North Texas Regional Institutional Review Board (IRB)

University of North Texas Health Science Center

Protocol Synopsis for Research Project Involving Human Subjects

PROTOCOL INFORMATION

Title of Research Activity: *Evaluating Providing Feeding Advice via Text Messaging in Primary Care to Prevent Onset of Early Pediatric Obesity* ***(Baby Bites Texting Project)***

Name of Principal Investigator: Nusrath Habiba, MD

Institution: UNTHSC

Names of each Co-Investigator: Paul Bowman, MD, Kathleen Davis, PhD, Marilyn Massey-Stokes, EdD

Sponsoring Agency / Company (if applicable): NA

Sponsor's Protocol Number (if applicable): NA

A. Specific Aims –

Pediatric overweight and obesity are conditions which may have onset in very early life. One study indicates that the median age of onset of pediatric overweight is 15 months or less.[1] In addition, increasing growth channels in the first six months of life is associated with higher rates of obesity at five years.[2] Thus, targeting obesity-preventive feeding practices in the first year of life is important to prevent early obesity. Preventing early obesity will help to achieve one of the Healthy People 2020 objectives, which is to "reduce the proportion of children aged 2 to 5 years who are considered obese".[3] Yet limited research on early obesity prevention programs is available.[4-14] Promising practices include longer duration of breastfeeding, avoiding introduction of sugar-sweetened beverages (SSBs), promoting appropriate transitions to first foods, and responsive feeding.[15-23] Currently, healthcare providers often provide handouts at well visits with copious information on feeding, safety, abuse prevention, and more. This information is well intended but easily ignored. Text messaging is an emerging method of providing health prevention advice in an easily accessible format. Without efficacious, cost-effective methods to prevent early obesity, rates can be expected to stay high, increasing the burden of obesity-related disease.

Our long-term *goal* is to identify best practices to prevent early pediatric obesity. The overall ***objective*** of this proposal is to test the efficacy of a text-messaging program to provide parental feeding advice on feeding practices and weight-for-length z scores. Our central *hypothesis* is that targeted, text messages will be an effective tool to promote heathy feeding practices among parents. Our program will be based on the Health Belief Model[24]. In particular, the text messages will be constructed to promote motivation for behavior change by influencing perceived susceptibility to the risk of early obesity, demonstrating to parents the benefits of long breastfeeding duration and healthy feeding practices, reducing perceived barriers to adopt healthy feeding practices, providing cues to adopt healthy feeding behaviors, and providing practical tips for adopting behaviors to improve self-efficacy related to healthy feeding practices.

Aim: Compare the impact of targeted text messages versus usual care on feeding practices of parents of infants at 2-4, 6-9 months, and 12 months and on infant weight-for-length z scores at 6-9 and 12

months. *Hypothesis:* Text messages will be more effective at generating obesity-preventive feeding practices and normal weight-for-length z scores compared to usual care.

B. Background and Significance –

Childhood obesity poses a great risk to the health of US children and adults because it is associated with increased risk for health problems including hyperlipidemia, diabetes, hypertension, and fatty liver disease.[25-35] Rapid weight gain in infancy is associated with obesity in both children and adults.[20, 36-41] Factors known to be related to early rapid weight gain and obesity include parental obesity, birth weight, early cessation of breastfeeding, and early introduction of solids.[1-2, 4-23] Since birth weight is non-modifiable, encouraging adoption of hypothesized obesity-protective parental feeding practices such as breastfeeding, avoiding SSBs, appropriate introduction of first foods, and responsive feeding is essential. [15-22] Motivating parents to modify these early childhood feeding practices will promote achievement of one of the Healthy People 2020 objectives: to reduce obesity in children ages 2 to 5.[3]

Parents may seek feeding advice from healthcare providers, but the most frequent source of advice is other parents, including family members, friends, or parents on social media.[42-43] Reliance on family and friends is related to the perception that the provider may not be empathetic or the advice may not be practical.[42-43] Limited provider time during well child check-ups may contribute to this perception. In a typical 15-minute visit, the provider must examine the child, discuss his growth, relay important safety information, provide immunizations, and address parenting concerns, leaving little time to discuss feeding. However, because parents visit their child's healthcare provider frequently during the first two years of life, this is a logical place to for the healthcare provider to touch the greatest number of infants across all socioeconomic groups by providing information to parents regarding healthy feeding practices.

