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

NCT04977947

4/17/2023

Instructions:

1. Complete **all** sections of the protocol template. By clicking on headers in the Table of Contents below, the form will navigate you directly to that section.
2. If a section does not apply, list Not Applicable as advised.
3. Refer to documents, templates, checklists, SOPs, and worksheets as advised throughout the protocol in **Blue**. Each document referred to in blue contains a hyperlink to the RAP library to obtain the documents (CONTROL + CLICK)
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5. Upload this completed document into a New Study Submission in RAP (https://rap.irb.uc.edu/irb), on the Basic Information Page under "Protocol".

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STUDY SUMMARY:

PROTOCOL TITLE:	Reducing Health Disparities through an Adaptive Healthy Eating Program for Underserved Infants in a Home Visiting Program
PRINCIPAL INVESTIGATOR:	Cathleen Stough, PhD
VERSION NUMBER/DATE:	Version 1, 7/17/2020
SHORT TITLE:	Reducing Health Disparities through an Adaptive Healthy Eating Program for Underserved Infants in a Home Visiting Program)
RESEARCH INTERVENTION(S)/ INVESTIGATIONAL AGENT(S):	Behavioral intervention
IND/IDE #:	Not Applicable

STUDY SPECIFIC ABBREVIATIONS/ DEFINITIONS:	HEMI: Healthy Eating for My Infant; ECS: Every Child Succeeds; GLA: group-level assessment; SES: socioeconomic status; BMI: body mass index; CCHMC: Cincinnati Children's Hospital Medical Center; IRB: Institutional Review Board; ISM: independent safety monitor	
FUNDING SOURCE	National Institute of Nursing Research	
FUNDING LOCATION	☒	**Funds are held in Sponsored Research Services for a Grant or Contract (funds are held internally at UC)**
	☐	**Funds are from a department account (held internally at UC)**
	☐	**Funds held in a corporate account from a Contract (funds held externally from UC)**
	☐	**No funding**

PROTOCOL:

1.0 OBJECTIVES	**1.1 Describe the purpose, specific aims, or objectives.**
	This study seeks to develop and test an adaptive, empirically-supported, culturally and contextually relevant infant obesity prevention program (Healthy Eating for My Infant, HEMI) developed in partnership with the community. HEMI targets healthy eating among infants who are at risk for health disparities and obesity starting at 3 months of age. HEMI will be delivered through home visits in conjunction with an existing home visiting program, Every Child Succeeds (ECS), and will involve community members and key community stakeholders in the design and delivery of the program. HEMI utilizes a behavioral and educational approach targeting problem solving to overcome barriers, behavioral rehearsal and practice of healthy behaviors, promoting readiness to change, goal setting, self-monitoring, and behavioral tracking. HEMI will be tailored to meet the needs of individual families; two standard treatment modules will be provided to each family by a study interventionist focusing on infant nutritional requirements, responsive feeding, and mealtime behaviors. Two additional treatment modules will be selected to address the unique needs articulated by each family (e.g., food insecurity, eating healthy on a limited income, emotional eating, engaging other caregivers, maternal mental health). Modules will also consider the influence of maternal trauma history and mental health on feeding and eating behavior, given the known high prevalence of these risk factors among families in ECS. HEMI also includes two peer counselor-led sessions during which families can discuss implementation of recommendations and barriers to change with a member of their community who can problem solve and support change. Aim 1: Collaboratively develop the content and design of the HEMI program through a community- engaged group-level assessment (GLA) qualitative methodology

	involving stakeholders in a home- visiting program serving at-risk youth and their families. Aim 2: Examine whether the HEMI program, a 6-month personalized obesity prevention program for infants, is effective and acceptable/relevant for families receiving home visiting services.
	1.2 Describe the hypotheses to be tested.
	We hypothesize that families and peer counselors involved in delivery of the program will find the treatment appropriate, satisfactory, relevant, and helpful as rated on a treatment satisfaction questionnaire, post-treatment debriefing interviews, and measurement of treatment completion rates. We also hypothesize families receiving the program (n = 15) will have a lower proportion of infants with BMI > 85th percentile compared to infants in control families who receive standard ECS content only (n = 15). Secondarily, differences in child diet between the treatment and control group will be examined.
2.0 BACKGROUND	**2.1 Describe the relevant prior experience and gaps in the current knowledge.**
	Pediatric obesity poses significant health risks across the lifespan and disproportionately affects youth from low-income or underrepresented racial and ethnic backgrounds (1, 2). Youth from underserved populations experience increased morbidity and mortality secondary to pediatric obesity (3). Infancy and early childhood provide an ideal window for prevention given this is a time of rapid growth with lasting metabolic and behavioral consequences (4). However, few infant obesity prevention programs target obesity-related health disparities in underserved populations (5). Home visiting programs offer an avenue for overcoming accessibility barriers to provide services for underserved, low-income, or racial and ethnic minority families. Home visiting programs targeting obesity prevention have been successful in improving some isolated obesity-risk factors (6) but have not been able to achieve an overall positive impact across obesity-risk factors, reductions in high weight-for-length (7), or long-term outcomes. This may be the result of programs offering standardized treatment content that is not adapted to the specific needs of each individual family and that is not contextually and culturally relevant. Development of pediatric obesity is complex with unique factors and circumstances influencing risk of each individual (8, 9). For example, trauma-history is known to significantly impact feeding and eating behaviors through a number of both physiological and behavioral pathways, but few obesity programs directly target this complex risk factor (10). Given the complex barriers to healthy lifestyles among underserved populations,

development of a program to address these unique needs requires involvement of the community that the program is intended to serve rather than simply relying on work that has been done with other populations. Obesity prevention programs for at-risk underserved infants tailored to the specific barriers to healthy eating and feeding for individual families have not been developed.

2.2 Describe any relevant preliminary data.

Not Applicable

2.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge.

There are significant health disparities in obesity prevalence, which is a national epidemic impacting nearly 20% of U.S. youth (12). Hispanic youth (23.6%) and non-Hispanic black youth (20.4%) are at greater risk than their non-Hispanic white counterparts (14.7%; 13). Obesity rates are nearly double for youth whose caregiver has a high school diploma or less (22.3%) compared to youth whose caregiver is a college graduate (11.6%). Obesity also disproportionally affects youth in households with lower incomes, although this relationship differs across population subgroups (e.g., race/ethnicity, sex; 14). The pathway to obesity begins in infancy meaning that prevention programs during toddlerhood and the preschool years may already be too late to address the earliest risk factors for obesity. Youth who go on to develop severe obesity begin to deviate from their normal- weight peers in their growth trajectories by 4-6 months of age (15). Body Mass Index (BMI) ≥ 85th percentile at 6 and 12 months is a strong predictor of subsequent obesity (15). Infants with elevated BMIs have the greatest cumulative incidence of obesity in adulthood (16).

The ecological model of childhood obesity posits that child factors (e.g., diet), family factors (e.g., feeding practices, home food environment), and community factors (e.g., socioeconomic status [SES], access to healthy food) are all contributory to childhood obesity (8). Early feeding and eating behaviors are the health behaviors that have most consistently been implicated in obesity risk in infancy, while research on the relation between sleep, physical activity, and screen time in infancy and obesity risk has provided a less consistent picture (17). Early feeding and eating behaviors that increase future obesity risk include inappropriate bottle feeding, beverage intake, protein intake, early introduction of solid foods, parental feeding practices (e.g., restrictive parenting practices), parental modeling of healthy eating, and early diet variety (17-20). Infants from families of low SES display greater rates of these early unhealthy eating patterns and elevated growth trajectories, meaning health disparities in obesity risk start during infancy (21, 22). Children from racial and ethnic minority groups display more rapid weight gain, earlier introduction of solid food, and higher rates of maternal restrictive feeding practices during infancy compared to their non-

Hispanic white counterparts (23). The Institute of Medicine's Committee on Obesity Prevention Policies for Young Children put forth targets for reducing childhood obesity based on known risk factors including: promoting the consumption of a variety of nutritious foods, encouraging and supporting breastfeeding during infancy, creating a healthful eating environment that is responsive to children's hunger and fullness cues, and helping adults to increase children's healthy eating (24).

