Aspiration of Gastric Residual Contents

NCT 01863043

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Protocol

Research Design. A randomized clinical trial will be conducted to determine the benefits of omitting aspiration of residual gastric contents (RGC) prior to feedings on nutritional outcomes and gastrointestinal integrity and functioning of premature, very low birth weight (VLBW) infants. VLBW infants will be randomly assigned to one of two groups. Group 1 will receive standard care; that is, physical parameters of feeding intolerance and NEC will be assessed and RGC will be aspirated prior to each feeding. In Group 2, physical parameters for feeding intolerance and NEC will be assessed but RGC will not be aspirated. To determine nutritional outcomes, the following factors will be evaluated: (1) weekly enteral intake for the first 6 weeks of life, (2) time to reach full enteral feedings, (3) hours of parenteral nutrition (PN), (4) diagnosis of parenteral nutrition associated liver disease (PNALD), (5) growth indices, (6) hours of central venous line (CVL) access, (7) episodes of late onset sepsis (LOS), (8) length of hospital stay. The presence of gastrointestinal bleeding and inflammation will be measured by (1) presence of blood in the stool, and (2) fecal calprotectin levels. Furthermore, plasma levels of gastrointestinal peptides including serum gastrin and motilin will be measured as indicators of gastrointestinal function. See Table 1.

Sample and Setting. The proposed study will follow a prospective cohort (N = 120) of racially and economically diverse VLBW infants for 6 weeks following birth. The infants will be born to mothers who are English or Spanish speaking and who are 18 years of age or older. VLBW infants will be sampled by convenience from the neonatal intensive care unit (NICU) at Shands Children's Hospital, a Level III tertiary care center. The hospital is part of the University of Florida and includes a 52 bed NICU. The hospital catchment area encompasses north central Florida and southern Georgia, a predominantly rural and semi-rural population. Approximately 100-110 VLBW infants are delivered there per year. In the preliminary study, 70% of mothers consented for the study. Inclusion criteria for the infants are as follows: (1) born at 32 weeks or less of gestational age, (2) birth weight equal to or less than 1,250 grams, and (3) infant receiving some enteral feedings by 72 hours of age and parenteral feedings by 24 hours of age. Exclusion criteria for the infants are as follows: (1) congenital or chromosomal abnormalities, (2) complex congenital heart diseases and congenital anatomic gastrointestinal abnormalities, (3) Infants will be withdrawn from the study if any of the following occur: grossly bloody stools, radiologic evidence of NEC, or other intestinal complications such as perforation.

Sample Size Determination / Power Analysis. In the preliminary study, 40 premature, VLBW infants had a mean enteral intake at 14 days of 72 mL/kg/d (SD=65). To detect a 50% improvement to 108, we would require 104 evaluable subjects in a non-sequential design for Primary 1.1 to achieve 80% power at P=0.05 (two-sided). To accommodate one interim analysis, we employed the minimax method of Shuster et al (2002), with first look after 66 evaluable subjects have been accrued. If $|Z|>2.28$ we shall stop for significance. If $|Z|<1.12$, the study will be reviewed for possible futility. There will be no stopping for futility. Otherwise, the study will accrue 120 evaluable subjects (54 more). No competing two stage design can achieve a lower worst case scenario average sample size than this one's 89 evaluable. Intent-to-treat will be followed as closely as possible. However, to accommodate dropouts including deaths (15%) and infants who develop NEC (7%) we expect to accrue 160 subjects.

Randomization. Within 72 hours of life and within 24 hour of initiating feeds of less than 20 mL/kg/d, informed consent will be obtained from the mothers, and infants will be randomly assigned to one of two groups by random length permuted blocks of sizes 4, 6, or 8 to maintain approximate balance assigned to each treatment group.