Several recent studies have addressed preventing early obesity through well child group visits, home visits, handouts, and posters; however, there is little consistency between studies regarding method, length, and intensity of intervention.[4-14] Several studies have lacked grounding in health behavior theories.[4-6, 9] Improved outcomes have included feeding practices in two studies[7, 12] and slightly lower weight-for-length z scores in some.[5, 9-12] Nevertheless, there is still a pressing need for lower cost, lower labor prevention methods that are theoretically-based.

Mobile health (mHealth) presents an opportunity to provide just-in-time, targeted information to parents. Research forays into mHealth are expanding and have addressed diverse health issues but have varied in efficacy and have often lacked supportive theory.[44-48] Text4Baby, a national mHealth initiative established in 2010 through a government-corporate partnership, has a broad infant health focus, including infant safety, with little focus on feeding practices. It has yet to release rigorous analysis of data and was not established with research in mind.[49] Another mHealth project targeting feeding behaviors with the goal of preventing early obesity has been initiated in Australia; however, its findings have not yet been released, and the population targeted in Australia is substantially different than the US population.[50] Finally, another mHealth initiative targeting feeding behaviors with the goal of preventing early obesity has been developed by an infant formula company. It is supported by health behavior theory but formative research or pilot testing was not done prior to deployment.[51] Text-messaging to prevent obesity has yet to be studied within a well-child primary care setting in the US. However, mHealth breastfeeding promotion efforts have been shown to improve breastfeeding rates, [52] thus there is promise in using this method to change infant feeding practices.

The investigators propose to conduct a pilot randomized controlled trial (RCT) to compare the efficacy of targeted text messages to usual primary care to prevent early pediatric obesity. Text messaging is a highly feasible and relatively inexpensive intervention, which if found to be effective, could be widely implemented. This project also has the potential to justify and guide the integration of technology into pediatric primary care.

C. Preliminary Studies - A focus group was conducted with the target population in the UNTHSC Pediatric Clinic to better understand what parents of infants think about breastfeeding, formula feeding, introduction of solids, causes of early obesity, and text messaging as a form of communication with their infant's healthcare provider. The focus groups revealed that parents were receptive to receiving text messages about feeding from their child's healthcare provider, and the qualitative data was used to identify common themes regarding feeding infants that were important to parents. Parents discussed their attitudes about and benefits and barriers related to both breastfeeding and formula feeding. They also discussed their attitudes towards when and how to introduce solid foods and when and how to introduce sugary foods and beverages. They often mentioned parental fault in not understanding when their baby was hungry and overfeeding as a cause of early obesity, along with feeding the "wrong" foods. Based on a review of the literature and focus group results that revealed important information related to constructs of the Health Belief Model[24] (HBM), the HBM was chosen as a theoretical basis for this text-messaging intervention.

Furthermore, a preliminary analysis of a text-messaging survey completed by parents of infants revealed that framing of the messages (loss-framed versus gain-framed) did not differentially affect the positive view of the message except for messages relating to benefits of breastfeeding and those relating to self-efficacy. For messages representing these constructs of HBM, gain-framed messages were viewed more positively. Framing did not impact their perceived likelihood of adopting the desired behavior, regardless of the message's positivity score. In addition, it showed that 41% of participants preferred receiving messages once a week, 19% preferred a greater frequency, and 16% did not have a preference. The majority of participants (47%) preferred to receive text messages in the morning. Nineteen percent did not have a preference.

