PHS Human Subjects and Clinical Trials Information

OMB Number: XXX

Expiration Date: XXXX

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	● Yes ❍ No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	● Yes ❍ No
Is the Project Exempt from Federal regulations?	❍ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	[redacted]	No

Section 1 - Basic Information (Study 1)

1.1. Study Title *

[redacted]

1.2. Is this study exempt from Federal Regulations * ❍ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	❍ No
1.4.b. Are the participants prospectively assigned to an intervention?	❍ Yes	● No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	❍ Yes	● No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	❍ Yes	● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- [Redacted] risk screening, brief risk reduction counseling and referral to preventive resources

2.2. Eligibility Criteria

adults with high [redacted] risk (defined as [redacted] risk score >X or [redacted] >X% or [redacted] >XX mg/dL) living in the target [redacted] counties.

2.3. Age Limits	Min Age: 18 Years	Max Age: 70 Years
2.3.a. Inclusion of Individuals Across the Lifespan	Individuals_Across_the_Lifespan.pdf	
2.4. Inclusion of Women and Minorities	Inclusion_Women_Minorities.pdf	
2.5. Recruitment and Retention Plan	Recruitment_and_Retention_Plan.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	STUDY_TIMELNE.pdf	
2.8. Enrollment of First Participant	0X/0X/2024	Anticipated

Inclusion of Individuals Across the Lifespan

Sample Age and Rationale. In aim 1, we will include 3X community stakeholders through our existing partnerships in [redacted] counties (1X per county). Participants will include Hispanic adults with self-reported [redacted], community leaders, community health workers, and health practitioners living in the target [redacted] counties. These participants will be selected because they represent end-users who may facilitate, receive, or deliver the services offered in the health units. As such, they will form the team that will design the health unit and its delivery system.

In aim 2 we will include all adults 18-70 years who are identified as at-risk of [redacted] based on the screening. The rationale for including adults younger than 35 years (like the screening recommendations suggest) is to prevent missing high-risk individuals at younger ages in this population of [redacted] Hispanics. The inclusion criteria is capped at 70 years based on [redacted] screening recommendations from the US Preventive Task Force.

Expertise of the Investigative Team for this Population. All study team members have experience working on interventions/prevention with adults from diverse populations.

Facilities Designed for This Population. The mobile unit will be especially designed to work with adults. All clinical screening tools have been validated for use in adult populations.

Age Range Contribution to Purpose of the Study. In aim 2, we will include age as a covariate and conduct exploratory analysis based on age groups. The age distribution of the individuals identified as high-risk is also of interest.

Inclusion of Women and Minorities

Gender inclusion. The community design team for aim 1 will aim to include an equal number of male and female participants. The [redacted] units will attempt to serve men and women equally. The gender composition of the sample for the aim 2 analysis will depend on two factors: the proportion of male and females that request services from the [redacted] unit and the prevalence of [redacted] risk by sex.

Ethnic minority inclusion. [Redacted] Hispanics are the main target of this study. The [redacted] unit will serve everyone that requests services, but for the purposes of the analyses we will include only those of self-identified Hispanic ethnicity.

Rationale and Outreach for Selection of Sex/Gender and Racial/Ethnic Group members. The study has been designed to be inclusive of all Hispanic adults who reside in target counties. We anticipate that we will have adequate representation across gender and efforts will be made to address potential gender selection bias during the design phase (aim 1). The study team will also monitor gender distribution during the implementation of aim 2 to account for potential selection bias.

RECRUITMENT AND RETENTION PLAN

Aim 1. We will identify a convenience sample of 3X community stakeholders through our existing partnerships in [redacted] counties (1X per county). Participants will include Hispanic adults (≥35 years of age) with self-reported [redacted], community leaders, community health workers, and health practitioners living in the target [redacted] counties. These participants will form the design team and will represent end-users who may facilitate, receive, or deliver the services offered in the health unit model. Their participation will involve two main activities: 1) serve as a community advisory board to steer research activities and 2) form the team that will design the [redacted] unit and its implementation system.

Aim 2. This will be a single group pilot-test study among users of the health unit model. We will recruit a convenience sample of 2XX users that meet the following criteria: adults with [redacted] risk (defined as [redacted] ≥X or [redacted] ≥X% or [redacted] ≥XX mg/dL) living in the target [redacted] counties. We expect at least 8X% retention based on our previous studies with Hispanics, however, if 5X% of users are lost to follow up, we would obtain a confidence interval with 0.10 (±10%) margin
of error to assess reach (primary outcome).

Recruitment and Retention. Reticence to participate in the screenings may be greater for some Hispanic groups, especially those who are undocumented or of lower socioeconomic status. To address this, we will work with community partners that are trusted by the Hispanic community and have a long history of serving these groups. Similarly, high attrition has been reported amongst Hispanics in health interventions. We expect the participatory design process to minimize attrition and will monitor the recruitment and data collection closely to trouble shoot as needed and maximize retention. In addition, we are prepared to take additional steps to increase enrollment, such as increasing the number of health unit visits, adding new settings for events, and promoting events through our community partners. Additional steps we will take to minimize loss to follow up include calling at more convenient hours for participants, texting or using WhatsApp to schedule calls, and having native Spanish speakers complete the calls.

