FORM C

IRB #	HSC20110460H

RESEARCH DESCRIPTION

If an item does not apply to your research project, indicate that the question is "**not applicable**" – do not leave sections blank

For Sections: **1**. "Purpose and Objectives"; **3**. "Study Design"; and **4**. "Study Population," and **5 – 12**, you may copy and paste the relevant passages from the sponsor's full protocol or grant application (citing the page number and section is **unacceptable**). Section 2, "Background" is the only part of this form where you may cite the relevant passages (page number and section) from the sponsor's full protocol or grant application. This section may be used to also describe local standards of practice or add information pertinent to the local IRB review of a multicenter study.

Click once on the highlighted entry in each box to provide your response. Click the item number/letter or word, if hyperlinked, for detailed instructions for that question. If your response requires inserting a table, picture, etc, you may need to first delete the box that surrounds the answer and then insert your table or other special document.

Title of Project:

ENLACE: A Promotora-Led Physical Activity Intervention Trial for Latinas in Texas

1. Purpose and objectives. *List the purpose and objectives:*

ENLACE: A *Promotora*-Led Physical Activity Intervention Trial for Latinas in Texas (ENLACE) takes a comprehensive multi-level approach to promoting MVPA among a particularly underserved segment of the Latina population by attending to individual attitudes and skills, socio-cultural factors and environmental influences to behavior change. The proposed group-randomized controlled trial builds on formative and pilot research (funded by a National Heart, Lung and Blood Institute R21, HL087765) conducted by a team with extensive experience in behavioral interventions and outreach with Latino and financially disadvantaged populations. *ENLACE*—a Spanish term meaning to link, connect, or join—reflects the joint community-academic research partnership that generated the pilot intervention, as well as the *promotora*-led approach that builds on and enhances health connections between Latinas and their existing social networks. Input from a community advisory group and participatory community assessment in the recruitment areas will contribute to developing the most culturally and environmentally relevant intervention possible.

The **long-term goal** of the *ENLACE* is to reduce obesity and obesity-related morbidity and mortality by increasing the number of Latinas who meet national PA guidelines for adults[9]. We **hypothesize** that Latinas at the PA intervention sites will significantly increase their MVPA levels as a result of addressing their specific individual and environmental barriers and enhancing their social support and collective efficacy, compared to Latinas at the attention-control sites.

Primary aim: Test the effect of a 16-week, *promotora*-led PA intervention on minutes per week of MVPA (primary outcome) among Latinas in South Texas, compared to an attention-control group.

Secondary aims: a) Test the effect of the 16-week *promotora*-led PA intervention on physical fitness and weight maintenance (secondary outcomes); b) assess the maintenance of primary and secondary outcomes 6 months after the end of the intervention; c) examine the role of self-efficacy for PA, social support, decisional balance, and collective efficacy as mediators of changes in MVPA; and d) evaluate the impact of Latinas' social and community environment context on their success (or failure) in increasing MVPA and maintaining the behavior change.

Eight community resource centers (CRCs) in four Lower Rio Grande Valley (LRGV) counties—Starr, Hidalgo, Willacy and Cameron—will be randomly assigned to either the *ENLACE* PA Intervention (4 CRCs) or the attention-control condition (4 CRCs). We will recruit 864 Latinas ages 18 - 64 who do not meet national PA guidelines from *colonias* (unincorporated settlements where many people live in impoverished conditions and lack basic services) in the service area of the eight CRCs. Participants from CRCs randomized to the *ENLACE* PA Intervention (N = 432; 108 women per CRC) will receive the 16-weekly *promotora*-led group sessions, followed by 24 weeks of a maintenance intervention (monthly *promotora*-delivered newsletter and bi-monthly telephone counseling). The goal for the 16 weeks will be for women to engage in 30 minutes per day of MVPA on 5 or more days per week. The attention-control group (N = 432; 108 women per CRC) will receive 8 *promotora*-led group sessions twice a month on home safety/first aid and monthly generic health education materials during the maintenance intervention period. Standardized measurement of primary and secondary outcomes will occur at baseline, immediate (16 weeks) and delayed (40 weeks) post-intervention.

2. Background.

Describe past experimental and/or clinical findings leading to the formulation of your study.

For research involving investigational drugs, describe the previously conducted animal and human studies.

For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol.

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Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference.

You may reference sponsor's full protocol or grant application (page number and section) or if none, ensure background includes references.

a. Background

See Section D (pages 121-123)

b. Current practice

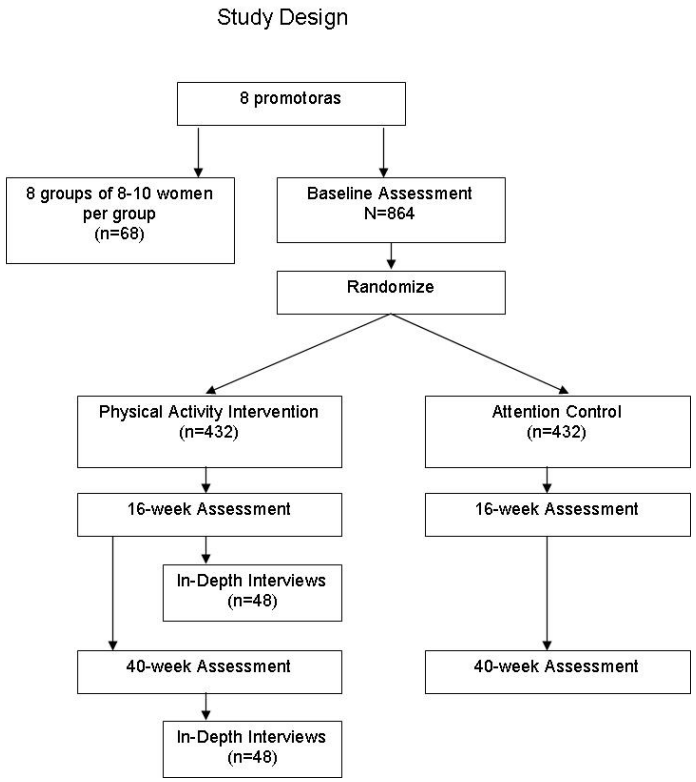
Promotoras at the CRC do not offer any formal physical activity interventions. Physical activity resources that exist (e.g., walking trails, parks and gyms) are available for use by public.

3. Study Design.

Describe the study design (e.g., single/double blind, parallel, crossover, etc.) Consider inserting a scheme to visually present the study design.

D.2.1. Overview of Study Plan and Design

We propose a 5-year study to test the effectiveness of a culturally appropriate, theory-based intervention to increase MVPA among Latinas in the LRGV. This study is a continuation of our ENLACE pilot study. We will involve 8 CRCs affiliated with the Colonias Program in the study. The CRCs will be randomized to one of two conditions: (a) ENLACE PA intervention (n=4 CRCs), or (b) attention control (n=4 CRCs). By randomizing at the CRC-level the intervention can be implemented by the promotora to all study participants, thus reducing the risk of contamination that would be present with promotora- or participant-level randomization. This approach also allows us to implement an ecological intervention, where each CRC can implement and promote PA activities and display materials to support the intervention messages. A total of 864 Latinas ages 18-64 years will be recruited from within the service area for these 8 CRCs. The study will be conducted in 3 cohorts of 288 women (36 per CRC in each cohort). Participants will be assessed at baseline, 16 weeks (immediate post intervention), and 40 weeks (delayed post intervention). The primary outcome is minutes per week of MVPA. Secondary outcomes are physical fitness and weight maintenance. Consistent with our approach, we will establish a community advisory group and engage promotoras in conducting participatory community assessments. Finally, we will recruit sub-sample of 4 intervention participants from each CRC cohort to complete two in-depth interviews, immediately following the PA intervention (16 weeks) and after the maintenance intervention period (40 weeks), to evaluate the impact of Latinas' social and community environment context on their success (or failure) in increasing MVPA and maintaining the behavior change.