D. Investigator Experience - Dr. Habiba is an experienced pediatrician and Associate Professor in the Department of Pediatrics at the University of North Texas Health Science Center (UNTHSC) with ample research interest and background in investigating obesity and type 2 diabetes in children. She has conducted several clinical trials and research studies involving children, has published in peer reviewed journals Thus, she is experienced with conducting research in a clinical setting. She will be collaborating with Dr. Paul Bowman, Chair and Professor of Pediatrics, UNTHSC and two researchers from Texas Woman's University (TWU)—Drs. Kathleen Davis and Marilyn Massey-Stokes. Dr. Bowman has about 40 years of clinical and research experience and has published about 100 articles in peer reviewed journals. Dr. Davis has a long background as a pediatric dietitian and has worked with parents of infants providing counseling and advice for over 17 years. She also has past experience conducting survey-based research. Dr. Massey-Stokes is a Certified Health Education Specialist and a Certified Health and Wellness Coach who has over 28 years of experience in health education and health promotion, including presentations and publications on child and adolescent health. Dr. Massey-Stokes also has experience conducting both quantitative and qualitative research. Drs. Davis and Massey-Stokes will be working with experts in research methods from the Center for Research Design and Analysis at TWU.

E. Experimental Design and Methods -

1) *Methods and Procedures* - Thirty to 40 parent/infant dyads/triads of infants aged 3-30 days (15 to 20 parent/infant dyads in each group) will be recruited from the UNTHSC Pediatric Clinic.

Parents will be screened to be sure they qualify to participate in the study (See attached Screening Form). Parent(s) will read, have the opportunity to ask questions about, and sign the informed consent form and the HIPPA Authorization Form. Each parent who agrees to participate will complete a Participant Information Form with information about their own height, weight, age, race/ethnicity, primary language, and family history. They will also provide the phone number to their mobile device on the data collection sheet, their child's date of birth, and indicate if they will be answering the surveys since only one parent will be permitted to answer the surveys. To participate, at least one parent must agree to answer the surveys. Then, the participants will be randomized to one of the following groups: feeding text messaging or usual care with safety text messaging. A computer-generated blocked randomization schedule with balanced distribution with regards to sex will be used to place

infants into groups. This stratified allocation will be concealed in opaque, sequentially-numbered sealed envelopes, and opened by study staff. While parents recruited may vary in weight status, income, and race/ethnicity, in a pediatric primary care setting randomizing participants into groups based on these multiple criteria, which are not gathered on parents of patients would be burdensome for clinic staff. Thus, parent participants will be randomized into each study group (usual care or text-messaging) based only on sex of the infant.

After research staff know the group assignment, they will enroll parents into the study using the child's date of birth and the parents' mobile phone numbers. See the figure below for the sequence of enrollment events.