Standard Infant Feeding Protocol. As per standard NICU protocol, all infants will begin receiving PN within 24 hours of life. In addition, all infants will have an orogastric (OG) or nasogastric (NG) tube placed upon admission to the NICU and begin receiving enteral feeding of less than 20 ml/kg/d within 72 hours. Length of insertion of the OG/NG tube is determined by measuring from the tip of the nose to the tip of the ear lobe and then halfway between the xyphoid process and umbilicus (Ellett et al., 2011). Minimum insertion length based on the weight of the infant (Cordero et al., 2011). If the infant receives an X-ray upon admission, placement of the OG/NG tube is verified. Placement is also verified if additional X-rays are taken during the study as per usual OG/NG placement protocol in the NICU. Depending on the infant's gestational age, weight, and clinical status, feedings are initiated at up to 20mL/kg/d and advanced daily by no more than 20mL/kg/d toward a goal of 120-150mL/kg/d divided into 8 equal feedings per day using the established University of Florida Children's Hospital NICU feeding guidelines. Mom's own breast milk is encouraged, and donor breast milk provided if mothers own breast milk is unavailable. Prior to each feeding, the OG/NG tube is checked for proper placement by the bedside nurse verifying the insertion length with the initial measured insertion length. In addition, the nurse assesses the infant for any signs or symptoms of feeding intolerance or NEC (i.e., abdominal distension and/or tenderness, increased abdominal girth, visible bowel loops, presence of emesis, and visible blood in the stool). It is standard protocol to aspirate RGC prior to each feeding. However, for this study, this will only occur in infants randomized to Group 1. Kangaroo Care (holding of an infant dressed only in a diaper upon someone's bare chest) can positively affect growth and improve feeding tolerance (Conde-Aqudelo et al., 2011)) Kangaroo care is encouraged in this NICU and nursing protocols have been established to provide support to all mothers regarding provision of kangaroo care.

Research Procedure. The procedures used in this study will be the same as those successfully used in the preliminary study. Following consent by the mothers, infants will be randomized, and baseline demographic data will be collected from their medical charts. Over the first 6 weeks of life the following additional information will be collected at specified time periods from their medical charts: weekly enteral intake, days to full enteral feedings (120 mL/kg/d), hours of PN, evidence of PNALD (level of direct bilirubin, alkaline phosphatase, aspartate aminotransferase (AST) and alanine aminotransferase (ALT)), growth indices (weekly weight, head circumference and length), medications, hours with a CVL, episodes of presumed or culture proven LOS (occurring > 7 days of life), days to discharge, evidence of stage 2 or greater NEC, evidence of aspiration pneumonia on chest radiograph, episodes of ventilator associated pneumonia and guaic status of stools. Additionally, one stool sample will be collected at 3 and 6 weeks to test for fecal calprotectin levels. 1mL of blood will be collected during a routine blood draw between 7 and 14 days of life to test for serum gastrin and motilin levels. If ventilated, tracheal aspirate samples will be collected on days 1, 3, 5,7,14, 21, 28 and 35 from routine tracheal aspirate suctioning. As kangaroo care is a potentially confounding factor, episodes and duration of kangaroo care between mother and infant will recorded on the Kangaroo Care log sheet located at the infant's bedside by either the mother or the nurse. See Table 1.

Aim 1. The primary aim of this study is to determine the risks and benefits of aspirating RGC and the clinical benefits of omitting aspiration of RGC prior to enteral feedings on the nutritional outcomes of premature VLBW infants. Both groups will have a sign placed on their isolettes stating which group they are assigned to and whether the nurse should or should not aspirate RGC. Although already documented on the infant's flow sheet, the sign will also include an area for the nurse to document the OG/NG insertion depth. Those personnel who are not involved with the study infants will be unable to be blinded since information regarding gastric residual volume and color is placed in the chart by the nursing staff and monitored by clinicians making decisions regarding enteral feeding plans. The PI is a neonatal nurse practitioner in the NICU

and will not be involved in the feeding plans for any subject in the study. The nurses at this research institution were willing to comply with the protocol in the past and have agreed to do so again. During the pilot study there were no known protocol deviations involving nursing staff. The only difference in care is that the infants in Group 1 will continue to have RGC aspirated prior to each feeding, and Group 2 will not have RGC aspirated. RGC are obtained by gentle aspiration of gastric contents from the indwelling OG/NG tube into a syringe. Decisions regarding advancement of feedings will be made according to the University of Florida Children's Hospital NICU feeding guidelines, including consideration of the physical assessment for signs and symptoms of feeding intolerance and NEC. Data to be collected for Aim 1 are found in Tables 1 and 2.

