Reducing Health Disparities Through an Adaptive Healthy Eating Program for Underserved Infants in a Home Visiting Program (Healthy Eating for My Infant; HEMI)

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

Title of Study: Reducing Health Disparities through an Adaptive Healthy Eating Program for Underserved Infants in a Home Visiting Program

Introduction:
You are being asked to take part in and allow your child 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 the National Institute of Nursing Research.

Who is doing this research study?
The person in charge of this research study is Cathleen Stough, PhD, of the University of Cincinnati (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 have made a program to help support families in healthy eating for their babies. In this project, we will be delivering the program for the first time to families. We want to see whether families think the program is helpful and whether it helps support families in healthy eating for their baby. The program will talk about things like what to feed your baby, how to feed your baby, and common challenges families run into when trying to do these things. We will also help to support and empower your family to make the changes you are interested in making. We will work with you to help you meet your own goals for your family.

Who will be in this research study?
About 30 children will take part in this study. Your baby may be in this study if they are 2 months old at the time of your first study visit, were a single birth (not a twin or multiple birth) and have no major medical conditions requiring specialized feeding. You (the parent) must also be a fluent English or Spanish 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?
All families will do 2 study visits when your baby is 2 and 9 months old. The visits will take about 90 minutes. In the visit you will:

- In the first visit, you will complete informed consent.
- You will complete a survey about basic information about your yourself and your baby (such as age, gender, race), your feeding of your baby, your babies eating behavior, your stress and adjustment as a parent, and access to food.
- We will also measure your baby's weight and length.
- Within 2 weeks of each of the visits, you will complete 3 interviews about what your baby ate the day before by phone.

Some families will also be part of a healthy eating program for 6 sessions, but some families will not do this part. It is decided at random who does the program; it is like a coin toss. You will find out at this visit whether your family will be part of the program. Which group you are in will not change anything about the *Every Child Succeeds (ECS)* program you are already in. All families will continue to be in the *ECS* program.

If you are in our healthy eating program, you will do six 1-hour long visits when your child is 3, 4, 5, 6, 7, and 8 months of age. These visits will happen in addition to your usual *ECS* visits. You will have 2 counselors who will work with you, a peer counselor and someone from the UC study team. We will talk about child nutrition, feeding your child, what to do at mealtimes, and things that can make it harder for your family to reach their healthy eating goals (e.g., stress, mental health). We will work with you to help you set goals for your baby that you want to work towards. You will also get to choose what some of the visits are about, and we will give you a list of topics. We will make audio recordings of the treatment sessions so we can look at how well our staff are giving the program. This recording will not be stored with your name. Recording will be listened to only by our research staff, who are paying attention to the interventionists' work rather than family responses (e.g., like a shadow visit for an ECS visit). Families who receive the program will also have the opportunity to participate in parent social support texting and virtual Zoom groups where you can attend monthly 30-minute Zoom meetings to discuss aspects of the program and receive and provide support to other parents receiving the program. The text message support will consist of a group chat for all families receiving the program. A research moderator will provide periodic prompts and questions in the group chat to engage conversations, and families will also be encouraged to initiate conversation in the chat to seek support from one another. This will also be available for families to continue after completing the program if they wish to do so. Families who receive the program will also give feedback on how they liked the intervention at their last study visit.

Being in the study will take about 12 hours if you receive the intervention and about 3 hours if you do not receive the intervention.

We may contact you in the future about being part of future research studies (e.g., to see how your baby is growing and doing after being part of our study). We will use the most recent contact information *ECS* has 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 or in the ECS program.

Are there any risks to being in this research study?
People from our study will come to your home to do the study. This may make some people uncomfortable. People from our study will take safety precautions when coming to your house to avoid bringing illness into your home, but this is still a risk.

If you do the program, you will talk about things like mental health and stress, which may make some people feel uncomfortable. We can provide you information about supports to help you get care for your mental health. Part of the intervention will be done by a peer counselor, who may be someone who lives in your community. We will try to make sure this is someone you do not

know. All peer counselors learn how to keep people's information private in case they do see you in a different place outside the intervention or if they do already know the person.

There may be other risks we do not know about yet. There is an outside person not involved with our study who will help us identify if there are any risks of the program.

Are there any benefits from being in this research study?
You may not get any benefit of being in this study. If you are in the program, you will receive information about how to help your child eat healthy. Being in this study may help people in the future with ways to help their child be healthy 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 $40 gift card after completing the initial study visit and a $60 gift card after completing the final study visit.

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 in the *ECS* program. You may simply choose not to 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 research 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 and peer counselors will see your data and your identity and information will be kept private. The only exception to maintaining your information private is if we notice during the study that a child is being abused or neglected.

We will do these things to keep your data safe and confidential:

- Your information will be kept in a 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 we will not say who the participants

were. People at the University of Cincinnati and the National Institute of Nursing Research may look at the study records.

What are your and your child's legal rights in this research study?
You keep all your legal rights in this study. The researchers, people funding the research, and the institutions are responsible if something happens (e.g., breach of confidentiality).

What if you or your child has 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 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 or your child would otherwise have.

You may give your permission and then change your mind and take your child out of this study at any time. To take your child out of the study, you should tell Cathleen Stough (Cathleen.Stough@uc.edu, 513-556-5589) or tell the research assistant when they call you about a visit.

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

You Child's Name (please print) _____

Your Child's Date of Birth _____ (Month / Day / Year)

Parent/Legal Guardian's Signature _____ Date _____

Signature of Person Obtaining Permission _____ Date _____