UC RIVERSIDE | Research Integrity

Institutional Review Board (IRB)
DATE: April 5, 2023

APPROVAL NOTICE

INVESTIGATOR: Cheney, Ann **Faculty Advisor:** N/A

DEPARTMENT: Social Medicine, Population & Public Health - SOM **Administrator:** Moran, Ashley

PROJECT TITLE: **"Grow Well/Crecer Bien: Addressing Childhood Obesity in Low-income Families"**

IRB NUMBER: **HS - 22-208** **APPROVAL:** April 5, 2023 **EXPIRATION:** Not Applicable

FUNDING SOURCE: **NIH/NIMHD U54 MD013368**

SPECIAL CONDITIONS: None

NOTE: Approval by the UCR Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Allowable research and scholarly activities are dependent on the current status of the University's Campus Return level (https://campusreturn.ucr.edu/) and may continue to change. Additionally, other institutional clearances and approvals may be required (e.g., EH&S, IBC, IACUC, other institutional IRBs). **Accordingly, the project should only begin if the campus status allows it, and all required approvals have been obtained.**

THE UCR IRB HAS REVIEWED THE PROPOSED USE OF HUMAN PARTICIPANTS IN THE REFERENCED APPLICATION AND APPROVED IT BASED ON THE FOLLOWING DETERMINATIONS:

1. Level of Review - 45 CFR 46.110 (#4, 6 and 7) Expedited
2. Special Population - 45 CFR 45 Subpart D (Children)
3. Risk - Minimal
4. The risks to participants are minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk.
5. The risks are reasonable in relation to the anticipated benefits to individual participants and the importance of the knowledge that may reasonably be expected to result.
6. The selection of participants is reasonable and equitable.
7. The PI has had the appropriate human subjects research training.
8. Consent - Signed Consent Approved AND Documentation waived per 46.117(c) with Verbal consent obtained

IRB approval is effective from date of this notice and good for the date indicated. Review *may be* required to keep project active.

THE INVESTIGATOR SHALL PROMPLTY REPORT THE FOLLOWING TO THE IRB:
(1) Changes to the application (e.g., increase the number of participants, or changing the participant population, recruitment methods, procedures, documents) via an amendment, or
(2) Unanticipated problems involving risk to participants or others (please contact the IRB for instructions).

DATE APPROVED April 5, 2023

DR. DERICK FAY, CHAIR, IRB
DESIGNATED UCR IRB MEMBER

UC RIVERSIDE | Research and Economic Development

For use by ORI only:
Expedited #4/#6/#7

IRB Designate Approval:
APPROVED
4.5.23

HS- **22-208**

IRB Application for Use of Human Participants/subjects in research

(*For use by UCR faculty researchers, students, visiting professors, and postdocs*)

Please Note: Given the COVID-19 pandemic, allowable research and scholarly activities are dependent on the current status of the University's Campus Return level and may continue to change. For up to date information on the status of the campus, please visit: https://campusreturn.ucr.edu/.

I – General information

This IRB application must be typed out and submitted via e-mail (irb@ucr.edu) along with all the appendices and signatures. All the applicable questions should be answered. Do not delete or alter any questions on this application form. Try to follow the suggested length requirements and focus on ethical issues. There are embedded resources and tools on our website and throughout this IRB application. **Hand-written applications will not be accepted.**

1. Title of Research Study

Grow Well/Crecer Bien: Addressing Childhood Obesity in Low-income Families

2. Researcher (e.g., UCR faculty, student, postdoc, visiting professor)

Title (e.g., Dr., Mr., etc.): Dr.	Name: Ann Cheney
NetID: acheney	Department: Social Medicine Population and Public Health
Phone: 501-352-8526	Institutional e-mail: ann.cheney@medsch.ucr.edu
Alternate contact (e.g., research coordinator, department administrator) name: Ashley Moran	Alternate contact Institutional e-mail: Ashley.Moran@medsch.ucr.edu

3. UCR Status

Faculty (50% or f/t) ☒ Doctoral ☐ Masters ☐ Undergrad ☐ Post-Doctoral ☐
Visiting professor/External researcher ☐ Other ☐ (specify:)

4. UCR Faculty Advisor or Sponsor

a) List the UCR Faculty Advisor or Sponsor. Advisor or Sponsor must meet PI eligibility as defined by UCR Policy #527-3. (Q4a is to be filled out only if the person in Q2 is a UCR student, trainee, postdoc, or visiting scholar; for faculty research, this question should be blank):

Title (e.g., Dr., Prof):	Name:

Net ID:	Department:
Institutional e-mail:	

b) Department Information (for UCR faculty or Faculty advisor)

Department Chair / Dean name: Mark Wolfson, PhD, Department of Social Medicine Population and Public Health, UCR School of Medicine

5. Key Personnel

Are co-investigators involved in this project? Yes ☒ No ☐
List all key personnel in the Project Roster. This is a separate document that must be attached with this IRB application as an appendix.

6. Training: Provide details on your and the research team's experience with this type of research. Please provide details on study-specific training that will be provided (excluding the online CITI course).

(Max ¼ page)

Dr. Ann Cheney is a medical anthropologist and an expert in community engaged health disparities research and mixed methods designs, involving quantitative and qualitative methods, with low-income and underserved populations including Latinx and Indigenous Latin American communities. She is bilingual English/Spanish. Maria Pozar is community investigator and leads health disparities research with Latinx and Indigenous Latin Americans in the eastern Coachella Valley. She is bilingual Spanish/Purépecha, an indigenous language spoken in Michoacán Mexico. Both hold expertise in community nutrition education and prevention. Dr. Alison Tovar, co-investigator, holds her PhD in nutrition and expertise in interventions to reduce risk for early childhood obesity among low-income Latinx families. Dr. Evelyn Vázquez, co-investigator, holds her PhD in education and expertise in qualitative and mixed methods research on health disparities in low-income Latinx families. Academic team members, including research assistants, are bilingual English and Spanish. The community health workers are either native Spanish speakers or bilingual Spanish and Purépecha speakers.

Community health workers and the Community Investigator listed on the study protocol completed the CANRA training; they also participated in two in-person trainings on the study design of the pilot randomized controlled trial, data collection, intervention implementation and additional one-on-one trainings for data collection and intervention implementation. See attached agendas for more information on study training sessions.

7. Funding

a) Is this study funded?

☒ Funding obtained	If YES, provide the PAMIS award number(s):
☐ Funding applied for	If YES, provide the anticipated start date:
☐ No Funding required	If YES, explain why no funding is needed:

b) If obtained or applied for, what are the type(s) and source(s) of funding (check all that apply)? If No Funding required, skip to the next question. Please note it is your responsibility to update the IRB if your funding status changes.