Aim 2. Aim 2 will determine the effect of routine RGC aspiration on gastrointestinal bleeding and inflammation. All stools will be tested for blood by the bedside nurse for the first 6 weeks using point of care guiac test kits, with the results recorded on the infant's flow sheet. Subsequently, this information will be collected and recorded by the project coordinator. Stool will be collected by the bedside nurse at 3 and 6 weeks of age and placed in a vial which is enclosed in a Ziploc® plastic bag and attached to the infant's isolette. Initial inflammatory changes have been seen in the intestinal tract of infants 4 days after an insult and the decision to test at 3 and 6 weeks was made to allow sufficient time for intestinal inflammation to occur from GRC aspiration (Saarinen et al., 2002). . The vial will be collected by the project coordinator who will take the sample to the co-investigator's (J. Neu, MD) existing research laboratory where the calprotectin level will be analyzed. This lab is currently successfully involved with and is proficient in fecal analysis of calprotectin levels. The results will be collected and recorded by the project coordinator.

Aim 3. Aim 3 will determine the effect of routine RGC aspiration on gastrointestinal function as evidenced by gastrointestinal peptide activity. Serum levels of gastrin and motilin will be measured on all infants between 14 and 21 days depending upon the timing of a routine blood draw. Since all GRCs are not discarded, waiting until between 14-21 days will allow adequate time for potentially one or more GRC to be discarded. 1 mL of blood will be taken during a routine blood test. All samples will be sent to the laboratory at Shands Children's Hospital at the University of Florida for testing, and lab values will be extracted and recorded by the project coordinator.

Statistical Analysis. Data will be entered into the RedCap system by the research assistant. For the primary hypothesis (P1.1), the total weekly enteral intake will be compared between the two randomized treatment groups via a two-sided Welch-corrected T-test. For sample sizes of this magnitude, the central limit theorem assures us that this is an assumption-free analysis, even if the underlying population variances differ. An interim analysis of P1.1 will also be done as described in the Power Analysis section below. Secondary hypotheses S1.1-S1.7 will be tested in the same manner as the primary hypothesis P1.1. For secondary Hypothesis S2.1 (S3.1), [S3.2], we shall compare the personal fractions of positive stools (gastrin levels) [motilin levels] respectively via two-sided Welch-corrected T-tests. For secondary hypothesis S2.2, we shall use a repeated measures analysis of variance to compare the groups with respect to week 3 and week 6 calprotectin levels. . Actual P-values will be reported, and each hypothesis will be accompanied by a point estimate and 95% confidence interval estimate for effect size. For descriptive purposes, a P-value of under 5% will be declared significant. The study is powered strictly around the primary hypothesis P1.1. Withdrawal rates will be compared between the treatments in a tertiary manner using survival analysis (time to withdrawal), via a logrank test.

Expected outcomes. Based on the preliminary study, it is reasonable to expect that infants who do not receive routine aspiration of RGC will have better nutritional outcomes, evidence of less gastrointestinal bleeding and inflammation, and improved gastrointestinal function.

Data Entry and Management. All data will be entered into a REDCAP database having integrated data quality and consistency checks (e.g., data-range) as part of the data procedure. Data quality will be monitored and assured: 1) as reported; and 2) as entered into the database. For the former, all hardcopy forms will be visually inspected before data entry. Furthermore, a manual comparison of randomly selected data hardcopy forms with data output listing generated from the study database will be performed, and consistency checks will be generated by SQL or SAS programs as part of routine data cleaning procedures. All subjects eligible for enrollment will be registered and entered into the study database designed by the project coordinator.