Despite the importance of obesity prevention during infancy, few programs target this age group (n = 18), and less than half of those (n = 7) are effective (25). Effective programs to date have addressed maternal and family health behaviors, infant feeding, infant physical and sedentary activity, infant sleep, and formula supplements.25 The effectiveness of these programs does demonstrate that early child growth trajectories are amenable to change and that these changes can be maintained long-term (26). While there are very few effective infant obesity prevention programs in general, there are even fewer programs that are accessible and relevant for infants in underserved minority groups who are at-risk for health disparities.

Home visiting is an avenue for delivery of programs targeting young children from underserved, at-risk, and low SES populations by overcoming many of the barriers that contribute to disparities in healthcare access and service (27). Most home visiting programs employ a curriculum focusing on effective parenting, infant safety and health, developmental milestones/kindergarten readiness, and ensuring connections to community resources. While some home visiting programs targeting obesity prevention in at-risk underserved preschoolers have been developed (28-31) a need for such programming for underserved infants remains (27). Early efforts to provide obesity prevention programs via home visiting have been somewhat successful. The Early Childhood Obesity Prevention Program (ECHO; 6) targeted early obesity risk factors in infancy (e.g., diet, sleep, breastfeeding, and activity) through intervention sessions utilizing a maternal skills-based and behavioral approach involving building connections to community resources. ECHO was successful in improving breastfeeding and some sleep outcomes. Similarly, a home visiting program among high-risk Native-American infants and toddlers was effective for reducing child weight, energy intake, and restrictive feeding practices (32). The Intervention Nurses Start Infants Growing on Health Trajectories (INSIGHT) program also used home visits to target responsive feeding and effectively reduced weight gain and BMI (33). However, there is a significant gap in utilization of home visiting programs as a means of delivering primary obesity prevention programs. Only 17% of home visiting programs for young children address infant or child feeding cues, only 11% address complementary foods, and only 6% address diet variety, vegetable intake, eating dysregulation and fussiness, portion sizes, or healthy snacks (34).

While home visiting infant obesity prevention programs have resulted in change to some specific obesity-risk factors, a broad impact on other crucial outcomes, such as infant weight-for-length or other diet variables, has been lacking. For example, ECHO (6) did not impact diet beyond breastfeeding or infant weight, and the reductions in BMI found by the INSIGHT program were only modest and BMI percentiles did not differ between the treatment and control group (33). The relative ineffectiveness of many current infant obesity prevention programs may be because they implement a one-size-fits-all approach rather than tailoring content to the unique barriers to health for specific families, including families from underserved, at-risk, and low SES groups. For example, current obesity prevention programs in infancy have generally failed to explicitly address the complex influence of trauma history and mental health on eating and feeding behaviors. This is despite several possible pathways between trauma, stress, and obesity-risk (e.g., emotional eating and overeating, changes to reward and regulatory neural circuits, changes to endocrine processes related to appetite regulation, role of gut microbiome; 10). Programs targeting maternal healthy eating behaviors among low-income families have found trauma-experiences to be a barrier for mothers (35). There is a need for individualized obesity prevention programs for infants that are culturally and contextually relevant for families in underserved and minority groups. Low-income mothers participating in Women, Infants, and Children (WIC) have reported dissatisfaction with the use of a one-size-fits-all approach to dietary and feeding guidance (36). Obesity programs are not often tailored to the needs of underserved populations and fail to involve members of the community in design and delivery of treatment, which may be why children from ethnic and racial minority groups, low-income homes, or other at-risk groups demonstrate poorer outcomes (37, 38) and attrition rates (39-43).

Prior research has under-utilized community-engaged approaches to infant obesity prevention. Methods that incorporate community members into all phases of project implementation allow increased communication, transparency, and trust between academia and the community. This partnership can increase participant engagement, community ownership of the project, understanding of community needs, and sustainability and dissemination of study results (44). Involving families from underserved groups in development of interventions improves the suitability of programming for meeting family needs, reduces attrition, increases recruitment, and improves patient outcomes (45-48). Adaptive interventions can enhance child outcomes by providing the information needed for that specific individual (49). Delivery of prevention efforts through home visiting programs that have prior established relationships with families also reduces the lack of trust and transparency that may prevent families from minority groups from receiving healthcare services.

3.0 RESOURCES AVAILABLE	**3.1 Describe the resources available to conduct the research. Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period, e.g. how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?**
	The current study is a collaboration between researchers at two institutional sites with a dedicated emphasis on research and scientific advancement and a long history of funding by the National Institutes of Health. UC and CCHMC have a long-standing history of research collaborations. These two institutions are located approximately one mile apart, making ongoing meetings and sharing of resources between these two institutions an ease. PI Dr. Stough and all graduate students in her research laboratory have also completed the badging/security process at CCHMC, easing their access to resources and facilities at CCHMC. Activities for the current study will be performed across UC and CCHMC campuses with primary administrative work, recruitment activities, data storage, and data management occurring at the UC campus. We do not anticipate difficulty with reaching adequate study enrollment given the number of eligible participants significantly exceeds the number of participants required for this pilot trial (i.e., approximately 400 families will enroll in ECS during the 6-month recruitment period and only 30 families are required for study enrollment). Our team has a successful track record of enrollment of ECS families into supplemental intervention trials. However, it is possible we may encounter participant attrition. We will take several safe guards to reduce attrition. All intervention and study visits will be conducted in participants' homes to reduce barriers to attendance. Multiple methods for contacting families will also be obtained, including contact information for friends and family members who are likely to know the location of participants should they be temporarily out of contact. Regarding the GLA phase, GLA and action planning sessions will be scheduled at times likely to be convenient to participants, such as evenings and weekends, and if we encounter recruitment challenges, we could conduct multiple GLA sessions to meet participant availability.
	3.2 Describe the time that you will devote to conducting and completing the research, i.e. percent effort.
	PI will have 15% effort on this project.
	3.3 Describe the availability of medical of psychological resources that subjects might need as a result of an anticipated consequences of the human research.
	The intervention tested in this study (HEMI) is trauma-informed and includes trauma-specific treatment components if participants have a significant trauma history. This is because stress and trauma can have a significant impact on feeding and eating, and we know rates of trauma are high in our target enrollment population. The research study

	interventionists are graduate students in Clinical Psychology and trained in discussion and treatment of trauma. However, families may feel uncomfortable talking about these topics, and our research study can provide psychological referral resources if families would like that information.
	3.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.
	All research staff involved in protocol activities will undergo training supervised by the PI. Interventionists for HEMI are advanced graduate students in Clinical Psychology who have extensive training and experience with handling confidential and sensitive information, and they will also receive training regarding working with individuals with a trauma-history pertaining specifically to this project. Peer counselors delivering the program will receive training regarding handling of confidential information and sensitivity in possible dual relationships where they may interact with participants in social or community settings.
	3.5 Describe the facilities you have access to that will allow you to conduct the research.
	The Healthy Kids Lab, directed by Dr. Stough, is located in the Psychology department at UC and adjacent to her office. The lab consists of 6 rooms totaling over 1,000 sq. ft. The graduate and undergraduate research staff rooms of the laboratory include three new Dell PC desktop computers (i.e., purchased within the last three years). These computers are all equipped with statistical software (SPSS) and have the capability for remote access to other software (e.g., SAS, Mplus) through the UC virtual desktop. The PI also has a Dell Latitude 7370 and docking station with monitor located in her office. UC offers technical assistance on site, and the College of Arts and Sciences offers their own Technology Support Team to serve faculty and students. UC has a protected, internal server where electronic data files can be safely stored and backed up, allowing password-protected access to designated users.
4.0 INVESTIGATOR EXPERIENCE	**4.1 Detail the investigators' experience as it pertains to the study.**
	Dr. Stough has a significant track record of research in the areas of child eating, feeding behaviors, and obesity-risk specifically among young children (e.g., infants, preschoolers), including a National Institutes of Health T32 Research Fellowship with training specifically in Child Behavior and Nutrition. Dr. Stough's extensive