☒ Government funding (e.g., NIH, NSF, CDFA, Riverside County, etc.) Source: NIH/NIMHD U54 MD013368
☐ Industry (e.g., Pharmaceutical, biotech, etc.) Source:
☐ Non-profit sponsor (e.g., AHA, Bill & Melinda Gates Foundation, John Templeton, etc.) Source:
☐ Other Source:
☐ Departmental Funds

8. Conflict of Interest review (Promoting Research Objectivity):

Do you or any other study personnel (or the spouse, registered domestic partner and/or dependent children thereof) have a direct or related financial interest that might affect, or even appear to affect, the rights and welfare of participants involved in this research?

☐ Yes ☒ No (If Yes, please contact PRO for a separate review)

9. Additional Reviews

a) Has the research project received a scholarly, scientific, or peer review prior to this submission (this may involve a review by a funder, faculty supervisor, or a departmental committee):

☒ Yes, specify: NIH review panel.
☐ No (NB: IRB recommends a prior scholarly review for studies that are more than minimal risk)
☐ Pending, specify:

b) Will this research require review by any of the following (check all that apply):

☒ None – UCR IRB is the only approval required
☐ UCR Institutional Biosafety Committee (IBC): Research using biohazardous materials including any human-derived materials such as blood, body secretions, and tissues, primary and established cell lines
☐ UCR Stem Cell Oversight Committee (SCRO): Research using human pluripotent cells
☐ UCR Institutional Animal Care and Use Committee (IACUC): Research using vertebrae animals

II – Study Summary

10. Abstract (suitable for a lay audience)

(Max ¼ page)

This research uses community based participatory research (CBPR) to engage low-income Latinx families in research to pilot test an adapted nutrition education program compared to an existing nutrition education program. The goal of the research is to provide nutrition education on healthy infant feeding to reduce risk for early childhood obesity.

11. What is the scholarly rationale for this study?

(Max ½ page)

The prevalence of obesity in early life remains unacceptably high, especially among low-income children, most are ethnic minorities. Marked ethnic disparities are evident by two years of age, which suggests that existing interventions are not adequate. Early prevention is critical, especially for low-income children. For example, among Latino children high body mass index during infancy renders them three times more likely than other children to be obese by age 6. The disparity observed at this young age presents a window of opportunity to intervene early through existing nutrition programs that foster healthful eating habits, which track into childhood and continue into adulthood. Yet, few prevention programs intervene during infancy, and those that do, do not incorporate feeding styles and practices into nutrition education, do not account for the involvement of caregivers other than parents in infant feeding, and/or 3) start too late. The proposed research addresses these gaps by moving beyond healthy eating to better understand and promote healthy feeding. This project, which focuses on an-at-risk child population, has great potential to address our nation's growing crisis of childhood obesity, which can dramatically improve the health of millions of low-income children, their families, and their future children.

12. What are the study hypotheses or research questions?

(Max ¼ page)

This research will implement and evaluate an existing healthy infant feeding intervention, Healthy Beginnings, which was developed for English-speaking low-income mothers in Australia and delivered by public health nurses via in-home visits. We will test the efficacy of an adapted version of this intervention in comparison to the original intervention.

Aim 1. Pilot test an adapted nutrition education program of, compared to the original program curriculum.

- Using a pilot randomized control trial with 30 mother-infant-caregiver triad (15 intervention, 15 control) determine the feasibility, acceptability, and preliminary efficacy of the adapted intervention compared to the original intervention. We hypothesize that the adapted intervention will be feasible, acceptable to study participants, and efficacious in addressing feeding styles and practices and caregivers' role in infant feeding.

We anticipate that the intervention will be feasible to deliver and acceptable to mothers and caregivers, and that the mother—infant-caregiver triads randomized to intervention with the adapted Healthy Beginnings curriculum compared to the treatment as usual control group will demonstrate greater improvements in outcomes (i.e., infant feeding knowledge and use of recommended feeding practices) after 6 months compared to the control group.

III – Study Design and Methodology

13. Study Timelines

Estimated start date for involvement of participants: February 1, 2023 or upon approval of the IRB protocol.
Estimated completion date for the involvement of participants: Feb. 28, 2024

14. Location of Research

a) Where will this study take place? If there is an online component, provide details.

(Max ¼ page)

The research will be carried out in Inland Southern California, specifically communities of the Coachella Valley and surrounding area. The PI, Dr. Ann Cheney and Co-Investigator Evelyn Vázquez, along with graduate and undergraduate research assistants are located at UCR. Co-I, Alison Tovar, and research coordinator/assistant, Andrea Ramirez, is located at Brown University. Community Investigator, Maria Pozar, is located in the Coachella Valley. All research takes place at UCR. The research will primarily engage Latinx and Indigenous Mexican (e.g., Purépecha) communities in Inland southern California.

b) Is this a collaborative or multi-site study? Yes ☒ No ☐

- **Collaborative or cooperative studies involve investigators from two or more institutions working together to conduct a research project. Different research activities can occur at different sites or the study can be a single-site study that involves personnel from multiple institutions.**
- **Multi-site studies use the same research procedures outlined in a single protocol that is carried out at multiple institutions (e.g., a clinical trial where participants will be enrolled at each participating site, or an educational intervention implemented at each participating site).**

c) If YES, please provide details how this collaborative relationship will be established:

Will the investigators submit separate IRB applications at their own institutions to cover their own research activities?	**Yes ☐ No ☒**
If NO, will the investigators seek to establish a reliance agreement where one IRB will serve as the 'IRB of Record'? • **If YES, please identify the institution whose IRB will be the IRB of record:** UCR will be the IRB of record. Alison Tovar and Andrea Ramirez at Brown University will be part of the investigative team. This agreement has been discussed and approved with Brown collaborators and their IRB. A reliance will be documented using SMART IRB. We will set up the reliance upon IRB approval. **IRB reliance (or "single IRB review") is a legal arrangement that allows one IRB to review a study that is occurring at multiple sites or to review a single-site study that involves personnel from multiple institutions. Opportunities for single IRB review are established by entering into formal IRB reliance agreements.**	**Yes ☒ No ☐**

d) If research is taking place within a community or an organization, describe how access will be obtained. Are there any special considerations for obtaining consent? Access letters may be requested from the community or organization. Sample Access Letter template can be found on the ORI Resources page. Attach any relevant supporting documentation as appendices.

(Max ¼ page)

This research team will partner with healthcare systems serving low-income families in the inland desert region, including UCR Health and the Coachella Valley Free Clinic, an outreach clinical arm of Coachella Valley Volunteers in Medicine all of whom will assist with recruitment of mothers into the study. The CVFC, a student-led clinic that

provides medical care to patients on the 2nd Saturday of the month in Mecca, CA. Dr. Cheney is faculty supervisor of this clinic and Ms. Pozar oversees a team of community health workers that support the clinic. As described below, infant anthropometric measurements will be collected at this clinic. A letter of access signed by Dr. Cheney, the primary faculty supervisor, is included as an appendix (see Appendix B– Healthcare Systems - Access Letters of Support). Once additional letters are obtained from our healthcare systems partners, we will submit the access letters to the IRB for review.

