Project Title: Developing a Text-Message Enhanced Physical Activity Intervention for Latino Men

NCT Number: NCT02512419

Contents:

1) **Research Protocol:**
Please note, that the date on the research protocol is the latest version of that form that the UCSD IRB has. The date is generic to the template version, not specific to the submission or approval date. That protocol was approved on the most recent date of 7/27/18.
2) **UCSD IRB Approval**
Most recent approval date: 7/27/18
3) **Statistical Analysis Plan**

UCSD Human Research Protections Program
New Biomedical Application
RESEARCH PLAN

Instructions for completing the Research Plan are available on the HRPP website.
The headings on this set of instructions correspond to the headings of the Research Plan.
General Instructions: Enter a response for all topic headings.
Enter "Not Applicable" rather than leaving an item blank if the item does not apply to this project.

Version date: 9/30/2013

1. PROJECT TITLE

Developing a Text Message Enhanced Physical Activity Intervention for Latino Men (Activo)

2. PRINCIPAL INVESTIGATOR

Bess Marcus, PhD

3. FACILITIES

Altman Clinical Translational Research Institute (ACTRI), East Campus Office Building (ECOB), Stein Clinical Research Building, Vista Community Clinic, South County Career Center, or off-site UCSD Facility.

4. ESTIMATED DURATION OF THE STUDY

2 Years

5. LAY LANGUAGE SUMMARY OR SYNOPSIS (no more than one paragraph)

The aim of this study is to build upon our tailored print intervention by developing new text-delivered intervention materials to complement our print-based physical activity (PA) intervention. In Phase 1 we will conduct 6 focus groups with Mexican and Mexican American (MA) men to determine content, frequency, and types of text messages desired, and to identify cultural themes to incorporate into existing and new materials. Themes from the focus groups and sample text messages will be presented to a confirmatory focus group panel. Phase 2 will be a 6-month pilot randomized controlled trial with MA men (N=60) to test the text-enhanced, Spanish language, individually tailored PA intervention vs. publicly available, Spanish language health education materials, including information on PA, diet, and stress management. This will be followed by post-intervention qualitative interviews to solicit suggestions for improvements to help further refine the program. The proposed pilot will support a future R01 to establish the efficacy of this multi-media, multi-level PA intervention for MA men.

6. SPECIFIC AIMS

Primary Aims:

1. Aim 1: To conduct the formative research necessary to develop new text message-based materials based on Social Cognitive Theory (SCT) constructs and a resulting text messaging intervention program to complement and enhance our current print-based PA intervention for MA men.

2. Aim 2: To determine the feasibility, acceptability, and preliminary efficacy of the text message enhanced PA intervention for MA men. We hypothesize that those randomized to the text message enhanced PA intervention condition will report greater increases in weekly minutes of PA after six months than those randomized to the health education control condition.

7. BACKGROUND AND SIGNIFICANCE

Back and Significance

The proposed research addresses serious public health concerns (inactivity, health disparities) in a large, rapidly growing population of Mexican and Mexican American (MA) men who are markedly less physically active than men of other ethnicities and suffer from higher prevalence of conditions related to sedentary lifestyle. While this population is clearly in need of physical activity (PA) interventions, to date none have specifically targeted MA men. In fact, the majority of PA interventions for Latinos have exclusively included women and/or are designed around female preferences. The proposed study will address the needs and barriers to PA in MA men by developing text message-delivered intervention materials based on Social Cognitive Theory (SCT) to complement an individually tailored, theory-based print material PA intervention for Spanish speaking MA men. Text messaging could be a particularly effective and appealing channel for increasing PA in this target population as it allows for participant interaction, real-time accountability, and immediate feedback, features which MA men in the demonstration trial of our print intervention specifically requested. Text-based interventions have been shown to improve a number of health behaviors, including PA. A recent review of texting interventions found that they were generally well received and effective in reducing inactivity, weight, and waist circumference, and a meta-analysis found a moderate effect size (g = 0.54) for using mobile devices to increase PA. However, few of these trials targeted underserved populations, and none specifically targeted Latinos. Cell phone ownership is high in Latino adults (86% vs. 84% in non-Latino

Whites), and Latinos are actually the most likely to use mobile phones for text messaging, with 85% reporting regularly sending and receiving texts (compared to 79% of Whites). Thus this is a familiar, convenient channel for delivering new intervention materials. Additionally, as Latinos also face environmental barriers to PA, in the current proposal we will enhance the individually tailored psychosocial print-based materials by developing materials targeting barriers in home and work environments. This multi-media, multi-level approach has potential for broad reach at relatively low cost, which could help reduce health disparities.

Preliminary Studies/Previous Work

Study Team: Dr. Marcus (PI) and colleagues have spent the past 25 years developing and testing empirically supported individually tailored PA interventions (e.g., R011HL64342, R01HL69866). This intervention was culturally and linguistically adapted for Latina women and successfully implemented in this underserved population in two studies (R21NR009864, R01NR011295). We have extensive experience in designing, implementing and evaluating theory-based, culturally-adapted PA interventions for Latinos (Drs. Marcus, Pekmezi, Larsen, Hartman, Nodora), using text messaging for promoting behavior change (Dr. Patrick), environmental influences on PA (Dr. Sallis), recruitment and retention of Latinos (Drs. Marcus, Rojas, Pekmezi, Larsen, Nodora), and statistics (Dr. Dunsiger). See Table 1.

Table 1. Past Studies of Research Team that Directly Relate to the Current Proposal

PI/ Funding: Description	Results
Culturally and linguistically adapting an empirically supported theory-based print PA intervention for Latinas	
Marcus (PI) R21NR009864: 1) 25 cognitive interviews to clarify content of translated/ back translated materials and measures; 2) 6 focus groups on PA barriers for Spanish speaking Latinas (N=34); 3) Pilot RCT of adapted intervention (N = 93 Latinas).	Themes from participant feedback were incorporated into the intervention including: 1) Literacy level; 2) Daily stressors/Negative Mood; 3) Lack of Time; 4) Neighborhood Safety; 5) Lack of Motivation; 6) Partner Support. RCT findings: Mean increase of 130.71 min/week (sd=242.52) from baseline to six months amongst intervention participants compared to 84.92 min/week (sd=118.26) amongst controls.
Marcus (PI) R01NR011295: Ongoing RCT to test the efficacy of the culturally/ linguistically adapted, individually tailored print intervention for Latinas (N=268).	82% speak only Spanish or more Spanish than English at home. Six month findings indicate significantly greater increases in at least moderate intensity PA from baseline to 6 months (M=71.66 min/week, sd=89.92) for Intervention vs. Control (M=29.58 min/week, sd=84.37), p<.01.
Preliminary efforts to identify and address the specific PA intervention needs and preferences of MA men	
Marcus (PI) UCSD Intramural funds: Individual interviews with Spanish speaking MA men (N=10) about PA intervention needs and preferences.	Culturally-specific themes included 1) Importance of family, 2) Gender roles ("Machismo"), 3) Demanding and irregular work schedules, 4) Preference for team sports, 5) Cultural norms, 6) Preference for Spanish language, and 7) A need for accountability.[15] Intervention was adapted in response to feedback. See Appendix H for full details of cultural modifications.
Marcus (PI) UCSD Intramural funds: Single arm demonstration trial of the resulting, tailored theory-based print PA intervention for Spanish-speaking MA men (N=10) followed by individual interviews.	100% retention and significant increase in PA at 3 months (mean increase =124.20 min/week, sd=154.86, p=0.032). Participants indicated high satisfaction but that participation and motivation could be enhanced by: 1) greater accountability, 2) more contact with staff, 3) shorter and more frequent tips, and 4) real-time updates on PA opportunities. Participants also expressed interest in receiving PA text messages.
Text Message Intervention Studies	
Patrick (PI) R21CA115615: Focus groups to identify quantity/timing of text messages for weight loss intervention in overweight/ obese men & women. RCT to test resulting text message intervention (N=65).	At 4 months, intervention group lost more weight than controls (4.34 pounds more; p=0.02). Adherence to responding to text messages was high. Overall satisfaction with the intervention was also high, with 96% of participants stating that they would recommend the intervention to friends and family.
Patrick (PI) R01CA138730: Ongoing follow-up to R21 using formative research to develop Spanish-language intervention and then conduct a 12-month RCT (N=298).	Focus group feedback was used to develop culturally appropriate text messages for Latinos. Overweight/obese English (n=236) and Spanish (n=62) speakers were randomized to a 3 arm weight loss intervention: text message only, text message plus counseling, or usual care.