	background with development, delivery, and empirical evaluation of behavioral health interventions targeting weight management and healthy eating among children has given her the expertise necessary to develop and evaluate the intervention proposed in the current project. Specifically, among young children, she has developed a behavioral intervention targeting healthy introduction of solid foods to infants and has served as a clinician and researcher examining the effectiveness of multiple weight management programs targeting preschoolers. Dr. Stough has also served as a home visit interventionist for a weight management program tailored specifically for preschoolers and was principal investigator for a research study using home visits to examine mealtime behaviors among young children. Her general training and varied experiences in clinical child psychology have also led to my understanding of general child development, adjustment, and functioning, including the impact complex psychosocial situations can have on child development and behavior.
5.0 STUDY ENDPOINTS	**5.1 Describe any primary and secondary study endpoints.**
	The current project is projected to begin in January 2021 and data collection will last approximately 2 years. We anticipate the first Aim will begin in January 2021 and the second Aim involving delivery of the intervention will begin in June 2021.
	5.2 Describe any primary and secondary safety endpoints.
	Adverse events will be assessed throughout the study protocol.
6.0 PROCEDURES INVOLVED	**6.1 Thoroughly describe the study design.**
	The study consists of 2 aims. The first aim is a qualitative study design that will utilize 3 visits to work with participants to get their feedback and ideas regarding development of a healthy eating intervention for infants. The second aim is a pilot randomized control trial utilizing a pre-post study design to assess efficacy and feasibility of a healthy eating intervention for infants.
	6.2 Detail the procedures being performed, specifically the interaction or intervention with human subjects and/or their identifiable information. Please be clear and concise and provide information relevant to the current study. For example, please be sure that what will be done for this research is explained and differentiated from activities that have already taken place or will be submitted for future review. Please note that details about recruitment and consent are asked in later questions.
	We recognize that the situation and risks of data collection are rapidly changing at this time related to COVID-19. Given some of our study procedures will not begin until June 2021, we will rely on following the safety precautions and protocols required due to the COVID-19 pandemic at that time. We will follow all requirements for in-person

research and recommended safety practices in place at the time of the start of this study.

Aim 1: We will use Group Level Assessment (GLA), a structured, qualitative research method, to understand ECS caregivers' needs, resources, and barriers to healthy infant eating and feeding, including the influence of trauma history. GLA is a participatory, large-group method which allows for diverse groups of stakeholders (in this case, ECS leadership, community partners such as WIC or community nursing agencies, home visitors, and mothers currently receiving ECS programming) from different backgrounds to engage in generating and evaluating data together. GLA is particularly appropriate where there may be a perceived hierarchy, such as between families and ECS board members, as it encourages minority opinions within a safely structured process. GLA will focus on development of participant-driven data and relevant action plans regarding how HEMI can be designed to benefit families. Data are collaboratively generated and interactively analyzed among the group itself, which has participatory and time sensitive advantages over other qualitative methods such as focus groups. Data are generated in GLA sessions through a 7-step structured process guided by a neutral moderator. Each participant will participate in 1 GLA session lasting approximately 2.5 hours. We will do three separate GLA sessions with approximately 15 participants per session; each participant will engage in only 1 GLA session. This session will be conducted remotely via telecommunication. Group members will be provided written prompts to stimulate ideas regarding healthy eating and feeding among infants and families, barriers to behavior change, needs of a program for ECS families, and the influence of trauma history on eating and feeding. Participants will provide written responses to these prompts. Participants will then spend time individually reacting to other participants' responses and reflecting on the implications of the data. Next, major themes are identified based on responses within small groups of 5-8 participants. After the report out of themes, the large group will process the findings and begin to identify the most important themes.

Participants from the GLA, community advisory board, and peer counselors will be invited to a session where themes and priorities co-identified will be used to develop an action plan for what content will be included in HEMI. This session will occur in-person or through telecommunication depending on COVID-19 requirements and recommendations at the time of the study. The study team (led by PI Stough) will then refine standard modules and develop adaptive modules in response to the action plan. In a second action planning session, the study team will present the modules to the community stakeholders for comment and modification.

Aim 2: Thirty families enrolling in the standard ECS program prenatally or shortly after birth will be recruited for a pilot trial of HEMI (15 control, 15 intervention). Participants will be infants and their mothers. We will recruit mothers of infants of

both sexes. Mothers will be specifically targeted (rather than other caregivers) because this is the population at the ECS program where we are delivering the intervention. ECS enrolls approximately 800 mother-child dyads per year, well exceeding our required sample size. ECS home visitors will refer all eligible pregnant participants to our research coordinators, who will contact each woman to schedule the first study visit. Inclusion criteria are: 1) child age 2 months at enrollment, 2) English or Spanish speaking, 3) maternal age > 18 years, 4) singleton, and 5) no major congenital anomalies or medical conditions requiring specialized feeding. Families will be invited to participate in this study in addition to standard ECS services and engagement in this study will not impact their ability to participate in the standard program. 1:1 randomization to the control or treatment condition will occur at the time of the baseline visit.

Participants will complete home-based baseline and post-treatment study visits when the child is 2 months and 9 months of age. Families randomized to the intervention condition will participate in six treatment sessions delivered as monthly 1-hour home or virtual visits based on the desires, interests, and needs of families, when the child is 3, 4, 5, 6, 7, and 8 months of age in addition to participation in the standard ECS visits. Given the program's target of behavior change and use of behavioral strategies, interventionist-delivered HEMI sessions will be provided by advanced clinical psychology doctoral students (supervised by a licensed clinical psychologist, PI Stough) accompanied by support staff. Two peer counselor-led sessions will be delivered as 1-hour home or virtual visits, based on the desires, interests, and needs of families and peer counselors, when the child is 5 and 8 months of age. Families in the control condition will receive the standard ECS content and complete baseline and post-treatment visits.

6.3 Describe procedures being performed to monitor subjects for safety or minimize risks.

Based on the size (n = 30) and complexity of the trial (e.g., unblinded trial) and the minimal risk of the study intervention to participants, this study will utilize an independent safety monitor (ISM) whose primary purpose will be to provide guidance regarding adverse events and safety issues. The ISM will be a medical expert (e.g., pediatrician, nurse) who is independent of the study and able to provide external and unbiased evaluation through consultation pertaining to safety issues. This person will be available in real-time on an as-needed basis should any concerns regarding adverse events or other safety issues arise. The ISM will be identified during the study start-up phase. The ISM will review relevant participant safety data and make recommendations regarding continuation, modification, or termination of the trial due to safety risk. Communication with the ISM will occur on an as-needed basis when safety concerns arise as well as annual meetings with the study PI to discuss overall trial safety data.

The following potential adverse events will be assessed throughout the study period: occurrence of choking episodes during infant feedings (at each study visit and interventionist-led treatment session), growth faltering (monitored at each interventionist-led treatment session for infants in the treatment condition; length and weight will be monitored for all participants [i.e., treatment and control] at baseline and post-treatment), and unexpected adverse events.

Study participants will be informed of any changes to the known risks and benefits of participating in the current study, including if it is identified that treatment participants are at greater risk for adverse events. If participants in the treatment arm experience greater adverse events, possible discontinuation of the study or modification of the intervention will be considered under the guidance of the ISM.

6.5 Where applicable, list and describe the data collection tools such as surveys, data collection forms, etc. All tools described should be uploaded in the RAP Smart Form on the Local Site Documents page unless they are standardized, validated tools.

Demographics Form. Participants in both the intervention and GLA methodologies will complete a demographics form. There is a separate demographic form for each of these methodologies because the interventionist participants will be asked additional demographic details about their participating child, while GLA participants will only report their own adult demographics.

Maternal Feedback on Intervention: Maternal Feedback on the Intervention will be obtained through a quantitative survey and a qualitative interview. The quantitative survey consists of Likert scale ratings on whether they perceived the intervention as suitable, occurring at the right time, being presented clearly, and helpful; mothers will also rate satisfaction with the intervention and their confidence in implementing the recommendations made by the study team. Qualitative interviews will be conducted with each family by a research staff member who was not the study interventionist (to prevent potential bias) to obtain feedback regarding additional information that would be helpful to add to the program, content that was not helpful and could be eliminated from the program, other changes they would like to see to the program, and aspects they would like to see stay the same about the program.