15. Participant Population: Please describe the participants/subjects. List the inclusion/exclusion criteria. Include any age, language, gender, or race-related inclusion/exclusion criteria and provide a justification for the use of these criteria. If applicable, please provide a rationale for your choice in sample size and/or sample size calculation.

If you are conducting research in languages other than English, translated versions of the participant-facing research materials (e.g., informed consent, recruitment materials, measures, etc.) must be submitted for review along with the Certificate of Translation form.

(Max ¼ page)

Latina mothers, their infant, and their identified caregivers will be part of the intervention study. Mothers will be eligible if they 1) identify as Latina, 2) 18 years or older, 3) speak English, Spanish or Purépecha; 4) mother (biological, adoptive, foster) of an infant ages 4 months or younger, who had a normal birth weight (greater than or equal to 5 lbs., 8 oz.), 5) live in Inland Southern California; 6) income eligible (mothers or their children) for government programs such as WIC, Early Head Start, MediCal, CalFresh and similar programs, 7) willing to have a community health worker enter your home to provide 30-45 minute in person sessions once per month over 6 months, 8) have another caregiver 18 years or older who participates in at least 3 hours of care per week and agrees to participate in the home sessions. We anticipate a sample of 30 mothers-infants-caregiver triads in the study, totaling 90 participants.

Additionally, community health workers and healthcare staff will participate in interviews on the feasibility of recruiting participants into the study and delivering the intervention. Community health workers and healthcare staff will be eligible if they: 1) participate as a member of the study team as a community health worker or partnered with the study team as a healthcare staff member at a participating site (e.g., UCR Health) and 2) were involved in the recruitment of participants, data collection, and/or delivery of the intervention.

Andrea Ramirez, a native bilingual English-Spanish speaker translated the documents and signed the certificate of translation form. Dr. Cheney reviewed all Spanish translations.

Maria Pozar, a native Spanish and Purépecha speaker, will orally translate material from Spanish to Purépecha as this is an oral rather than written language for all Purépecha speaking participants who request to communicate in this language. She will translate orally from Spanish to Purépecha the orientation material, pretest and posttest survey questions, brief satisfaction survey questions, and infant anthropometric data collection.

Yesenia Pozar, a native Spanish and Purépecha speaker, will translate material from Spanish to Purépecha as well. Yesenia Pozar will translate orally any intervention material for Purépecha speaking participants, including material delivered during in home sessions, phone check ins, and WhatsApp posts. Both are native Purépecha and Spanish speakers.

16. Special Populations

a) Will any participants/subjects be specifically recruited from the following categories listed below (check all that apply):

☒ **Under the age of 18**
The focal participant is mothers of infants 0-4 months of age. We will ask mothers to include their infants o-4 months of age for the purposes of collecting data on their infant's height, weight, and body fat composition. However, mothers can choose to be in the study and not include their infant

☐ **Prisoners, probationers, or parolees**

☐ **Pregnant women, fetuses, or neonates**

☒ **Other characteristics that may cause them to be considered 'vulnerable' (e.g., cognitively impaired, educationally/economically disadvantaged, patients, students, staff, history of distrust, etc).**
Describe: The population may be considered educationally and economically disadvantaged due to limited access to formal education and reliance on contingent labor as most are immigrants to the US and work in agriculture as farm laborers or the service sector.

b) If YES, please justify the use of the above populations, and detailing what additional safeguards will be included in the study to protect the rights and welfare of the subjects and will there be direct benefits. If NO, skip to the next question.

(Max ¼ page)
Participants could fall within the category of educationally/economically disadvantaged as the participant population is primarily low-income, immigrant Latinx and Indigenous Mexican. This population has limited access to formal education and also tends to have limited literacy. There are several ways that we address such vulnerabilities. First, community health workers, who are members of the community with similar educational and economic backgrounds, are part of the research team and recruit participants into the study as well as lead data collection and analysis efforts and will implement the adapted curriculum. In this way, our team is able to build trust with vulnerable community members and ensure their confidentiality and protection as human subjects in research. Trust building is important to minimize coercion as the community health workers can answer participant questions and provide information for participants to make informed decisions about research participation. Additionally, we carefully consider the amount of time participants will partake in research activity and compensate participants in a way that addresses any potential costs to research participation (e.g., cost of data on cell phone or internet use). We also consider the time of events (e.g., evenings, weekends) so that we can accommodate participants who do not have the option to leave work or ask for time off to participate in research. Additionally, we offer the option of compensation (gift cards) to participants being hand delivered by community health workers to home addresses. We offer this option as some participants may not have a reliable postal service and may not be able to access their compensation via email or postal services.

17. Recruitment: Describe the mode of communication and how participants will be approached. Any recruitment materials, e-mails, & scripts must be submitted for review as appendices.
If you are recruiting participants through a subject pool (e.g., Psychology Department subject pool), please refer to the UCR Policy on the Use of Subject Pools in Human Subjects Research.

(Max ¼ page)
We will collaborate with two healthcare systems serving low-income families, UCR Health and CVFC, who will assist with recruitment of participants into the study (see *Appendix B* for Letters of support). Healthcare staff at UCR Health include Dr. Jean Russell, listed as study personnel on our project roster. Additionally, community health workers who are also part of the staff at the CVFC, including Sonia Rodriguez, Mary Bautista, Ana Gonzalez, and Yesenia Pozar, will disseminate flyers at the CVFC. Per this method, our healthcare system partner or community health worker will

share the recruitment flyer and use a recruitment script and share the study recruitment flyer with mothers who access their clinical services. For all interested mothers, clinical staff will write down their name on a recruitment form and send the form via an encrypted email to the study PI, Dr. Ann Cheney (see *Appendix C.* Recruitment Script). We will also disseminate study flyers via study team members' networks (see *Appendix D*. Recruitment Flyer). Study team members, including CHWs (as listed on the project roster this includes: Sonia Rodriguez, Mary Bautista, Guadalupe Vieyra, Maria Molina, Nancy Del Castillo, Solangel Cruz, Sandra Ramirez, Ana Gonzalez, Blanca Quintero, Yesenia Pozar) will disseminate the flyer via their social networks. We will ask all study personnel posting via social media to monitor posts to ensure individuals are not tagged or inappropriate comments made. If possible, we will disable the option for comments and tagging. If tagging or inappropriate comments are made, study team members will delete the person tagged as well as any inappropriate comments. Additionally, CHWs will recruit mothers at offices and lobbies of partnering organizations. For all Interested individuals a study team member will contact them to assess their eligibility (see *Appendix E*. Eligibility Screening Tool). Additionally, we will post the study flyer to social media, including Facebook and Instagram @GrowWell_CrecerBien. The researchers are the administrators of the accounts and will post study material directly on the sites.