8. PROGRESS REPORT

N/A

9. RESEARCH DESIGN AND METHODS

Overall Design: The present study will be conducted in two phases. In **Phase 1** we will conduct formative research to further enhance our empirically supported, theory-based, personally tailored PA print materials by 1) developing interactive and tailored text message PA intervention components to meet the needs and preferences of Spanish-speaking MA men, and 2) incorporating culturally specific themes and creating materials tailored to neighborhood environments. In **Phase 2**, we will conduct a pilot RCT to test the text-enhanced individually tailored PA intervention for MA men vs. a health education control arm.

Phase 1: Formative Research: Our goal with the formative research phase of this study is to inform the development of a text message enhancement to address the concerns of MA men identified in our pilot work, and to incorporate culturally specific themes into text and print intervention materials. Specifically, we plan to build upon our existing theory-based individually tailored intervention by developing interactive and tailored text message intervention materials that address the feedback of the MA men by increasing accountability, providing more frequent contacts, allowing for interactivity between participants, and improving motivation. Focus groups will also be used to determine the most useful features of tailored environmental reports.

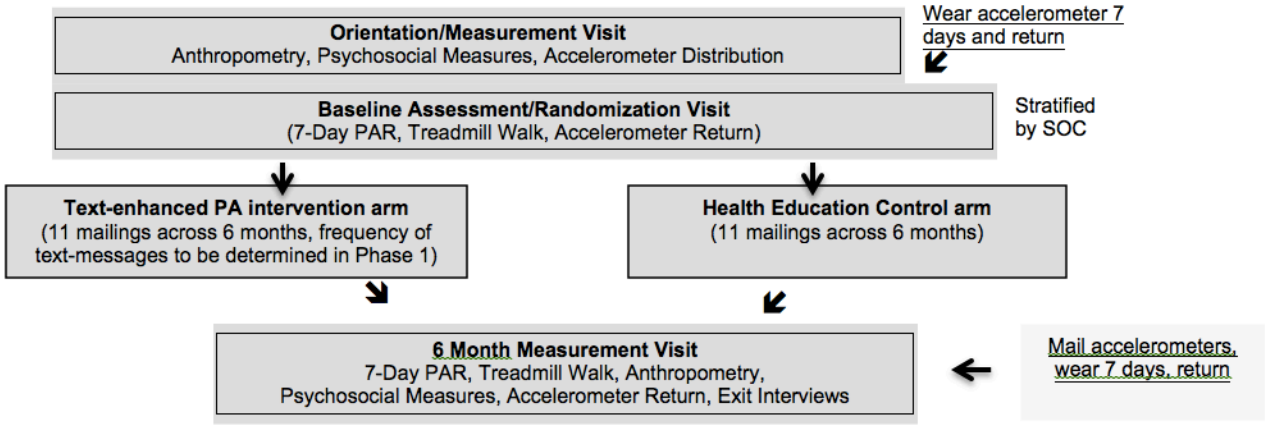
We will conduct 6 focus groups with 6 to 8 MA men per group or one-on-one meetings with a staff member if needed. Eligibility includes: a) self-identified as MA; b) able to speak and read Spanish; c) currently engaging in less than 60 minutes of activity per week; and d) no health-related contraindications for becoming more active including history of coronary heart disease, diabetes, stroke, osteoarthritis, or orthopedic problems (see Phase 2 for further detail). The focus groups will be lead by a bilingual, bicultural researcher; each focus group is expected to last 1 hour.

We will use data from the focus groups to develop the text messaging intervention materials and program and identify cultural themes to incorporate into print and text materials. After the text message enhancement has been developed we will invite a random sub-sample of the men who participated in the focus group to attend a confirmatory panel (n=6). This provides an opportunity to confirm intervention preferences and correct any misunderstandings, as well as allow the participants to further elaborate upon initial focus group responses. Sample text messages will be provided so participants can approve/disapprove any changes and new content.

Qualitative Data Analysis: For qualitative data analysis, all focus groups will be audio taped and translated into English. A content analysis will be conducted to generate themes related to PA intervention needs and preferences of the MA men that will aid in refining the text message enhancement. Bicultural staff members and other investigators, will analyze the transcripts in a two-step process. In the first step, two investigators will read through the transcripts to look for themes that are consistent with prior literature and theory (a deductive process) and gender- and cultural-specific themes that are revealed by the participants themselves to be common across MA men (an inductive process) to develop a set of codes/labels and definitions for the themes. In the second step, two investigators will use this set of codes to label each statement within the transcripts. Transcript coding will be compared between investigators and inconsistencies will be discussed among all investigators until consensus agreement of the appropriate code is achieved. All text and coding will be done with the use of NVivo qualitative software. This content analysis will be used to inform the development of the text-enhanced PA intervention for MA men.

Phase 2: Pilot Randomized Controlled Trial: We will randomize 60 MA men into a 6-month pilot trial of the resulting text-enhanced PA intervention for MA men vs. a health education control. The procedures for recruitment, pre-trial screening, and monitoring derive from our team's experiences conducting similar trials (e. g., R21NR009864, R01NR011295, R01HL64342). See Figure 1. Although it is preferred that participants attend all visits in person, they will be informed during the telephone screening process that modified versions of study visit can be offered via phone in the event that they are not able to travel to the study site.