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4. Study Population(s).

You will be drawing subjects from one or more populations. In medical research, for example, a population can be individuals with type 2 diabetes controlled with diet, or a population of healthy individuals. In social behavioral research, a population can be individuals attending an education program, etc.

4.a. How many different populations are you enrolling in this study?	3
4.b. For each different population, provide a short descriptive **label**: *(e.g., normal-healthy, diabetics, parents, children, etc.)* *Copy and paste additional labels as needed →*	1. Community Mapping Participants 2. Intervention & Control Groups 3. In-Depth Interview Participants

4.c. For each specific population identified in **4b**, provide the following information in the table provided below.

*(For studies with **more than one** population, copy all of table 4.c. and paste to insert additional tables.)*

Population # 1	**Population Descriptive Label:** Community Mapping Participants

(1)	Identify the criteria for **inclusion**:
Participants will be women 18 thru 64 years old who self-identify as being Hispanic and reside within the specified areas.	
(2)	Identify the criteria for **exclusion**:
N/A	
(3)	**Recruitment Process – identifying potential subjects** Describe plans about how the population will be **identified** for the purpose of recruiting. *(e.g., database search, personal contacts, referrals, patients under the care of the research team, etc.)*
With support from the Texas A&M Colonias Program, we will involve 8 CRCs in the trial. Promotoras will recruit through existing social networks. Each promotora will invite a group of 8 – 10 Latinas from their local communities to participate in a series of two participatory community mapping sessions at their respective CRC.	

Who will access PHI to **identify** potential participants? *Select one* Note: Not applicable because recruitment will occur through community outreach. No database or PHI will be accessed to identify eligible participants.

☐	Only those with existing legitimate access to PHI will use it to identify potential subjects
☐	There is a need to allow those without existing legitimate access to PHI to use it to identify potential subjects *(submit Form J, HIPAA Waiver)*

(4)	**Recruitment Process – first contact** Describe how **initial contact** will be made with potential subjects (e.g., researchers will contact potential subjects or subjects will contact the researchers or make appoints to see researchers after learning of the study). Describe how those making initial contact have a legitimate access to the subjects' identity and the subjects' information. *(Consider whether a HIPAA Waiver is needed to disclose PHI to member of the research team who do not have legitimate access.)*
Promotoras will approach women in person at community resource centers to determine eligibility and interest. Persons that are interested will be asked to provide their name, contact information, preferred method and time of contact. The promotora will contact the potential subject by phone to invite her to participate in a series of two participatory community mapping sessions at their respective CRC.	

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(5)	**Recruitment process – setting** Describe the **setting** in which an individual will be initially approached. (e.g., private room, inpatient unit, waiting area, group setting, over internet, over phone, in public). Also, describe all interaction between the research staff and the potential subject between the time they contact the research team or vice versa and the time they sign a consent form (including pre-screening activities-see instructions for detailed guidance)
Promotoras will approach women in person at community resource centers determine eligibility and interest. Recruitment will take place at neighborhood and community settings located within the CRC's designated service area.	
(6)	**Recruitment process - advertisements** Will any advertising be used? ☑ Yes (attach) ☐ No ☐ Pending (will submit an amendment after approval)
	If yes, please see Section 4, Form L for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. Promotoras will conduct eligibility screening in person or by telephone. Using a script, promotoras will describe the purpose of the conversation and ask if the prospective subject is willing to answer some questions to determine if she is eligible to participate.
(7)	**Consent Process** Describe the consent/assent **procedures** that will be used by the research team. • Include how: information is provided; the consent interview is conducted; the consent is signed. • Identify the study staff who will conduct the consent interview by their roles (e.g., investigator, research nurse). ***** If the consent process of a single subject will involve more than one member of the research team, describe how this process will be coordinated from start to finish. ****** If you expect this population will have individuals likely to have diminished decision-making capacity (not including incompetent or impaired decision making capacity), describe the assessment process for determining whether the individual is capable of giving informed consent (i.e., evaluation criteria, time intervals)
On the day of the first mapping session, prior to the start of the session, consent will be obtained by a member of the research staff. Research staff will review an information sheet that describes the study and associated risks and benefits according to UTHSCSA's IRB protocols. Participants will receive 1 copy of the information sheet to keep for reference. The information sheet is self-explanatory and written at an appropriate literacy level for the study population, and will be available in both Spanish and English. Promotoras and research staff are bilingual and can describe the study procedures in both English and Spanish.	
(8)	**Consent Process – time between initial contact and obtaining consent** Describe the **timing** of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent. *(e.g., take consent home, waiting period of X hours, after consulting with family members, etc.)*
Consent will be obtained after eligibility screening and before engaging in community mapping sessions. There may be time between the eligibility screening and obtaining consent.	
(9)	Describe measures taken to **minimize** the possibility of coercion or undue influence during consent.
Participants will be informed that their participation is voluntary in nature, that they may cease participation at any time and that their refusal to participate in the research study will not affect their relationship with UTHSCSA, the Texas A&M Colonias program, or the CRC.	
(10)	Will subjects from this population be assigned to different research groups? *(e.g., treatment and control group)*
	☐ Yes ☑ No
If yes, list the groups by inserting a short descriptive title for each group. *E.g., experimental group A, B, etc., control group, etc.* - these labels are needed for the Risk: Benefit Analysis section	

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4.c. For each specific population identified in **4b**, provide the following information in the table provided below.
*(For studies with **more than one** population, copy all of table 4.c. and paste to insert additional tables.)*

Population # 2 — **Population Descriptive Label:** Intervention & Control Groups

(1) Identify the criteria for **inclusion**:

Participants will be women 18 thru 64 years old who self-identify as being of Hispanic, have a personal telephone; reside within and intend to stay in the specified areas over the entire study period; able to understand Spanish; and do not currently meet PA level recommendations. They must be willing to attend the intervention sessions, complete standardized measurement and agree to randomization. Participants must be physically able to participate in a moderate intensity walking program and able to understand and verbally respond to questions.

(2) Identify the criteria for **exclusion**:

Persons who are pregnant, insulin dependent diabetic, have uncontrolled hypertension, or undergoing therapy for life-threatening illnesses (chemotherapy or radiation therapy) will be excluded. Positive (risk) responses on the PA Readiness Questionnaire (PAR-Q) and subsequent physician disapproval on the PA Readiness Medical Examination (PAR-Med-X) will be cause for exclusion70. Participants will be excluded if they already get 5+ days per week of 30 min. of moderate-intensity PA based on their responses to the six questions concerning frequency and duration of moderate and vigorous intensity PA from the Behavioral Risk Factor Surveillance Survey2.The Eligibility Screening Form used in the pilot is in Appendix D.

