Protocol Title: **Early Fortification of Human Milk for Very Low Birth Weight Infants and Effects on Growth Velocity**

Principal Investigator: *Zanna Wynter, DO*

1. Objectives

Describe the purpose, specific aims, and hypothesis:

The purpose of this investigation is to determine whether early fortification of human milk feeds improve growth outcomes for very low birth weight infants (VLBW) (birth weight 1000-1500 grams). We hypothesize that introducing higher caloric feeds at the onset of enteral feeds will improve early growth metrics in VLBW infants as compared to infants who begin human milk fortification after the first week of life, which represents our present standard of care. The primary outcome for this study is growth velocity (g/kg/day) at 28 days of life.

2. Background

Describe the background and rationale for the study:

Human milk, maternal or donor milk, is the standard of care for feeding premature infants. However, human milk alone does not provide sufficient energy, protein, fat, and micronutrients to meet the demands of the VLBW premature infant. Thus, slow growth can persist for preterm infants and catch-up growth can be incomplete even after discharge from the NICU, and slow extra-uterine growth (weight, length, and head circumference) is associated with poor neurodevelopment and lower intelligence in school age children born preterm. Using human milk fortifiers (HMF) increase nutrient density of human milk and allows for infants to maintain a human milk-based diet, which has been shown to reduce the incidence of necrotizing enterocolitis (NEC) and improve cognitive outcomes in preterm infants.

Fortification of human milk is institution-specific and no standard of care has been recommended regarding the timing of fortification of human milk feeds in preterm infants. Much of the concern for earlier fortification arise over whether comorbidities, such as NEC and feeding intolerance, will be more prominent in infants provided early fortification versus delayed fortification. To date, no studies have demonstrated a relationship between human milk fortifiers and the incidence of NEC or feeding tolerance. Thus, delays in introducing HMF may represent an unwarranted safety concern that interferes with supplying an appropriate nutrient-enriched diet to preterm infants. For example, 34.3% of preterm infants are diagnosed with post-natal growth failure at the Children's Hospital of Georgia. Further, later introduction of HMFs may lead to longer time to reach full enteral feeds, total duration on total parental nutrition (TPN), or duration of central venous line use. Current available evidence suggests that fortification of human milk starting at the first feed is safe and well-tolerated and may have substantial benefit for preterm infant growth.

3. Inclusion and Exclusion Criteria

List the inclusion/exclusion criteria:

Inclusion:

1. Birth weight 1000-1500 grams
2. Admitted to AU NICU within 24 hours of life
3. Maternal intent to use human milk (maternal or donor milk)

Exclusion:

1. Congenital anomalies including congenital heart disease or other major defect requiring surgical intervention
2. Feeds not started within first 96 hours of life
3. Intrauterine growth restriction (IUGR) defined as <3rd % on a gender specific Fenton growth curve

4. Number of Subjects/Records/Samples Collected

Indicate the total number of subjects to be accrued/records reviewed/samples collected across all sites:

The sample size was determined assuming an alpha level of 0.05, power of 80%, a common standard deviation of 3.64, and a two-sided two-sample t-test to examine differences in weight growth velocity at 28days between the two feeding protocol groups. The mean for the standard of care group (fortification beginning on day 8) was 10.6% and for the intervention group (fortification beginning on day 1) was 12.3, 12.6 and 13.6. The sample size required for each mean difference is below

Assumed Mean in Each Group		Sample Size
Fortification Day 8	Fortification Day 1	per Group
10.56	12.25	74
10.56	12.56	53
10.56	13.56	25

A sample size of 25 per group, for a total of 50 subjects will be needed.

5. Recruitment Methods

Describe when, where, and how potential subjects will be recruited:

All neonates admitted to the NICU who have a birth weight of 1000-1500 grams will be eligible for this study. Screening will include chart review to ensure inclusion criteria is met. Parents (legal guardians) of eligible neonates will be approached for study participation by the PI or co-Investigators.

6. Multiple Site ☒ N/A

7. Reliance Agreements/Single IRB ☒ N/A

8. Procedures Involved

a. *Describe the procedures involved to include those procedures that are standard evaluation and/or care and those that are solely for research purposes:*

Feeding Protocol
All VLBW infants in AU's NICU are provided a standard feeding protocol that has been in use since 2011 and includes fortification of human milk with Enfamil High Protein Liquid Human Milk Fortifier (HP HMF) on feeding day 8. Study participants will be randomly assigned to receive standard of care (ie fortification on feeding day 8) or fortification on feeding day 1. In general, feedings for preterm infants are started in the first 48 hours.

b. *Describe and explain the study design:*
If the study involves multiple conditions where each condition involves different procedures, please provide a table that breaks down the procedures by condition and in chronological order. Include when and where they are performed.