Figure 1: Phase 2 Randomized Controlled Trial Intervention Schema



Telephone Screening: To reduce the likelihood of adverse events, participants will be phone screened for factors that may increase risk of injury. Potential participants with medical or psychological problems that could make adherence with the study protocol difficult or dangerous will not be included. Exclusions include history of coronary heart disease, history of myocardial infarction, symptoms of angina, type 1 diabetes, uncontrolled hypertension, stroke, osteoarthritis, osteoporosis, orthopedic problems that would limit activity during the following six months, currently engaging in more than 90 minutes of activity per week or any other serious medical condition that would make physical activity unsafe. Other exclusion criteria will include hospitalization due to a psychiatric disorder in the past 3 years, BMI above 45 kg/m2 and/or taking medication that may impair physical activity tolerance or performance (e.g., beta blockers). After screening is completed, eligible and interested participants must agree to be randomly assigned to one of the intervention conditions and provide written consent to participate in the research protocol. In addition, participants will be informed that in the event that they cannot attend an in-person visit at any of our study sites, they will have the option to complete the visit via phone. All in-person visits (including those occurring at our off-site UCSD facilities) will be conducted by our trained study staff. Descriptions of both in-person visits and phone visits are provided below.

In-Person Visits:

Orientation/Measurement Visit: Following telephone screening for eligibility, interested individuals will be asked to attend an in-person orientation session in which a bilingual/bicultural research staff member will provide information about the study. During this session, all questions regarding participation in the study will be answered. Participants will then be asked to read and sign a consent form approved by the university's institutional review board. Participants will also complete anthropometric measures and an initial battery of psychosocial measures during this visit. Self-reported height and weight will be accepted. At the end of this visit, the participant will be given and instructed on how to use an accelerometer during the next seven days.

Baseline/Randomization Visit: One week after the orientations/measurement visit, the participant will return the accelerometer, complete a 10-minute treadmill walk at moderate intensity (3-4 miles per hour) to demonstrate understanding of moderate intensity activity, and complete the 7-Day Physical Activity Recall (PAR). At that time, participants will be randomly assigned to one of two conditions: 1) a text-message enhanced, Spanish language, individually tailored, print-based physical activity intervention; or 2) a Spanish language print-based health education control.

Months 1-6: After randomization, participants will fill out monthly mailed questionnaires for 6 months. Individuals randomized to the physical activity arm will receive individually tailored reports generated by a computer expert system along with messages appropriate for their stage of motivational readiness for physical activity adoption immediately following completion of the questionnaires. Those randomized to the health education control condition will also receive monthly mailed questionnaires and materials on health

topics related to cardiovascular disease, such as nutrition, physical activity, and stress management information. Participants will also be receiving text messages related to exercise or health and wellness depending on their group assignment. The schedule and amount of contact will be the same across conditions.

6 Month Assessment: All participants will be asked to attend an in-person visit at 6 months to recomplete all measures completed during the initial measurement visit and baseline visit.

Telephone Visit:
In the event that participants cannot attend any of our in-person visits, they will have the option to complete the visit via telephone. Details of each of these visits are provided below.

Orientation/Measurement Visit:
Following telephone screening for eligibility, participants will be asked to schedule a phone call visit in which a bilingual/bicultural research staff member will provide information about the study and review the consent documents. Details of the informed consent process via phone are addressed in section 12. Also following the telephone screening, participants will be mailed the UCSD IRB approved informed consent documents along with a battery of psychosocial questionnaires. Once the participants have received the mailings, a phone call with a bilingual/bicultural research staff member will occur where the participants will be provided with information about the study and the staff will review the informed consent documents.

If the participant decides to participate in the program, they will then be asked to sign the consent documents and mail back in a pre-paid envelope that we will provide. Once we have received the signed informed consent documents, a staff member will inform the participants that they can now complete the mailed questionnaires and return them to us. The informed consent documents and questionnaires will be sent in separate envelopes when being mailed, although they will be sent at the same time-point. It will be clearly stated on the questionnaire packet that they are NOT to complete the battery of questionnaires until we have received their signed informed consent document in the mail.

Once we have received the signed informed consent documents and completed psychosocial measures, staff will then schedule another call with the participant to provide additional information regarding the randomization visit as well as instructions on how to use an accelerometer that will be mailed to them. During this phone visit, the following components cannot be conducted: STOHFLA measure and anthropometric measures including height, weight, blood pressure, and bioelectrical impedance analysis. Self-reported height and weight will be collected as an alternative.

Baseline/Randomization Visit: Project staff will mail the accelerometer as well as the materials for the randomization visit. Upon receiving the accelerometer, participants will be asked to wear this device for 7 days and return to us in a provided pre-paid envelope. Once our staff has received this device, they will schedule the phone randomization visit. During the randomization visit participants will complete the 7-Day Physical Activity Recall (PAR) and be randomly assigned to one of two conditions: 1) a text-message enhanced, Spanish language, individually tailored, print-based physical activity intervention; or 2) a Spanish language print-based health education control. During this phone visit the 10-minute treadmill walk cannot be conducted.

6 Month Assessment: Similar to the baseline/randomization visit, in the event that participants cannot attend their in-person visit, they will have the option to complete the visit via phone. During this phone visit, the following components cannot be conducted: the 10-minute treadmill walk and anthropometric measures (as stated above). Self-reported height and weight will again be collected as an alternative.

Treatment Conditions
Text-Enhanced Physical Activity Intervention Arm: The Spanish-language PA intervention is based on SCT and Transtheoretical Model (TTM), and emphasizes behavioral strategies for increasing activity levels (i.e., goal-setting, self-monitoring, problem-solving barriers, increasing social support, rewarding oneself for

meeting PA goals). At baseline participants will receive a pedometer, set a detailed PA goal, problem-solve around barriers to achieving their PA goal, and receive recommendations for walking/jogging routes, parks with athletic equipment and playgrounds, and other places to be active surrounding their work or home. They will receive regular mailings: weekly in month 1, bi-weekly in months 2 and 3, and monthly in months 4 to 6. Mailings consist of: 1) Manual matched to the participant's current level of motivational readiness to change, based on TTM; 2) Individually tailored computerized expert system feedback reports based on the participant's answers to monthly questionnaires (see Measures) that compares participants to their prior responses (progress feedback) and to individuals who are physically active (normative feedback) on: self-efficacy for PA and cognitive and behavioral strategies associated with PA behavior change (processes of change); 3) PA tip sheets addressing PA barriers. These print materials have been modified for MA men based on cultural themes identified during our formative work and trial (e.g. focus on family, team sports, "Machismo," etc.). Participants will also receive the text message intervention that will be developed as part of Phase 1 of this proposal. Based on our previous formative research, reviews of the literature, and theories of behavior change we anticipate using interactive, tailored, and culturally adapted text messages to: 1) increase accountability, 2) help navigate their environment, 3) increase competition, 4) increase motivation, 5) inform about local events, 6) focus on the family, 7) provide social support, and 8) increase the study's connectivity with participants. See Table 3 for proposed text messages, examples of text messages, and how they fit with SCT. Participants will receive $5 per month to defray the costs of the text messages.