(3) **Recruitment Process – identifying potential subjects**
Describe plans about how the population will be **identified** for the purpose of recruiting.
(e.g., database search, personal contacts, referrals, patients under the care of the research team, etc.)

With support from the Colonias Program, we will involve 8 CRCs in the trial. Promotoras will recruit through existing social networks. Recruitment will take place at neighborhood and community settings located within the CRC's designated service area.

Who will access PHI to **identify** potential participants? *Select one* Note: Not applicable because recruitment will occur through community outreach. No database or PHI will be accessed to identify eligible participants.

☐ Only those with existing legitimate access to PHI will use it to identify potential subjects

☐ There is a need to allow those without existing legitimate access to PHI to use it to identify potential subjects
(submit Form J. HIPAA Waiver)

(4) **Recruitment Process – first contact**
Describe how **initial contact** will be made with potential subjects
(e.g., researchers will contact potential subjects or subjects will contact the researchers or make appoints to see researchers after learning of the study).
Describe how those making initial contact have a legitimate access to the subjects' identity and the subjects' information. *(Consider whether a HIPAA Waiver is needed to disclose PHI to member of the research team who do not have legitimate access.)*

Promotoras will approach women by telephone and in person at community resource centers to determine eligibility and interest. Persons that are interested will be asked to provide their name, contact information, preferred method and time of contact. The promotora will contact the potential subject by phone to conduct an eligibility screening.

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(5)	**Recruitment process – setting** Describe the **setting** in which an individual will be initially approached. (e.g., private room, inpatient unit, waiting area, group setting, over internet, over phone, in public). Also, describe all interaction between the research staff and the potential subject between the time they contact the research team or vice versa and the time they sign a consent form (including pre-screening activities-see instructions for detailed guidance)
Promotoras will approach women by telephone and in person at community resource centers. Recruitment will take place at neighborhood and community settings located within the CRC's designated service area.	
(6)	**Recruitment process - advertisements** Will any advertising be used? ☑ Yes (attach) ☐ No ☐ Pending (will submit an amendment after approval)
	If yes, please see Section 4, Form L for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use.
(7)	**Consent Process** Describe the consent/assent **procedures** that will be used by the research team. • Include how: information is provided; the consent interview is conducted; the consent is signed. • Identify the study staff who will conduct the consent interview by their roles (e.g., investigator, research nurse). * If the consent process of a single subject will involve more than one member of the research team, describe how this process will be coordinated from start to finish. ** If you expect this population will have individuals likely to have diminished decision-making capacity (not including incompetent or impaired decision making capacity), describe the assessment process for determining whether the individual is capable of giving informed consent (i.e., evaluation criteria, time intervals)
Prior to conducting the telephone eligibility screening, promotoras, using a script, will describe the purpose of the telephone call and ask if they are willing to answer some questions to determine if they are eligible to participate. Prior to enrolling in the study, consent will be obtained by a member of the research staff by signing the consent form that describes the study and associated risks and benefits according to UTHSCSA's IRB protocols. Participants will receive 2 copies of the consent form, one for the study and one for the participant to keep for reference. The consent forms are self-explanatory and written at an appropriate literacy level for the study population, and will be available in both Spanish and English. Promotoras are bilingual and can describe the study procedures in both English and Spanish.	
(8)	**Consent Process – time between initial contact and obtaining consent** Describe the **timing** of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent. *(e.g., take consent home, waiting period of X hours, after consulting with family members, etc.)*
Consent will be obtained after prescreening and before any baseline assessments are administered or subjects are instructed on the use of activity monitors. There may be time between the eligibility screening and obtaining consent.	
(9)	Describe measures taken to **minimize** the possibility of coercion or undue influence during consent.
Participants will be informed that their participation is voluntary in nature, that they may cease participation at any time and that their refusal to participate in the research study will not affect their relationship with the CRC or UTHSCSA.	
(10)	Will subjects from this population be assigned to different research groups? *(e.g., treatment and control group)*
	☑ Yes ☐ No
If yes, list the groups by inserting a short descriptive title for each group. *E.g., experimental group A, B, etc., control group, etc.* - these labels are needed for the Risk: Benefit Analysis section 1. Intervention Group 2. Control Group	

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4.c. For each specific population identified in **4b**, provide the following information in the table provided below.
*(For studies with **more than one** population, copy all of table 4.c. and paste to insert additional tables.)*

Population # 3	**Population Descriptive Label:** In-Depth Interview Participants

(1) Identify the criteria for **inclusion**:

Participants will be a sub-set of the participants (women 18 thru 64 years old who self-identify as being of Hispanic) who participated in the PA intervention. All participants in the PA intervention that complete the 16 week immediate post intervention assessment will be in the population to be sampled for the qualitative interviews. After each cohort completes the 16 week assessment, 4 participants per CRC, stratified by success or failure (based on level of improvement in MVPA), will be randomly selected to take part in a two-part series of individual, in-depth interviews (N=64). Participants will be classified as successful if they show a minimum increase of 15 minutes/day MVPA (objectively measured).

(2) Identify the criteria for **exclusion**:

Participants who participated in the PA intervention but did not complete the 16-week immediate post intervention assessment or did not show a minimum increase of 15 minutes/day MVPA (objectively measured) will not be eligible to participate in the in-depth interviews.

(3) **Recruitment Process – identifying potential subjects**
Describe plans about how the population will be **identified** for the purpose of recruiting.
(e.g., database search, personal contacts, referrals, patients under the care of the research team, etc.)

All participants in the PA intervention that complete the 16 week immediate post intervention assessment will be in the population to be sampled for the qualitative interviews. After each cohort completes the 16 week assessment, 4 participants per CRC, stratified by success or failure (based on level of improvement in MVPA), will be randomly selected to take part in a two-part series of individual, in-depth interviews (N=64). Participants will be classified as successful if they show a minimum increase of 15 minutes/day MVPA (objectively measured).

Who will access PHI to **identify** potential participants? *Select one* Note: Not applicable because recruitment will occur through community outreach. No database or PHI will be accessed to identify eligible participants.

☐ Only those with existing legitimate access to PHI will use it to identify potential subjects

☐ There is a need to allow those without existing legitimate access to PHI to use it to identify potential subjects
(submit Form J. HIPAA Waiver)

(4) **Recruitment Process – first contact**
Describe how **initial contact** will be made with potential subjects
(e.g., researchers will contact potential subjects or subjects will contact the researchers or make appoints to see researchers after learning of the study).
Describe how those making initial contact have a legitimate access to the subjects' identity and the subjects' information. *(Consider whether a HIPAA Waiver is needed to disclose PHI to member of the research team who do not have legitimate access.)*

Promotoras will approach PA intervention participants who are randomly selected from the eligible participants at their CRC to determine interest. Persons who are interested will be invited to be interviewed twice, immediately after the 16-week and 40-week assessments.