Community health workers and healthcare staff will be recruited into the study via email. As indicate above, the CHWs are members of the study team. The healthcare staff will be members of UCR Health or CVFC for whom we have direct contact. The project coordinator, Arianna Zimmer, will send an email following a script to all community health workers and healthcare staff involved in the study via partnering healthcare organization (e.g., UCR Health) inviting them to participate in a one-on-one interview (see *Appendix X*. Recruitment of Community Health Workers and Healthcare Staff). Because the Community Health Workers are members of the research team listed on the roster and we will already have the email addresses of healthcare staff members, we will already have their email addresses and will use thus reach out to those collaborating community health workers and healthcare staff members.

18. Compensation: Will participants be compensated for their time? Describe the methods, amount and schedule for payment. What will happen to compensation if participants chose to withdraw? If no compensation is being offered, please justify why.

(Max ¼ page)

Mothers and caregivers will be compensated for their time as well as receive a welcome gift to include a physical copy of the nutrition education material and a gift of an approximate $20 value (for mothers this will be a diaper bag and for other caregivers a bag such as a tote or lunch bag). All participants will receive the following: 1) $25 for their participation in the orientation session; 2) $75 for their participation in the pretest survey; 3) $125 for their participation in the posttest survey. The purpose of an increased amount from baseline to follow-up is retain participants in the study and compensate participants for their time spent completing the brief satisfaction surveys after the completion of the in-person home visits and phone call check ins. Participants will receive a total of $225 in gift cards for full participation in the study. (Infants will not receive separate gift cards, rather their mothers will receive the gift card.) Throughout the study period, all participants (regardless of their assigned group) will also be eligible for a drawing with a gift valued up to $25. The raffle will be done once per month for participants in both the intervention and control group. For Group A – Grow Well participants (mothers and caregivers) that opt into the optional participant satisfaction one-on-one interview and are selected, will receive a $25 gift card for their time.

Mothers and caregivers will receive their funds (gift cards) immediately after the orientation, completion of the pretest survey and the posttest survey, and optional interview. They will receive the welcome gift after they have been randomized to either Group A or Group B as the welcome gift for Group A will also include the Grow Well

intervention booklet. For Group A, the community health worker will deliver the welcome gift during the first in-home session. For Group B, a team member will mail participants their welcome gift via postal services or deliver it to their home following placement in Group B. If they are selected for the drawing, they will receive the gift via the postal service or delivered to their home to be sent/delivered within several days of having been selected.

CHWs and healthcare system partners who participate in the qualitative interviews to assess feasibility of the intervention study will receive a $25 gift card for their time. They can opt into receiving the gift card via email or postal mail.

Gift cards will be shared with participants depending on how they select delivery on the consent form, thus either by email, mail, or delivered to home. All consent forms offer these options and participants can select the best option for them. If participants have begun the research and then chose to withdraw, they will still be provided the compensation to thank them for their interest and time.

19. Reimbursement: Will participants personally incur any expenses as a result of participation (e.g., fuel, missed work)? If no reimbursement is being offered, please justify why.

(Max ¼ page)
Participants will not incur any expenses because of participation as events will occur online via Zoom or phone, in their community, or when they access healthcare services.

20. Procedures

a) Describe how human participants will be involved in the research. If there is to be an intervention or interaction with the participants, describe what the researcher and participants will do, who will conduct the procedures, where and when the procedures will take place, how frequently, for how long, what equipment will be used, etc.

(Max ½ page)
Human subjects will be involved in the research via the pretest and posttest survey, brief satisfaction surveys, anthropometric body measurements, and one-one-one interviews. The research involves data collection around the implementation of an infant nutrition education curriculum (i.e., the adapted version of Healthy Beginnings). This is an intervention study and a pilot randomized control trial (RCT) with an intervention arm and a control group to determine: 1) the preliminary efficacy of the adapted intervention on mothers' and caregivers' infant feeding knowledge, use of recommended feeding practices, and infant anthropometric measurement outcomes 2) the feasibility of implementing the intervention and its acceptability among mothers and caregivers, and 3) the feasibility of collecting infant anthropometric data.

The pilot RCT will include an intervention and control group and will be carried out over 6 months or 24 weeks and will involve 30 mother-infant-caregiver triads. Both mother and caregiver have to agree to participate in the study to be enrolled. If the caregiver declines, then the mother cannot participate; and vice versa if the mother declines, then the caregiver cannot participate. The eligibility screening tool asks mothers if another caregiver who cares for their infant at least 3 hours per week would be willing to participate in the study with them. If the mother answers no, then the mother is not eligible to participate in the study. Enrollment is ongoing and will begin the first week of every month from April to August 2023. The mother-infant-caregiver triad will be enrolled in the study upon recruitment and begin the study as soon as the infant is 4 months of age, which aligns with the dissemination of packet 1 that includes nutrition education for families of infants 4 to 6 months of age. In this design, participants will be randomized into the intervention or control group: intervention group will be Group A: Grow Well and will

receive the adapted Healthy Beginnings Curriculum (n= 15 mother-infant-caregiver triad) and the control group will be Group B: Healthy Steps and will receive the Healthy Steps curriculum or treatment as usual as this is the curriculum commonly shared during well baby visits (n= 15 mother-infant-caregiver triad). Randomization will occur once base-line data is collected. Comparisons will be made between the intervention and control groups during the first 6 months of the intervention. The focus is on Latinx Spanish-speaking families; however, all our material is in English and Spanish to accommodate language preferences. Additionally, if a mother or caregiver prefers Purépecha, a language commonly spoken in the region, a Purépecha-speaking team member can translate orally from Spanish to Purépecha as this is an oral and not written language.

Intervention Design

Group A - Grow Well. Our team collaborated with mothers and caregivers to adapt the Healthy Beginnings curriculum (http://www.healthybeginnings.net.au) for low-income Latinx immigrant families and communities. The curriculum focuses on healthy eating through education on nutritional content, parental and caregiver roles, and responsibilities for food preparation and family mealtimes. The intervention also encourages use of responsive feeding practices (i.e., responding to baby's hunger and fullness cues), as well as communication skills and conflict resolution strategies regarding baby's feeding. The original Healthy Beginnings curriculum includes material for mothers of infants 0 to 24 months. For the purposes of the pilot project, we will implement and evaluate material for infants 4 to 12 months (see *Appendix F.* Adapted Healthy Beginning Modules 4 to 12 months). The rationale for focusing on this age range is solid food introduction and transition to eating family meals occurs during this time. The intervention will be six months and include three components: 1) 30-45 minute monthly in-person delivery of material to mother and other caregivers; 2) 15-to-20-minute monthly phone call with mothers, and 3) being part of a WhatsApp group chat to receive weekly posts. Study team community health workers (CHWs) will deliver the intervention. All CHWs will participate in a training (in Spanish) on how to deliver the intervention prior to the start of the research.