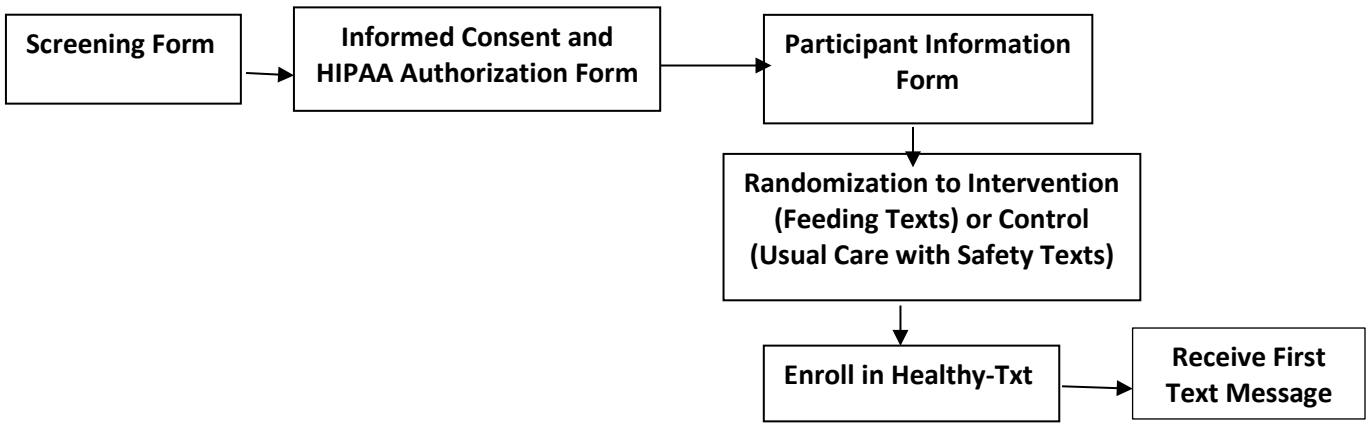

Figure 1: Flow and Sequence of Enrollment Events

Both groups of participants will receive an initial text message. Then, they will receive minimally-customized, motivational text messages[54] up to two to four times per week[55] during their first 12 months of life. These messages will be free of charge except for any potential carrier message and data rates. During the infant's first weeks of life, frequency may be higher (up to four times in the infant's first four weeks of life) and then decrease to once per week as the infant gets older. Intervention participants will receive text messages with feeding advice and handouts provided to all clinic patients with feeding and general infant safety advice. Control, usual care participants will receive handouts with feeding and general infant health and safety advice and text messages with general infant health and safety advice. The schedule for sending texts is noted in the attached Excel files containing feeding and safety information. The schedule for distributing handouts with both feeding advice and general infant health and safety advice is noted below, and the handouts are included as attachments.

Intervention and Control Participants

Days/Months	Handout-Feeding and Safety Advice
3-30 days **(2-5 days and 1 month visits)**	**A.Inf.PH.2-5day** **A.Inf.PH.1month**
2-4 months **(2 and 4 month visits)**	**A.Inf.PH.2month** **A.Inf.PH.4month**
6-9 months **(6 and 9 month visits)**	**A.Inf.PH.6month** **A.Inf.PH.9month**
12 months	**A.Inf.PH.12month**

Parents will have the opportunity to opt out of the messages by replying "STOP" at any time. Opting out will be viewed as non-participation. Short (less than 160 character) text messages will be provided at scheduled intervals. Parents who indicate their infant will be breastfeeding will receive messages aimed at supporting breastfeeding. Parents who indicate their infant is receiving formula will receive messages aimed at supporting appropriate formula feeding. When babies/parents are ready to start solids, the parents will text "solids" to 41411 to begin receiving messages pertaining to feeding their baby solids. Messages will offer motivational, gain- or loss- framed, feeding-related messages, which will not convey information regarding past, present or future medical conditions or care. Some messages will contain links to a parent landing page (Web page), where parents may read content with more information on feeding advice. The landing pages will also contain links to appropriate external web pages with additional information or videos related to feeding and infant nutrition care. The text messages will be delivered using a service called Healthy-Txt, which is in use in other pediatric primary care settings (such as UCLA) to provide appointment reminders and other messaging.[56] TWU nutrition and health studies professors, UNT-HSC pediatricians, nutrition graduate students, and a TWU communications professor specializing in feeding assisted with development of the text-messaging content and Web landing page materials. Participants will not be able to respond to texts. Participants will receive a text with the first text in each group to "Remember to call 911 in a medical emergency".

Texas Health Steps is the recommended schedule for well visits with a pediatric healthcare provider for patients enrolled in Texas Medicaid. The following visits are recommended: 3-5 days, 2 weeks, 2 months, 4 months, 6 months, 9 months, 12 months, 15 months, 18 months, and 2 years. Insurance companies allow well visits at the same interval. Not all parents are able to bring children according to this precise schedule; thus, slightly flexible age ranges will be used for each data collection. The project proposes to gather data from both groups of parents only between 3-30 days, 2-4 months, 6-9 months, and 12 months so that parents who miss attending one of the scheduled visits can be caught at the next one. To track feeding practices, at the 0-30 day, 2-4 month, 6-9 month, and 12 month visits, parents will be given a link to answer questions in a mobile survey in PsychData adapted from the National Health and Nutrition Examination Survey Diet Behavior Nutrition Questionnaire[57] with additional questions on responsive feeding practices from the Infant Feeding Style Questionnaire (IFSQ)[58-59]. This link will also be sent by text if the survey is not filled out at the scheduled visit. To track actual intake, one of the research staff will call parents of infants between 2-4 months, 6-9 months, and at 12 months to conduct a 24-hour recall of the infant's intake. The Healthy-Txt messaging system captures only the data specified by the research protocol. For this study, Healthy-Txt will gather data on whether participants opt out of participation, responses to yes or no questions in the text messages, and whether participants access landing page information. This data is linked to the participants' (parent's) mobile phone number. Finally, a chart review of each participating infant's chart (part of the participating parent/infant dyad) will be conducted by one of the research staff employed at the UNTHSC pediatric clinic. The research staff will keep a master list of the infant's medical record number (MRN) and a randomly assigned participant ID number. They will use this master list to collect the following data from the infant's chart: age, weight, and height at 0-30 days, 2-4 month visit, 6-9 month visit, 12 month visit.