Peer Counselor Feedback on the Intervention: Interviews will be completed with peer counselors after all study participants have completed treatment. Open-ended questions will be asked such as: What aspects of the intervention did you feel were most helpful for families? What are additional things not currently offered in the intervention that you think could be helpful to families? Did you feel adequately

trained to provide the intervention? How do you feel participants utilized your role as a peer counselor? How could the peer counselor sessions be improved?

Infant Anthropometrics: Infant weight and length will be measured in duplicate at each in person treatment and study visit using a mobile digital SECA baby scale and portable infant length board. The scale will be calibrated using a known weight, and will be zeroed prior to assessment. Infants will be weighed in a clean diaper without clothes. The length board has a stable headboard and a moveable foot board, and will be placed on a flat, hard surface. All length measurements will be taken using the right leg, with assistance from the mother as needed to hold the infant still while the right leg is extended flat and the foot flexed against the foot board. Weight measurements will be taken to the nearest 1.0 gram and length measurements to the nearest 0.5 cm. Infant BMI standardized for age and sex will be calculated from the WHO 2005 growth standards.

24-hr Dietary Recall Interviews: Infants' dietary intake will be assessed via three random dietary recall interviews conducted by phone within +/-2 weeks of their baseline and post-treatment study visits. Trained interviewers from the Schubert Research Clinic Bionutrition Core, blinded to study condition, will employ the USDA automated multiple-pass method (AMPM), a standardized approach which has been shown to improve accuracy of dietary intake data collected (Moshfegh et al., 2008). Mothers will be provided ahead of time with visual aids to assist with estimating portion sizes during the telephone interview; visual aids will reflect age-appropriate foods, portions, and serving containers to facilitate reporting (Anater et al., 2018). Nutrition Data Systems for Research (NDSR; Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN) software and foods database will be used to assess total daily energy and macronutrient intake as well as food group servings consumed.

6.6 Describe all data that will be accessed and collected during the study and how that data will be obtained (how it will be accessed).

The primary study measures listed above will all be collected for the purposes of this research study in accordance with the procedures outlined above. All research participants are also participants in the Every Child Succeeds home visiting program, and information from the ECS records may also be accessed.

6.7 If there is a long-term follow-up plan (once all research related procedures are completed), what data will be collected during this period.

There are no current plans for long-term data follow-up. However, this may be of later interest based on study outcomes, and therefore the consent form mentions the possibility that researchers may contact participants in the future about additional research.

7.0 DATA AND SPECIMEN BANKING	**7.1 If data or specimens will be banked for future use, describe where the data or specimens will be stored, how the data or specimens will be accessed, and who will have access to the data or specimens.**
	We will retain identifiable information for 2 years after this research ends, to permit longer-term follow up. After that point, all identifying data will be destroyed, and only deidentified study data will be retained for future analyses.
	7.2 If specimens are being stored, list the data to be stored or associated with each specimen.
	Not Applicable
	7.3 Describe the procedures to release data or specimens, including: (the process to request a data/specimen release, approvals required for release, who can obtain data or specimens, and the data to be provided with the specimens.
	Data will only be available to members of the study research team.
8.0 SHARING OF RESULTS WITH SUBJECTS	**8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe the process for sharing. If you do not intend to share any results, please state that here.**
	Results will not be shared with participants or any of their medical providers.
9.0 STUDY TIMELINES	**9.1 Describe the duration of an individual subject's participation in the study. List the number of study visits or frequency of study visits.**
	For Aim 1, participants who participate in the GLA only will be in the study for 1 visit on one day. If participants choose to participate in the optional Action Planning session, they will do 2-3 visits over the course of approximately 2 months. For Aim 2, individual subjects will be in the study for approximately 8 months. Depending on randomization, participants will either complete 2-3 total visits at the beginning and end of the 8-month timeline or complete 8 monthly visits.
	9.2 Describe the timeline allotted for the enrollment of subjects.
	Subjects will be enrolled during the first year of grant funding.
	9.3 Describe the estimated date for the investigators to complete this study (complete primary analysis).
	Data collection for this study will span 24 months, with the projected start date of January 2021. Primary analysis will be completed within a year of the last data collected for the current project.

10.0 INCLUSION AND EXCLUSION CRITERIA & VULNERABLE POPULATIONS

10.1 Describe how subjects will be screened for eligibility.

For Aim 2, participants will be screened for eligibility via phone call from study staff prior to their baseline visit.

10.2 Describe/list the inclusion/exclusion criteria for the study.

Inclusion criteria for the GLA methodology are that the person is involved in the Every Child Succeeds home visiting program. This involvement will include a number of different roles such as board member, community partner, mother receiving service, former participant in the program, etc. Participants must also be either English or Spanish speaking.

Inclusion criteria for the intervention methodology are: 1) child age 2 months at the time of the baseline study visit, 2) English or Spanish speaking, 3) maternal age is equal to or over 18 years, 4) singleton, and 5) no major congenital anomalies or medical conditions requiring specialized feeding.

10.3 Indicate specifically whether you will include each of the following vulnerable populations. Check all that apply. (You may not include members of the below populations as subjects in your research unless you indicate this in your inclusion criteria and are approved by the IRB to include them in your research) The member checklists are for reference only to ensure you provide appropriate safeguards and justification. The checklists do not need to be completed.

☐	**Adults unable to consent (cognitively impaired individuals) (HRP-417 – MEMBER CHECKLIST Cognitively Impaired)**
☒	**Individuals who are not yet adults (infants, children, teenagers) (HRP-416 – MEMBER CHECKLIST Children)**
	☐ **Individuals who are not yet adults and are, or may become, wards of the state.**
☒	**Pregnant women (a woman shall be assumed pregnant if she exhibits and of the presumptive signs of pregnancy, such as a missed menses, until the results of a pregnancy test are negative or until delivery.) (HRP-412 MEMBER CHECKLIST Pregnant Women)**
☐	**Non-Viable Neonates (HRP-413 – MEMBER CHECKLIST Non-Viable Neonates)**
☐	**Uncertain Viability Neonates (HRP-414 – MEMBER CHECKLIST Uncertain Viability Neonates)**
☐	**Prisoners (HRP-415 – MEMBER CHECKLIST Prisoners)**

10.4 If the research involves individuals listed in 10.3 or other individuals who are vulnerable to coercion or undue influence, please justify based on

	the applicable checklist and describe additional safeguards included to protect their rights and welfare.
	Participants in the pilot testing of the HEMI program will be infants enrolled at 2 months of age and their mothers. Our obesity prevention program specifically targets healthy eating between 3-8 months of age making it necessary for our study to include infants as the targeted population. All study staff have experience working with child populations, and the investigative team has significant experience in clinical care and research with children. Cincinnati Children's Hospital Medical Center is a facility 100% devoted to research and treatment of children, and PI Dr. Stough's lab (i.e., the Healthy Kids Lab) was established specifically for research regarding children's health. The Every Child Succeeds home visiting program provides services to families who are pregnant or with young children. Therefore, some Every Child Succeeds families who participate in the GLA phase may be pregnant women.
	10.5 If the research involves or may involve individuals who are students or employees where the research is taking place, please describe additional safeguards included to protect their rights and welfare.
	Not Applicable
11.0 NUMBER OF SUBJECTS	**11.1 Indicate the total number of subjects to be accrued.**
	For Aim 1, there will be no more than 100 participants. For Aim 2, we will recruit 30 infants and their mothers.
	11.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures.
	Approximately 15 women enroll in the ECS program each week (~800 per year), providing a large sample pool from which to enroll participants. We anticipate that 50% (n=400) of eligible ECS mother-child dyads will be referred to the study (~7-8 per week). Participants will receive their enrollment visit when the child is 2-months of age. Informed by retention data from the ECS program, 85% (n=340) of the participants will remain active in the program when child is 2-months of age (criterion for eligibility). We anticipate 60% will agree to participate in the study (~4 per week).
12.0 RECRUITMENT METHODS	**12.1 Describe when, where, and how potential subjects will be recruited.**
	GLA Phase: Leadership, board members, community partners, and home visitors will be invited for involvement in the GLA through personal correspondence and advertising through standard ECS communications and meetings. Participating families will be informed about the study by ECS home visitors. Word-of-mouth and snowballing (i.e., one participant informing others who might be interested in the

