Cover Page

Breast vs Bottle Study

Protocol

Study Abbreviation	BvB
Project Start Date:	12 August 2018
Project End Date:	31 July 2020
Principal Investigator:	Dr. Alison Ventura
Sponsor:	NIH, NICHD
Protocol Creation:	5 September 2018
Protocol ID:	2018-143-CO
Version	1

PROTOCOL TITLE: Family Feeding Study (The Breast vs Bottle Study)

TITLE OF THE RESEARCH:

The Family Feeding Study (The Breast vs Bottle Study)

NAME AND DEPARTMENT/AFFILIATION OF THE PRIMARY INVESTIGATOR:

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STATEMENT OF PURPOSE, BENEFITS, AND HYPOTHESES:

A substantial proportion of US children, adolescents, and adults are overweight or obese,[1] and evidence-based prevention strategies are needed to reverse these trends.[2] One of the earliest postnatal risk factors for obesity is rapid weight gain during infancy.[3] There is substantial evidence showing formula/bottle-fed infants are at greater risk for rapid weight gain than breast-fed infants,[4,5] however, the mechanisms underlying this association are still unclear. Previous researchers have hypothesized that bottle-feeding facilitates feeding practices that are responsive to contextual cues, such as the amount of formula in the bottle, instead of responsive to infants' signals of hunger and fullness.[6] Additionally, certain formulas (including those that are most commonly fed to U.S. infants) are less satiating than other formulas or breast-milk,[7] suggesting that maternal attention to infant feeding behaviors may be especially critical to ensure infants fed these formulas do not over-feed.[6,8] However, emerging research has illustrated that mothers may be more prone to overfeed during bottle-feeding, regardless of what is in the bottle, which suggests bottle-feeding practices are an independent risk factor for rapid weight gain and important target for prevention efforts.[5,9]

Although current recommendations[10-13] and prevention programs[14-19] aimed at reducing risk for rapid weight gain and obesity have predominately focused on promoting responsive feeding practices (i.e., mothers' sensitive responsiveness to infants' behaviors during feeding interactions) to reduce risk for overfeeding,[20] a number of knowledge gaps remain,[11] making the evidence-base for these prevention efforts sparse.[21-23] Herein, three key limitations of previous research are highlighted.

First, previous research has predominantly focused on comparing groups of breastfeeding versus formula- or bottle-feeding mothers; much of this research has shown that, as a group, formula-/bottle-feeding mothers use more controlling and less responsive feeding practices than breastfeeding mothers.[24-29] However, it is well-documented that mothers who chose to breastfeed and who breastfeed for longer durations tend to have higher levels of education and socioeconomic status and have more social support than their formula-/bottle-feeding peers;[9,30] thus, breastfeeding mothers differ from bottle-feeding

mothers in a number of ways that may also influence their feeding styles, making it unclear whether feeding mode – or unmeasured covariates – are the primary driver of differences in maternal feeding practices and styles during breast- versus formula-/bottle-feeding. To date, no studies have used a within-subject design to observe mothers during breast- *and* bottle-feeding, which would allow for a more direct comparison of how maternal feeding practices may differ within these different feeding contexts.

Second, it is also important to note that, for the majority of mothers and infants, feeding patterns are complex and involve varied combinations of human milk- and formula-feeding, as well as breast- and bottle-feeding. Data on infants' milk feeding patterns across the first year of life indicate that only ~8% of infants are exclusively breastfed from the breast (i.e., never receive formula or bottles),[31] whereas ~25% of infants are exclusively formula/bottle-fed from birth.[32] Thus, the dichotomy of mother into breast- versus formula/bottle-feeding likely oversimplify most mothers' early feeding experiences. Studies that examine how mothers feed across these different feeding contexts – rather than attempt to classify mothers into discrete feeding groups – would allow for a more comprehensive understanding early feeding interactions.

The proposed research will directly address these research gaps to better understand the early feeding experiences most relevant to today's families. It will also provide important preliminary data for novel approaches to the primary prevention of obesity, through family-based interventions that would promote mothers' responsiveness to infant cues.

To this end, we propose a within-subject, experimental study that will address the following aims:

Specific Aim 1: To examine whether maternal sensitivity to infant cues moderates effects of feeding mode on infant intake.