Table 3: Types of text messages to be used based on Qualitative Research and Social Cognitive Theory

Social Cognitive Theory Construct	***Intervention needs/ Type of SMS***	***Types of text messages***
Behavioral Capability/ Reinforcement	*Need for Accountability/ Interactive, sent at specified times/days*	*1) Matched to day/time of exercise goal: "Have you exercised yet today? YES/NO";"YES"; "Great job!"* *2) Text message to log/collect info*
Reciprocal determinism	*Built environment/ Tailored information*	*1) Places to be active near their home/work: "There's a great park with a soccer field at 1234 Main St."*
Observational Learning	*Increase Competition/ Group messages*	*1) Highlight success and encourage competition: "Someone reported over 12,000 steps yesterday, can you beat him?"*
Outcome expectations/ Self-efficacy	*Increase motivation through culturally relevant benefits and barriers/ Informational*	*1) Benefits of PA: "Having a rough day? Exercising is a great way to lower stress!"* *2) Address barriers: "Work day seem too busy to be active? Look for places that you could get 10 min in, like during a lunch break"*
Reciprocal determinism	*Local activities/ Group messages*	*1) Text messages about community events: "Fiesta del Sol is this weekend, it's a great place to go walking with the family."*
Observational Learning/ Self-efficacy	*Focus on family/ Activity prompts*	*1) Text messages targeting the family: "Is the family home? Go on a walk together before dinner time!"*
Observational Learning/ Outcome expectations	*Social Support/ Participant Interactive*	*1) Way for participants to communicate with each other through group text messages via the server.*

Health Education Control arm: The health education control arm will receive the publicly available NHBLI Spanish-language booklets on heart-healthy behaviors for Latinos, which include information on PA, diet, and stress management. Similar to intervention participants, control participants will receive tip sheets on related health topics. The health education content was vetted in our individual interviews with MA men who expressed a strong interest in receiving and reading these materials. Mailed contacts for the control group will be on the same schedule as the mailed contacts for the intervention condition (weekly month 1, bi-weekly months 2 and 3, and monthly months 4 to 6). Participants in the health education control arm will also complete monthly questionnaires relevant to the topics of their materials.

List of Measures

7-Day PAR Interview provides an estimate of total weekly minutes of PA.
Demographics measure will assess age, education, income, race, and marital status, and acculturation scale.
Stages of Change for Physical Activity (SCPA) measure has successfully been used to stage-match treatment.
Processes of Change for Physical Activity (POC) measure contains 10 subscales that address a variety of

cognitive/behavioral processes related to PA behavior change.
Self-Efficacy For Physical Activity (SE) measures self-efficacy to become physically active across diverse contexts.
Neighborhood Environment Walkability Scale, Abbreviated (NEWS-A) assesses various aspects of the built environment related to walking, neighborhood aesthetics, and traffic.
ActiGraph. For the week prior to each 7-Day PAR assessment, all participants will wear an Actigraph, which measures movement and intensity of activity.
Health-O-meter medical scale will be used to measure body weight and height.
Short Test of Functional Health Literacy in Adults (STOHFLA) tests literacy for English and Spanish speaking patients in healthcare settings.
Consumer Satisfaction Measure was used by our research team in past trials and adapted for the current study to assess feasibility/acceptability of this the text-enhanced PA intervention.
Wellness Questionnaire assesses knowledge about health topics presented in the control materials.

10. HUMAN SUBJECTS

For Phase 1 we will recruit 48 participants and for Phase 2 we will recruit 60 participants. Participants in both phases will be sedentary (i.e., participating in moderate or vigorous physical activity two or less times per week for 30 minutes each time or less) men between the ages of 18-65 who self-identify as Mexican or Mexican-American. Participants in Phase 1 will participate in focus groups to guide development of the text-message components. Participants in Phase 2 will participate in a randomized clinical trial of a text-enhanced culturally and linguistically adapted, Spanish language, mail-delivered print intervention to promote physical activity.

Phase 1: Interested men will be telephone screened for eligibility. Interested and eligible men will be invited to attend a focus group to discuss preferences surrounding text-messages to increase physical activity. A randomly selected sub-sample of participants will be asked to return for a confirmatory panel. All participants will provide written consent to participate.

Phase 2: We will recruit men to enroll in a randomized controlled trial of the newly developed text-enhanced physical activity intervention compared to a publicly available, Spanish-language health education control, including PA, diet, and stress management information.

Eligibility Requirements for Phase 1 and 2: We will recruit men between the ages of 18-65 who self-identify as Latino and own a cell phone capable of sending and receiving text messages.

Exclusion criteria for Phase 1 and 2: To reduce the likelihood of injury participants will be screened with the Physical Activity Readiness Questionnaire. Potential participants with medical or psychological problems that could make adherence with the study protocol difficult or dangerous will not be included. Exclusions include history of coronary heart disease, history of myocardial infarction, currently engaging in more than 90 minutes of activity per week symptoms of angina, type I diabetes, uncontrolled hypertension, stroke, osteoarthritis, osteoporosis, orthopedic problems that would limit activity during the following six months, or any other serious medical condition that would make physical activity unsafe. Other exclusion criteria will include hospitalization due to a psychiatric disorder in the past 3 years, BMI above 45 kg/m, and/or taking medication that may impair physical activity tolerance or performance (e.g., beta blockers). The study physician will advise on medical questions that arise when screening for eligibility.

11. RECRUITMENT AND PROCEDURES PREPARATORY TO RESEARCH

Recruitment will follow a community-based, participatory model in that key community-based organizations and their leadership will be consulted and involved in recruitment. As in previous studies, we will employ multiple recruitment strategies. These strategies include:

1) We will recruit through local physicians (through the UCSD Department of Family Medicine) whose patient populations are largely Mexican and Mexican-American. Some of these physicians are Latino and bilingual. These physicians will provide potentially eligible participants (or their family members) with information on the study.
2) Targeting both directly to Mexican and Mexican American men who may be eligible, and to Latinas who could refer eligible male family members.
3) Posting and distributing flyers and advertisements in public areas, community organizations, and

community events with high traffic of Mexican and Mexican American men.
4) Posting and distributing flyers and advertisements on websites and on email list serves.
5) Going out into the community, such as by attending community events, health fairs, talk shows etc. to actively recruit and inform participants about the study. This will include doing presentations and collecting names and contact info of interested potential participants.
6) We will list our study on UCSD's CTRI ResearchMatch database and will use this resources to contact potentially interested participants.
7) Paid advertisements through print ads, web-based ads, radio, TV, and other venues.
8) We will be creating a Facebook business page exclusively for the advertisement of the Activo Study according to the IRB study guidelines.

Recruitment efforts will be not be limited to the Greater San Diego area, and will expand across the United States where applicable (websites, radio, TV, etc.)