	assessment) will also be largely utilized. Prior to the start of the GLA session, participants will be provided with the required elements of consent. Intervention Pilot Testing: Participants will be families participating in the Every Child Succeeds (ECS) home visiting program. These participants will be recruited by ECS home visitors. Home visitors will refer eligible participants to our research coordinators who will contact families via phone to tell them more about the research study. Interested families will complete a screening over the phone with a study research coordinator to assess inclusion criteria. If a child meets inclusion criteria and the family is interested in participating, they will be scheduled for a first study visit. Because of the home visitor time it will take to complete referrals, we need to compensate them for their time. We will be paying home visitors or the agency employing home visitors $15 per each referral completed. Because this is compensation for their time and is not a finders fee, they receive $15 per referral even if the family says no and decides to not participate in the study or even if a family is not reached to further discuss the study.
	12.2 Describe the source of the subjects.
	Participants will be leaders, board members, community partners, home visitors, and families from the Every Child Succeeds (ECS) program. ECS was founded in 1999 and provides home visiting services to sociodemographically at-risk mothers in Southwestern Ohio and northern Kentucky. Mothers are eligible for participation if they meet at least one of 4 demographic factors: unmarried, low income, under the age of 18, and inadequate prenatal care. Administered by CCHMC, ECS has up to 3,000 families enrolled at any given time served by 115 home visitors in nine locally-embedded community agencies.
	12.3 Describe the materials that will be used to recruit subjects. (Attach copies of these documents in the Recruitment section on the local site documents page in RAP. For advertisements, attach the final copy of printed advertisements (avoid making copies until approved in case modifications are required). When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape)
	For Aim 1, participants will be recruited through emails and word of mouth including use of the Recruitment Flyer uploaded in the RAP system. For Aim 2, recruitment will occur via verbal referral by ECS home visitors and will utilize IRB approved recruitment flyers.
13.0 COMPENSATION FOR SUBJECTS	**13.1 Describe the amount, method, and timing of payments to subjects.**
	For Aim 1 (GLA), participants will earn $20 in gift cards for participating in each visit. Participants will have the option to be part of 1-3 visits, and so can earn up to a total of $60.

	For Aim 2, participants will receive up to $100 for participating: $40 after participating in the baseline visit (when the infant is around 2 months of age) and $60 for completing the post-treatment visit (when the infant is around 9 months of age). We are providing this amount to participants through gift cards. At enrollment, participants will receive lab-branded materials such as a notepad to record study appointments, pen, and tote bag; the total value of these items is less than $25. When families complete the intervention, they will also receive a token to celebrate their graduation from the program which will be valued at less than $15 (e.g., a t-shirt for their child with the lab name, a stuffed animal for their child with the lab name on it). s
14.0 WITHDRAWAL OF SUBJECTS	**14.1 Describe the anticipated circumstances under which subjects will be withdrawn by the study team from the research without their consent.**
	Not Applicable
	14.2 Describe any procedures for orderly termination.
	Not Applicable
	14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection, withdrawal of previously collected data upon request, etc.
	Consent may be withdrawn by the participant at any time during the study. Participants will be made aware of this right during the consent process.
15.0 RISKS TO SUBJECTS	**15.1 Describe the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. It may be useful to include: a description of the probability, magnitude, duration, and reversibility of the risks. Consider the physical, psychological, social, legal, and economic risks.**
	Potential risks to participants are expected to be relatively low. Participants will be informed of the efforts that will be made to keep their responses confidential, and the limits of confidentiality will also be reviewed. Potential risks of choking or growth faltering will be monitored at each study contact. Also, there is increased risk of COVID-19 exposure at the present time. However, telecommunication could be used for completion of all study visits if necessary per COVID-19 recommendations and protocols at the time of data collection to reduce this risk for participants (see 15.5).
	15.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
	Not Applicable
	15.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject or the subject's partner be or become pregnant.
	Not Applicable

	15.4 If applicable, describe risks to those who are not subjects.
	Not Applicable
	15.5 Describe the procedures and actions taken to mitigate the risks to subjects and others.
	Families will be notified if our independent safety monitor (ISM) identifies any greater risk in the treatment condition, but at this time we do not believe there is any increased risk from our treatment. An ISM external to the study team will be identified to assess any potential changes in the known risks of participating in this study. Our study team will also minimize participant and study staff COVID-19 exposure, transmission, and infection by implementing all COVID-19 related policies and procedures in place at the time of data collection. Telecommunication strategies may be used rather than in-person data collection if warranted based on COVID-19 risk and recommendations. Any in-person activities will only be adopted when the university COVID-19 research guidelines permit these activities to resume. The IRB will be notified via RNI at that time, if indicated by revised guidelines.
16.0 POTENTIAL BENEFITS TO SUBJECTS	**16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. It may be useful to include: the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit to subjects. Do not include benefits to society or to others.**
	Mothers may benefit from participation in the study through receipt of a potentially efficacious intervention to promote healthy infant feeding and reduce subsequent obesity-risk.
17.0 DATA MANAGEMENT AND CONFIDENTIALITY	**17.1 Describe the data analysis plan, including any statistical procedures or power analyses.**
	Aim 1: GLA data analysis will be conducted in real-time by the participants during the session. Participants will reach consensus on overall themes and action items. Aim 2: Proportion of infants with BMI ≥85th percentile will be compared between the treatment and control group using a Fisher's exact test of independence, including all randomized participants in an intention to treat framework. If baseline differences are found between groups, these baseline variables will be included in an adjusted logistic regression model with odds ratios of the intervention group estimated relative to the control group. Sensitivity analyses will examine the impact of treatment fidelity on intervention efficacy. Secondary outcomes of infant diet diversity and servings of fruits and vegetables will be evaluated using general linear models, adjusting for baseline characteristics as needed. Infant biological sex and participation in other supplemental nutrition programs (e.g., WIC) will be explored as potential moderators of treatment outcomes.
	17.2 Describe the steps that will be taken to secure the data.

Aim 1: For aim 1, participants will complete demographic information in an online survey. In this survey, they will also need to indicate their email address in order to receive their electronic gift card for participation in the group. They will also be asked on the form their interest in participating in subsequent action planning groups, and we will use their email to contact interested participants. In order to secure confidentiality of demographic data, we will remove the potentially identifying email address from the database as soon as the groups are completed.

Aim 2: Demographic information and maternal quantitative feedback on the intervention will be obtained through an online survey using the data capturing system REDCap. Maternal qualitative feedback on the intervention will be obtained via interview at the post-treatment study visit, and peer counselors will also complete qualitative interviews with research staff to provide feedback on the intervention. All data will be identified with ID numbers only, and the list linking ID numbers to participant names will be kept in a password-protected document separate from all other participant data on a password protected computer and secure server. Only study staff will have access to participant identifiable information during the study.

17.3 Describe any procedures that will be used for quality control of data collection.

Infant anthropometric measurements will be recorded on paper-and-pencil forms, and dietary information will be retrieved via phone interview. All other maternal-report measures will be completed through a REDCap survey on a tablet. REDCap software is administered by the Center for Clinical and Translational Science and Training (CCTST). The REDCap survey and database will be built by study staff, and tested for accuracy until all issues have been resolved prior to moving the survey into production for data collection. Only study staff will have access to the REDCap database.

Each treatment session will be audio recorded to monitor treatment fidelity. Recordings will be coded by study staff who are not providing the intervention for whether each of the treatment components outlined in the treatment module is covered at each session.

All data will be labeled with a subject ID only and stored on password protected computers, on secure network drives, or in locked filing cabinets. Consent forms will be stored in a separate locked filing cabinet. The document linking study ID number to participant names will be password protected and stored in a location separate from other study data. Data collected on paper-and-pencil forms will be entered into the study database by study staff. All manually entered data will receive a second-pass review to ensure accurate entry. Data entry date and the person entering data will be documented on each paper-and-pencil form.

Electronic data and files will be stored on a secure internal network drive with user-level access. This network is backed up in accordance with standard UC IT procedures. A secure restricted data drive will be used to share data electronically with study team members at CCHMC.