1. Subjects will be randomly assigned to one of two groups using blocked randomization to ensure equal allocation throughout enrollment. Blocks of size 4 and 6 will be randomly determined and then the group assignment will be randomly permuted within each block. Initiation of enteral feedings, enteral volume advancement, and weaning off parental nutrition will follow the standardized NICU feeding protocol.
2. Subjects will be fed a diet of human milk per standard NICU feeding protocol. Should maternal milk supply be inadequate to meet daily volume needs, donor milk will be used per standard NICU feeding protocol. Importantly, mothers (or guardians) must provide written consent for donor human milk. This consent is separate from the study consent and will be required for study participation.
3. Enfamil High Protein Liquid Human Milk Fortifier (HP HMF) will be used to fortify maternal milk.
4. Parenteral nutrition will be provided as outlined in the standard NICU feeding protocol and will be consistent with parenteral intake provided to all VLBW infants in the NICU regardless of study participation.
5. Enfamil HP HMF will be added to provide 22 calories/ounce on the initiation of enteral feeds for the intervention group (feeding day 1). For the control group, Enfamil HP HMF will be added to provide 22 calories/ounce when enteral feeding volume reaches 80 mL/kg/day (feeding day 8). Caloric density will be advanced to 24 calories/ounce at feeding day 10 for both groups. The caloric density progression follows the standard NICU fortification practices.

Blinding Procedures

Feeding tolerance is largely subjective. As an important secondary outcome, we will blind all healthcare personnel to study group allocation for the first 7 feeding days.

1. Upon consent, participants will be randomized to one of two study groups.
2. The milk bank in the NICU is responsible for all human milk preparation. Milk bank technicians will receive the group allocation for each participant and prepare human milk with/without fortification according to standard formulations.
3. Group allocation for each participant will be recorded by milk bank technicians on the daily feeding sheets (standard procedures for all infants). Group allocation and fortification will be confirmed by one study member of the study team who will be unblinded (co-Investigator Canfield who is the NICU dietician that oversees the milk laboratory).
4. Blinding will be accomplished by removing the caloric content from the label for all study participant. In the field that contains calories, "study participant" will be entered. Blinding will occur during the first 7 feeding days and calorie content will be recorded on feeding day 8 and all subsequent feeding days.

Intervention Group

	Parenteral Nutrition/IV Fluids				Enteral Feedings Given by 30-60 minute bolus q 3 hours NG/OG		Intervention Group
Feeding Day	Glucose mg/kg/min	Protein, g/kg	Lipids, g/kg	IVF, mL/kg	Enteral Feedings, mL/kg	Feeding Type	Notes
Day 1	6-10	3.5-4	3	80-130	20	Human Milk +HP HMF	Add Enfamil High Protein Human Milk Fortifier to 22 calories
Day 2	6-10	4	3	80-130	20	Human Milk +HP HMF	
Day 3	6-10	4	3	90-110	40	Human Milk +HP HMF	
Day 4	6-10	4	3	90-110	40	Human Milk +HP HMF	
Day 5	6-10	4	3	70-90	60	Human Milk +HP HMF	
Day 6	6-10	3-4	3	70-90	60	Human Milk +HP HMF	
Day 7	6-10	2.5-4	2	50-70	80	Human Milk +HP HMF	
Day 8	6-10	2-3.5	2	50-70	80	Human Milk +HP HMF	
Day 9	6-10	1-2	1-2	30-50	100	Human Milk +HP HMF	

Day 10	6-10	1	1	30-50	100	Human Milk +HP HMF	Increase Human Milk Fortifier to 24 calories
Day 11	6-10	0-1	0-1	10-30	120	Human Milk +HP HMF	Add Supplements: NaCL or Bicitra 1.3 mEq/kg/day
Day 12	0	0	0	0	140	Human Milk +HP HMF	Add Supplements: $MgCO_3$ 6 mg/kg/day Zinc 1 mg/kg/day
Day 13	0	0	0	0	150	Human Milk +HP HMF	Add 6 mg/kg/day Ferinsol
Day 14	0	0	0	0	150	Human Milk +HP HMF	Add 800 IU/day of Vitamin D [400 IU given BID]