If participants do not complete feeding surveys, a single reminder text will be sent from a Google phone number belonging to one of TWU collaborators (405-771-6542). The text will state "Thank you for participating in the Baby Bites Texting Project! We hope you are happy with your text messages. Please remember to fill out all surveys (just 4 over the study) to receive all incentives. Here is a link to fill one out: https://bit.ly/2yWIxju." If you are receiving messages about feeding and need to switch message groups (move into the formula group or start the solids group of messages), please contact KDavis10@twu.edu or respond to this text."

2) *Data Analysis and Data Monitoring* - Surveys will be administered on-line on the parents' own mobile devices using a program called Psych Data, which is in compliance with IRB requirements. Each participant will receive a unique respondent ID number. Each survey will be proceeded by a research statement. Data on demographics, language spoken, and other personal information on the participants will be collected, stored, and accessed separately and then linked using secure methods. In addition, survey pages cannot be viewed by clicking the "back" button so that someone else using the participant's mobile device cannot read their answers. All surveys are placed in a Secure Survey Environment to ensure that they are not retrievable. They are encrypted using 256-bit SSL technology

to encrypt both the questions and the responses. Data is stored on a secure server, and the researcher has full control over the data.

The information on the infant's age, weight, and height gathered from the electronic medical record (EMR) will be stored in a spreadsheet together with the randomly assigned participant ID number. No identifying information will be stored together with the MRN on the master list. The master list will be stored on a secure drive in the UNTHSC department of pediatrics. Only the PI, and the research coordinator will have access to the master list. The de-identified spreadsheet with the infant age, height, and weight data will be shared with the TWU collaborators and research staff for analysis. Information from the 24-hour recall will be recorded on a data collection form with only the randomly assigned participant ID number and when analyzed will be stored in a spreadsheet with only the randomly assigned participant ID number. The co-investigators, together with Dr. Habiba, will be responsible for analyzing the data with assistance from statisticians in the Center for Research Design and Analysis at Texas Woman's University.

Descriptive statistics will be used to describe mean, median, standard deviation, and range for all continuous variables in each group. Frequency and percentage will be calculated to demonstrate categorical variables in each group. Then, independent t tests will be conducted to compare continuous demographic variables between the two groups, and cross-tabulation using chi-square test will be used to compare categorical demographics between the two groups. The relationships between demographic variables and baseline outcomes will also be examined to identify whether any demographic variables need to be controlled for in the primary analyses. In addition, feeding practices will be compared between the two groups using repeated measures analysis of variance (ANOVA) or repeated measures analysis of covariance (ANCOVA). All data will be analyzed using IBM SPSS, version 25, and a $P<0.05$ is considered significant. The number of participants in part two was determined using a moderate effect size (f=0.25) with 0.8 power to detect a difference between the two groups. With repeated measures ANOVA (2 groups x 3 time points), a total of 37 participants including a 30% drop out rate were required for adequate power.

3) *Data Storage and Confidentiality* – Research data, in hard copy or electronic form (CD, flash memory drive), will be stored and managed in a secure manner according to NIH guidelines as well as state and institutional policies and practices. Further, research documents, including electronic documents containing subject data, identifiers, and linked data, will be securely stored on a password-protected computer and in locked containers (file cabinets, lockers, drawers, etc.) in accordance with standard document management practices. At all times, only listed key personnel specifically designated and authorized by the Principal Investigator shall have access to any research-related documents. All such personnel will be properly trained and supervised regarding the management and handling of confidential materials. The Principal Investigator will assume full responsibility for such training, supervision and conduct.