17.4 Describe how data or specimens will be handled study wide as outlined below.

	17.5 What information will be included in the data or associated with the specimens?
	Research materials will be obtained from participants at the baseline and post-treatment study visits and via telephone interviews. This includes demographic information and maternal quantitative feedback on the intervention. Research staff will also complete infant weight and length measurements using a mobile SECA baby scale and infant length board. Dietary information will be obtained via telephone interviews with trained staff from the Schubert Research Clinic Bionutrition Core.
	17.6 Who will have access to the data or specimens?
	Only study staff will have access to participant identifiable information during the study.
	17.7 Where and how data or specimens will be stored?
	Electronic data will be stored on a secure internal network drive with user-level access. This network is backed up in accordance with standard University of Cincinnati IT procedures. A secure restricted data drive will be used to share data electronically with the study team members at CCHMC.
	17.8 How long the data or specimens will be stored?
	We will retain identifiable information for 2 years after this research ends, to permit longer-term follow up. After that point, all identifying data will be destroyed, and only deidentified study data will be retained for future analyses.
	17.9 If applicable, how data or specimens will be transported?
	Not Applicable
	17.10 Who is responsible for receipt or transmission of the data or specimens?
	Data will be received or transmitted through a secure network drive or connection. The PI will be responsible for data receipt and transmission.
18.0 PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS	**18.1 For more than minimal risk research, describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether the subjects remain safe.**
	Not Applicable. Although the study is considered only minimal risk research, an independent safety monitor (ISM) will be identified during the study start-up phase and whose primary purpose will be to provide guidance regarding adverse events and safety issues. Information regarding the data safety monitoring plan (DSMP) is presented below, even though the study is considered minimal risk.
	18.2 What data are reviewed, including safety data, untoward events, and efficacy data?
	The ISM will review relevant participant safety data and make recommendations regarding continuation, modification, or termination of the trial due to safety risk.

	Communication with the ISM will occur on an as-needed basis when safety concerns arise as well as annual meetings with the study PI to discuss overall trial safety data.
	18.3 How will the safety information will be collected?
	Adverse event data collection sheets have been established for recording adverse events reported by participants. These forms will be completed at each treatment session (i.e., Session 1, Session 2, Session 4, Session 5, and Post-Treatment) or study visit conducted by a research staff interventionist (i.e., not done at peer counselor-led sessions). For choking episodes, the date of the episode, details of the episode (e.g., food being eaten, situation in which eating occurred), and any intervention required (e.g., medical attention) will be recorded. For growth faltering, caregivers will be asked to describe their concerns regarding their child's growth. Additionally, infant weight will be recorded at each study visit and treatment session (i.e., Session 1, Session 2, Session 4, Session 5, and Post-Treatment) conducted by a research staff interventionist (i.e., not done at peer counselor-led sessions). All other potential adverse events reported to study staff will also be documented.
	18.4 The frequency or periodicity of review of cumulative data.
	Regularly scheduled meetings between the ISM and PI will occur annually. Emergency meetings will be scheduled by the PI if immediate concerns arise between regularly scheduled meetings.
	18.5 Who will review the data?
	An independent safety monitor (ISM) will be identified during the start-up phase of the study timeline and will provide guidance regarding adverse events and safety issues.
	18.6 The statistical tests for analyzing the safety data to determine whether harm is occurring.
	ANOVAs will examine the number of adverse events in the control versus intervention group.
	18.7 Any conditions that trigger an immediate suspension of research.
	Study participants will be informed of any changes to the known risks and benefits of participating in the current study, including if it is identified that treatment participants are at greater risk for adverse events. If participants in the treatment arm experience greater adverse events, possible discontinuation of the study or modification of the intervention will be considered under the guidance of the ISM. Any action resulting in temporary or permanent suspension of the study will be immediately reported to the funding agency program official.

19.0 PARTICIPANT PRIVACY	**19.1 Describe the provisions to protect participants' privacy and to minimize the intrusiveness of the study questions or procedures.**
	Participant responses will be linked to their study ID # rather than their names. Only study staff will have access to the file linking study ID# and names. All identifying information as defined by the HIPAA Privacy rule will be removed (e.g., birthdates) 2 years after the research ends. Study staff will also receive training on information related to confidentiality and session content management. This training includes education about treatment content (e.g., responsive feeding, infant obesity risk factors) and specific treatment recommendations, strategies for active listening, skills for asking sensitive questions, and how to manage sensitive/confidential information.
20.0 COMPENSATION FOR RESEARCH RELATED INJURY	**20.1 For more than minimal risk research, describe the available compensation in the event of research-related injury.**
	Not applicable.
	20.2 Provide a copy of contract language relevant to compensation for research-related injury.
	Not Applicable
21.0 ECONOMIC BURDEN TO SUBJECTS	**21.1 Describe any costs that subjects may be responsible for because of participation in the research.**
	There are no anticipated costs that participants may be responsible for.

22.0 CONSENT	**22.1 Obtaining consent – Check applicable and complete the corresponding section(s). Please note, sections 23-28 each apply under different circumstances. Please complete the correct sections as checked in this section (e.g. if you do not request a waiver of documentation of consent, do not complete section 24)**	
	☒	**The research team will obtain written consent from all subjects. (Complete section 23) (HRP-502M TEMPLATE Medical Informed Consent or HRP-502S TEMPLATE SBER Informed Consent or HRP-502V TEMPLATE VA Informed Consent)**
	☒	**The research team will obtain consent from all subjects but is requesting a waiver of documentation (signature) of consent. (Complete sections 23 and 24) (HRP-502I TEMPLATE Information Sheet)**
	☐	**The research team is requesting a waiver or alteration of the consent process. (Complete section 25)**
	☐	**The research team is requesting Exception from Informed Consent for emergency research. (Please complete the EFIC supplement document and upload under number 3 on the local site documents page in RAP)**
	☐	**The research team will enroll Non-English-speaking subjects and obtain consent (written or otherwise). (Complete sections 23 and 26)**
	☒	**The research team will enroll subjects who are not yet adults (infants, children, teenagers) and will obtain written consent from the subject's parent(s) or guardian(s). (Complete sections 22 and 27) (Parent Permission Template)**
	☐	**The research team will enroll adult subjects unable to provide consent (cognitively impaired individuals) and will obtain written consent from the subject's Legally Authorized Representative. (Complete sections 23 and 28)**

23.0 CONSENT PROCESS	**23.1 Where will the consent process take place?**
	For Aim 1, participants will review an information sheet containing all elements of consent before the first GLA visit. They will indicate their consent to participate by logging on electronically to participate in the visit. For Aim 2, the consent process will occur at the participant's baseline visit, prior to completion of any study procedures.
	23.2 Is there a waiting period available between informing the prospective subject and obtaining the consent?
	For Aim 1, participants will have time to read the information sheet and decide whether to participate or not before the GLA visit. For Aim 2, interested mothers will be contacted by the study staff via phone. Mothers will be provided information about the study procedures and inclusion criteria will be assessed. If inclusion criteria are met and a mother is interested in participating, a baseline study visit will be scheduled when the child is around 2 months of age. At this visit, informed consent will be obtained.
	23.3 Describe: • **The role of the individuals listed in the application as being involved in the consent process.** • **The time that will be devoted to the consent discussion.** • **Steps that will be taken to ensure the subjects' understanding.** • **Steps that will be taken to minimize the possibility of coercion or undue influence.**

	Consent will only be obtained by trained study staff listed in the application as being involved in the consent process. Participants will be informed of the voluntary nature of their participation and the fact that refusal to participate does not in any way result in the reduction or denial of other home visiting services. They will be informed that the purpose of the study is to evaluate the effectiveness of an intervention targeting healthy infant feeding, and they will be informed regarding study procedures. They will also be told that HEMI visits will be digitally recorded for fidelity purposes. Participants will be informed that even if they agree to participate, they may withdraw their consent at any time without affecting the other services that they receive from ECS. Informed consent will be completed prior to the start of any study procedures. They will be given a copy of the consent form. Because of the possibility that some mothers will have limited literacy skills, we will read the procedures section to all mothers. Moreover, we will verbally reiterate that participation is voluntary, they can leave at any time, and that home visiting services will not be affected by their decision. A consent checklist has been developed to ensure that all components of consent are addressed. For Aim 2, consent will be completed electronically via REDCap. The IRB approved consent will be modified to an electronic format in REDCap that includes all the same elements found on the paper document (i.e. IRB number, approval dates, and UC logo, etc.). The elements of the consent requiring a signature will be added as a generate field. The instrument includes fields to capture full name, signature, and date and time of the signature for the consenter, and witness and conditional text that states that all signatures are associated with the Subject ID# registered in the database. When completed REDCap will generate a footer that contains the long date and time the document was submitted and “Confidential” listed in the header as an added precaution to preserve the research participants confidentiality. Subjects will elect either a printed or electronic copy of the e-consent document. If electronic consent cannot be completed via REDCap due to lack of accessibility to internet access, or due to comfort level with using technology, a paper copy of consent will be completed. Signed copies of the consent will be printed and kept secure with all printed files for this research study. After completion of consent, they will then be randomized into the treatment or control condition. The consent process will take less than 30 minutes.