12. INFORMED CONSENT

Upon seeing study recruitment flyers and advertisements, interested individuals will call the study line to learn more about the study. After hearing a brief description of the study, participants will decide if they would like to participate in a brief telephone phone-screening interview to assess initial eligibility. Screening interviews are audiotaped and scripted. The screening interview script has a checkbox for the research staff to document receiving permission from the prospective participant to proceed with the screening interview. Furthermore, participants will be reminded throughout the phone-screening interview that participation is voluntary and can be ended at any point, thus minimizing the possibility of coercion or undue influence. In addition, this documentation can be verified through audiotapes of the screening interviews. A waiver of documented consent is requested for this oral screening process based on meeting the following UCSD IRB criteria:

a) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality

b) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Following telephone screening, interested individuals will be asked to attend an in-person (group or individual) or phone orientation session. Trained bilingual/bicultural research staff with sufficient knowledge of the study to answer any questions regarding the study and appropriate IRB/CITI training will provide information about the study. During the session, all questions regarding participation in the study will be answered. All potential participants will be fully informed of the study's procedures and requirements that are also thoroughly described in the informed consent. Thus, interested individuals will have sufficient time to read and consider whether to participate. Furthermore, participants will be reminded throughout the orientation that participation is voluntary and can be ended at any point, thus minimizing the possibility of coercion or undue influence. Methods of documenting consent/assent/permission/authorization to participate in the actual study will include having the prospective participant and research staff sign, initial, and date the consent forms. The research staff will obtain consent/assent/permission/authorization in English or Spanish, whichever language is preferred by the prospective participant. If the individual prefers, a copy of the consent form may be mailed prior to the face-to-face meeting to provide more time to consider the study. However, the final consent form must be signed in-person prior to participation in the focus group or individual meeting. All participants will also receive a signed copy of the consent form and a copy of the Experimental Subject's Bill of Rights. Both Spanish and English versions of these documents will be provided.

For phone sessions, staff will discuss with the participant the steps to maintain confidentiality during these visits. For example, it will be required for participants to complete the phone sessions in a private place with no one else around (this protects the privacy of the subject as well as the inadvertent transmission of voice of a non-consented person). Regarding audio recording of the in-person and telephone sessions, participants voluntarily sign an audio recording release consent form approved by the university's institutional review

board. All of the procedures above regarding the consenting process remain the same via phone. Note: although telephone is an option to review the consent and answer any questions regarding the consent during the orientation session, participants will not actually be consented via telephone. Participants will still need to sign and mail back their informed consent to participate in the study.

The information being communicated to the participant during the consent/assent/permission process will not include exculpatory language through which the participant is made to waive or appear to waive any of the participant's legal rights or release or appear to release the Research, Sponsor, the University or its agents from liability for negligence.

13. ALTERNATIVES TO STUDY PARTICIPATION

The alternative to study participation is to not participate.

14. POTENTIAL RISKS

Complications associated with moderate intensity exercise training (orthopedic injury)
Likelihood: Rare
Minimization: Participants will be screened for orthopedic problems, particularly gait disturbances, before enrolling, and they will be monitored throughout the 6-month intervention. Specifically, participants will be instructed to alert us of any orthopedic injury sustained as soon as possible. This will trigger a call from our projector director and/or study physician. If an injury has occurred, we will request that the participant follow-up with his primary care provider before continuing in the study. If participants are unable to complete the treadmill walk at the baseline visit due to physical/medical limitations, they will be deemed ineligible.

Loss of Confidentiality
Likelihood: Rare
Minimization: Confidentiality will be maintained by numerically coding all data, disguising identifying information, and keeping all data in locked file drawers. All information obtained from participants will be accessible only to research staff. All texting between participants will be relayed through the study server, so individual telephone numbers will not be shared. Participants will have the ability to opt out of receiving group text messages.

15. RISK MANAGEMENT PROCEDURES AND ADEQUACY OF RESOURCES

Potential complications associated with moderate intensity exercise training at levels recommended by the CDC/ACSM are rare. However, subjects may find exercising uncomfortable and may experience sprains, other soft tissue injuries, or bone injuries. At the start of the study all participants will be given an instruction sheet that details what to do for common exercise-related injuries, as well as the Project Director's contact information. In addition, we will require each participant to complete a monthly Health Expense Form. Since participants are enrolled on rolling basis, these forms will be reviewed by the project coordinator within 24 hours of being received. Any injuries that may have occurred because of, or in relation to, exercise training that are noted on the Health Expense Form will be relayed by monitoring team within 24 hours. Although the likelihood is low, our research staff has well-established procedures for monitoring and responding to adverse events resulting from moderate intensity physical activity, as well as loss of confidentiality.

Participants will be asked to notify us immediately (no later than 24 hours) if they sustain an injury. Procedures and protocols for reporting and managing adverse events, are addressed in the NINR approved Data Safety Monitoring Plan, previously submitted to the IRB.

16. PRIVACY AND CONFIDENTIALITY CONSIDERATIONS INCLUDING DATA ACCESS AND MANAGEMENT

Informed Consent: There is a potential risk of participating in a group orientation session. During the consenting process other participants will be in the room, which could lead to a loss of your confidentiality. While we ask all participants to protect and respect other people's confidentiality, we cannot guarantee that all participants will abide by this request. Although information about the study and the informed consent process will be conducted in a group setting, the research staff will also be available to discuss any questions or concerns privately. Participants will also have the option of reading, discussing and signing the consent forms in a private area if they prefer. In addition, we will take all necessary and possible precautions to avoid loss of confidentiality during group orientation sessions, including only referring to individuals by their first names, with no mention of last names.

Procedure for Collection of Data: Research participants will complete baseline questionnaires, as dictated by the study protocol. All data collected are considered part of the subject's confidential record and will be placed in a locked file cabinet within 24 hours of acquisition as designated by the study's Data Manager. All data will remain confidential. A file that associates the subject name with that subject's study identification number will be maintained. This file will remain locked in a file cabinet and will not be stored with the actual study data.

Accelerometers: The data collected from the accelerometers will be used as primary data. Data downloaded from the accelerometers will be incorporated into the database that contains all other collected study data. Backup copies of the original downloaded files will be maintained on the university network.

Storage of Collected Data: All paper data will be stored in a locked file cabinet. Data will only be removed when coded, entered, or audited. The study's Data Manager will be responsible for the secure storage of all project questionnaire data. Collected data will be de-identified by a data manager to ensure that all personal identifiable information cannot be connected to the data provided by participants through the surveys. All de-identified data will then be backed up and stored onto a secure, password protected, shared network at UCSD. The shared network will require a login and password in order to gain access to the data. Only the data manager will have access to the data in its raw state. All other authorized staff (e.g., research assistants, and Project Director) will view de-identified data via forms and reports created by the data manager.

Data Entry Requirements: All data will be coded by a research assistant prior to entry. Any ambiguity in responses to questions will be brought to the attention of the Data Manager for clarification. If the Data Manager is unsure how to code the response, the matter will be brought to the attention of the study's Principal Investigator. The Data Manager will maintain a log so that future occurrences of problems will be handled in the same manner.

The data entry system will require a login identification and password in order to gain access to the data. Where appropriate, validation and range rules will be applied to the actual entry fields. Only the Data Manager will be able to view the data in its raw state. All other authorized staff (Principal Investigator, research assistants, and Project Director) will view data via forms and reports created by the Data Manager.