Hypothesis 1: We hypothesize that when mothers exhibit low sensitivity to infant cues, their infants will consume significantly more during bottle-feeding compared to breastfeeding. When mothers exhibit high sensitivity to infant cues, no differences will be seen for intakes during bottle- compared to breastfeeding.

Specific Aim 2: To identify key predictors of low maternal sensitivity to infant cues.

Hypothesis 2: We hypothesize that characteristics of mothers (e.g., weight status, race/ethnicity, socioeconomic status, parity) and infants (e.g., sex, weight status, temperament, clarity of cues) will predict levels of sensitivity to infant cues during both bottle- and breast-feeding.

Exploratory Aim: To examine whether maternal-infant behavioral and physiological synchrony differ between bottle-feeding vs. breastfeeding. Through frame-by-frame coding of maternal and infant behaviors and collection of ECG data from mothers and infants during feeding interactions, we will assess whether maternal-infant behavioral and physiological synchrony differ between bottle- and breastfeeding interactions.

METHODS:

Subjects

Mothers and their healthy, term infants of either sex will be eligible. Infants must be between birth and 24 weeks of age and prior to the introduction of solid foods. We will recruit breastfeeding infants who also have experience feeding from a bottle. Infants who were preterm, have a latex allergy, have medical conditions that interfere with feeding, or who are exclusively formula-feeding will be excluded from this study. Mothers will be recruited from ads in local newspapers, Women, Infant & Children (WIC) offices, mass mailings, online sites, and a list of past participants who have asked to be notified of future studies. The sample will reflect the community of San Luis Obispo and Santa Barbara Counties (89% white, 22% Hispanic, 2% Black, and 4% Asian).[44] See Appendix I for our recruitment flier.

We will aim to recruit a sample of 40 mother-infant dyads. Participants will be given an honorarium of up $50 ($25 per visit).

We will screen potential participants for eligibility during an initial recruitment and screening call. During this call, an overview of the study protocol will be discussed with the potential participants. Mothers who indicate they are interested in participating will be asked a series of screening questions (Appendix II) to determine eligibility. Mothers' responses to these questions will be recorded on the Screening Questions Report Form (Appendix II).

Inclusion Criteria:

- All mothers must be 18 years or older
- Infants must be between 0- and 24-weeks of age
- Infants must be prior to the introduction of solid foods
- Infant must have experience with feeding from a bottle
- Mother is predominantly or solely responsible for infant feeding

Exclusion Criteria:

- Preterm birth (i.e., gestational age <37 weeks)
- Medical conditions that interfere with feeding
- Low birth weight (<2500g)
- Maternal smoking during pregnancy
- History of slow growth or failure to thrive
- Weight for length percentile <5th
- Diagnosed developmental delay (e.g., Down's syndrome)

The following vulnerable populations will be included in our study:
Individuals who are not yet adults (infants).

The following vulnerable populations will not be included in our study:
Adults unable to consent, pregnant women, prisoners

Experimenter

Dr. Ventura has extensive training and expertise in the theoretical and practical understanding of the bidirectional influence of parents and children during feeding interactions, and objective and subjective measurement of bidirectional interactions during feeding. As a graduate student of Dr. Leann Birch at the Pennsylvania State University, she received both theoretical and practical training in the assessment of parental influences on children's dietary intake, eating behaviors, and health outcomes, as well as the influence that children have on parent feeding and parenting behaviors. She gained extensive experience with using questionnaire-based methods to assess parents' feeding attitudes and practices in the longitudinal research she conducted with Dr. Birch. She continued to use these methods after graduate school to assess the feeding practices of low-income parents of preschool children. She also developed a qualitative, semi-structured interview to assess parents' perceptions of common problems they encountered while feeding their children, as well as strategies they used to deal with these problems. As a postdoctoral fellow working with Dr. Julie Mennella at the Monell Chemical Senses Center, she received extensive training in the design of observational studies of parent-child feeding interactions during formula/bottle-feeding. She also developed methods that allow for the effective observe mealtime interactions in minority and other populations while minimizing influence on the observed behaviors. Additionally, she recently became certified in two well-known behavioral coding systems: the Facial Action Coding System and the Nursing Child Assessment Satillite Training Parent-Child Feeding Interaction Scale.

Design

This is a within-subject experimental study. Mother-infant dyads will visit our laboratory 2 times for approximately 2 hours each visit; visits will be separated by 1 day. During these visits, mother-infant dyads will be observed while feeding under two conditions:

1) **Breastfeeding Condition:** During one visit, the mother will breastfeed her infant as she typically would at home.

2) **Bottle-feeding Condition:** During one visit, the mother will feed expressed

As illustrated in the Table, conditions will be randomly assigned and counterbalanced.

Table. Example Order of Conditions and Study Timeline for Mother-Infant Dyads

Visit:	1		2
Dyad A	Breastfeeding	1 day	Bottle-Feeding
Dyad B	Bottle-feeding		Breastfeeding

Note: Order of conditions will be randomly assigned and counterbalanced.

Protocol and Measures

During the three days prior to and throughout the experimental period, mothers will be asked to refrain from introducing additional foods or liquids to their infants. To encourage adherence, mothers will keep a daily record of when and what they feed their infants. We will call mothers the evening before each visit to assess their restraint from introducing new liquids and solids, and assess whether disruptive events (e.g., sickness) have occurred that may affect infant or maternal behaviors during study participation. At the beginning of each visit we will interview the mothers about when the infant last fed and slept and whether any disruptive events occurred during the previous 24 hours. Each of the testing sessions will occur at the same time of day to control for infants' circadian rhythms and variation in intake and mother-infant dyads will arrive approximately one hour prior to a time when the infant typically takes a feeding.[44] The remainder of the visit will consist of: 1) assessment of infant and maternal anthropometrics; 2) feeding observation; and 3) assessment of mothers typical feeding practices and styles and infant temperament.

1) **Assessment of Infant and Mother Anthropometrics.** A trained research assistant will collect weight and length/height measurements in triplicate for infants and mothers using an infant scale/infantometer (models 374 and 360; Seca, Hamburg, Germany) and adult scale/stadiometer (model 736; Seca, Hamburg, Germany), respectively. Infant weight and length measurements will occur prior to the observed feeding session and infants will be changed into a fresh diaper and light-weight "onesie" to control for diaper weight and clothing thickness. Infant anthropometric data will be normalized to z-scores using the World Health Organization Anthro software version 3.0.1

(http://www.who.int/childgrowth/en/) to calculate age- and sex-specific z-scores. Mothers' weight and height data will be used to calculate Body Mass Index (BMI = weight [kg] / height [m]^2).

2) **Feeding Observation.** During each visit, mothers will be instructed to feed their infants as they normally would at home. The feeding session will be video-recorded using three synchronized video cameras (GoProHero 4, California, USA). The video cameras will be placed at three different angles, facing the mother-infant dyad. The experimenter will move to a different room (with a 1-way mirror providing a view into the testing room) during the feeding to minimize the influence of the presence of the experimenter on mothers' feeding behaviors, but will be available to the mother if any questions or problems arise. Infant intake will be assessed by pre- and post-weighing the baby on an infant scale for breastfeedings or the bottle using a top-loading balance (Ohaus SP601 Scout Pro Portable Balance; Ohaus, Ontairo, Canada) during bottle-feedings. We will also note whether the infant finishes the bottle.

   During each feeding observation, we will also assess both the mother's and the infant's physiological response to the feeding using electrocardiogram (ECG). ECG is widely used in studies of mother-infant dyadic interactions to assess the physiological response of both members of the dyad to social stressors, as well as a marker of synchrony during shared interactions.[33-38] The National Institutes of Health (NIH) and other public health organizations recognize that ECG is painless, harmless, and completely safe for infants and adults. ECGs do not give off electrical charges, such as shocks, and provide a minimally invasive means of assessing the heart's electrical activity. There is minimal risk of developing a mild rash where the electrodes are attached, but the rash usually goes away without treatment and we will attempt to minimize skin irritation by applying a hypoallergenic gel to the electrode before placing it on the individual's skin, minimizing any irritation.

   For the infant, two disposable pediatric electrodes will be placed on the infant's chest and one electrode will be placed on the infant's back immediately prior to the start of each feeding. Similarly, for the mother, three disposable electrodes will be placed on the chest immediately prior to the start of each feeding. ECG signal will be assessed using a BioPac MP150 data acquisition system (BioPac Systems, Inc., Goleta, CA). ECG and behavioral coding data (see below) will be synchronized to enable assessment of the correspondence between physiological and behavioral outcomes.

   After each visit, three trained coders who are unaware of the experimental conditions and hypotheses of the study will score the videotaped records using an event recorder program (Observer XT, version 14; Noldus Information Technology, Heerlen, the Netherlands). Coders will conduct frame-by-frame analysis of each video to determine the length of each feed, the frequency of infant hunger and satiety cues, and mothers' feeding behaviors. All coders will

also be trained to use the Nursing Child Assessment Parent-Child Interaction Feeding Scale (NCAFS). The NCAFS is a reliable and valid means of observing and rating mother-child interactions during a feeding session. It is validated for use with mothers and their infants of 0- to 1-year of age and can be applied to a breast, bottle, or table food feeding/eating episodes. The NCAFS contains 76 observable behaviors that are organized into six subscales. Four subscales describe the mother's responsibility to the interaction: Sensitivity to Cues, Response to Distress, Social-Emotional Growth Fostering and Cognitive Growth Fostering. Two subscales describe the child's responsibilities: Clarity of Cues and Responsiveness to Mother. Thus, a strength of the NCAFS is the ability to understand the bidirectional nature of mother-infant feeding interactions under different feeding conditions.

Reliability will be established prior to full coding of all videos. To this end, coders will code 10 common videos and will double-code 10 additional videos. Inter-coder comparison of the common videos will be used to establish inter-coder reliability. Intra-coder comparison of the double-coded videos will be used to establish intra-coder reliability. Full coding will not commence until a Kappa > 0.80 is reached for all coders.

3) **Assessment of Mother and Infant Characteristics:** Over the course of the three visits, we administer the following questionnaires to the mothers:
    1. Family Demographics Questionnaire (Appendix III)
    2. Wellness Questionnaire (Appendix IV)
    3. Baby Basic Needs Questionnaire (Appendix V)
    4. Infant Behavior Questionnaire – Revised (Appendix VI)
    5. Baby Eating Behavior Questionnaire (Appendix VII)
    6. Infant Feeding Styles Questionnaire (Appendix VIII)
    7. Parenting Confidence Questionnaire (Appendix IX)
    8. The Parental Distraction Questionnaire (Appendix XI)
    9. Future Studies Database Form (Appendix XII)

Study data will be collected and managed using REDCap electronic data capture tools hosted at Cal Poly.[19] REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Participants will complete questionnaires at home (on their personal computer) or at our laboratory on a password-protected iPad designated for this study. Paper versions of the data collection forms will be used if technical difficulties occur or if the mother prefers this method; data collected via paper forms will then be entered into the REDCap tool by a trained research assistant.

Additional Safety Considerations

To ensure infants are receiving safe and high quality breast milk, mothers will be provided with instructions regarding proper breast milk storage and transit (Appendix XIII) to ensure the breast milk or formula brought to each visit does not spoil or sour during transit to our laboratory. Bottles will be reused between visits. Thus, after each visit, we will advise mothers to wash all bottle components in accordance with the World Health Organization (WHO) guidelines for cleaning, sterilizing and storing feeding and preparation equipment (http://www.who.int/foodsafety/publications/micro/PIF_Care_en.pdf). This will entail 1) proper hand washing, 2) washing all bottle components with hot soaper water and a bottle brush, 3) rinsing all bottle components with safe water, and 4) sterilizing all bottle components using a microwave bottle sterilizing system (Medela Quick Clean Micro-Steam Bags, Medela, McHenry, IL).

Additionally, we will provide participants with a handout explaining the ECG procedure. This handout emphasizes the safety of this procedure for both adults and children and directs the participants to further resources for learning about the ECG procedure (Appendix XIV).

