, DO PGY5, Neonatal Fellow Division of Neonatology	**Principal Investigator telephone number (available 24/7 and for emergencies):** 770-608-0868 zwynter@augusta.edu
Sub Investigator(s):	**Faculty Advisor:** Brian Stansfield, MD

Key Information Section

You may be eligible to take part in this research study. Taking part in this study is completely voluntary.

This form contains information that will help you decide whether to take part. All of this information is important, but here are some key important points to keep in mind:

- It is completely up to you whether you take part in this study.
  - Even if you decide to join the study, you are free to leave at any time if you change your mind.
- This is research; researchers do research to learn about many different things.
- The purpose of this study is to measure how preterm babies grow when fed human milk with fortifier beginning on the first day of feedings.
  - Participation in this study is expected to take 4-12 weeks or until your baby reaches 36 weeks corrected age or is discharged from the hospital.
  - All procedures in the study are minimally invasive. No laboratory measurements (blood or urine) will be taken for the sole purpose of this study.
  - Fortification of human milk starting with the first feeding, compared to fortifying after the first week of feeding, could result in improved growth in preterm infants. We will seek to understand whether early addition of fortifier improves preterm infant growth.

- You are not required to take part in this study. Your baby's feeding plan will not change should you decline to participate in the study.

If you are a legally authorized representative, or parent, permission from you is required. If the research involves a child, their assent (agreement) may also be required. When we say "you" in this consent form, it means the research subject; "we" means the staff involved with this study.

You are being asked to take part in this research study because you have:

1. An infant with a birth weight between 1000-1500 grams who was
2. Admitted to the NICU within 24 hours of birth and you
3. Intend to use either your own human milk and/or donor human milk

The purpose of this document is to:

- Explain your rights and responsibilities
- Explain the purpose of the study
- Describe what will happen if you decide to take part in this study
- Explain the potential risks and benefits of taking part in the study

Participation in research studies is voluntary. Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand.

Please tell the study staff if you are taking part in another study.

Why is this study being done?

The purpose of this study is to understand how early addition of a fortifier to human milk feedings impacts growth of preterm infants.

There will be up to 50 participants enrolled at the Children's Hospital of Georgia at Augusta University, the only site where the research is being conducted.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, 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.

How long will I be in this study?

Your active participation in this study is expected to take 4 to 12 weeks or until your baby

reaches 36 weeks corrected age or is discharged from the hospital. You can choose not to be in the study or stop participating at any time without penalty or loss of any rights or benefits you are entitled to. Please talk to the study staff first before you stop participating in the study.

What will happen to me in the study?

- Your baby will be fed following the standard NICU feeding protocol based on birth weight.
- Human milk, either mother's own milk or donor human milk, will be used for feeding.
- The standard feeding protocol in our NICU is to add Enfamil High Protein Human Milk Fortifier to the human milk because human milk alone does not provide enough nutrients to promote growth in the preterm infant.
- Your baby will be randomly assigned to either the control group or the intervention group.
- For this study, the intervention group will have the Enfamil High Protein Human Milk Fortifier added to your baby's first feeding on feeding day 1. If your baby is assigned to the control group, or you choose to not participate in the study, the Enfamil High Protein Human Milk Fortifier will be added on feeding day 8 as per the standard feeding protocol.
- Your baby's body measurements (weight, length, and head circumference) will be measured by study staff and the information will be recorded for study purposes.

What tests and/or extra tests will I have if I take part in this study?

No additional laboratory measurements will be taken for the sole purpose of this study.

Laboratory tests to measure nutrition status will be measured according to the standard of care for preterm infants.

Normal procedures/assessments	Fortification at feeding day 1 (Study intervention)	Fortification at feeding day 8 (Standard protocol)
Mother's own milk used as base diet or donor milk	✓	✓
Fortifier added to provide extra calories, protein, fat, vitamins, and minerals	✓	✓
Weight, length, and head circumference measured weekly	✓	✓
Blood and urine samples collected to measure nutrition status	✓	✓
Vitamin D supplement given	✓	✓
Iron Supplement given	✓	✓

Baby is monitored for signs of feeding intolerance	✓	✓

What are the risks of being in this study?
As a result of your participation in this study, there is a risk for development of NEC, necrotizing enterocolitis, an intestinal infection. Daily abdominal circumferences and feeding tolerance will be monitored for early detection of NEC. Blood and urine collection pose minimal risk and no laboratory samples will be taken for the sole purpose of this study.

There may be more risks that are not known or not expected.

The study staff will tell you about new information that may affect your health, welfare, or willingness to stay in this study should it become available after starting the study.

Will I benefit from this study?
This study is not designed to benefit you directly. The study results may benefit others in the future.

What are my other choices if I do not take part in this study?
You are not required to take part in this study. Your baby's feeding plan will follow our standard protocol in the NICU.

Who will see my study information?
Study team members will be able to see your study information. Your records may also be reviewed in order to meet federal or state regulations. Reviewers may include the Augusta University Institutional Review Board (the committee who oversees safety of volunteers in research studies), institutional officials, and outside agencies.