Audit/Verification of Entered Data: Primary outcome data will be subject to 100% cross-referencing with the original paper copy. This audit must have an error rate less than 1%. If the verification fails the audit, all data will be re-entered, the original computer files discarded, and the newly re-entered data audited. This process will continue until the audit no longer exceeds the maximum allowable error rate. All audits will be supervised and documented by the study's Data Manager.

All other entered information will be subject to a 20% sample that will be cross-referenced with the original paper copy. This audit must have an error rate of less than 1%. If the sample fails the audit, all data will be verified against the paper originals. If the error rate of the complete audit is greater than 1% then all data will be re-entered, the original computer files discarded, and the newly re-entered data audited. This process will continue until the audit no longer exceeds the maximum allowable error rate. At the discretion of the Principal Investigator, the full audit may be omitted in favor of a complete re-entry of the original paper data. All audits will be supervised and documented by the study's Data Manager.

Final Storage of Collected Data: Once data have been coded, entered, and passed audit verification, paper copies of data will be housed at a facility that specializes in the storage of medical/research information. This housing facility will not be at UCSD. This is a location that specializes in housing secure research files offsite. A commonly used company that other UCSD research groups have used for this purpose, is the Iron Mountain Storage facility. These data will only be sent to this location once it has been coded, entered, passed audit verification, and is no longer needed for the duration of the study. Only the subject's study identification number will be present on the forms. All electronic data will be backed up and stored onto a secure, password protected shared network. Any indication of the subject's name will be removed from the questionnaires prior to its archiving. The destruction date of these files will be at least 7

years from the termination of the study and will be authorized by the Principal Investigator of the research study.

Access to Cleaned Computer Data: Once the study is complete, and all data have been collected, entered and passed the audit process, the Data Manager will make the data available to the Principal Investigator and her designates. Only the Principal Investigator can give permission for the release of aggregated study data. No confidential information may be released without the express written consent of the study subjects. Only copies of the finalized data will be released. The original data file will remain in its pristine state.

17. POTENTIAL BENEFITS

Participants who increase their physical activity may experience a number of health benefits associated with a physically active lifestyle. Additionally, the results will be used to further understand the unique factors related to promoting physical activity adoption and maintenance among MA men, and will inform the design and testing of a larger trial. The risks to participants in this study are judged to be minor.

18. RISK/BENEFIT RATIO

The risks to participants in this study are judged to be minor. The anticipated benefits are great as the results will be used to further understand the unique factors related to promoting physical activity adoption and maintenance among Mexican and Mexican-American men. Health disparities and associated sedentary lifestyles remain an enormous public health problem.

19. EXPENSE TO PARTICIPANT

There will be no expenses for participation in the study.

20. COMPENSATION FOR PARTICIPATION

Phase 1 Compensation: To compensate participants for their time and travel, they will receive $10 for participating in the focus group session, and an additional $10 for transportation reimbursement. If they are asked to return for the confirmatory panel, they will receive an additonal $20. We will provide snack food for the participants to consume during their group or individual meeting. Finally, participants will also receive validated parking to cover the cost of parking on the UCSD Campus during their meeting. If they decide to leave the study early, we will still cover the cost of their parking; however, they will only receive the $10 if they participate in the entire session (unless special circumstances occur). All monetary compensation will be in the form of SCRIP.

Phase 2 Compensation: Participants will receive $10 for completing monthly questionnaires, and $25 for completing your in-person 6-month visit. Participants who complete *all 6 monthly questionnaires* will receive an additional $50 bonus incentive. In addition, participants will receive a $10 incentive for returning their accelerometer during the randomization visit. If participants are not able to come to our office at 6 months but are able to complete parts of the assessment over the phone, they will be compensated with $10 for each partial assessment completed. To compensate participants for their travel, they will also receive $10 for each in-person visit. If they choose to complete any of your visits via phone, they will not receive compensation for travel. Participants will also receive $5 per month to defray the costs of the text messages. All monetary compensation will be in the form of SCRIP, a payment that resembles a check but does not contain their name or personal information. Participants do not need to change their behavior (exercise more) to participate or receive the compensation.

21. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES

Dr. Bess Marcus, PhD, Principal Investigator. Dr. Marcus is a Professor and the Chair of the Department of Family and Preventative Medicine. Dr. Marcus has spent 25 years developing and studying methods for increasing physical activity among sedentary adults and has served as PI on numerous grants on this topic. Dr. Marcus will oversee all aspects of the project and will be responsible for the training and supervision of the staff and the scientific integrity of the project. She will also be responsible for monitoring the quality control of all aspects of the study. Dr. Marcus will be responsible for producing scientific reports and manuscripts based on the results of the study.

Kevin Patrick, M.D. (Co-Investigator, Text-message development and implementation): Dr. Patrick has extensive research experience with formative research, survey methodology, measurement technologies,

behavioral interventions and information technology (IT). His work focuses upon the use of text messaging, smartphone apps, mobile video, the mobile web and Facebook apps to promote health behavior change. Dr. Patrick will oversee the development and implementation of the text-message enhancement for the intervention.

James Sallis, Ph.D. (Co-Investigator, Built Environment): Dr. Sallis is a Distinguished Professor in the Department of Family & Preventive Medicine at UCSD with extensive experience with research focusing on physical activity and the built environment. Over the past 30 years he has led funded research projects on physical activity in a variety of populations, including Latinos, and has published more than 450 articles. Dr. Sallis will guide the development and the implementation of the intervention components targeting the built environment to increase physical activity.

Jesse Nodora, Ph.D (Co-Investigator, Community Collaborations and Intervention Development): Dr. Nodora is a bilingual and bicultural Assistant Professor in the Department of Family & Preventive Medicine at UCSD.He will focus on developing community relationships to aid in recruitment as well as to help develop culturally relevant intervention content. As a co-investigator, he will also work closely with the research team to address participant recruitment as well as cultural factors related to Mexican and Mexican American men.

Carlos Rojas, M.D. (Co-Investigator, Study Physician): Dr. Rojas is a bilingual and bicultural physician who is board certified in Family Medicine and Geriatric Medicine and is the Medical Director of Family Medicine at the Hillcrest offices of the UCSD Family Medicine Practice. Dr. Rojas will provide essential recruitment support by encouraging potentially eligible UCSD Family Medicine Practice patients to participate in the study, and by working with his fellow physicians to encourage referrals. Additionally, Dr. Rojas will provide consultation to Dr. Marcus regarding medically related participant eligibility matters.

Shira Dunsiger, Ph.D. (Consultant): Dr.Dunsiger at The Miriam Hospital and Brown University School of Public Health, has considerable expertise in statistical methods for longitudinal and incomplete data; she is active in developing new statistical methodology for analyzing longitudinal data from behavioral medicine, and has collaborated with Dr. Marcus and other investigators on studies related to both exercise promotion and smoking cessation. Dr. Dunsiger will oversee all statistical aspects of the project and will formulate the primary and secondary analyses. She will be responsible for the development of statistical models for the analysis of the primary and secondary aims and collaborating on scientific reports and manuscripts based on the results of the study. Dr. Dunsiger is currently the biostatistician for Dr. Marcus's projects R01CA15995401, R21NR009864, and R01NR011295, which utilize many of the same measures and analyses as the current study.