Table 1. Instruments

Variable	Measurement
Demographic data	Gestational age, birth weight, maternal history, prenatal and perinatal complications and medication, mode of delivery, Apgar scores, resuscitation at birth and neonatal acuity (SNAP II) score, medications and disease processes associated with decreased intestinal motility, episodes and duration of KC
Nutritional factors (1-8) below	
1. Enteral intake	Weekly 24-hour enteral feeding intake in mL/kg for first 6 weeks; Type of feeding received
2. Time to full feeds	First day infant received ≥120 mL/kg/d of enteral feedings
3. Hours of TPN	Number of hours infant received some PN for days 1-42
4. PNALD	Weekly or biweekly liver function tests (level of direct bilirubin, alkaline phosphatase AST and ALT) for first 6 weeks
5. Hours of central venous line access	Number of hours infant has a central venous line for days 1-42
6. Episodes of late onset sepsis	Episodes of culture proven or presumed sepsis (treated with 7-10 days of antibiotics but with negative cultures) during week 1- 6 weeks of life
7. Growth indices	Weekly weight. length, and head circumference
8. Length of hospital stay	Days infant remains in hospital from birth until discharge
Episodes of NEC	Episodes of radiologic evidence of NEC during the first 6 weeks
Gastrointestinal bleeding and inflammation (1-2) below	
1. Presence of blood in stools	Positive or negative guiac of all stools for first 6 weeks
2. Fecal calprotectin levels	Level of fecal calprotectin at 3 and 6 weeks
Gastrointestinal function	Serum levels of gastrin and motilin at 14-21 days
Respiratory aspiration of gastric contents (1-3) below	
1. Pepsin level in tracheal aspirates	Pepsin level in the tracheal aspirates of ventilated infants on day ,7,14, 21, 28 and 35
2. Presence of aspiration pneumonia	Presence of aspiration pneumonia on all radiographs
3. Presence of ventilator associated pneumonia	Presence of positive tracheal aspirate on ventilated infants

Table 2: Timetable for Collection of Data

Data	Time Period Collected
Demographic data	Upon entry into study and during 6 week study period
24-hour enteral feeding intake in mL/kg	Weekly for 6 weeks
Time to full feedings	Recorded daily until 120mL/kg/d reached
Hours of PN	Daily for 42 days
Evidence of PNALD	Weekly or biweekly liver function tests (level of direct bilirubin, alkaline phosphatase AST and ALT)for first 6 weeks
Hours of central venous line access	Daily for 42 days
Episodes of late onset sepsis	All incidences of culture proven or presumed (treated for 7-10 days but with negative cultures) for weeks 1-6.
Growth indices	Weekly weights, head circumferences and lengths
Days to discharge	Days infant is hospitalized
Episodes of radiologic evidence of NEC	All incidences for 6 weeks
Results of stool guaic	Every stool for 6 weeks
Fecal calprotectin levels	3 and 6 weeks
Serum levels of gastrin and motilin	14-21 days
Pepsin level of respiratory aspirate	Day 1,3,5,7,14 21, 28 and 35 in ventilated infants
Evidence of aspiration pneumonia	All radiographs for 6 weeks
Respiratory cultures	All respiratory cultures done on ventilated infants for 6 weeks

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INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your baby's participation is entirely voluntary. If you choose for your baby to participate you can change your mind at any time and withdraw him/her from the study. He/she will not be penalized in any way or lose any benefits to which he/she would otherwise be entitled if you choose not to have your baby participate in this study or to withdraw. If you have questions about your baby's rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Routine aspiration of residual gastric contents in very low birth weight infants

3. Who do you call if you have questions about this research study?

Principal Investigator: Leslie A. Parker, PhD, NNP-BC

(352) 215 9360

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4. Who is paying for this research study?

The sponsor of this study is the National Institute of Health

5. Why is this research study being done?

In most hospitals, babies such as yours are being feed both through their mouth and through their veins. The feeding goal is to slowly increase the amount of food given to your baby through their mouth, so that we can stop feeding through his\her vein. Currently, right before we give your baby more food through their mouth, we suck out anything remaining in their stomach, through a feeding tube that your baby has in place. The main reason for checking what is left over is to make sure we are not over-feeding your baby. This checking can happen up to 8 times a day. Some researchers have suggested that checking for this left over food can cause more harm by hurting the lining of your baby's stomach, and that by doing this, it takes longer for your baby to stop having to receive some food through their vein.