	23.4 Describe how consent of the subject will be documented in writing.
	A written information sheet has been established for Aim 1. For Aim 1, documentation will be not be required since all study procedures are occurring virtually and the consent form would be the only document linking participant names to the study. For Aim 2, consent will be documented through the completed fields in the REDCap e-consent form. Documentation of consent is then stored within the REDCap online capture system and will be downloaded to our secure UC lab drive.
	23.5 Describe the conditions under which you believe it would be appropriate to obtain ongoing consent from the subjects.
	Ongoing consent will be obtained if significant study changes require participants to complete new study procedures or other unforeseeable study changes occur that may warrant ongoing consent.

24.0 WAIVER OF DOCUMENTATION OF CONSENT	**24.1 Justification for waiver of consent documentation. Check all that apply and provide rationale for all checked items. Please note that certain combinations of the selections below may justify a waiver of documentation. Please refer to HRP-411 – MEMBER CHECKLIST Waiver of IC Documentation to determine if your study qualifies for a waiver of documentation, and which boxes to check to justify the waiver.**	
	☐	**N/A not requesting a waiver of documentation of consent.**
	☒	**The research presents no more than minimal risk to subjects.** The GLA phase (Aim 1) of the current study is considered minimal risk. These meetings will not be audio- or video-recorded and contact information will only be collected and used for those individuals expressing interest in participating in more than one GLA. Following the last meeting, all identifiable information linking GLA members to the study will be destroyed.
	☒	**Written information describing the research is to be provided to the subject, subject parent(s) or guardian(s), or subject Legally Authorized Representative.** Written information describing the research will be provided to each participant via the Information Sheet. Research participants are encouraged to print this form, review it, and it for their records.
	☐	**Written information describing the research does not need to be provided to the subject, subject parent(s) or guardian(s), or subject Legally Authorized Representative.** Not Applicable
	☒	**The research involves no procedures for which written consent is normally required outside of the research context.** The research is limited to procedures for which written consent would not normally be required outside of the research context (i.e., online virtual meetings or phone calls).
	☒	**The only record linking the subject and the research would be the consent documentation.** This part of the study (Aim 1) uses an online virtual meeting or phone call methodology and is not associated with more than minimal risk to participants. If signed consent were obtained, this would be the only identifying information linking the participant to their survey responses.
	☒	**The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.** The rationale for changing the consenting procedure for Aim 1 (GLA) is that we have no credible need to collect and maintain the identities of our research participants beyond their participation in the planning meetings for the study. In doing so, we would introduce the unnecessary risk that an individual's identity could be connected to their data and input, and thus by collecting and maintaining signed consent forms, we introduce the potential risk of a breach of confidentiality that would not otherwise exist.
	☐	**The subjects are members of a distinct cultural group or community in which signing forms is not the norm.** Not Applicable

	☒	**There is an appropriate alternative mechanism for documenting that informed consent was obtained.** Participants will be presented with an Information Sheet, but it will not require the participant to sign the form. Instead, participants will agree to participate by continuing with study procedures (i.e., online virtual meeting or phone call) after receiving the Information Sheet. If they decline to participate, they will not be asked to continue on with the GLA meetings.
	☒	**The research is not FDA-Regulated.**
	☒	**The written script of the information to be provided orally, electronically, or on paper (information sheet) includes all required and appropriate additional elements of consent disclosure. When requesting a waiver of documentation, an information sheet is required. This box should always be checked for a waiver of documentation. (Follow HRP-502I TEMPLATE Information Sheet)** Participants will be sent the Information Sheet that is identical to a conventional informed consent form and contains all necessary information.
	☐	**Other Describe**Not applicable
25.0 WAIVER OR ALTERATION OF CONSENT PROCESS	**25.1 Justification for waiver or alteration of the consent process. Check all that apply and provide a rationale/explanation for all checked statements. Please note that certain combinations of the selections below may justify a waiver of or alteration of consent. Refer to HRP-410 – MEMBER CHECKLIST Waiver of IC Process to determine if your study qualifies for a waiver or alteration of consent, and which boxes to check to justify the waiver or alteration.**	
	☒	**N/A Not requesting a waiver or alteration of consent process.**
	☐	**The research does NOT involve non-viable neonates.** Rationale/Explanation
	☐	**The research involves no more than Minimal Risk to subjects.** Rationale/Explanation
	☐	**The research could NOT practicably be carried out without the waiver or alteration.** Rationale/Explanation
	☐	**The waiver or alteration will NOT adversely affect the rights and welfare of the subjects.** Rationale/Explanation
	☐	**Whenever appropriate, the subjects will be provided with additional pertinent information after participation.** Rationale/Explanation
	☐	**The research is NOT FDA regulated.** Rationale/Explanation
	☐	**Other** Describe any other reasons/explanations for request of waiver/alteration

26.0 CONSENT OF NON-ENGLISH-SPEAKING SUBJECTS	**26.1 Indicate what language(s) other than English are understood by prospective subjects or representatives. (Please note that if non-English speaking subjects will be consented, translated consent forms must be uploaded into the consent section of the RAP Smart Form. For Greater than minimal risk studies, a third-party translation certificate is also required. For minimal risk studies, the consent must be translated by someone independent of the study team and their credentials should be provided.)**
	Participants will be enrolled who are English or Spanish speaking, and therefore consent will be done in English and Spanish. A letter has been uploaded with the credentials of the translators who translated the Information Sheet and Consent Form into Spanish, and the Spanish version of these documents has been uploaded.
	26.2 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate that language that will be used by those obtaining consent.
	Spanish speaking families will be enrolled. They will complete consent using a consent document in Spanish and consent will be completed with a Spanish speaking researcher. All elements of the consent process will be completed in Spanish.

27.0 CONSENT OF SUBJECTS WHO ARE NOT YET ADULTS (infants, children, adolescents)	**27.1 Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g. individuals under the age of 18 years (Ohio))**
	Participants recruited for Aim 2 (only) are infants whose mothers will be consented only if they are at least 18 years of age. We will also include this in the discussion and verification of inclusion criteria in the written informed consent document. Aim 1 participants are all adults over 18 years of age.
	27.2 Describe whether parental permission will be obtained. (Parent Permission Template)
	Parent permission will be obtained from: • One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
	27.3 Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.
	The ECS program from which participants are recruited only enrolls legal guardians and their children, and therefore it is known that all mothers are the legal guardian.
	27.4 Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. (HRP-502Y Youth Assent or Medical Assent Template)
	Assent will not be required as children enrolled in this study are infants.
	27.5 When assent is obtained, describe whether, and how, it will be documented.
	Not Applicable