How will you keep my study information confidential?
Study records that identify you will be kept confidential except as required by law. You will not be identified in study records or publications disclosed outside Augusta University.

What will happen to my identifiable private information/biospecimens once collected?
Identifiers might be removed from your identifiable private information or identifiable biospecimens collected as a part of this research. After such removal, the information or biospecimens could be used for future research studies or be distributed to another investigator for future research studies without getting additional informed consent from you or your legally authorized representative

What are my costs (what will it cost me) for taking part in the study?
It will not cost you anything to take part in the study other than basic expenses like transportation.

Will I be paid for participation in this study?
You will not be paid for taking part in this study.

Who can answer my questions about this study?
You can ask questions about this study at any time. Please contact the study staff listed on page 1 of this document if you have questions about:

- Study procedures
- Reporting an illness, injury or other problem
- Leaving the study before it is finished
- Expressing a concern about the study
- Any other questions you may have about the study

Who can I contact to discuss my rights, problems, concerns, questions, or complaints I have as a study participant?
Contact the Augusta University Institutional Review Board at (706) 721-1483.

Could there be any harm to me if I decide to stop participating in the study before it's finished?
If you decide to stop taking part in the study, the study staff and healthcare team will discuss ways to safely remove you from the study, which may include no change to the current feeding protocol, an adaptation of the standard feeding protocol, or change to the current standard feeding protocol. You should follow the instructions provided to you by the study staff and your healthcare team.

If you stop participating, the study staff will not collect any more information on you. However, the information that the study staff has collected up to the point of you withdrawing from the study may be used as part of the study and cannot be removed.

Can I be removed from the study?
Yes, you may be removed from the study if:

- The baby develops necrotizing enterocolitis (NEC), an intestinal infection
- The baby develops a GI perforation (a hole in the GI tract)
- The baby receives any amount of cow's milk formula

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to Augusta University and AU Affiliates to use or disclose your health information that identifies you for the study described earlier in this document.

The health information Augusta University and AU Affiliates may use or disclose for this study includes information in your medical or dental record, results of physical exams, medical or dental history, lab tests or certain health information indicating or relating to your condition.

The health information listed above may be used by and/or disclosed to the following, as applicable:

- Researchers and their staff;
- The sponsor of the study including its agents such as data storage banks or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Health insurers or payers in order to secure payment for covered treatment;
- Parents/Guardians of children younger than 18 years
- Vendors to facilitate payment or reimbursement for your participation in this study;
- Federal/state agencies and Augusta University and AU Affiliates committees having authority over the study. These may include, but are not limited to:
    - The Institutional Review Board (IRB) overseeing this study;
    - Committees with quality improvement responsibilities;
    - Office of Human Research Protections;
    - Privacy and Security staff for oversight and investigations;
    - Food and Drug Administration;
    - National Institutes of Health;
    - Other governmental offices as required by law.

Augusta University and AU Affiliates are required by law to protect your health information. By signing this document, you authorize Augusta University and AU Affiliates to use and/or disclose your health information for this research.

Once your information has been disclosed outside Augusta University and AU Affiliates, it may no longer be protected by federal laws and regulations and might be further disclosed by the persons or institutions receiving the information.

Please note that:

Augusta University and AU Affiliates may not withhold treatment whether or not you sign this Authorization.

You may change your mind and take back (revoke) this Authorization at any time. If you revoke this Authorization, Augusta University and AU Affiliates may still use or release health information and any data and/or specimens already obtained about you as necessary for this study. If you revoke this Authorization, you cannot continue to participate in this study. To revoke this Authorization, you must write to the Principal Investigator listed at the top of this document.

You may not be allowed to see or copy the study information described on this Authorization as long as the study is in progress. When the study is complete, you have a right to request a copy of your personal health information collected for the study.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the study will reveal your identity without another signed authorization from you.

You will be given a copy of this Authorization. This Authorization does not have an expiration date. If you have questions or concerns about this Authorization or your privacy rights, please contact the Augusta University and AU Affiliates Enterprise Privacy Officer at 706-721-0900 or the toll-free compliance and ethics hotline at 1-800-576-6623.

Regulations require that you be given a copy of the Augusta University and AU Affiliates Notice of Privacy Practices describing the practices of Augusta University and AU Affiliates regarding your health information**.**

PARENTAL STATEMENT OF CONSENT

I have read this form and the information in it was explained to me and my child. My taking part in the study is voluntary. All of my questions were answered. I will receive a copy of this form for my records. I agree to take part in this study. **My child is not giving up their legal rights by my signing this form.**

_____
Child's Name (print)

_____
Parent or Child's Legally Authorized Representative Name (print)

_____ _____
Signature of Parent or Child's Legally Authorized Representative Date /Time (00:00)

INVESTIGATOR STATEMENT

I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. They have voluntarily agreed to participate. I have documented this action in the participant's medical record source documents or research chart source documents, as applicable. A copy of this signed document will be placed in the participant's medical record or research chart, as applicable. A copy of this document will be given to the participant or the participant's legally authorized representative.

_____
Printed name of Investigator obtaining consent

_____ _____
Signature of Investigator obtaining consent Date /Time (00:00)