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(5)	**Recruitment process – setting** Describe the **setting** in which an individual will be initially approached. (e.g., private room, inpatient unit, waiting area, group setting, over internet, over phone, in public). Also, describe all interaction between the research staff and the potential subject between the time they contact the research team or vice versa and the time they sign a consent form (including pre-screening activities-see instructions for detailed guidance)
Promotoras will approach PA intervention participants who are randomly selected either by telephone or in person at community resource centers to determine interest in participating in the in-depth interviews.	
(6)	**Recruitment process - advertisements** Will any advertising be used? ☑ Yes (attach) ☐ No ☐ Pending (will submit an amendment after approval)
	If yes, please see Section 4, Form L for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use.
(7)	**Consent Process** Describe the consent/assent **procedures** that will be used by the research team. • Include how: information is provided; the consent interview is conducted; the consent is signed. • Identify the study staff who will conduct the consent interview by their roles (e.g., investigator, research nurse). * If the consent process of a single subject will involve more than one member of the research team, describe how this process will be coordinated from start to finish. ** If you expect this population will have individuals likely to have diminished decision-making capacity (not including incompetent or impaired decision making capacity), describe the assessment process for determining whether the individual is capable of giving informed consent (i.e., evaluation criteria, time intervals)
Prior to engaging in in-depth interviews, promotoras will obtain consent from participants. Consent will be obtained by a member of the research staff by signing the consent form that describes the study and associated risks and benefits according to UTHSCSA's IRB protocols. Participants will receive 2 copies of the consent form, one for the study and one for the participant to keep for reference. The consent forms are self-explanatory and written at an appropriate literacy level for the study population, and will be available in both Spanish and English. Promotoras are bilingual and can describe the study procedures in both English and Spanish.	
(8)	**Consent Process – time between initial contact and obtaining consent** Describe the **timing** of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent. *(e.g., take consent home, waiting period of X hours, after consulting with family members, etc.)*
Consent will be obtained prior to engaging in in-depth interviews There may be time between the eligibility screening and obtaining consent.	
(9)	Describe measures taken to **minimize** the possibility of coercion or undue influence during consent.
Participants will be informed that their participation is voluntary in nature, that they may cease participation at any time and that their refusal to participate in the research study will not affect their relationship with the CRC or UTHSCSA.	
(10)	Will subjects from this population be assigned to different research groups? *(e.g., treatment and control group)*
	☐ Yes ☑ No
If yes, list the groups by inserting a short descriptive title for each group. *E.g., experimental group A, B, etc., control group, etc.* - these labels are needed for the Risk: Benefit Analysis section	

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5. Informed Consent for Research Involving Non-English Speaking Subjects – *choose either A, B or C*

A.

☐ **N/A**. The primary investigator for this study will request a waiver of consent for all subjects in this study. (go to #6)

☐ **N/A** This study does not involve interaction with living individuals; *(limited to use of identifiable information)*. (go to #6)

OR

B. ☐ **Only individuals who speak English will be enrolled**. *(if checked select one of the two statements below)*

☐ There is **no** expected direct benefit for those participating. (go to #6)

☐ There is an expected direct benefit for those participating. Excluding non-English speaking individuals is acceptable because: *(insert the rationale for excluding this population below* -- then go to #6)

[Insert rationale here]

OR

C. ☑ **Individuals who do not speak English will be enrolled**.
The translated consent will be submitted to the IRB:
Select one Form B, item 12 should be checked

☑ Immediately following approval of the English consent.
(go to c(1) and c(2) below)

☐ Only after a potential non-English speaking participant is identified. Since this plan will delay enrollment pending IRB approval of a translated consent, provide justification that prospective non-English speaking subjects will not be excluded from beneficial research.
Choose one of the choices below:

☐ There is **no** expected direct benefit for those participating. (go to c(1) and c(2) below)

☐ There is an expected direct benefit for those participating.
Provide justification why the delay is acceptable below, then (go to c(1) and c(2)below)

Insert the reason a delay is acceptable here

C (1) If you are recruiting non-English speaking subjects, Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language).

Recruitment and data collection staff will be bilingual. They will be trained to be conduct participant recruitment and data collection according to UTHSCSA's IRB protocols.

C (2) In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary.

Participants will choose their language of preference.

6. Research Plan / Description of the Research Methods:

6.a. Provide a **comprehensive narrative** describing the **research methods**.
Provide the **order in which tests/procedures will be performed**,
the **setting** for these events and a description of the **methods used to protect privacy** during the study.
Provide the **plan for data analysis** (include as applicable the **sample size calculation)**

Randomization. After baseline data collection, random assignment to experimental condition will use the following procedure: the PI will designate 8 slips of paper as intervention or control (4 intervention, 4 control) and place them into individual sealed envelopes. The sealed envelopes will be shuffled and assigned a number 1 through 8 (written on the outside of the envelope) and given to the Measurement Coordinator in a larger envelope. As each center completes baseline assessments for the first cohort, the Measurement Coordinator will draw an envelope and open it, and will record the CRC name and group assignment into a tracking database. Once randomized, the CRC will remain in the same condition for all 3 cohorts.

Pre-Intervention Activities. Community participation in the *ENLACE* intervention research includes input and advice from the Community Advisory Group (CAG) and incorporation of findings from community mapping sessions with women in the community into the program implementation plan. Members of local communities; representatives of Latino-serving community based organizations; and regional public health practitioners have been identified to participate as members of the. The group will consist of approximately 8-10 community members who will provide advice on all aspects of conducting the research successfully in the community, including establishing trust and community acceptance, identifying recruitment strategies, insuring cultural appropriateness of the methods and materials, determining logistics, retaining participants, and providing participant incentives. The CAG, chaired by Dr. Parra-Medina, will meet quarterly in the first year of the trial and twice a year thereafter. Additional stakeholders, community members or technical advisors will be recruited for their expertise, skills or knowledge as needed.

To gain a better understanding of the unique social and environmental context of communities served by the 8 CRCs in the study, we will develop a community profile for each CRC and engage community members in participatory community assessments. In Year 1 we will compile demographic, epidemiologic, and environmental data for the 4 LRGV counties; where available we will collect neighborhood-level data for the communities surrounding the CRCs. Census data for block groups will provide indicators of economic variability (i.e., female headed households, unemployment, % families under the poverty line and % families with children <5 years) and residential stability (i.e., criminal activity, % renters, and % of residents who have lived in their home >5 years). Health status indicators will be gathered from national surveillance data. Summary tables of socio-demographic and environmental variables relevant to the context for PA and community health will be developed for each CRC. These objective community indicators will create a snapshot of the community context and provide a backdrop for the qualitative exploration of perceptions and potential impact of the social and environmental barriers and assets/enablers.

Drs. Messias and Sharpe will be responsible for developing the research protocols for training the *promotoras* to engage community representatives in a variety of community assessment, asset mapping, and capacity-building activities[71, 72]. Community mapping is an approach that involves residents in a collective inventory of community assets (e.g., physical, social, cultural resources), using a wide range of activities (e.g. web-based mapping, interviews or focus groups with residents, walking/driving tours). The resulting "maps" and inventories are used to identify opportunities for community improvement and developing strategies to address gaps or needs. Each *promotora* will invite a group of 8 – 10 Latinas from their local communities to participate in a series of two participatory community mapping sessions at their respective CRC. Participants will receive $20 incentive for participating in each session. The primary focus of these activities will be to identify and assess social and environmental factors related to PA. Trained observers will record detailed field notes during the mapping sessions and will collect the participants' story maps created during these sessions[72]. Following each mapping session the investigators and data collectors will review and summarize the data emerging from the participatory activities. The qualitative and quantitative data from the mapping sessions, including group activities, systematic environmental observations, and the resulting community-developed maps will be analyzed and summarized using descriptive qualitative and quantitative methods. Findings from these participatory community assessment activities will be shared with the CAG and incorporated into the *ENLACE* intervention content[73].