In home sessions. For all in-home sessions, the CHWs will follow scripts. The scripts will provide instruction on delivering infant nutrition information, recommended infant feeding practices, and communication and conflict resolution strategies, and self-care practices for mothers and caregivers (see *Appendix G.* Community Health Worker Scripts for In-home Sessions). At the end of the in-home sessions, the CHW will work with the mothers and caregivers to set goals for infant care and feeding, communication strategies, and self care (see *Appendix H*. Goal Setting).

Phone calls. The CHWs will call (phone or video depending on participant preference) mothers one time per month of the intervention to check in on the goals and answer questions (see *Appendix G*. Community Health Worker Scripts – refer to section for Phone Call Check ins with mother). This call will occur two weeks after the in-home session and be approximately 15 to 20 minutes in length.

*WhatsApp group chat***.** Study team members will post weekly to a group chat that includes the mothers and caregivers in the intervention group (see *Appendix I.* WhatsApp Posts). The posts will include feeding information, infant nutrition, and caregiver communication. The posts are based on information provided in the adapted Healthy Beginnings 4–12-month booklets. The group chat will also be a virtual space for participants to interact and support each other. Mothers will be in one group chat and caregivers in a separate group chat. A team member will oversee this group and post weekly.

Group B - Healthy Steps. The control group will receive treatment as usual and will receive material frequently distributed throughout healthcare systems serving low-income patients. For the Healthy Steps curriculum for

infants 4 to 12 months of age packets are distributed at baby wellness visits at 4-, 6-, 9-, and 12-month visits (more information about the Healthy Steps program including handout material can be found here: https://www.healthysteps.org/). The Healthy Steps program provides information packets on developmental milestones, sleeping, and play (see *Appendix J*. Healthy Steps Curriculum). Healthcare providers hand out these packets to caregivers at the end of well-baby visits as take-home information. Mothers randomized to the control group will receive this information in the mail during first week of months 1, 3, and 5 of the study. The CHWs will call mothers the first week of months 1, 3, and 5 of the study to confirm receipt of the packets. Participants will be instructed to read the material. No other interaction will occur.

Zoom procedures

Zoom will be used for the orientation as well as baseline and follow up data collection and one-on-one interviews. We will create a password protected Zoom session with a unique link, meeting ID number and password per session that study team members will share directly with participants via text message or email (participants will be blind copied). Once participants enter the Zoom space, we will ask them to change their screen name to a pseudonym or will help them change the name, so their real name is not visible. Participants will have the option to keep their camera off or turn it on.

If participants have restricted access to the internet to access Zoom, we will accommodate in several ways. First, for participation in the orientation and any data collection via Zoom, we will provide the Zoom conference line information and the unique meeting ID so participants can access the Zoom space via phone. Second, for those who have limited digital connection and want to connect via Zoom, we will use our team's hotspots to connect a study computer/laptop to WIFI. CHWs will deliver the computer/laptop and hotspot to participants. Third, for participants who prefer in-person orientation or data collection sessions, we will coordinate with the participant to conduct these activities in person at an agreed upon location.

Audio recordings

We will digitally record via Zoom the one-on-one interviews. If the participant enters Zoom via video, we will use the audio recording and delete the video recording. Recording is mandatory for participation in the qualitative interviews. All recordings will be uploaded to a password protected folder on the UCR SOM secure network and will be deleted from the Zoom folder; audio files will be deleted after the transcription process is complete.

Orientation Session

Prior to data collection, participants will be invited to attend an orientation to the project via Zoom. During the orientation session, they will be informed about the study design including an intervention and control group and that randomization will be into one of these two groups: Group A: Grow Well (intervention) and Group B: Healthy Steps (control) (see *Appendix K*. Orientation to Study). While this is not research, we will provide participants with a $25 gift card for their time.

Data Collection

Data collection will begin at the start of each month meaning week 1 will align with the beginning of the calendar month and week 24 will align with the end of the calendar month.

<u>Baseline and follow up data collection.</u> Pretest and posttest surveys will be collected at baseline (week 1), and at six month follow up (week 24). Prior to the start of the RCT, trained study team members will administer the pretest survey to mothers and their other caregivers. Data collection will occur via phone or Zoom, depending on the

participant's preference; each survey will last about 30-45 minutes. The survey will collect data on sociodemographic questions (e.g., income, education, language, mental health), infant feeding practices using the validated Infant Feeding Scale Questionnaire (Thompson et al., 2009), communication skills and conflict resolution strategies around feeding between the mother and other caregiver, and questions about breastfeeding, formula feeding, and family mealtimes (see *Appendix L*. Pretest and Posttest Survey for Caregivers and *Appendix M*. Pretest and Posttest Survey for Mothers). All participants (mothers and caregivers) will receive $75 for completion of the pretest data collection and $125 for completion of the posttest data collection. The purpose of an increased amount from baseline to follow-up is to compensate participants for the completion of the brief satisfaction surveys throughout the study and retain participants in the study over six months. (While only Group A participants will complete the brief satisfaction surveys, for purposes of equity all participants will receive $125 at the end of the study.) In the final week of the study (week 24), study team members will administer the posttest surveys. The posttest survey will include the same questions as the pretest survey except it will not include the socio-demographic questions and will include a satisfaction survey. Only participants assigned to Group A – Grow Well will respond to the satisfaction survey questions. Participants can refuse to answer or skip any questions in either the pretest or posttest survey. If participants exit out of the study, their data will be removed from analysis.

Anthropometric data collection. Anthropometric data will be collected at baseline and follow up. Because data will be collected at the CVFC, held the 2nd Saturday of the month, baseline data will be collected in week 2 of the intervention and follow up data in week 22. Trained medical students and CHW study team members will collect anthropometric data, weight, length, and body fat composition from infants at the beginning and end of the study period. We will collect infant weight using an infant scale, length using an infant measuring device that infants lay on, and body fat composition using fat calipers (see *Appendix N*. Anthropometric Data Collection). Mothers will be invited to bring their baby to the clinic for the purposes of data collection. However, if a mother is unable to bring their baby to the clinic, a study team member will collect data at the mother's home. Data collection will take approximately 10-15 minutes. Dr. Cheney who is trained in infant anthropometric data collection will train study team members to collect and record these data prior to data collection. Participation in the study require infant anthropometric data collection. If participants exit out of the study, their infant's anthropometric data will be removed from analysis.

Feasibility. After the completion of the implementation of the intervention, the study team will determine the feasibility of CHWs delivering the intervention in person with mothers and other caregivers present. We will conduct qualitative debriefing interviews with the CHWs (n=3) who implement the intervention, as well as with healthcare staff recruiting mothers into the study (n=3) (see *Appendix O.* Community Health Workers and Healthcare Staff Interview Guide). The debriefing interviews with CHWs will obtain information on the ease of delivering the intervention in-person with mothers and caregivers present, ease and utility of the phone check-in, the recruitment and retention of participants, and collection of infant anthropometric data. The debriefing interviews with healthcare staff will assess ease of recruiting mothers in a healthcare setting and communicating contact information with study team members These interviews will be 30-60 minutes, audio recorded, and analyzed using rapid analytic techniques of template and matrix analysis. Study team members will listen to the audio recordings, complete a summary template, and use a matrix to identify themes. Participants will receive a $25 gift card for their time.