Dorothy Pekmezi, Ph.D. (Consultant): Dr.Pekmezi at The University of Alabama at Birmingham, has extensive experience conducting qualitative research and in culturally adapting physical activity interventions for underserved populations. She has served as a Co-Investigator on several of Dr. Marcus' studies culturally adapting and assessing physical activity interventions for Latinas (R21NR009864, R01NR011295). As a consultant, Dr.Pekmezi will participate in structuring and conducting focus groups and expert panels in Phase 1. She will also help develop and conduct follow-up interviews after the pilot trial, which will help develop the texting component. Dr.Pekmezi will also participate in developing the quality control procedures and conducting the quality control for the intervention and for the measurements. She will also provide feedback to the study staff and ensue the quality of the intervention delivery and assessment throughout the study period.

Sheri Hartman, Ph.D. (Collaborative Investigator): Dr. Hartman is an Assistant Professor in the Department of Family and Preventive Medicine with an established history of working with Dr. Marcus' team as a Co-Investigator on numerous grant-funded studies including a grant testing an internet intervention to increase physical activity in Latinas (RO1CA159954). Dr. Hartman is clinical psychologist with extensive training and experience promoting health behavior change. She has developed quality control procedures and

conducted the quality control evaluations for two grant funded studies (R01DK064902, R18DK079880). For the current study Dr. Hartman will advise on developing the quality control procedures and conducting the quality control for the intervention and for the measurements. In addition, Dr. Hartman will assist with report, abstract, manuscript, and grant preparations.

Sarah Linke, Ph.D., M.P.H. (Collaborative Investigator): Dr. Linke is an Assistant Clinical Professor in the Department of Family Medicine & Public Health with an established history of working with Dr. Marcus' team on numerous grant-funded studies including a grant testing an internet intervention to increase physical activity in Latinas (RO1CA159954). Dr. Linke is clinical psychologist with extensive training and experience promoting health behavior change. She led the development and modification of the website for a similar study examining the effects of an Internet-based PA intervention for Latinas (RO1CA159954). For the current study, Dr. Linke will lead the oversight of the text messaging component. In addition, Dr. Linke will assist with staff supervision, human subjects protection, and report, abstract, manuscript, and grant preparations.

Britta Larsen Ph.D. (Collaborative Investigator): Dr. Larsen is an Assistant Professor in the Department of Family and Preventive Medicine at UCSD. She has worked in supportive roles on Dr. Marcus' PA intervention studies with Latinas, and served as the project director for intramurally funded research adapting and testing this intervention for Mexican and Mexican American men. For the current study Dr. Larsen will advise on the focus groups, and help develop the texting component. She will also assist with preparing manuscripts based on study findings.

Raul Fortunet (Study Coordinator, Intervention Delivery): Mr. Fortunet is bilingual and bicultural and will be responsible for consenting participants, delivering the intervention, conducting randomization sessions and goal setting, training research staff, recruitment activities, participant tracking, and conducting focus groups. Mr. Fortunet has worked with Dr. Marcus for four years and has significant experience with managing study logistics, delivering culturally adapted interventions, and ensuring high-quality control of the research protocol. He has performed similar duties in two of our other studies (R01NR011295; R01CA159954) and has established standard operating procedures as well as quality control checks to ensure efficient intervention delivery.

Andrea Mendoza, M.P.H. (Research Associate for Assessment): Ms. Mendoza has a M.P.H. degree in Health Promotion, Education and Evaluations as well as a BA in Film Studies and Computer Science. She is bilingual and bicultural and will be responsible for all assessment-related tasks including conducting orientation, measurement, and follow-up visits. She will also be responsible for telephone screening for eligibility, scheduling of participants, and data entry.

Mario Munoz, Ph.D. (Assistant Project Director): Dr.Munoz is a Postdoctoral Employee in the Department of Family Medicine & Public Health. He has a PhD in Rehabilitation Sciences with a background in exercise sciences. He will be responsible for fostering relationships with community contacts and overseeing all recruitment activities which will include use of local media outlets (newspaper and radio), flyers distributed and posted at community events or sites, presentations at community functions or centers, and the community clinics. He will also be responsible for telephone screening for eligibility, scheduling of participants, and data entry.

Mayra Cano (Research Assistant): Ms. Cano is a bicultural, bilingual researcher currently working as a research assistant in our lab. She will conduct baseline and six month assessments as well as data entry, and will be responsible for administrative tasks of the study, telephone screening for eligibility, consenting participants and scheduling of participants. To ensure scientific rigor as well as avoidance of inadvertent study contamination due to interviewer knowledge of assigned condition, she will have no knowledge of condition assignment when conducting assessment interviews. She is already trained in interview protocol (including certification for conducting the 7-Day Physical Activity Recall) as well as quality control measures, and is well versed in the research application of accelerometers that will be mailed to participants (to be

worn during the week prior to assessment interviews) as well as the downloading and cleaning of data from these devices.

22. BIBLIOGRAPHY

Larsen, B. A., Dunsiger, S., Hartman, S., Nodora, J., Pekmezi, D., Marquez, B., Noble, M.L., Rojas, C., & **Marcus, B. H.** (2014). Activo: Assessing the feasibility of designing and implementing a physical activity intervention for Latino men. *International Journal of Men's Health*, *13*(1), 60-71.

Larsen, B. A., Noble, M. L., Murray, K. E., & **Marcus, B. H.** (2014). Physical activity in Latino men and women: Facilitators, barriers, and interventions. *American Journal of Lifestyle Medicine.* doi: 10.1177/1559827614521758.

Patrick K, Raab F, Adams MA, et al. A text message-based intervention for weight loss: randomized controlled trial. *J Med Internet Res.* 2009;11(1)

23. FUNDING SUPPORT FOR THIS STUDY

NIH/NINR R21NR014911

24. BIOLOGICAL MATERIALS TRANSFER AGREEMENT

Not applicable.

25. INVESTIGATIONAL DRUG FACT SHEET AND IND/IDE HOLDER

Not applicable.

26. IMPACT ON STAFF

Not applicable.

27. CONFLICT OF INTEREST

None.

28. SUPPLEMENTAL INSTRUCTIONS FOR CANCER-RELATED STUDIES

Not applicable.

29. OTHER APPROVALS/REGULATED MATERIALS

None.

30. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT

None.

141174

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

TO: Dr. Bess Marcus

RE: Project #141174
Developing a Text Message Enhanced Physical Activity Intervention for Latino Men

Dear Dr. Marcus:

The above-referenced project was reviewed and approved by one of this institution's Institutional Review Boards in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56), including its relevant Subparts. This approval, based on the degree of risk, is for 365 days from the date of **IRB review and approval** unless otherwise stated in this letter. The regulations require that continuing review be conducted on or before the 1-year anniversary date of the IRB approval, even though the research activity may not begin until some time after the IRB has given approval.