Control Group

	Parenteral Nutrition/IV Fluids				Enteral Feedings Given by 30-60 minute bolus q 3 hours NG/OG		Control Group
Feeding Day	Glucose mg/kg/min	Protein, g/kg	Lipids, g/kg	IVF, mL/kg	Enteral Feedings, mL/kg	Feeding Type	Notes
Day 1	6-10	3.5-4	3	80-130	20	Human Milk	
Day 2	6-10	4	3	80-130	20	Human Milk	
Day 3	6-10	4	3	90-110	40	Human Milk	
Day 4	6-10	4	3	90-110	40	Human Milk	
Day 5	6-10	4	3	70-90	60	Human Milk	
Day 6	6-10	3-4	3	70-90	60	Human Milk	
Day 7	6-10	2.5-4	2	50-70	80	Human Milk	
Day 8	6-10	2-3.5	2	50-70	80	Human Milk + HP HMF	Add Enfamil High Protein Human Milk Fortifier to 22 calories
Day 9	6-10	1-2	1-2	30-50	100	Human Milk +HP HMF	
Day 10	6-10	1	1	30-50	100	Human Milk +HP HMF	Increase Liquid Human Milk Fortifier to 24 calories
Day 11	6-10	0-1	0-1	10-30	120	Human Milk +HP HMF	Add Supplements: NaCL or Bicitra 1.3 mEq/kg/day
Day 12	0	0	0	0	140	Human Milk +HP HMF	Add Supplements: $MgCO_3$ 6 mg/kg/day Zinc 1 mg/kg/day
Day 13	0	0	0	0	150	Human Milk +HP HMF	Add 6 mg/kg/day Ferinsol

Day 14	0	0	0	0	150	Human Milk +HP HMF	Add 800 IU/day of Vitamin D [400 IU given BID]

Nutrient Supplementation

In addition to HMF, other nutrients will be supplemented per the standard NICU feeding protocol. Supplementation of these nutrients will be provided to both study and non-study participants on the same feeding day.

1. **Vitamin D:** Routine supplementation of Vitamin D will be given as 600 IU of Vitamin D (300 IU BID) per feeding protocol. Additional Vitamin D may be added based on serum results of 1, 25-Dihydroxy Vitamin D level per standard NICU procedures.
2. **Iron:** Routine supplementation of iron will be given per feeding protocol as 6 mg/kg/day (3 mg/kg/day BID).

1. *Data Types and Source Records:*

Briefly describe the actual source records or measures that will be used to collect data about participants. (All surveys, interview scripts, and data collection forms will be attached elsewhere in the application. Do not add other documents to the protocol.) Describe what data will be collected and how it will be collected at all measurement/data collection time-points.

Data will be collected from the patient's EMR. Data to be collected include: date of birth, gender, estimated gestation age (EGA), Apgar score at 1 and 5 minutes, weights, head circumference, length, z-scores for weight, length, and head circumference, total volume of feeds and TPN, number of missed enteral feeds, maternal milk vs donor milk volumes. Laboratory data including basic metabolic panel, magnesium, phosphorus, alkaline phosphatase and urine sodium, potassium and magnesium will be collected on day 22 as per the current standard of care. No blood collections or other procedures will be performed specifically for the study. Clinical outcomes will be collected to include: incidence of metabolic acidosis, NEC, oxygen requirement at 36 weeks, PDA, and death.

Anthropometrics

Anthropometrics are measured as part of the standard physical assessment of the preterm infant. For this study, all anthropometric measurements and calculations will follow AU's standard preterm infant physical assessment guidelines.

Weight

1. Body weight will be measured within 24 hours of birth and then every 7 days until 28 days of life and again at 36 weeks post-menstrual age (PMA).
2. Measurement of weight will be performed by the principal investigator (PI) and/or co-Investigators
3. Weight will be measured (x 2) on a tared infant scale calibrated to the nearest 10 grams. Weights will be recorded in grams (g). Discrepancies of greater than 20g will be repeated.
4. Infants will be weighed without a diaper.
5. Average weight will be recorded in the EMR and documented in the database.
6. Weight will be plotted on a gender-specific Fenton growth chart in the EMR and the percentile recorded in the database

Weight Gain

1. Weight gain and growth velocity (GV) will be calculated at 28 days of life and 36 weeks PMA.
2. Weight gain will be recorded as g/day
3. GV will be calculated as follows and recorded in the database:

$$\text{GV (g/kg/day)} = \frac{[1000\ x\ (Wn - W1)]}{(Dn - D1) x [\frac{Wn + W_1}{2}]}$$