Fidelity. Throughout the delivery of the intervention, the study team will also determine fidelity or how well the delivery of the intervention adheres to instructional procedures. To assess fidelity, research assistants (RAs) will participate in 30% of the in-person sessions and phone calls with the CHWs as they deliver the curriculum to mothers and caregivers. For the in-home sessions, RAs will join the sessions virtually via Zoom on tablets that CHWs will bring with them to the visit. For the phone calls, the RAs will join the call with the CHWs and mothers. For both in-person sessions and phone calls, the RAs will use a checklist to assess how well the CHWs follow the instructional scripts on material to share and activities to complete (see *Appendix P*. Fidelity Checklist- Research Assistant).

Additionally, the CHWs will use a checklist to assess their perceived fidelity to the program, which they will complete after each in-home session and phone call check in (see *Appendix Q*. Fidelity Checklist- Community Health Worker).

Satisfaction. Throughout the delivery of the intervention, the study team will determine the satisfaction with the intervention among participants in the intervention group (i.e., Group A- Grow Well) using brief surveys to assess mothers' and caregivers' perceptions of and satisfaction with the adapted curriculum. For the Grow Well group, after each in-person session and phone call check-in, the CHWs will provide participants with a QR code to access a brief satisfaction survey that will take about 5 minutes to complete. Appendix *W.* Brief Satisfaction Surveys includes both the survey to assess satisfaction after the in-home session and the survey to assess satisfaction after the phone call check ins. Additionally, at the completion of the intervention, study team members will conduct interviews with 15-20 participants (mothers and caregivers) in the intervention group (i.e., Group A- Grow Well). The interviews will assess perceptions of and satisfaction with the curriculum received. The interview will include open-ended questions about content, format, length, and cultural relevance of the curriculum (see *Appendix R*. Participant Satisfaction Interview). Study team members will conduct the interview by phone or Zoom after completion of the six-month study period. These interviews will be 30-45 minutes, audio recorded, and analyzed using rapid analytic techniques of template and matrix analysis as well as inductive approaches using MAXQDA qualitative analysis software. Participants will receive a gift card of $25 for their time.

References

Thompson AL, Mendez MA, Borja JB, Adair LS, Zimmer CR, Bentley ME. Development and validation of the infant feeding style questionnaire. Appetite. 2009;53(2):210–21

b) If you are using a dataset, please list out the variables you will be accessing. If you are using the Psychology Subject Pool, please list out the pre-screening data you will be collecting on your participants.

(Max ½ page)
NA

21. Deception

a) Does this study involve deception or intentional lack of disclosure?

☐ **Yes** ☒ **No**

b) If YES, justify and indicate how participants will be debriefed. Indicate if participants are free to withdraw or selectively edit data after being fully debriefed. If NO, skip to the next question.

(Max ¼ page)

22. Research Results: If relevant, please describe what information/feedback, if any, will be provided to the subjects and/or communities after their participation in the project is complete. How will they be able to access the information? If relevant, describe the debriefing process.

(Max ¼ page)
Participants will be provided with our project webpage and social media handles (Facebook and Instagram @GrowWell_CrecerBien) where they can access additional information and resources (see A*ppendix S*. Dissemination

Activity Website). We will inform participants that once the study is complete and community reports developed, study results will be shared with the community via the web page and social media platforms. The results will only be shared in aggregate meaning that individual data will not be shared/disseminated.

23. Consent Process - Ensure you are following the UCR Informed Consent Guide. Sample Informed Consent Templates can be found on the ORI Resources page.

a) Describe the process that will be used to obtain informed consent. How will it be recorded? Who will be authorized to conduct the process? Note that it's the quality of the consent that's most important not the format.

(Max ¼ page)

The study program coordinator will review the consent form via phone and obtain verbal consent from all participants prior to the start of data collection for all activities. For all participants partaking in in-person activities, which includes mothers or caregivers opting to complete the survey in person, infant anthropometric measurements either at the CVFC or at mother's home, and/or participation in in-person sessions, we will obtain written informed consent. This will occur at the first baseline data collection (survey or infant anthropometric measurements) or in-person intervention session (for participants randomized to Group A), whichever occurs first. Thus, all mothers (given that infant anthropometric data will be collected in person) will provide written informed consent. However, it is possible that for caregivers randomized to Group B and that choose virtual or phone data collection, we will not obtain written informed consent if in-person activities will take place. Participants will be provided a copy of the consent form via email, text, or hardcopy. The study team member will review the consent form, provide the opportunity for the participant to ask questions, and be made aware that they can stop their participation in the study at any point. Participants will be provided with a copy of the consent form and asked to follow along with the team member who will read out loud each section of the consent form. Participants will be given the opportunity to ask questions prior to providing their verbal consent. This procedure will be used with each participant.

During the consent process participants will be made aware that de-identified data sources including the transcripts of interviews, survey data, and infant anthropometric data will be de-identified. All records that include participants identifiers, such as the tracking files and audio files will be deleted after data collection and analysis. Participants will be informed that they can opt out of the study at any point during the 24-week study period and request for their data to not be included in the research. All participants will receive a study identification number to maintain confidentiality and privacy for all data collected. All data will be kept in a password-protected folder on the SOM secure server; once the data have been analyzed any records will be deleted (see Appendix T. Randomized Controlled Trial Consent – Mothers and Appendix U. Randomized Controlled Trial – Caregivers).

For mothers and caregivers in the intervention group (Group A- Grow Well), they will be given the option to opt into the satisfaction one-on-one interview and will be asked to provide their verbal consent (see Appendix Z. Consent – Participant Satisfaction Interview).

For the CHWs and healthcare staff in the one-on-one feasibility interviews they will be asked to provide their verbal consent (see *Appendix V*. Feasibility Consent - Community Health Workers and Healthcare Staff).

b) If you are applying for a waiver of documented consent (e.g., verbal, online, etc.) or a waiver or alteration of the consent process (e.g., not obtaining consent at all), please explain how you are meeting the conditions for the waiver or alteration as outlined in the UCR informed Consent Guide.

(Max ¼ page)
In addition to written informed consent, we are also requesting a waiver of documented consent for data that will be collected via Zoom or phone. The electronic consent form will be on the Qualtrics platform and will be administered orally to all participants who will also be provided an electronic version of the consent form via the chat in Zoom or if calling into the Zoom platform, we will text or email them the consent form.

24. Will anyone other than the participants provide consent (e.g., parents, guardians, legally authorized representatives, etc.)? Describe the process by which capacity/competency will be assessed.