D.2.4.2. *ENLACE* PA Intervention Activities. Consistent with national PA guidelines, participants randomized to the *ENLACE* PA intervention will be encouraged to engage in moderate to vigorous intensity PA for 30 minutes on 5 or more days per week. The *promotora*-led intervention will consist of 16 weekly sessions that include 30 minutes of group health education plus 30-45 minutes of group exercise. The sessions address the determinants of knowledge, perceived barriers and benefits, behavioral skills, self-efficacy, reinforcement and social support for the behavioral outcome of increasing MVPA. Didactic approaches include information provision, discussion, active learning, guided practice, self-reevaluation, and modeling. Participants will receive a pedometer and a set of resistance bands (3 resistance levels). *Promotoras* will demonstrate the use of pedometers, walking techniques, strength exercises with resistance bands, and self-assessment of exercise exertion level. Participants will start their PA program slowly, gradually increasing both frequency and intensity over the 16 weeks in order to meet the study goal. Pedometers will be used as a PA self-monitoring and motivational enhancement tool. The *promotora* will advocate using steps per day as part of goal setting activities (e.g., focusing on increasing steps per day through bouts of walking). Women in the *ENLACE* pilot preferred (1) incorporating group exercise as a part of the health education sessions and (2) brisk walking and Zumba©. *Promotoras* will be trained to lead group exercise activities and will have access to an exercise DVD library, resistance bands, and yoga mats. These PA options and resources will also be available at the CRCs for participants' use outside the scheduled intervention sessions. In addition, *promotoras* will use the Volunteer Walk Leader Manual to recruit and train a cadre of volunteers to lead walking groups at the CRC. This manual, developed at the University of South Carolina, was translated into Spanish for use in the pilot study. (A copy of the manual is in Appendix C.)

D.2.4.3. Maintenance Intervention. Following the 16 week PA intervention, *promotoras* will begin the 24 week maintenance intervention that includes telephone counseling and newsletters. *Promotoras* will conduct motivational telephone counseling calls twice a month to follow-up on participant's PA progress and provide support and reminders on PA activities at local CRCs. They will also hand deliver a monthly newsletter to intervention participants homes. Face to face interaction is a key part of the *Colonias* Program outreach model.

Telephone Counseling. In order to have personalized contact, each participant in the intervention (but *not* in the attention

control condition) will receive brief (10 minute) telephone counseling calls from a *promotora*. We will adapt the HHER Lifestyle telephone counseling training and protocol for this intervention component[64]. The counseling calls will emphasize behavior change strategies, including self-monitoring, goal setting, reinforcement, problem solving, stimulus control, and enlisting social support. Goal setting will include PA frequency and duration, pedometer steps and use of community resources (e.g., goal might be to attend one community-based PA class, etc.). Telephone counseling for home-based health behavior programs has shown to be an effective, convenient, flexible, and safe delivery channel[74] for lower-income ethnic minority adults [63, 75]. During telephone counseling calls, *promotoras* will also ask the participant to read back information from her self-monitoring log. The frequency of monitoring will be negotiated by the participant and *promotora*. Frequent monitoring (i.e., daily) will be recommended, as degree of self-monitoring has been associated with better behavioral adherence in other studies[76, 77].

Newsletters. Intervention participants will receive six monthly newsletters over the course of the 24 week maintenance intervention. The newsletters will be tailored for each community center and include a role model story, community PA resource highlights and a calendar of community PA programs, activities and events. This newsletter will be bilingual, culturally appropriate, and written no higher than a 6th grade educational level.

D.4.2.4. Environmental Change. Social ecological models[33, 34, 78] emphasize that the environment is an important influence on health behavior. We will work with *promotoras* at the four *ENLACE* PA intervention CRCs to create a site atmosphere that promotes PA. Examples might include educational posters, promotional activities to increase awareness and appeal of existing resources, notices of related community events, and a display board highlighting the *ENLACE* Program and participants who have been successful in the program. *Promotoras* will also increase the number of PA program offerings at the CRC by identifying and training volunteer walk leaders and using an exercise DVD library to offer regularly scheduled group exercise classes.

D.4.2.5. Attention Control Intervention. Attention control participants will receive a research-tested first aid and home safety program developed for Hispanic migrant adolescents and their families[79]. We selected the home safety/first aid as the attention control condition because changes in these behaviors should have no impact on PA, the curriculum is available in Spanish, and has been shown to improve first aid knowledge and emergency response skills. In addition, the *Colonias* Program staff indicated it was relevant topic for families in the *colonias*. The program includes 8 sessions that last 1.5-2 hours. These sessions will be offered twice per month to extend them over a 16 week period. The session content ranges from identifying household safety hazards to disaster preparedness. During the 24 week maintenance phase, *promotoras* will contact participants by phone each month and conduct monthly home visits to distribute health education materials on first aid and home safety from CDC, state health department and other reliable health organizations (e.g., Red Cross). Attention control participants will not receive telephone counseling calls.

Measurement and Evaluation

Standardized data collection protocols will be carried out for all participants at baseline, 16-, and 40-weeks.

Primary Outcome Measures:

Physical Activity. We will use two measures of PA. Accelerometers: Participants will be instructed to wear accelerometers over seven consecutive days. The Actigraph GT3X 16Mb activity monitor is small, light weight, and designed to detect vertical acceleration that allows for the detection of normal human motion and reject high frequency vibrations encountered in activities such as operation of a lawn mower. The filtered acceleration signal is digitized and the magnitude is summed over a user-specified time interval. At the end of each interval, the summed value or activity “count” is stored in memory and the integrator is reset. For the proposed study, participant will wear the monitor for one week and a 1-minute time interval will be used. Freedson et al.[82, 83] assessed the validity and inter-instrument reliability of the ActiGraph monitor in adults. Activity counts were strongly correlated with energy expenditure during treadmill walking and running (r = 0.86) We will determine the total time per day spent in moderate and vigorous PA by using adapted cut points previously established by Freedson et al.[82, 83] Participants will need to wear the accelerometer for at least 10 hours per day and on at least 3 of the 7 days for reliable measurement of activity. Sharpe and Parra-Medina have used activity monitors in previous studies and had high compliance (81%) with the activity monitor protocol in the pilot study[84]. (See Appendix D for accelerometer log). Self Report: We will use a comprehensive self-report measure to characterize participants’ type, pattern, nature, and amount of PA in a typical week. The Community Health Activities Model Program for Seniors Physical Activity Questionnaire (CHAMPS) is a 41-item self-report measure of PA was developed originally for older adults, but it has been used with general adult populations[64, 85]. We will use the measure as originally developed, but we will modify those items that are geared for older adults to be age-neutral (e.g., replace “visit a senior center” with “visit a community center”). For the proposed study, we will use total minutes per week spent in moderate and vigorous PA as the primary outcome measure. The CHAMPS has strong psychometric properties and has also been shown to be sensitive to change in intervention studies[85].