W= weight in grams
D = day
1 = interval of time chosen
n= the end of the interval of time chosen

Head Circumference

1. Head circumference will be measured within 24 hours of birth (x 3) and then every 7 days until 28 days of life and again at 36 weeks PMA. Discrepancies of greater than 0.5cm will be repeated.
2. Measurement of head circumference will be performed by the principal investigator (PI) and/or co-Investigators
3. Head circumference will be measured with a Seca® non-stretch, Teflon® measuring tape.
4. The tape will be applied firmly around the head above the supraorbital ridges, covering the most prominent part of the frontal bulge anteriorly, and over the part of the occiput that gives the maximum circumference.
5. The greatest of three measurements will be recorded in centimeters (cm) and average recorded.
6. Measurements will be recorded in the EMR and documented in the database.

Length

1. Body length will be measured within 24 hours of birth (x 2) and then every 7 days until 28 days of life and again at 36 weeks PMA.
2. Length will be measured on a length board with a stationary head piece and adjustable foot piece.
7. Measurement of length will be performed by the principal investigator (PI) and/or co-Investigators
3. One examiner will hold the infant's head with the Frankfurt plane in the vertical position and apply gentle traction to bring the top of the head into contact with the fixed headboard. The second examiner will hold the infant's feet, toes pointing directly upward, and also applying gentle traction to bring the movable footboard to rest firmly against the infant's heels.
4. The average of two measurements, agreeing within 0.4 cm, will be recorded.
5. Measurements will be recorded in the EMR and documented in the database.

Z-scores

1. Z-scores for weight, length, and head circumference will be retrieved from the EMR. Z-scores will be calculated at 28 days of life and 36 weeks PMA.
2. Z-scores are calculated by Cerner® (Cerner®, North Kansas City, MO) and recorded on the Fenton growth curve in the EMR

Mother's Milk Collection

1. Mother's milk collection will follow standard NICU milk collection procedures: All study participants will be provided with:
    a. Instructions for milk collection, written and verbal
    b. Access to a hospital grade electric breast pump, individual pump kit, and a comfortable place to express

c. A manual breast pump will be provided upon request
d. Sterile, single-use breastmilk collection containers
e. Milk collection labels with a unique bar-code generated by the Cerner Bridge® bar-code system

2. All breastmilk will be processed and prepared in the NICU Milk Lab by trained technicians per standard policy and procedure.
3. The Cerner® Bridge label on each container of breastmilk will be scanned and recorded into the Cerner® Bridge breastmilk management system.
4. All containers of mother's milk collected in one 24 hour span of time will be pooled into a single container per standard NICU Milk Lab procedure. Expiration date and times will be adjusted by Cerner® Bridge once each container is scanned and combined.

2. *Describe the procedures performed to lessen the probability or magnitude of risks:*

   As the only intervention that deviates from current standard of care is the use of HMF from feeding day 1 to feeding day 7, we do not anticipate any unique risks for study participants in either group. All SOPs for the handling of human milk and bedside feeding will be followed.

3. *Describe the duration of an individual subject's participation in the study and the time involved also include the overall duration of the project:*

   Neonates will be enrolled in the study from birth until 36 weeks post-menstrual age or discharge from the NICU, whichever comes first. Estimated time in the study is two to twelve weeks depending on gestational age at birth.

9. Data and Specimen Management

a. *Describe the data analysis plan, including any statistical procedures:*

☐ N/A

All statistical analysis will be performed using SAS 9.4 and statistical significance will be assessed using an alpha level of 0.05. Descriptive statistics within fortification group (day 1 or day 8) will be determined including means and standard deviations for continuous variables, frequencies and percentages for categorical variables, and medians and interquartile ranges for ordinal variables. Distributional assumptions will be examined before testing and if violations to the assumptions occur a transformation or nonparametric methods will be used. Missing data will not be imputed.

To examine differences between the two groups and assess for potential confounding variables two-sample t-tests will be used for continuous variables, chi-square tests will be used for categorical variables, and Wilcoxon Rank Sum tests will be used for ordinal data. Variables that will be examined include all collected EMR data (e.g., demographics, feeding related, laboratory, and clinical measures) and anthropometric measures.