(Max ¼ page)
Because we will include infants who are approximately 4 months old, the mother enrolled in the study will provide consent for their infants to participate in the study. Specifically, infants will be involved in the collection of anthropometric measurements. If mothers chose not to provide consent for their infants to participate in anthropometric measurements, they will still be able to participate in the study

25. Withdrawal: Where applicable, please describe how participants will be informed of their right to withdraw from the study and outline the procedures that will be followed to allow them to exercise this right. Also, what will happen if data has already collected (e.g. previous data will be kept, all data will be destroyed, etc.)?

(Max ¼ page)
The consent form contains language indicating participants' right to withdraw from the study at any point. During the consent process, participants will be informed that they can opt out of the study at any point during the 24-week intervention study period or during the qualitative interviews (if they opt into this data collection activity) and request for their data to not be included in the research. At the beginning of the study, participants will receive a study identification number that will be linked to the data they provide. We will create a document that includes the participant's name and study ID #. Only select members of the investigative team, including Dr. Cheney (PI), the project coordinator (Arianna Zimmer), and graduate student researcher (Gabriela Ortiz) will have access to this file, which we will store on a password protected file on the UCR SOM server. Once all data collection is complete, we will destroy this file.

Thus, during the consent process, participants will be informed of their right to withdraw from the study at any time both in writing via the consent document and verbally from the consenting study investigator/team member. When reviewing the consent forms, the interviewer will inform participants about the voluntary nature of their participation and their right to withdraw from the study at any point during the research. The study team member will make clear the following: 1) the participant can notify the study investigators/staff of their wish to withdraw and 2) after confirmation of withdrawal; all data collected from the participant will be destroyed and will not be included in study analyses or deliverables. Participants will be able to leave any data collection activity at any time and can withdraw from the study at any point. Withdrawal will not affect their relationship to UCR or partnering healthcare systems such as UCR Health or the CVFC.

All data will be kept in a password-protected folder on the SOM secure server; once the data have been analyzed any records will be deleted.

26. Privacy, Confidentiality & Data

a) Privacy: Where and how will participants be providing information? Are the researchers collecting identifying information (e.g., names, addressed, phone numbers, DOBs, phone numbers, licenses, audio/video recordings, etc.)? If yes, please describe:

(Max ¼ page)
Researchers will obtain participants' contact information, including cell phone and email address, to share information on accessing the Zoom platform and to call participants to schedule and conduct interviews. Postal addresses will also be obtained to mail out participant incentives (e.g., gift cards, welcome gift). Phone numbers, email addresses, and postal addresses will only be used for the purposes of data collection and compensation. The consent forms include an option to opt into future research on the health and wellbeing of Latino and Indigenous Latin American communities. For all those who opt into future research, their names and contact information will be recorded in a separate database only accessible to study team members.

To protect participant information when we collect survey data, we will remove all responses regarding incentive payment (e.g., address to send gift card) and place it on a separate document then delete the information once payment has been sent.

Furthermore, we will transcribe the audio file of the recorded one-on-one using a transcription service, Go Transcript, that will transcribe the audio recordings. After audio files are transcribed, a team member will then listen to the audio recording and review the transcribed document correcting for accuracy. In the correction process, transcripts will be de-identified meaning that names, places, or similar forms of identification will be removed.

Here is Go Transcript's policy for confidentiality/privacy and their protocol for storing data:
Go Transcript (gotranscript.com) has a Non-Disclosure Agreement:

- All transcribers must sign an NDA to assure clients of their secure transcription practices
- Transcriptionists sign job-specific NDAs for certain tasks as required by clients

Privacy and Confidentiality:

- All files are kept on Go Transcript servers only and are encrypted while sending them over the internet
- All files are cut into small parts of 5-10 mins. The whole file cannot be obtained by the same transcriptionist, no one will work on more than 1 part of the same file
- Actions of transcriptionists are always monitored
- After the transcription is complete, the file will be deleted off their system

b) Confidentiality: Describe the procedures used to protect the confidentiality of participants. If not relevant, describe any limitations to protecting the confidentiality of participants whether due to the law or method used (e.g., confidentiality is not appropriate). For storage of electronic identifiable information outside of a secure server environment, UCR requires the use of encryption software.

(Max ¼ page)
We will collect identifying information, including name, contact information, and address to distribute gift cards to participants. Name and contact information will be linked to a study identifying number (SIN) and stored on a password protected file. The SIN will be linked to pretest and posttest data, anthropometric body measurements, and qualitative interviews. The SIN will not be linked to any identifiers to protect participant confidentiality.

c) Data: Where will the data be stored and for how long? Who will have access to identifying information and for what reason?

(Max ¼ page)
Any data with identifiers such as tracking files will be stored until all data have been collected and analyzed. Digital copies of files such as survey responses and audio files will be stored in a password protected folder on the UCR School of Medicine secure server. Any data shared with study personnel including responses to socio-demographic

surveys, audio recordings of interviews, transcripts, will be stored on a password protected server accessible only by study personnel listed on the roster. At the end of the study, audio recordings will be deleted, and de-identified transcripts will be kept. Similarly, responses to the socio-demographic survey will be downloaded from Qualtrics as an excel file and the survey will be deleted from the Qualtrics platform. De-identified transcripts will be imported into MAXQDA, a qualitative data analysis software, for analysis purposes. Per NIH Per NIH's Data Management & Sharing Policy, participants will be informed via the consent forms that their data may be used for future research without their additional consent after identifiers have been removed from the data.

27. Possible Risks

a) Please check off all potential risks to participants as individuals or as members of a community or to the researchers that may arise from this research. Please acknowledge risks even if remote or unlikely.

Physical Risks (e.g., bodily contact, administration of substance):	**☒ Yes ☐ No**
Psychological/emotional risks (e.g., feeling uncomfortable or upset):	**☒ Yes ☐ No**
Social risks (e.g., economic, loss of status or reputation):	**☒ Yes ☐ No**
Legal risks (e.g., arrest or subpoena):	**☐ Yes ☒ No**

b) Describe the possible risks and consider the probability and magnitude of possible harms and discomforts. Describe the procedures that will be used to minimize potential risks to participants.

(Max ¼ page)

The focus of the research is on childhood obesity risk reduction and includes providing participants with education about healthy infant feeding practices and communication amongst caregivers. It may be emotionally and psychologically difficult to discuss children's health especially if mothers and caregivers have children or family with childhood obesity, diabetes, and related chronic health conditions. The study team will minimize these risks by creating a safe space for sharing during the delivery of infant nutrition education to mothers and caregivers. We will do this by informing participants that they do not have to answer any questions that might be uncomfortable. We will also let them know that we can take a break if they need to calm themselves, or that we can switch to a different, less difficult/uncomfortable topic.