Secondary Outcome Measures:

Physical Fitness. The YMCA 3 minute step test will be used to assess changes in cardiorespiratory fitness associated with increased PA[86]. We will also apply the equations developed by Juraca et al.,[87] should we find that women cannot perform the standard fitness assessment.[86, 87]

Anthropometrics. Weight (to the nearest 0.1 kg) and % body fat, will be measured using a portable Tanita Body Composition Analyzer SC-331S. Height (measured to the nearest 0.1 cm) will be obtained using a stadiometer at baseline only. Participants will be asked to remove their shoes prior to both measurements. BMI will be calculated as weight (kg)/height squared (m^2). Waist circumference will be measured at the midway between the iliac crests and the lower ribs, whereas hip circumference will be measured at the level of the greatest protrusion of the buttocks when the subject is standing erect with feet together. All will be measured twice and the average used. We will use the definition of weight maintenance proposed by Stevens et al.,[88] indicating that a change in body measurement (BMI or % body fat) <± 3% is consistent with weight maintenance in adults.

Mediator Variables:

Self Efficacy. Sallis et al.'s[89] self-efficacy scales for exercise behaviors (12 items) have been widely used and have strong psychometric properties, with test-retest reliability ranging from 0.43 to 0.68, internal consistency ranging from 0.83 to 0.93, and demonstrated criterion-related validity[89].

Social Support. The social support for PA (13 items) is based on Sallis et al.'s[90] scale, where participants rate the extent to which family and friends are supportive of PA changes. These measures have shown acceptable test-retest reliability (r = 0.55 to 0.86), internal consistency (alpha = 0.61 to 0.91), and concurrent criterion-related validity[90].

Benefits and Barriers. Marcus et al.'s Decisional Balance Scale for PA[91] assesses perceived benefits (pros) and perceived barriers (cons) of PA.

Collective Efficacy. Sampson et al.'s[92] measure of collective efficacy is composed of two related subsclaes scales on mutual trust/cohesion and shared expectations for social control.

Center for Epidemiological Studies Depression Scale (CES-D) assesses depressive symptoms and has acceptable internal consistencies of .87 and above[93, 94].

Perceived Stress Scale (PSS-10) examines the degree to which specific situations are deemed as stressful in the past week. The PSS is well validated and has been used in many studies examining the association between stress and health[95].

Perceptions of Environmental Supports. The 10 items were adapted from the International Physical Activity Prevalence Study (IPS) Self-Administered Environmental Module to assess environmental supports and capture participants' sense of community opportunities for PA.

Food Frequency Questionnaire (FFQ) is approximately a 110 food item questionnaire designed to estimate usual and customary intake of a wide array of nutrients and food groups that is to be conducted by interviewer-administration.

Demographic Variables:

Demographic data (collected at baseline only) will be used to describe the study participants and facilitate statistical analyses where potential confounding by these variables should be controlled. Information will include age, current marital status, educational attainment, acculturation, nativity, current employment status and occupation, household size, family income.

In-Depth Interviews:

Individual in-depth interviews will be conducted with a subset of participants in the PA intervention. The purpose of the interview is to explore participants' personal experiences of behavior change and identified barriers and enablers to success/failure, including intrapersonal, social and environmental influences (Aim 2d). These qualitative data will complement and explicate quantitative findings from the intervention (Aim 2c). All participants in the PA intervention that complete the 16 week immediate post intervention assessment will be in the population to be sampled for the qualitative interviews. After each cohort completes the 16 week assessment, 4 participants per CRC, stratified by success or failure (based on level of improvement in MVPA), will be randomly selected to take part in a two-part series of individual, in-depth interviews (N=64). Participants will be classified as successful if they show a minimum increase of 15 minutes/day MVPA (objectively measured). Each participant selected will be interviewed twice, immediately after the 16 week and 40 week assessments.

Process Evaluation. The evaluation plan will be modeled after the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) Framework, a systematic approach for evaluating public health interventions that broadens the evaluation criteria to include context, external validity, and issues relevant to program adoption, implementation, and maintenance[100].

Quantitative Data Analysis Plan: Prior to inferential procedures, extensive descriptive analyses will be conducted for each outcome measure at each time point (baseline, immediate post-test, delayed posttest and follow-up) for both intervention and control groups. Descriptive statistics including means, ranges, standard deviations and percents will be computed for the measures, together with ninety-five percent confidence intervals for the means and other continuous measures. Graphical procedures including boxplots and histograms will also be employed to more closely examine the distribution of the continuous measures. Data transformations will be used as indicated. Bivariate associations between the measures and selected demographic variables will be evaluated using correlation coefficients and contingency table analyses where appropriate.

*Primary Outcomes (Aim 1 & Aim 2b)***.** MVPA outcomes will be self-reported behavior of a typical week measured with the CHAMPS instrument (minutes/week MVPA) and objective measurement from the accelerometer (minutes/day MVPA). Averages for each MVPA outcome at each time-point will be calculated and compared for the intervention versus the attention-control group and ANOVA tests will performed to evaluate for significant differences between groups. Assessment will be made to determine direction- e.g. increases or decreases- of change between baseline and post-intervention, and baseline and 6-month follow-up. Using STATA 11 to conduct our modeling we will use a regression that is both multilevel and temporal in nature. Mixed-effects regression can be conducted using the xtreg , xtgee and xtlogit command in STATA 11 SE[102], depending on the structure of the outcome variable. In this case, time-points of measurement are nested within subjects in a random intercept model. Random coefficient modeling will be conducted using random effects variables at level 2 (subject level) that will be both fixed (nativity, occupation, education, baseline age, etc.) and time varying (perceptions over time, behavior over time, income). Below we represent the equation for a binomial outcome model

$\log(\mu ij) = x'ij\ \beta 1 + x'ij\ \beta 2$ (i= level1-repeated MVPA measures over time, j= level 2- Individual level covariates)

Whereas βij represents the expected change in the log of the mean unit change of xij A one unit change in xij corresponds to an increase βij in the log of the average.

Secondary Outcomes (Aim 2a). Similar methodology will be implemented in this analysis as in AIM 1. Our outcome variables

for aspect of the study will be physical fitness, BMI and anthropometric measures of body fat. Averages for physical fitness, BMI and body fat will be calculated for intervention versus the attention-control group and ANOVA tests will be conducted to evaluate significant cross-sectional differences between the intervention and attention-control groups. Evaluation of temporal changes between each time-point will be made. Mixed effect regression models will be conducted as described in Aim 1.

Mediation Analyses (Aim 2c). As outlined by MacKinnon[103, 104], mediation will be assessed by conducting two regression models. The first model will regress change in the hypothesized mediator (e.g., social support, self-efficacy) on intervention group (intervention vs. control) (α coefficient path). The second model will regress change in the outcome variable (e.g., MVPA) on intervention group and change in the hypothesized mediator (β coefficient path). To assess the magnitude of the effect for each potential mediator, the Sobel-Goodman test will be conducted using *sgmediation* in STATA 11 SE[105]. This method provides direct and indirect effect estimates, proportion of effect explained by mediator, and significance testing.

Attrition Analyses. We will compare all baseline demographic, cognitive, and behavioral variables of participants lost to follow-up with baseline data of the cohort, to determine possible selective or differential (by treatment condition) attrition. For instance, analyses will be conducted to determine if participants with greater weight or lower PA disproportionately drop out of the study. Selective attrition (i.e., do dropouts differ from the cohort as a whole?) will be considered a threat to external validity or generalization. Presence of differential attrition (i.e., difference in dropouts between treatment conditions) will be considered a threat to internal validity. To the extent that some subjects are lost to follow-up, analysis for the primary and secondary hypotheses will be carried out under the intent-to-treat principle.