   Surveys on PsychData are encrypted using 256-bit SSL Technology. This encrypts both the questions displayed and the participants' responses. All responses are automatically encrypted. Though highly unlikely, if interception of encrypted data occurs, the data cannot be encoded without the unique encryption key only held by PsychData. Data will be stored on PsychData secure server. It is then held in an isolated database that is only accessible by a researcher with the correct username and password. The researcher has control over all data recorded.

   Data gathered by Healthy-Txt on whether participants opt out of participation, responses to yes or no questions in the text messages, and whether participants access landing page information will be linked to the participants' mobile phone number. All Healthy-Txt data is stored on a secure server compliant with HIPAA guidelines.

4) *Setting* - The survey will be completed during in-office visits. Parents will be able to complete on-line, mobile surveys before, during, or after their appointment. This link will also be sent by text if the survey

is not filled out at the scheduled visit. Phone calls to patients' parents will also be made to collect 24-hour recalls of diet. Weight and length of infants will be collected using chart reviews of the infants whose parents participate in the study. Parents will receive text messages in their own locations using their own mobile devices.

Texas Woman's University's IRB will rely on the North Texas Regional IRB and will sign an Institutional Authorization Agreement upon approval of the study by the North Texas Regional IRB . (Sandy Owens, IRB Coordinator, irb@twu.edu; (940-898-3378)

5) *Laboratory methods and facilities* - N/A

6) *Estimated Period of Time to Complete the Study* –

Task	**Year 1** **(September 30, 2018-August 31, 2019)** **Quarters (3-months)**				**Year 2** **September 30, 2019-February 28, 2020** **Quarters (3-months)**	
	9/30-11/30	**12/1-2/28**	**3/1-5/31**	**6/1-8/31**	**9/1-11/30**	**12/1-2/28**
Participant Recruitment	X					
Data Collection	X	X	X	X	X	
Data Analysis		X	X	X	X	
Manuscript Preparation						X

F. Human Subjects - Describe the characteristics of the research population:

1) *Sample Size*: 30-40 parent/infant dyads. Both parents may participate and receive separate text messages, but one compensation item will be provided per family.

2) Describe both *Inclusion / Exclusion Criteria*.
Inclusion criteria will be:
   - Parents with age 18 and older. We don't include parents younger than 18 because it is suspected that their concerns regarding feeding and sources of feeding advice may be different compared to adult parents.
   - Healthy and term infants (born at 37 weeks or later) establishing care with the healthcare provider between 3-30 days of life and their infants (Parent/infant dyads).

- Parents must be able to speak and read English well. All researchers speak only English, thus we would like to pilot this in an English-speaking population first to make sure the messages are well crafted.
- Parents must have a mobile phone that can receive text messages and access the Internet.

Exclusion criteria will include:

- Infants with congenital anomalies, genetic disorders, or who develop failure-to-thrive during the intervention

3) Describe intended *gender, age range, intended racial and ethnic distribution*.
Both fathers and mothers are sought for participation. However, only one parent may fill out the questionnaires and will receive incentives for their participation. Participants must be adult parents of infants, but there is no upper age limit for participation. Because of the make-up of the clinic population, it is thought that about half of participants will be Hispanic to reflect the clinic population.
4) Identify the *source(s) from which you will obtain your study population*. All participants will be parents of infants and their infants attending the UNT-HSC Pediatric Clinic.

5) Describe plans for *recruitment of subjects*. Parents will be recruited during the first few in-office visits with their infant's healthcare provider. One of the students or the Research Coordinator will visit with interested parents, explain the consent form, answer questions about the study, and get consent. Those participants who decide to participate will be randomized into the control or intervention group at that time. They will fill out a basic information form including their cell phone numbers so that they may begin receiving text messages.

G. Risk/Benefit Assessment

1) This is a minimal risk project that involves providing basic information about feeding to parents of infants either through handout (control group) or text message (intervention group) and basic information about infant safety through text message (control group) or handout (intervention group). There is no direct benefit of participation to subjects other than a possible gain in knowledge and awareness about early nutrition, infant feeding practices (intervention), and infant health and safety guidelines (control).

2) Because the study is expected to provide useful information to parents of infants in a format that is convenient and acceptable to them, the minimal risk is considered acceptable.