This study includes infant anthropometric measurements. Obtaining infant height, weight, and percent fat using a caliber, can be uncomfortable for infants and they may cry. We will reduce this risk by training our team to collect these data as well as be mindful of infants' distress and stop data collection if infants are unable to stop crying. Additionally, a possible risk is breach of confidentiality as complete confidentiality cannot be guaranteed and its possible that participants may experience social risks, specifically loss of a day's wages. Many of the participants in our study are from farm working communities and often work on the weekends. We have purposefully decided to conduct research on Saturdays as people are less likely to work during the weekend than the weekdays. However, it is possible that participants may need to work during the time of the clinic. If this is the case, we will offer the option of a team member coming to the participant's home when it's convenient to them. If they then chose to bring their infant to the clinic it will be their decision.

A psychological/emotional risk of the study for mothers is regarding their postpartum mental health. There is a question on the pretest survey about self-harm. The specific question is: "The thought of harming myself has occurred to me." If the mother indicates "yes, quite often" or "sometimes" the interviewer will refer to the script on Appendix Y. The interviewer will follow the script to either connect the mother to the national suicide and crisis

lifeline- 988, and provide the resources with the mother and indicate mental health care services in the Inland Southern California region and check back in or pause to provide the mother with the mental health resources and then continue the interview.

28. Possible Benefits

a) Describe possible direct benefits to participants. If there are no direct benefits, please state so. Please note that compensation is not a benefit.

(Max ¼ page)
Participants may gain knowledge about healthy infant, child, and family eating, physical activity, and lifestyle changes. There may be potential benefit to others as there will be knowledge gained from participation in this program that participants can share with others in their family and community. Also, the information collected will help inform changes to improve early childhood obesity prevention programing.

b) Describe possible benefits to communities, society, or scientific knowledge in general.

(Max ¼ page)
This research has potential benefits for Latinx and Indigenous Latin American individuals, families, and communities as it can increase knowledge of chronic health conditions, especially early childhood obesity, and offer strategies to mitigate risk ultimately reducing disease burden.

29. The US research regulations define '*Minimal Risk*' as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. (45 CFR 46 & 21 CFR 50)

a) Do you believe your proposed research activities meet the above definition of *'Minimal Risk'*?
☒ Yes ☐ No

b) If yes, please elaborate by engaging your particular IRB proposal with the definition above.

(Max ¼ page)
This research does not require participants to share information that would create more distress than what is encountered in daily life or routine use of healthcare services.

****Final decision of whether an IRB application is minimal risk or higher is up to the IRB****

c) 30. Provide a list of appendices here for all additional materials submitted with this IRB application (e.g., Appendix A – Informed Consent; Appendix B – Interview Guide; Appendix C – References, Appendix D – Recruitment flyers/materials; Appendix E – Access letters). The list should be in the same order as you append the materials at the end of the document with headers for ease of review and referencing.

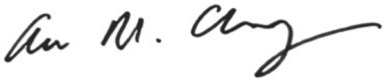
Appendix A. Project Roster
Appendix A1. Training Agendas
Appendix B. Healthcare Systems - Access Letter
Appendix C. Recruitment Script
Appendix D. Recruitment Flyer
Appendix E. Eligibility Screening Tool
Appendix F. Adapted Healthy Beginning Modules 4 to 12 months
Appendix G. Community Health Worker Scripts (In-home sessions and Phone Check ins)
Appendix H. Goal Setting
Appendix I. WhatsApp Posts

Appendix J. Healthy Steps Material
Appendix K. Orientation to Study
Appendix L. Pretest and Posttest Survey for Caregivers
Appendix M. Pretest and Posttest Survey for Mothers
Appendix N. Anthropometric Data Collection
Appendix O. Community Health Workers and Healthcare Staff Interview Guide
Appendix P. Fidelity Checklist-Research Assistant
Appendix Q. Fidelity Checklist- Community Health Worker
Appendix R. Participant Satisfaction Interview
Appendix S. Dissemination Activity Website
Appendix T. Randomized Control Trial Consent- Mother
Appendix U. Randomized Control Trial Consent - Caregiver
Appendix V. Feasibility Consent- Community Health Workers and Healthcare
Appendix W. Brief Satisfaction Surveys (In-home Sessions and Phone Call Check ins with Mother)
Appendix X. Recruitment of Community Health Workers and Healthcare Staff
Appendix Y. Self-harm Protocol and Resources
Appendix Z. Consent – Participant Satisfaction Interview

IV. Signatures

(If you have already provided signatures for this project in a previous application, there is no need to complete this section again. Electronic or scanned signatures are acceptable. Submitting a single picture/screenshot of all the signatures in place is acceptable. Inserting a jpeg of the signature is also acceptable.)

My signature as researcher, confirms that this study has been designed to protect human participants. I am responsible for the scientific and ethical conduct of the research and providing all reports and information to the IRB, as well as other related groups. I further confirm that I am not in violation of UCR's conflict of interest policy while participating in this research. All members of the research team are appropriately credentialed and trained to perform the work undertaken and all the research-related activities. I will provide all continuing review documentation to the IRB.

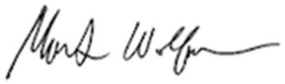


Researcher's signature ___ **_____** **Date: 2/10/23**

My signature as UCR faculty advisor and/or sponsor, confirms that this study has been designed to protect human participants. I have read and approved all aspects of this proposal. As a UCR faculty supervisor, I am ultimately responsible for the scientific and ethical conduct of the research and providing all reports and information to the IRB, as well as other groups. I further confirm that I am not in violation of UCR's conflict of interest policy while participating in this research. All members of the research team are appropriately credentialed and trained to perform the work undertaken and all the research-related activities. I will provide appropriate supervision to the undergraduate / graduate student or postdoc.

UCR Faculty Advisor's / Faculty Sponsor's signature _____ Date: _____

My signature as departmental chair, confirms that I am aware of the project and that it has received appropriate review prior to submission to the IRB. In addition, my administrative unit will follow guidelines and procedures to ensure compliance with all relevant UCR, state, federal govern research involving human participants. My signature also reflects the willingness of the department, faculty or division to administer the research funds, if there are any, in accordance with University policies.
If the chair is the faculty advisor or it is departmental chair's research, the Dean should sign below; if it is Dean's research, no additional signatures are required)

Chair's / Dean's (or designate's) signature  Date: 12/2/2022

IRB application submission instructions:

IRB applications must be submitted via email (irb@ucr.edu) with the required signatures in place. The application should be submitted as a single attachment in PDF or Word format. All the appendices are to be inserted in the single attachment in the order that they are listed in question Q30 with descriptive headers to facilitate cross-referencing and review of the application.

If this application is more than minimal risk, please note the submission deadlines for IRB meetings on our website. Ultimately, the IRB may choose to escalate an application for full board review if it deems the level of risk to be more than minimal. While this is a subjective assessment, it is not a haphazard one. For additional guidance and assistance, please visit the ORI IRB FAQ's and Resources pages.

For student/trainee or UCR-faculty sponsored IRB applications, all 3 signatures are required (student/trainee + UCR faculty + chair). For faculty research, only two are required (faculty + chair).