Qualitative Data Analysis Plan. Audio recordings of interviews will be transcribed verbatim in the source language and returned to the PI in paper and electronic (Microsoft Word) formats. A data collection assistant will review the paper transcripts for quality control purposes to make sure that the paper and electronic transcripts are as accurate and reflective of the interview as possible. All identifying information will be removed from transcripts. The transcript files will be imported into AtlasTi software for qualitative data management and analysis. All data in paper format will be stored in locked cabinets in locked offices. Dr. Messias will lead the qualitative analysis of the interview data in the source language, using thematic analysis procedures and the constant comparison method[97,106]. For presentation and dissemination, selected excerpts of the Spanish-language qualitative data will be translated into English.

Power and Sample Size: Power calculations were conducted to determine the minimum detectable effect size based on a desired power achievement =0.80 using Optimal Design[101]. Setting the standard effect size to 0.50 and an expected intraclass correlation of .01, we have calculated a minimum number of 83 subjects per site will be needed. Based on a 76% retention rate from the pilot study, we will sample an additional 25 subjects to maintain statistical power throughout study duration for a total of 108 per site and an overall total of 864 subjects.

In-Depth Interviews: With a resulting sample of 96 interviews, we anticipate meeting the requisites of saturation and sufficiency[96]. Saturation refers to the point in the study at which analysis of the interview data results in no new properties or dimensions[97]. The greater the amount of pertinent (on-topic) data obtained from participants, the smaller number of participants required for saturation; thus, well-devised and conducted interviews with skilled probing reduces the need for large sample sizes in order to fully assess the phenomena under [study98]. Sufficiency is the extent to which the participant sample encompasses the range of variability in the participant characteristics, especially those of known relevance to the topic[99]. Due to the relative homogeneity of our participants, a sample of 96 interviews is expected to be sufficient.

6.b. List of the study intervention(s) being tested or evaluated under this protocol

☐ **N/A -** this study does not test or evaluate an intervention. Skip to item 6.d.

#	Study intervention(s) being tested or evaluated under the protocol *Add or delete rows as needed*	Local Standard Practice Indicate whether the intervention is considered acceptable practice locally
1	Physical Activity Intervention	☑

6.c. Risk:Benefit Analysis of study interventions being tested or evaluated under this protocol

For each study intervention identified in section 6b above, complete a risk:benefit analysis table.

(Two tables are provided, copy & paste additional tables as needed or delete both tables if this study does not test an intervention)

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6.c.
Study Intervention #1
Physical Activity Intervention

List each group exposed to this intervention on a separate line. (e.g., experimental, control, Arm A, Arm B, etc **Or** state All Groups/Subjects	For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject's well being). If there are no benefits, state "none".
Intervention Group	none

For this intervention, **list the reasonably foreseeable risks**
List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).
(include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)
Do not delete frequency. The need to know what to report promptly later = a requirement to estimate frequency (Instructions).

	Not serious	**Serious**
Likely These risks are expected to occur in more than 20 out of 100 subjects.	• The potential risks involved in this project are minimal but include medical complications resulting from walking. The major risks of exercise training by adults are orthopedic and cardiovascular. Orthopedic problems are primarily of the overuse category and can usually be treated by rest and change in the mode of PA. Minor problems may occur, including temporary soreness or irritation of muscles, tendons, and joints.	• None
	Not serious	**Serious**
Less likely These risks are expected to occur in 5-20 subjects or less out of 100 subjects.	•	•
		Serious
Rare These risks are expected to occur in less than 5 subjects out of 100		• The major risks of exercise training by adults are orthopedic and cardiovascular. By far the greatest cardiovascular risk is exercise precipitated or aggravated sudden cardiac arrest. The likelihood of cardiac arrest during exercise in persons with underlying heart disease is associated with the degree of underlying heart disease, higher exercise intensity, and sporadic exercise participation.

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6.d. List of ALL other research procedures or components not listed in table 6.b.
All of the research procedures for this study should be listed in either table 6.b. or 6.d.

Consider grouping similar procedures under a single component. E.g., blood work, CT = safety assessments)
(Click here for example)

#	Research component • **individual procedures** *example:* **Eligibility Assessments** • History and physical • Questionnaire • Laboratory tests *Add or delete rows as needed*	**Column A** **Local Standard Practice** Indicate the number of times each procedure will be performed as stipulated in the research plan **that would be done as part of standard practice.**	**Column B** **Research Only** Indicate the number of times each procedure will be performed solely for research purposes *(any performed outside frequency or timing for acceptable local practice)*	**Column C** **Risks** List the reasonably expected risks under the following categories as appropriate: • Serious and likely; • Serious and less likely; • Serious and rare; • Not serious and likely; • Not serious and less likely
1	**Eligibility Screening**			
	Obtain consent		1	Serious and rare • Loss of confidentiality
2	**Physical Activity**			
	Accelerometry		3	None
	Self-Report (Community Health Activities Model Program for Seniors Physical Activity Questionnaire – CHAMPS)		3	None
3	**Physical Fitness**			
	YMCA 3-minute step test (cardiorespiratory fitness)		3	Not serious and less likely • Medical complications resulting from engaging in physical activity. The major risk of exercising is orthopedic injury. • Minor, temporary muscle soreness may also occur as a result of engaging in exercise activities.
4	**Anthropometry**			
	Body Mass Index		3	None
	Waist Circumference		3	None
	Body Fat Percentage		3	None
5	**Questionnaires**			
	Mediator variables (self-efficacy, social support, benefits and barriers, collective efficacy, Center for Epidemiological Studies Depression Scale (CES-D), Perceived Stress Scale (PSS-10), perceptions of environmental supports), Food Frequency Questionnaire (FFQ)		3	None
	Demographics		1	Serious and rare • Loss of confidentiality
6	**Qualitative Data**			
	Community Mapping		1	None
	In-Depth Interviews		2	None

7. Safety Precautions. *(Describe safeguards to address the serious risks listed above.)*

a. Describe the procedures for protecting against or minimizing any potential risks for each of the more than minimal risk research procedures listed above.

The risks of a moderate intensity PA program are minimal, even in those with health conditions. We will carefully exclude participants in the high-risk strata according to ACSM criteria. ACSM does not recommend exercise testing for those in low or moderate CHD risk strata. We will have regular contact with intervention participants and will monitor safety at these contacts.

During all data collection time points, study personnel will assure participants that participation is completely voluntary and may stop at any time. Participants will be informed that the decision to participate or withdraw from the study will not influence their relationship to the Colonias Program or other partner institutions. Participants will be told that their identities and their verbal, typed, or written responses will be kept strictly confidential. We will train data collection staff to store any written information and audio-tapes in a secure area (locked cabinet and room) and to separate the collected data from any participant identifiers (identifiers will be stored in another locked cabinet). Only the PI and research team will have access to all data. The PI will stress the need for confidentiality regarding collected data and the importance of storing data in secure locations to all study personnel during the training session and periodically throughout the study. All investigators have completed the required human subjects training and all personnel hired for the project will complete the training as part of their orientation to the project and prior to interacting with potential participants or handling any participant data.