3) This method of conducting research is at least as favorable as that provided by providing handouts because it is convenient. In preliminary research involving focus groups, all parents participating reported being willing to receive text messages with feeding advice.

4) Describe any potential RISKS OR DISCOMFORTS in detail.
There is a potential financial risk because carrier message and data rates may apply. Participants will be advised of this risk but will also be receiving incentives to help compensate for any potential financial risk.
There is an informational risk associated with participation due to possible breach of confidentiality or loss of privacy. To prevent loss of confidentiality each participant completing the survey through PsychData will receive a unique respondent ID number. Data on demographics, language spoken, and other personal information on the participants will be collected, stored, and accessed separately and then linked using secure methods. The information on the infant's age, weight, and height gathered from the electronic medical record (EMR) will be stored in a spreadsheet together with the randomly assigned participant ID number. No identifying information will be stored together with the MRN on the master list. The master list will be stored on a secure drive in the UNTHSC department of pediatrics. Only the PI and the research coordinator assigned to the project will have access to the master list. The de-identified spreadsheet with the infant age, height, and weight data will be shared with the TWU collaborators and research staff for analysis. Information from the 24-hour recall will be recorded on a data collection form with only the randomly assigned participant ID number and when analyzed will be stored in a

spreadsheet with only the randomly assigned participant ID number. Data being analyzed by the researchers at UNTHSC or TWU will be a de-identified set of data.
There is also an emotional risk associated with survey completion if evaluating text messages provokes an unwanted, emotional response. At the beginning of the survey, participants will be notified that they may exit the survey at any time without penalty. On the last page of the survey, participants will be advised to contact the co-investigator if they have problems, and they will also be given a link to click which will include resources if they need assistance with an emotional response.
There is a risk of loss of time. Reading text messages is voluntary, even for parents who have agreed to participate. Time spent in this activity is up to the discretion of the participants and will likely be useful to those parents who decide to spend time in this way. Time spent completing surveys will be kept as minimal as possible to achieve the stated research goals. Parents will be able to complete them using their mobile devices during their child's healthcare visit or afterwards if needed at their convenience. Participants will be compensated for their time and effort.

There is a risk that participants will feel coerced into participating in the researcher because of the recruitment flyer being provided by the healthcare provider or research coordinator. Participants will be advised at the beginning of the study and throughout the study that they are not required to participate, may discontinue participating at any time, and that their infant's medical care will not change in any way based on their participation or non-participation.

H. Payment/Compensation - Participants in the study will be entitled to receive $20 Wal-Mart gift cards to compensate for their time and effort and a potential risk of message and data rates. They will receive one gift card at six months and another at 12 months when the study is complete. They will also receive infant feeding supplies such as spoons, bibs, and bowls.

I. Subject Costs - Time: participants will be compensated for their time and effort. Transportation: Participants will not need to come to clinic more frequently than their infant's regular healthcare visits. Text messages will be provided free of charge.

J. List of KEY PERSONNEL.

Nusrath Habiba, MD, Primary Investigator (UNTHSC)
Paul Bowman, MD, Co-Investigator (UNTHSC)
Kathleen Davis, PhD, Co-Investigator (TWU)
Marilyn Massey-Stokes, EdD, Co-Investigator (TWU)
Leah Zimmerman, Study Coordinator (UNTHSC)
Madhavi Kaluva, student graduate research assistant (TWU)
Meredith Mannix, undergraduate student researcher (TWU)
Kerry Le, undergraduate student researcher (TWU)

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Attachments (in this order):

I. Consent Form - THE CONSENT FORM IS TO BE A SEPARATE DOCUMENT. It is important that this form follows the IRB-prescribed format and includes all the required elements and certain other elements when appropriate.

II. Recruitment Materials (ads, flyers, emails, etc.) to be used in this Study

III. Study Documents (questionnaires, survey instruments, clinical trial protocol, investigator's brochure, etc.)

IV. Evidence of Human Subject Training for ALL Key Personnel listed in the protocol.

V. Conflict of Interest Form, completed and signed by EACH Key personnel listed in the protocol.