28.0 CONSENT/ASSENT OF COGNITIVELY IMPAIRED ADULTS	**28.1 For potentially cognitively impaired adults, describe the process to determine whether an individual is capable of consent.**		
	Not Applicable		
	28.2 List the individuals from whom permission will be obtained in order of priority. (Please note that the consent form will require revision to add a signature line for LAR and authority of LAR).		
	Not Applicable		
	28.3 Describe the process for assent of the subjects. Indicate whether assent will be required for all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.		
	Not Applicable		
	28.4 If assent will not be obtained from some or all subjects, explain why.		
	Not Applicable		
	28.5 Describe whether assent of the subjects will be documented and the process to document assent.		
	Not Applicable		
29.0 HIPAA	**29.1 If you will use hospital or other healthcare provider records, data from a research data repository or any other information maintained by a hospital, academic medical center, or another healthcare entity, how will you gain access to the information? (check all that apply, i.e. if you will request a waiver for screening and obtain a signed authorization upon enrollment, check both).**		
	☒	**Not using HIPAA-protected information for any research activities**	
	☐	**Through a HIPAA Authorization signed by the participant (or their legally authorized representative).**	
	☐	**Requesting that the IRB approve a waiver of authorization in this application. Submit HRP-209 – FORM – UC Waiver of HIPAA Authorization**	
	☐	**As a limited data set under a data use agreement.**	
30.0 STUDY INTERVENTION/ INVESTIGATIONAL AGENT	**30.1 FDA – Select all that apply.**		
	☐	**Drugs/Biologics**	**The proposed research involves the administration of an article (e.g. drug, biologic, herbal preparation, dietary supplement, etc.) to a human where the article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or is intended to affect the structure or any function of the body. For both FDA and non-FDA approved article. Include HRP-306 –**

		WORKSHEET Drugs and Biologics in the submission in RAP.
☐	**Devices**	**Any research that involves the use of a device (medical or other devices, approved or investigational) to test the safety or effectiveness of the device or the device is the focus of the research. Note: This includes research that will use human samples to test the safety or effectiveness of a device. Include HRP-307 – WORKSHEET Devices in the submission in RAP.**
☐	**Data Collection**	**Any research that involves the collection of data or other results from individuals that will be submitted to, OR held for inspection by, the FDA. In general, this would include research that involves any data that will be provided (in any form) to a pharmaceutical, medical device or biotech company.**
☐	**Specimens**	**Any research activity where specimens (of any type) from individuals, regardless of whether the specimens are identifiable, are used to test the safety or effectiveness of any device (medical or other devices, approved or investigational) and the information will be submitted to, or held for inspection by, the FDA.**
☒	**Not Applicable**	**None of the above describes my research.**

30.2 Describe the study intervention and/or investigational agent (e.g. drug, device) that is being evaluated.

Not Applicable

30.3 Drug/Device Handling: Describe plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

Not Applicable

30.4 If the drug is investigational and has an IND or if the device has an IDE, or claim of an abbreviated IDE (non-significant risk device) include the information below:

- **Identify the holder of the IND/IDE/Abbreviated IDE**
- **Explain the procedures followed to comply with the sponsor requirements for FDA regulated research (as applicable, 21 CFR 11, 21 CFR 54, 21 CFR 210, 21 CFR 211, 21 CFR 312, 21 CFR 812, 21 CFR 820)**
- **If the PI holds the IND/IDE, please include the FDA Application and the FDA Letter of Acknowledgement on the Drugs/Devices page of the RAP Smart Form. Please also note that a Safety Monitoring Plan will be required if the PI holds the IND/IDE.**

Not Applicable

31.0 ADDITIONAL REVIEWS AND CONSIDERATIONS	**31.1 Check all that apply.**	
	☐	**The proposed research meets the definition of a clinical trial, is regulated by HHS, and requires that the consent form is posted to a federal website within 60 days of completion** **Clinical Trial: A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health-related or behavioral outcomes.**
	☐	**The proposed research involves embryonic stem cells or xenotransplantation.**
	☒	**The PI is responsible for registration of this study on www.clinicaltrials.gov. (Please contact the Human Research Protection Program with questions about clinicaltrials.gov)**
	☐	**The proposed research requires review by the Institutional Biosafety Committee (IBC). IBC review is required for research that will utilize infectious agents, select agents, recombinant DNA or viral gene transfer vectors, toxins for human gene transfer or genetically modified agent.**
	☐	**The proposed research requires Radiation Safety Committee (RSC) review. RSC review is required if the research involves participants being exposed to radiation for research purposes or an increase in frequency or duration of radiological imaging procedures.**
	☐	**UC Student is serving as Principal Investigator (Add the Faculty Advisor to the Study Team Members page in the RAP Smart Form and ensure that their CV is included in their RAP profile.)**
	☐	**UC study team members will be conducting research activities at international location(s).**
		If the research involves international locations, describe additional safeguards included to protect the rights and welfare of subjects recruited in these locations. Refer to HRP-399 – MEMBER WORKSHEET International Research for more information on the information required for review for international studies.
		Description, e.g. information about local research oversight, local context, etc.
	☐	**Collection of information that may include incriminating activities (e.g. illicit drug use, illicit sexual behaviors, fraudulent behaviors, theft, abortion or other related activities that may be illegal in some states, assault)**

	☐	**Review of UC Student records without obtaining consent. If so, a FERPA waiver is required. (Please reach out to Lorre Ratley with UC Office of General Counsel.)**
	☐	**Sharing of genomic information generated from NIH-funded research**
	☐	**UC Health services will be utilized (check applicable).** ☐ **Investigational Drug Services** ☐ **Imaging Services** ☐ **Lab Services**
	☒	**CCHMC Services will be utilized (check applicable).** ☐ **CICRL** ☐ **IRC** ☒ **SRC**
	☐	**Acute Care Research (Research that occurs within 24 hours of a visit to an emergency department or unscheduled admission, or within 24 hours of identification of a new or worsening condition – characterized by sudden onset requiring immediate care)**
	☐	**The research team will send data FROM the United States TO another country:** if so, list the country or countries here
	☐	**The research team will send data FROM another country TO the United States:** if so, list the country or countries here

32.0 REGULATORY OVERSIGHT	**32.1 Check the applicable federal oversite and/or funding.**			
	☐	**Environmental Protections Agency**	☐	**Department of Energy**
	☐	**Tribal Law**	☐	**Department of Defense**
	☐	**Department of Justice**	☐	**Department of Education**
	☐	**Food and Drug Administration**	☒	**Health and Human Services (NIH)**
	☐	**Office of Civil Rights**	☐	**National Science Foundation**
	☐	**Veterans Affairs *See Below**	☐	**Other Federal Agency**
	☐	***Check if you will enroll non-veterans**	☐	**ICH-GCP (E6)**
	☐	**Specify other federal agency/oversight** Name		

33.0 SETTING	**33.1 Where will research activities take place, including where data will be stored/accessed (check all that apply).**			
	☐	**Barrett Cancer Center**	☐	**Infectious Disease Clinic (Holmes-UC Health)**
	☐	**Blue Ash Campus**	☐	**Kettering Laboratory**

	☐	**Cincinnati State Technical and Community College**	☐	**Linder Center of Hope**
	☐	**Clermont College**	☐	**Liver Transplant Clinic (Medical Arts Building)**
	☐	**College of Allied Health Sciences**	☐	**Medical Sciences Building**
	☒	**College of Arts & Sciences**	☐	**Shriners Hospital**
	☐	**College of Business**	☐	**Talbert House**
	☐	**College Conservatory of Music**	☐	**UC Gardner Neuroscience Institute**
	☐	**College of Design, Art, Architecture & Planning**	☐	**UCMC (Emergency Department, Inpatient and Outpatient Units)**
	☐	**College of Education**	☐	**UCMC NICU**
	☐	**College of Nursing**	☐	**University of Cincinnati Physicians (UCP)**
	☐	**College of Pharmacy**	☐	**University Pointe Surgical Hospital**
	☐	**Crossroads Center**	☐	**VA – Cincinnati Medical Center**
	☐	**Drake Center**	☐	**VA – Chillicothe Medical Center**
	☐	**Genome Research Institute (Reading Campus)**	☐	**VA – Columbus Medical Center**
	☐	**Hoxworth: Inpatient Unit**	☐	**West Chester Hospital**
	☐	**Hoxworth: Outpatient Clinics**	☐	**Other UC/UC Health Affiliated location/clinic:** list location/clinic
34.0 EXTERNAL LOCATIONS	**34.1 List any external locations to UC or its affiliates.**			
	External institutions with collaborators: Cincinnati Children's Hospital Medical Center, Every Child Succeeds. CCHMC IRB will also be conducting their own review of this study.			

	35.1 List any references sited throughout the protocol below.

35.0 REFERENCE LIST

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