To examine differences between the two groups (day 1 vs. day 8), a simple two-sided two-sample t-test will be used as a preliminary test for differences in continuous outcomes (e.g., weight growth velocity, head circumference growth velocity, length growth velocity, zscores). Then, to control for various potential confounders or covariates, analysis of covariance (ANCOVA) will be used with the main effect of interest being the group effect. Covariates that will be adjusted for include gestational age, total number of feed interruptions, incidence of metabolic acidosis, and NEC. Because there are only two groups, no adjustment to the overall alpha level will be needed to control for multiple comparisons.

b. *When applicable, provide a power analysis:*

☐ N/A

The sample size was determined assuming an alpha level of 0.05, power of 80%, a common standard deviation of 3.64, and a two-sided two-sample t-test to examine differences in weight growth velocity at 28days between the two feeding protocol groups. The mean for the standard of care group (fortification beginning on day 8) was 10.6% and for the intervention group (fortification beginning on day 1) was 12.3, 12.6 and 13.6. The sample size required for each mean difference is below

Assumed Mean in Each Group		). Sample Size
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10.56	12.25	74
10.56	12.56	53
10.56	13.56	25

A sample size of 25 per group, for a total of 50 subjects will be needed.

c. *Describe how data and specimens will be handled:* Data will be collected and recorded on a coded spreadsheet that is stored on a research specific Box drive assigned by AU IRB.	☐ N/A
i. *What information will be included in that data or associated with the specimens?* The patient's date of birth, estimated gestational age, race, gender, weight, head circumference, length, biochemical results for a basic metabolic panel, phosphorus, Vitamin D, magnesium, APGAR score, Ballard score, Urine results for sodium, potassium, chloride, and magnesium, intake to include parenteral nutrition, enteral nutrition, medications, and supplements.	
ii. *Where and how data and/or specimens will be stored?* Code list will be stored on the Human research drive separate from the data maintained by AU IRB.	
iii. *How long will the data and/or specimens be stored?* Data will be stored for 2 years following completion of this study.	
iv. Who will have access to the data or specimens? Only the PI and co-investigators will have access to the data.	
v. *Who is responsible for receipt or transmission of the data and/or specimens?* Data will not be transported.	
vi. *How will data and/or specimens be transported?* Data will not be transported.	

10.Provisions to Monitor the Data to Ensure the Safety of Subjects ☐ N/A

The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

a. *Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.* *Daily abdominal circumferences will be done by nursing staff in addition to monitoring for signs of feeding intolerance.*
b. *Describe what data are reviewed, including safety data, untoward events, and efficacy data.*

Abdominal circumferences will be measured daily. Monitoring for feeding intolerance will be ongoing.
c. *Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).* *Bedside nursing staff documents abdominal circumferences in patient's charts. Any signs of feeding intolerance is relayed to the primary care team.*
d. *Describe the frequency of data collection, including when safety data collection starts.* *Abdominal circumferences are measured daily, starting at birth.*
e. *Describe who will review the data.* *Information will be reviewed by the PI and sub-investigators.*
f. *Describe the frequency or periodicity of review of cumulative data.* *Data will be reviewed weekly.*
g. *Describe any conditions that trigger an immediate suspension of the research.* *Developmental of NEC, necrotizing enterocolitis.*

11. Withdrawal of Subjects ☐ N/A

a. *If applicable, describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.* Subjects will be withdrawn from the study should they meet any one of the following criteria: 1. The subject's parent (s) or legal guardian request that the subject be withdrawn from the study. 2. If, in the attending neonatologist's opinion, continuation in the study would be detrimental to the subject's well being 3. If the participant requires supplemental enteral intake from infant formula or additives such as carbohydrate, protein, or fat modulars, therefore altering the content of the fortified milk beyond the HP HMF. 4. The subject is diagnosed with NEC stage IIb or higher as described by the Bell's stages. 5. The subject is diagnosed with a gastrointestinal perforation. 6. After a subject has been discontinued, he/she will not be allowed to re-enroll in the study. The reason for a subject being discontinued will be documented in the database.	☐ N/A
b. *If applicable, describe any procedures for orderly termination.*	☒ N/A

c. *If applicable, describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*	☒ N/A

12.Risks to Subjects

a. *List the reasonably foreseeable risks.* 1. Physical risks: Minimal risk of feeding intolerance due to early fortification. Feeding intolerance may present as spit up, irritability, or abdominal distention. Possibility of increased risk of developing NEC, an intestinal infection. 2. Psychological risk: no psychological risk 3. Social risk: no social risk 4. Legal risk: no legal risk 5. Parents or legal guardians have no financial risks associated with this study. 6. There will be no financial costs associated with inclusion in this study	
a. *If applicable, describe any costs that subjects may be responsible for because of participation in the research.*	☒ N/A
b. *If applicable, describe risks to others who are not subjects.*	☒ N/A

13. Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research.