The purpose of this research study is to find out the risks and benefits of checking or not checking the amount of formula or breast milk remaining in your baby' stomach before every feeding.

You are being asked to be in this research study because your baby is a premature baby who needs to be fed through a tube that goes from the mouth or nose to the stomach.

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

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your child's normal clinical care (even if he/she did not participate in this research study)?

Other than checking or not checking the left over food in your baby's stomach before each feeding, the care your baby receives will be the same as any premature baby who weighs less than 1250 grams (about 3 pounds). Feeds will be given through a tube into their stomach and will be increased daily until full feedings are reached. Administration of a special type of nutrition through the veins called parenteral nutrition will be provided until they are taking enough feeding for good nutrition and growth. Medications will be used as necessary per normal clinical care. Risks include feeding intolerance, necrotizing enterocolitis (an intestinal infection that occurs in 7-10% of premature infants) and spontaneous intestinal perforation (when a premature infant develops a hole in their intestines which occurs in 5% of very premature infants).

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Donated pasteurized breast milk will be used for feeding until your infant has reached 32 weeks gestation (2 months before they were due to be born) if the mother is unable or unwilling to provide their own breast milk.

7. What will be done only because your baby is in this research study?

If you decide to have your baby participate in this research study, your baby will be randomly assigned (like the flip of a coin) to either have the leftover food in their stomach removed before each feeding, or not have the leftover food removed before each feeding.

You and your baby's doctors and nurses will know whether your baby will have their left over food checked prior to each feeding. Infants in this study will all receive breast milk. If the mother is unable or unwilling to provide breast milk, donated pasteurized breast milk will be fed to the infant.

If your infant is receiving donor milk and is discharged before the end of the study, he/she will be transitioned to formula according to normal NICU care.

When your baby needs blood drawn as part of their regular care, we will take some of that blood and find out the amount of certain hormones (gastrin and motilin) the blood contains. We will do that when your infant is between 2 and 3 weeks of age. We will also have their bowel movements tested for signs of irritation in the intestine at 3 and 6 weeks of age, and the bacteria in their bowel movements will be analyzed each week for the first 6 weeks. If they are on a breathing machine, we will have the mucous that is routinely removed from their breathing tube tested for signs they have breathed in stomach contents. All the other laboratory and exams will be those that normally are recommended in the normal clinical care of very premature babies.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

Study procedures will be done until your baby is 6 weeks old. We will continue to collect medical information until he/she is discharged from the hospital or he/she reaches 20 weeks of age.

9. How many people are expected to take part in this research study?

170 infants will be enrolled in this study.

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WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

The risks of this study are those that may occur if your baby's left over food is not removed prior to each feeding. We are not sure what those risks will be, but we don't expect them to be different from the normal risk of feeding premature infants. These risks are minimized by watching for other signs of problems which could include measuring for increased abdominal size, changes in the color of the abdomen, vomiting, changes in the infant's breathing or heart rate, and loose or bloody stools.

Researchers will take appropriate steps to protect any information they collect about your baby. However, there is a slight risk that information about your baby could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about your child will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you or your baby. If you or your baby are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling your baby in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to have your baby remain in the study.

If you wish to discuss the information above or any discomforts your baby may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to your child for taking part in this research study?

There may or may not be any benefits for the subjects participating in the study. If your baby has their left over food removed before feeding, then there is no benefit to your baby. If your baby does not have their left over food removed before feeding, the potential benefits may be that your baby can increase the amount of food he\she eats faster than normal which could increase growth, and improved ability to accept feedings, which could result in removing the food being given by vein faster with less intestinal bleeding and improved gastrointestinal function.

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11b.How could others possibly benefit from this study?

The results from this study may help investigators to better understand the risks and benefits of checking or not checking the amount of formula or breast milk remaining in a premature baby's stomachs before every feeding which in turn may lead to improvement in patient care.

11c.How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Investigators listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want your baby to be in this study?

If you decide to not have your baby participate in this study, your baby will still receive the University of Florida & Shands Children's Hospital routine normal clinical care.

13a.Can you withdraw your baby from this study?