The PI will train staff to inform all participants that penalties will not occur for undesirable answers to questionnaires. Staff will, however, encourage honest answers. A quiet private environment will be available for questionnaire completion. Data will be stored in electronically on password protected servers. All study personnel will be trained on protocols for notification about problems or adverse events.

b. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects.

Although not expected, adverse events or the potential for adverse events will be immediately brought to the attention of the PI or Measurement Coordinator (e.g., anxiety/emotional upset from answering questionnaires, injury from participating in objective measures of physical activity). The PI and MC will develop detailed protocols that will be provided for everyone interacting with the participants in any phase of the study. The protocol will include specific instructions to follow in the case of any adverse event. Telephone numbers for home and office and cell phones and email addresses will be included. Any identified problems not directly related to the study (e.g., signs of depression or other mental health problems) will be immediately reported to the PI who will follow University procedures in these matters.

c. Will the safeguards be different between/among groups?

☐ Yes ☑ No

8. Confidentiality of the Research Information

a. Specify **where** the data and/or specimens will be stored and **how** the researcher will **protect the confidentiality** of subject information.

A. Protection of Subject Privacy – Data will be kept in strict confidence. No information will be given to anyone without permission from the subject. Confidentiality is assured by use of identification codes, password protected electronic files, and paper files stored under lock and key. Anthropometric assessments will be conducted in a private setting so that no one can overhear private information.

B. Database Protection –The database will be secured with password protection. The Evaluation Coordinator will receive only coded information, which is entered into the database under those identification codes. Attendance and Retention tracking databases that include participant names will be password protected. Unique participant numbers will be assigned prior to data collection so that participant names do not appear on paper or electronic questionnaires.

C. Confidentiality during AE Reporting –Adverse Event reports and annual summaries will not include subject-identifiable material. Each will include the participant's ID number only.

b. Will all electronic data be stored in accordance with the institution's information security policy and encryption standards?

☑ Yes ☐ No, if no explain below

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9. Payment. (payment of subjects should be included in the consent form)

a. Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study.

Participants will be compensated for their time at the conclusion of each of the three assessment periods.

b. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment.

IRB policy requires a provision for providing partial payment to subjects who withdraw before the completion of the research. For *VA research, payment to human subjects participating in research is prohibited when the research is integrated with the patient's medical care and when the research makes no special demands on the patient beyond those of standard medical care. Payment may be permitted, with IRB approval, under certain circumstances. Consult with the VA R&D Office to discuss payment of subjects*.

Incentives will be distributed as measurement tasks are completed. For each assessment period (baseline, 16-week and 40-week), $30 will be distributed to participants in three payments: a) $10 when participants provide informed consent, complete anthropometric and fitness assessments, psychosocial survey, and receive instructions for wearing the accelerometer and completing a brief self-report activity log (measurement Visit 1); b) $10 when participant completes the behavioral and dietary intake survey (measurement Visit 2) c) $10 when the participant wears the physical activity monitor and returns it to the research team with sufficient data recorded (measurement Visit 2 or Visit 3, if needed). All payments will be in the form of gift card.

Subjects participating in the in-depth interviews will receive a $20 gift card for each completed interview for a total of $40.

Subjects participating in the community mapping sessions will receive a $20 gift card for each completed session for a total of $40.

10. Costs to Subjects. (costs to the subject should be included in the consent form)

a. Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research.

The only cost for care would be for participants with positive responses to the PARQ and require physician approval (PAR MedX) to participate, however this would only be necessary prior to enrolling in the research.

b. Describe any offer for reimbursement of costs by the sponsor for research related injury care. (Attach a copy of the section of the clinical trial agreement or contract describing research related injury care – the information in this section must match the injury section of the consent form).

None

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11. PI-Sponsored FDA-Regulated Research

If the PI is the IND/IDE holder, or has agreed to perform any of the IND/IDE holder's sponsor obligations, the PI is considered a sponsor (sponsor investigator) and must meet additional requirements. (Form O, O-1 and P provide details)

[see Office of Clinical Research policies]

☑ N/A. The PI is not the IND or IDE holder, or has not agreed to perform sponsor obligations

a. Has the PI completed the CITI module: Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices?

☐ Yes ☐ No. If no, complete the training prior to submitting this protocol

b. Describe the PI's experience/knowledge/training related to serving as a sponsor-investigator.

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Abstract / Project Summary

Provide a succinct and accurate description of the proposed research. State the purpose/aims. Describe concisely the research design and methods for achieving the stated goals. This section should be understandable to all members of the IRB, scientific and non-scientific. This summary will also be needed in future IRB Progress Reports.

DO NOT EXCEED THE SPACE PROVIDED.

Hispanics/Latinos experience a disproportionate burden of obesity-related chronic diseases, threatening the future health of the nation's fastest-growing population. Physical inactivity has been linked to increased risk of obesity, type 2 diabetes, and various cancers. Latinos are more likely than non-Hispanic whites to fail to meet physical activity (PA) recommendations, and Latino women are less physically active than Latino men. The **goal** of the proposed *ENLACE* research project is to design, implement and evaluate a *promotora*-led PA intervention that takes a comprehensive, multi-level, community-based approach to promoting moderate-to-vigorous physical activity (MVPA) among a particularly underserved segment of Latinas. The intervention approach, based on the social ecological model, focuses on individual attitudes and skills, socio-cultural factors and environmental influences to behavior change. The proposed group-randomized controlled trial builds on formative and pilot research (funded by a National Heart, Lung and Blood Institute R21, HL087765) by a team of academic investigators and community partners with extensive experience working together to conduct behavioral interventions and outreach with Latino and disadvantaged populations. Eight community resource centers (CRCs) in four predominantly Latino counties in South Texas' Lower Rio Grande Valley will be randomly assigned to either the *ENLACE* PA Intervention (4 CRCs) or an attention-control condition (4 CRCs). We will recruit 864 Latinas ages 18-64 who do not meet national PA guidelines from *colonias* (unincorporated, impoverished, underserved Latino settlements) in the CRC service areas. Participants from CRCs randomized to the *ENLACE* PA Intervention (N = 432; 108 women per CRC) will receive 16 weekly *promotora*-led group sessions followed by 24 weeks of a maintenance intervention (monthly *promotora*-delivered newsletters and telephone counseling twice a month). The group sessions' behavioral goal is for Latinas to engage in 30 minutes per day of MVPA on 5 or more days per week. The attention-control group (N = 432; 108 women per CRC) will receive 8 *promotora*-led group sessions twice a month on home safety/first aid and monthly generic health education materials during the maintenance intervention period. The primary outcome is minutes per day of MVPA (measured with accelerometers). Secondary outcomes are physical fitness and weight maintenance. We also will evaluate self-efficacy, social support, decisional balance, collective efficacy and food frequency as mediators of MVPA changes. Standardized measurement of primary and secondary outcomes will occur at baseline, immediate (16 weeks) and delayed post-intervention (40 weeks). We **hypothesize** that Latinas in the *ENLACE* PA Intervention will significantly increase their MVPA levels as a result of addressing their specific individual, socio-cultural and environmental barriers and enhancing their social support and collective efficacy, compared to attention-control Latinas.