The use of oral consent has been granted. The IRB under CFR 46.117 (c) waives the requirement for the PI to obtain signed consent for screening because this research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.

The IRB determined that this project presents no more than minimal risk to human subjects in that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

As this project is currently closed to accrual and open for data analysis only, no re-approved consent forms will be provided to the PI.

Date of IRB review and approval: **7/27/2018**

On behalf of the UCSD Institutional Review Boards,

/ag

Anthony Magit, M.D.
Director
UCSD Human Research Protections Program
858-246-HRPP (858-246-4777); hrpp@ucsd.edu

Note: IRB approval does not constitute funding **or other institutional required approvals.** Should your studies involve other review committees such as Office of Clinical Trials Administration (OCTA), Office of Coverage Analysis Administration (OCAA), Conflict of Interest (COI), Protocol Review Monitoring Committee (PRMC), and committees under Environmental Health & Safety (EH&S) such as Institutional Biosafety Committee (IBC), Human Exposure Committee (HERC), and RSSC (Radiation Safety and Surveillance Committee), it is the researchers responsibility to ensure that all approvals are in place prior to conducting research involving human subjects or their related specimens.

Approval release date: 6/29/2018

UCSD HUMAN RESEARCH PROTECTIONS PROGRAM

GENERAL APPROVAL INFORMATION

The information below does not encompass all human subjects protections requirements, however, is intended to highlight those of significance to ensure awareness by researchers engaged in research involving human subjects or their related specimens and data.

Approval Letters and Consent Documents

Unless otherwise stated, approval letters will be accompanied by stamped, approved consents. Should a study be closed to accrual and no consent released as a result, this information will be documented on the approval letter. Also, any waivers will be documented in the approval letter (such as waiver of documented consent or waiver of authorization for use of PHI).

The PI must ensure approval is in place from other appropriate review boards (such as Radiation Safety, Institutional Biosafety Committee, Conflict of Interest, ESCRO, etc.)

If other institutions are involved, the PI must ensure that IRB approvals (or other administrative approvals) from those sites are secured and forwarded for the study file. In addition, PI's must ensure that the clinical trial agreement, as applicable, or other funding (such as a grant) is appropriately in place prior to conducting any research activities. IRB approval does not constitute funding approval.

Duration of IRB approval

The IRB may grant approval up to 365 days. (See 45 CFR 46.109(d) (DHHS) and 21 CFR 56.109(d) (FDA)). However, for some studies the IRB may grant approval for a lesser period or a specific number of subjects to allow for more frequent monitoring. The approval letter or related documentation will indicate this information.

Because IRB review of research studies must be completed at least annually, investigators should plan ahead to meet required continuing review dates. **Please submit complete continuing review documentation at least 45 days prior to the expiration date to guard against a lapse in IRB approval.** The signed continuing review facepages and any other required hard copies must be received by the HRPP office before the continuing review process can begin.

As a courtesy, automated continuing review reminders can be set-up by PIs at various intervals (75 days, 45 days, 30 days, for example) on the website at https://irb.ucsd.edu. However, as these are automated electronic messages based on data entered, and the HRPP cannot anticipate which type of software programs (such as spam-blockers or anti-virus software) may block receipt of the messages, **PI's are required to not rely upon notification, but have internal mechanisms which track continuing review submission times**. Ultimately, it is the PI's responsibility to initiate a continuing review application, allowing sufficient time for the review and re-approval process to be completed before the current approval expires.

Continuing review is required even if no changes are made, or if the only study activity is participant follow-up, and even if the only study activity is data analysis.

What happens if there is a lapse in IRB approval?

If the IRB has not reviewed and approved a research study by the study expiration date, **all research activities must stop**. This includes the following:

All research-related interventions or interactions with currently enrolled subjects (unless the IRB finds that it is in the best interests of the individual subjects to continue participating in the research interventions or interactions;*) recruitment and informed consent procedures; and continued collection and/or analysis of data/information.

**Exception:* Research-related interventions or interactions with enrolled subjects may continue if the IRB determines that stopping the research would jeopardize the rights or welfare of current subjects. The IRB will decide which subjects should continue receiving the intervention during the lapse in approval. A request for such an exception must be submitted in writing to the attention of the IRB Chair by the Principal Investigator. If any project activity—even activity required for participant safety—occurs or continues after the expiration date, the investigator is out of compliance with both federal regulations and university policy. Retrospective approval for work done after the expiration date cannot be granted.

Amendment/revision to an IRB approved study

IRB approval is required before implementing any changes in the approved research plan, consent documents, recruitment materials, or other study-related documents. Please see Amendment Fact Sheet at http://irb.ucsd.edu/amendmodchg.pdf for submission guidance.

Adverse Event and Unanticipated Problems Reporting

All problems having to do with subject safety must be reported to the IRB within ten working days. All deaths, whether or not they are directly related to study procedures, must be reported. For adverse events, please utilize the form found at https://irb.ucsd.edu/UPR_biomedical.doc. For deviations and other reports, a cover letter and any supplemental information appropriate to the review should be provided. Please see IRB Guidelines for more information at https://irb.ucsd.edu.

Changes in financial Interest or Conflict of Interest (COI) disclosure

Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the Independent Review Committee via the Conflict of Interest Office. If these changes affect the conduct of the study or result in a change in the required wording of the approved consent form, then these changes must also be submitted as an amendment request.

Statistical Analysis Plan

The primary aim of our pilot trial is to determine the feasibility and acceptability of the text-enhanced PA intervention. We will consider the intervention feasible if at least 80% of participants are retained at the 6-month follow-up. The intervention will be considered acceptable if at least 80% of participants respond favorably ("satisfied" or "very satisfied") to the question "In general how satisfied were you with the intervention?". Although interest is in the feasibility and acceptability of the text-enhanced PA intervention arm, we will calculate these rates for both groups and compare them using chi-squared tests. In addition, our data analytical strategy is designed to examine whether there are treatment effects favoring the text-enhanced PA intervention while assuring control for potential confounds not adequately controlled for by the randomization. Thus as a preliminary step, we will assess potential between-group differences in baseline characteristics (demographics, baseline activity level) using graphical methods, non-parametric and parametric tests as appropriate (e.g., Wilcoxin rank-sum test for skewed data, t-tests for normally distributed continuous data & chi-squared tests for categorical data). Any variables not balanced by randomization will be controlled for as covariates in subsequent analyses. We will estimate the preliminary efficacy of intervention compared to control using a generalized linear model in which we regress minutes/week of moderate to vigorous PA *(as measured by accelerometers)* at 6 months on treatment assigned, baseline value of the outcome and potential confounders (including those variables not balanced by randomization). To avoid the effects of outliers, we will apply a normalizing transformation (if necessary) to the outcome prior to analysis. Modeling is done using a likelihood-based approach and thus makes use of all available data (intent-to-treat sample) to produce consistent estimates of the regression parameters. We are aware that effect size estimates with small samples have large standard errors and wide confidence intervals. To determine the sample size for a clinical trial, the trial needs to have adequate power to detect a clinically relevant difference between treatment