You are free to withdraw your consent and to stop your baby from participating in this study at any time. If you do withdraw your consent, you and your baby will not be penalized in any way and you and your baby will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to have your baby participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your baby's participation safely.

If you have any questions regarding your baby's rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw your baby from the study, can information about you still be used and/or collected?

If you withdraw your baby from the study, no new information will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your baby's entire medical record. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research.

13c. Can the Principal Investigator withdraw your child from this study?

Your baby may be withdrawn from the study without your consent for the following reasons:

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- If your baby has a serious side effect or needs treatment not allowed in the study, or we determine that it is no longer in your baby's best interest to continue.
- If your baby is removed from the study, you will be asked to allow a final assessment (a physical exam and review of your baby's routine laboratory evaluations).

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to have your baby take part in this research study, will it cost you anything?

The Sponsor will pay for the following study-required services:

1) Tests to determine whether there is blood in the bowel movements (Guiac test)

2) Testing of the bowel movements for signs of inflammation in the intestine at 3 and 6 weeks

3) Analysis for bacteria in the bowel movements each week for the first 6 weeks

4) Testing of mucous from the breathing tube for signs they have breathed in stomach contents

5) Assessment for digestive hormone levels when blood is drawn between 2 and 3 weeks of age

If you receive a bill for these services, please contact one of the research team members listed in question 3 of this form.

Items/Services Not Paid for by the Sponsor

All other medical services your baby receives would have been provided to your baby even if your baby were not in this study. These services will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services.

15. Will you be paid for your baby taking part in this study?

No. You will not be paid for your baby's participation in this study. Any procedures, medications, or tests specifically required by the study will be performed or provide to your baby free of charge.

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16. What if your child is injured because of the study?

If your baby is injured as a direct result of your baby's participation in this study, only the professional services that your baby receives from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies. Please contact your insurance company for additional information.

No additional compensation is offered. The principal investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if your baby experiences an injury or have questions about any discomforts that your baby experiences while participating in this study.

17. How will your infant's health information be collected, used and shared?

If you agree to have your baby participate in this study, the Principal Investigator will create, collect, and use private information about your baby and your baby's health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your baby's protected health information may be collected, used, and shared with others to determine if your baby can participate in the study, and then as part of your baby's participation in the study. This information can be gathered from you or your baby's past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your baby's study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Full medical history,
- Physical examination information
- Complete blood counts, liver function testing, blood chemistries, blood tests for intestinal hormones
- Imaging studies such as x-rays, CT scans and MRIs

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- Results of tests determining whether there is blood or signs of intestinal inflammation in bowel movements and what bacteria are in the bowel movements
- Results of any cultures of the blood and mucus from the breathing tube
- Results of tests for breathing in stomach contents into the breathing tube

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify your baby. For example, the limited data set cannot include your baby's name, address, telephone number, social security number, photographs, or other codes that link your baby to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your infant's protected health information be collected, used, and shared with others?

Your baby's PHI may be collected, used, and shared with others to make sure your baby can participate in the research, through their participation in the research, and to evaluate the results of the research study. More specifically, your baby's PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To find out the risks and benefits of checking or not checking the amount of formula or breast milk remaining in premature baby's stomachs before every feeding.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your child's protected health information?

Only certain people have the legal right to collect, use and share your child's research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- Other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.

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- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your child's protected health information be shared with?

Your baby's PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States agencies who are responsible for overseeing research, such as the Department of Health and Human Services, and the Office of Human Research Protections .

Otherwise, your baby's research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your child's protected health information be used and shared with others?

Your baby's PHI will be used and shared with others until the end of the study and will be kept in a secure data base.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your baby's PHI. Your refusal to sign will not affect your baby's treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, your baby cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your baby's protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your baby's participation in this study. If you revoke it, no new information will be collected about your baby. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization | Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your baby's protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to have your baby participate in this study. You hereby authorize the collection, use and sharing of your baby's protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____ _____

Consent Signature of Parent/Legal Representative | Date

_____ _____

Print: Name of Legal Representative | Print: Relationship to Participant:

_____

Print: Name of Subject: