Official Title: Healthy Start to Feeding Pilot Trial

Brief Title: Healthy Start to Feeding Intervention

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Document: Informed Consent Form

University of CINCINNATI

**Parent Permission for Child's Participation in Research**
**And Adult Consent**
**University of Cincinnati**
**Department: Psychology**
**Principal Investigator: Cathleen Stough, PhD**

**Title of Study:** Healthy Introduction of Complementary Foods: An Obesity Prevention Program

**Introduction:**
You are being asked to take part in a research study. Please read this paper carefully and ask questions about anything that you do not understand.

This research is sponsored by University of Cincinnati (UC) Start-up Funds.

**Who is doing this research study?**
The person in charge of this research study is Cathleen Stough, PhD of the UC Department of Psychology. There may be other people on the research team helping at different times during the study.

**What is the purpose of this research study?**
We want to learn about an intervention to help parents introduce foods to their infants in a healthy way. Our intervention will tell parents about when to start giving solid foods to their infants. It will also give parents information about how to introduce solid foods and what foods to give. We want to know if parents find our intervention helpful and if parents use the information they learn.

**Who will be in this research study?**
About 40 infants and their parent will be in our study. To be in the study, your child needs to be 3 months old and not eating any food besides breast milk or formula yet. Your child also must not have a developmental delay, impaired motor skills, a condition that impacts feeding and eating, or been born before 36 weeks gestation. Your child also needs to have a weight-for-length $\geq 5^{th}$ percentile. You (the parent) must also be a fluent English speaker and an adult (over age 18).

**What will you and your child be asked to do in this research study, and how long will it take?**
You will come to Cincinnati Children's Hospital Medical Center (CCHMC) and UC for either 2 or 5 visits over a period of 6 months. All study participants will attend one 1.5-hour visit at CCHMC when their infant is 3 months old. At this visit, you will consent to participate and complete surveys about your infant's appetite, your feeding practices and beliefs, and demographics. We will also measure your infant's weight and length. You will also receive information about how to intervene if their child experiences a choking Then, we will randomly select half of families to participate in a 3 session intervention. If you are in the intervention, you will attend 3 treatment sessions (approximately 1 hour long each) at UC when your child is 4, 6,

and 9 months. At the sessions, you will receive information about giving your child solid foods and will practice feeding your child. We will make audio recordings of the treatment sessions so we can look at how well our staff are giving the intervention. All participants will also complete a final study visit at CCHMC when we will measure your child's weight and length and have you complete questionnaires about your child's appetite and diet and your feeding practices, beliefs, and thinking/memory/attention. Families who received the intervention will also give feedback on how you liked the intervention.

Being in the study will take about 6 hours if you receive the intervention and about 2.5 hours if you do not receive the intervention. The research will take place at UC in the Edwards Building and at CCHMC in the T Building.

We may contact you in the future about being part of future research studies (e.g., to see how your infant is growing and doing after being part of our study). We will use the most recent contact information we have for you to reach out to you. If you do not want to be contacted about possible future research opportunities, tell us at your last study visit. This will not have an impact on whether you can participate in this current study.

**Are there any risks to being in this research study?**
Starting to give your child complementary foods might make you feel nervous about your infant gagging or choking when eating foods. You might also feel nervous about your infant not gaining enough weight when they start eating new foods. Choking risk can be related to how old your child is, what types of food you give your child, and the feeding situation, such as how the child is sitting. You should always supervise your child when they are eating. However, we do not believe the risk of choking is any greater than if you were introducing your infant to foods while not being in this study. To reduce the possibility of risk, we will give you information about choking and healthy weight gain, such as to avoid hard foods, have your child sitting up when eating, and giving your child only age-appropriate foods We will also monitor if infants in our intervention have trouble with gaining weight or choking. If we find infants in the intervention are at greater risk for choking or growth problems, we will let you know immediately. If your child experiences a choking incident, you should call 911 for help. In addition to the risks listed above, you may experience a previously unknown risk.

**Are there any benefits from being in this research study?**
You may not get any benefit of being in this study. If you in the intervention, you will receive information about healthy ways to start giving your infant solid foods. Being in this study may help people in the future with learning healthy ways to start giving their infant solid foods and may help reduce later risk for obesity.

**What will you get because of being in this research study?**
You will be paid $100 in gift cards. You will receive a $50 gift card after completing the initial study visit and a $50 gift card after completing the final study visit. You will also not be required to pay for your parking when attending study or treatment visits, which is worth between $3-$10.

**Do you and your child have choices about taking part in this research study?**
If you do not want to take part in this research study, there will be no impact to your ability to receive services at your pediatrician office. You may simply not participate.

**How will your and your child's research information be kept confidential?**
Information about you will be kept private by using a study ID number on the forms instead of using your name or your child's name. We will keep a list of names and study ID numbers in a separate place than the research forms. Only the research team will see your data. Your identity and information will be kept private unless we have to tell authorities about abuse or immediate harm that may come to you or others.

Your information will be kept in Dr. Stough's research lab at UC. Paper copies of data will be kept in a locked filing cabinet in the research lab at UC. Electronic data will be stored on either password protected computers or a secure network drive. Audio recording of treatment sessions will be stored electronically on the secure UC network drive. These will be stored in a separate folder from any other participant data or names. Only study staff will have access to these recordings. Consent forms will be stored separately from study data. All data will be de-identified following completion of study analyses and publication with the exception of the document linking study ID numbers to participant names and the audio recordings. Paper copies of data, consent forms, and the document linking study ID numbers to participant names will be destroyed through secure shredding 5 years following the last publication of study results. The data from this research study may be published; but you will not be identified by name.

Agents of the UC may inspect study records for audit or quality assurance purposes.

**What are your and your child's legal rights in this research study?**
Nothing in this consent form waives any legal rights you may have. This consent form also does not release the investigator, the institution, or its agents from liability for negligence.

**What if you and your child have questions about this research study?**
If you have any questions or concerns about this research study, you should contact Cathleen Stough, PhD at Cathleen.Stough@uc.edu or 513-556-5589.

The UC Institutional Review Board reviews all research projects that involve human participants to be sure the rights and welfare of participants are protected. This research study has been registered on ClinicalTrials.gov, a private U.S. registry of clinical trials.

If you have questions about your and your child's rights as a participant, complaints and/or suggestions about the study, you may contact the UC IRB at (513) 558-5259. Or, you may call the UC Research Compliance Hotline at (800) 889-1547, or write to the IRB, 300 University Hall, ML 0567, 51 Goodman Drive, Cincinnati, OH 45221-0567, or email the IRB office at irb@ucmail.uc.edu.

**Do you or your child HAVE to take part in this research study?**
No one has to be in this research study. Refusing to take part will NOT cause any penalty or loss of benefits that you would otherwise have.

You may start and then change your mind and stop at any time. To stop being in the study, you should contact Cathleen Stough (Cathleen.Stough@uc.edu, 513-556-5589) or tell the research assistant when they call you about coming in for a visit.

**Agreement:**
I have read this information and have received answers to any questions I asked. I give my consent to participate in this research study. I will receive a copy of this signed and dated Parent permission - consent form to keep.

Child's Name (please print) _____

Parent's Name (please print) _____

Parent Signature _____ Date _____

Signature of Person Obtaining Consent _____ Date _____