Introducing higher caloric feeds at the onset of enteral feeds can improve growth outcomes for VLBW infants when compared to infants who begin fortification after the first week of life.

14. Confidentiality

Describe the procedures for maintenance of confidentiality.

1. Subjects are at risk of breach of confidentiality. All research team members have undergone confidentiality training (CITI, HIPAA, and PHI) and are aware of the consequences for breach of confidentiality.
2. To protect subject privacy, data folders in use during testing will not contain personal identifiers and forms containing personal identifiers will be kept out of public view.
3. All subjects will be given a unique identifier.
4. Research raw data will be stored on a drive that is password protected, and databases will be stored on the AU IT provided human research drive. Only the PI and the co-investigators will have access to the drive.
5. If an unanticipated research-related event arises, the PI will be immediately informed of the event. If the event requires medical attention, the study physicians will be contacted for decisions regarding further action as needed.
6. Data folders in use during testing will not contain personal identifiers. Any study information about subjects will only be given out with the parent's or legal guardian's permissions. If the results of this study are published, the names of the subjects will not be used.
7. Purging or destroying data will be done by shredding documents. PHI no longer needed will be deleted from databases.

15. Incomplete Disclosure, Authorized Deception, or Deception ☒ N/A

16. Consent Process

If you are obtaining consent of subjects describe the consenting process. Be sure to include the process to be used if enrolling illiterate, non-English speakers, individuals with impaired decision making capacity to consent, as applicable.

1. Written consent will be obtained prior to performing any study related procedures with the exception of the collection of weight, length, and head circumference within the first 24 hours of life. Under some circumstances, mother (or guardian) may not be approached for study participation or be able to provide consent within the first 24 hours (e.g. maternal co-morbidity or in-patient at outlying hospital). As collection of these metrics are standard for each patient admitted to the NICU and do not represent additional risk to the potential participant, we may collect these measurements prior to consent. If consent is not obtained, measurements will be included in the EMR but will not be included in any study database.
2. The subject's mother (or guardian) will provide written consent and HIPAA authorization using the current version of the IRB-approved forms. Consent from the father will be obtained if required by the local IRB in accordance with IRB requirements.
3. The PI (or co-I) will be responsible for obtaining informed consent and HIPAA authorization after the study has been explained and all questions answered. The original signed consent form will be filed in the subject's record in accordance with institutional policy and a copy will be provided to the subject's parents/legal guardian.
4. If a protocol amendment requires revision to the informed consent form, the revised IRB approved form will be used to obtain and document re-consent from the subject's parent/legal guardian for all subjects enrolled in the study.
5. The language of the consent documents will be English.

17. Compensation for Research-Related Injury

This section is not required when research involves no more than Minimal Risk to subjects. ☒ **N/A**

18. Qualifications to Conduct Research and Resources Available

Describe the qualifications of you and your staff to conduct this research. The IRB is looking for information such as area(s) of expertise, past research experience, relevant certifications, etc.

For international research or research with vulnerable populations, describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to conduct the research. When applicable describe the knowledge of the local study sites, culture, and society. Provide enough information so the IRB knows that you have qualified staff for the proposed research.

Note: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify people by role (e.g., coordinator, research assistant, Sub-Investigator, or pharmacist), a change to that person will not require prior approval by the IRB, provided that person meets the qualifications described above to fulfill their roles.

The PI is a board certified pediatrician and current neonatal fellow with AU. The faculty advisor is a board-certified neonatologist.

a. Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.

1. Subjects will be provided with the PI's contact information and encouraged to email with questions pertinent to enrollment in the study.
2. All necessary medical resources that subjects might need as a result of anticipated consequences of the human research are available at Augusta University Medical Center.
3. All study personnel are trained to fulfill their role in the specific study and have all training and credentials for participating in research studies at Augusta University Medical Center.

b. Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

The protocol and study documents will be reviewed at a study initiation meeting and all study personnel will be trained to perform study procedures (e.g. weight, length, and head circumference). Attendance will be recorded and kept with study records. Should amendments to the study be approved, personnel will be informed in writing and/or in person and additional training performed.