Statistical Analysis Plan

Power Analyses. We will aim to test a sample of 40 mother-infant dyads. Based on our previous experience, we estimate 20% of participants will drop out. Thus, 48 mother-infant dyads will be recruited to account for this predicted attrition rate. This sample size has been selected to ensure adequate power to test for statistical significance for Aim 1, which examines the impact of feeding mode and maternal sensitivity on infant intake. There is 80% power to detect a 43-mL difference in infant intake from breast to bottle between low and high sensitivity mothers, using $\alpha = 0.05$. This power calculation is based on a pilot study for which the between-subject standard deviation of the infant intake was 33.7; this calculation also assumes that the high sensitivity mothers will have a high correlation in infant intake between breast and bottle ($r = .70$), whereas low sensitivity mothers will have a lower correlation in infant intake between breast and bottle ($r = .30$).

Data Analysis. All analyses will be conducted using SAS version 9.4 (SAS Institute Inc., North Carolina, USA). To test our first specific aim (Aim 1: To examine whether maternal sensitivity to infant cues moderates effects of feeding mode on infant intake), we will use repeated-measures Analysis of Variance (RMANOVA) to assess the effect of condition (*bottle-feeding* vs. *breastfeeding*) on maternal sensitivity and infant intake. To test our hypothesis that maternal sensitivity to infant cues moderates associations between feeding mode and infant intake, moderation will be tested by including a condition with moderator interaction term in the RMANOVA for effect of feeding mode on infant intake. To assess our second specific aim (Aim 2: To identify key predictors of low maternal sensitivity to infant cues), we will categorize maternal sensitivity as higher or lower using median split; stepwise logistic regression analysis will then be used to identify the combination of characteristics of mothers (e.g., weight status, race/ethnicity, socioeconomic status, education, marital status, parity, extent of non-caregiver feeding, self-reported responsive and pressuring feeding practices) and infants (e.g., sex, weight

status, temperament, clarity of cues) that best predict mothers' levels of sensitivity to infant cues. To assess our exploratory aim (Exploratory Aim: To examine whether maternal-infant behavioral and physiological synchrony differ between bottle-feeding vs. breastfeeding) we will assess synchrony for maternal and infant behaviors and heart rhythms using a time-domain time-series analysis.[53,102] Cross-correlation functions between the maternal-infant behaviors and physiological responses will be calculated to assess degree of synchrony for each dyad and under each condition. RMANOVA will then be used to assess whether degree of behavioral and physiological synchrony differs between feeding conditions. For all relevant analyses, we will assess the possible influence of visit number and order of condition presentation on feeding outcomes, as well as adjust for baby size (weight-for-length), sex, and time since last feeding (a proxy for hunger level). Outliers will be included in the analysis and, when substantive, their impact on parameter estimates will be noted. Residuals will be examined to assess RMANOVA model conditions and necessary transformations of the response will be used as needed.

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Informed Consent Form

INFORMED CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT: <u>Infant Feeding Study</u>

Why are we doing this research?

A research project for observing infant feeding interactions is being conducted by Dr. Alison Ventura in the Department of Kinesiology and Public Health at California Polytechnic State University, San Luis Obispo. The purpose of the study is to help us to better understand infant feeding during typical feeding situations. We are interested in better understanding the ways in which mothers feed their infants. What we learn from this study will help us to figure out how to promote healthy feeding during early infancy.

What you should know about this research study:

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before and after you decide.

What will you be asked to do?

You and your baby are being asked to take part in this study by visiting our laboratory on 2 separate days (with visits separated by 1 day) for approximately 2 hours each day. Your visits will occur at the same time on all days. At the start of each visit, we will change your baby into a fresh diaper. We will then measure his or her weight and length. We will also measure your weight and height.

For the 3 days leading up to, and on the days of, your visits, you will be asked to complete daily food logs of when and what you feed your baby. We will also call you during this 3-day period to remind you to fill out the logs and to check in how your baby is doing.

During each visit, a trained research assistant will ask you to feed your baby as you normally would at home. On one day, you will breastfeed your baby and on the other day you will feed your baby expressed breast milk from a bottle.

Immediately prior to each feeding, the research assistant will place three small electrodes on you and your baby to measure heart rate during the feeding. The entire feeding session will be video-recorded. The video-recorders will be placed at the far corners of the room, about 10 to 12 feet from you and your baby. The research assistant will move to a different room during the feeding but will be able to see you through a 1-way mirror and will be available if you have any questions. After you feed your baby, the research assistant will ask some questions about the feeding and questions related to parenting experiences and your baby's personality. We will also ask about your infant feeding attitudes and practices, health history, and eating behaviors.

How long will the study last?

Participation for you and your baby will take approximately 5 hours of your time over a 6-day period; this estimate does not include the time it may take you to travel to the French Hospital Copeland Health Education Pavilion and return home on 2 occasions. During days 1 through 3, we will ask you to fill out feeding logs for your baby. This should take you ~15 minutes per day. We will call you on day 1 to remind you about the feeding logs and we will call you again on day 3 to check in on you and your baby. On day 4 you and your baby will visit our laboratory for ~2 hours. On day 5 you will not come into the laboratory, but will continue your feeding logs at home. On day 6 you will come into the laboratory again for ~2 hours.

Is there any way being in this study could be bad for your family?

The risk involved in this study is minimal. You may dislike being observed while feeding your baby. You or your baby may dislike wearing the electrodes during the feedings, or the electrodes or electrode cream may irritate you or your baby's skin. It is possible that your baby's breast milk could sour or spoil if not handled correctly during your transit to our laboratory. Additionally, you may feel uncomfortable answering questions we ask about your baby's feeding and health history. Please know that you may omit any questionnaire items you prefer not to answer and you have the right to opt out of any part of the study at any time.

We do not expect any other risks to participating in this study. If you or your baby should experience any discomfort related to this study, please be aware that you may contact Dr. Alison Ventura at (805) 756-5693 or akventur@calpoly.edu for assistance.

Your family is not required to participate in this research and may discontinue participation at any time without penalty. If you agree to take part in the research now and stop at any time it will not be held against you. But, if you do not want to be part of the study, we may still keep and use your study information.

What happens to the information we collect?

To ensure your family's privacy and confidentiality, all video-records, data sheets, and questionnaires with your information will be coded. When we want access to this information for later study, we will refer to the coded information so that your identity cannot be traced. All records and video-records will be kept within both locked physical files and on a secure, encrypted, university-managed server that only research personnel have access to.

In any written or oral presentation of research results, your family's identity will be kept private. Records that identify you and your baby may be inspected by authorized individuals such as the Cal Poly institutional review board (IRB), or employees conducting peer review activities. You consent to such inspections and to the copying of excerpts of your records, if required by any of these representatives. All study personnel have been trained at Cal Poly on the rights of human subjects. They are familiar with the rules for handling personal information.

Will being in this study help you in any way?

We cannot promise any benefits to you or your baby from your taking part in this research. However, you may enjoy becoming more aware of your baby's behaviors. You may also appreciate learning about new research in nutrition, food preferences, and mother-infant interactions. We also cannot promise any benefits to others from your taking part in this research. However, the findings from this study may help us to understand how best to promote healthy development during infancy.

Will you be compensated for your time?

If you agree to take part in this research study, you will receive $25 for each study visit you complete. You will be compensated at the end of each visit. You will not be compensated for visit days that you do not attend because you do not show up, withdraw, or are removed from the study.

Can you be removed from the research without your OK?

The person in charge of the research study or the sponsor can remove you and your baby from the research study without your approval. Possible reasons for removal include:

- If all or part of the study is stopped for any reason by the investigator or Cal Poly.
- If participation in the study is adversely affecting your family.
- If you fail to adhere to requirements for participation established by the researcher.

Who should you contact for more information?

If you have questions regarding this study or would like to be informed of the results when the study is completed, please feel free to contact Dr. Alison Ventura at (805) 756-5693 or akventur@calpoly.edu.

If you have concerns regarding the manner in which the study is conducted, you may contact Dr. Michael Black, Chair of the Cal Poly Institutional Review Board, at (805) 756-2894, mblack@calpoly.edu, or Ms. Debbie Hart, Compliance Officer, at (805) 756-1508, dahart@calpoly.edu.

If you agree to voluntarily participate in this research project as described, please indicate your agreement by signing below.

Signature of Participant	Date
Signature of Researcher	Date

If you agree to allow your baby to participate in this research project as described, please indicate your agreement by signing below.

Name of Child Involved in this Research: _____

Signature of Parent/Guardian	Date
Signature of Researcher	Date

Please keep one copy of this form for your reference.
Thank you for your participation in this research!