STUDY TIMELINE

Our team possesses relevant expertise to successfully complete the proposed study. The MPIs possess expertise in [redacted], [redacted], and chronic disease prevention. Additionally, Dr. [Contact PI's last name] is an expert in mixed-methods program evaluation and [redacted] health research, which complements Dr. [Co-PI's last name] expertise in [redacted] prevention. The MPIs also possess the experience and cultural competence to lead this study (both are Hispanics whose first language is Spanish). Dr. [Contact PI's last name] and Dr. [Co-PI's last name] have a history of collaboration and have developed an MPI management plan to complete the proposed study (see attached).

The team is strengthened by co-investigators with expertise in behavioral health and [redacted] prevention ([last name redacted]) and in public health services research with underserved communities in [redacted] settings ([last name redacted]). Further, we will work in collaboration with [University's] Center for [redacted], a long-standing [redacted] partnership [redacted] that will guide and support this study. The table below outlines the activities proposed for this study and the team expertise.

Activity	Team expertise	Year 1				Year 2				Year 3			
Project set up	Contact PI / Co-PI												
IRB submission / approval	Contact PI / Co-PI												
Aim 1: community engagement and recruitment	Contact PI / Co-PI / Co-I1												
Aim 1: data collection, analysis, design of health unit model and delivery system	Contact PI / Co-PI / Co-I2												
Aim 2: health unit roll out and data collection	Contact PI / Co-PI												
Aim 2: data analysis and final evaluation	Contact PI / Co-PI / Co-I2												
Report preparation and dissemination	Contact PI / Co-PI / Co-I1 / Co-I2												

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Strategic locations in [redacted] counties, [redacted]

OMB Number: 0925-0770

Expiration Date: 09/30/2024

Inclusion Enrollment Report 1

1. Inclusion Enrollment Report Title* : [Redacted] units for [redacted] prevention among Hispanics in redacted]

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Strategic locations in [redacted] counties, [redacted]

6. Comments:

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	100	100	200
Total	0	0	100	100	200

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	Human_subjects.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	❍ Yes ● No ❍ N/A
Single IRB plan attachment	
3.3. Data and Safety Monitoring Plan	
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	❍ Yes ● No
3.5. Overall structure of the study team	

Protection of Human Subjects

A. Risks to Human Subjects

A.1 Human Subjects Involvement and Characteristics

The proposed study will enroll 3X community stakeholders for aim 1 and 2XX [redacted] health unit users for aim 2. For aim 1, we will work with our community partners to recruit members of the community with [redacted], community leaders, community health workers, health providers serving the Hispanic community, and members of Hispanic-serving institutions in our target counties that will be invited to participate in the design team. This includes participating in interviews and group meetings based on the [kit name redacted]. For aim 2, we will enroll 2XX [redacted] unit adult users who live in the target counties, participated in the screening and are identified at high risk of [redacted], and consented to participating in the study.

A.2. Sources of Materials

Data collected in the proposed study will be obtained through the following methods: for aim 1 in person interviews, observation, and group meetings. For aim 2, in-person surveys, clinical testing, and phone calls.

A.3. Potential Risks

The study is considered to have minimal risk to participants. Main risks include discomfort during the clinical testing and loss of confidentiality. Participants will be given the option to not participate in the clinical testing or to skip any questions. Team members and community health workers will be trained to address concerns with the test results and to provide adequate counseling and referrals to relevant community resources. To minimize the risk of loss of confidentiality, identifying and contact information will be stored in a separate dataset than clinical data. All data will be stored in the Redcap system and will be password protected.

B. Adequacy of Protection Against Risks

B.1. Recruitment and Informed Consent

Members of the design team for aim 1 will be recruited through our community partners in [redacted] Counties and through the partnership database of the Center [redacted] . Written informed consent will be obtained at the beginning of the design phase and then verbal consent to record and use the information will be obtained at each focus group. For aim 2, all adult community members interested in receiving screening, referral or counseling services through the [redacted] unit will receive them independently of their willingness to participate in the study. General de-identified information will be collected from all participants to assess reach and prevalence of undiagnosed [redacted]. Informed consent to include their data in the analysis and to conduct the follow up calls will be obtained from participants meeting the following inclusion criteria: adults residing in the target counties, participated in the screenings and identified as high-risk for [redacted] based on the [redacted] or a [redacted] measurement >X%.

B.2. Protection Against Risk

Research staff will complete CITI training in research with human subjects, confidentiality protection, and HIPAA training prior to the study period. At the time of study entry, participants will be assigned a study identification number to be used on all study materials and data for the duration of the study. A master list that contains participant identifiers and contact information will be stored separately from databases containing health information and all data will be password protected. Anonymity will be assured to all research participants so that no name, organization, or representative will be named in any reports about the study data. All data collected will be used only for research purposes. The MPIs will be responsible for control of all data collected, including questionnaires, records and audio recordings.

Potential discomfort associated with completion of surveys will be minimized by informing participants that they may discontinue the interview or questionnaire at any time. The potential discomfort or concern associated with receiving screening results will be addressed through the brief health counseling, by proving additional resources and by providing contact information from the MPIs and community health workers if additional information is needed. The counselling will be designed to be language and culturally appropriate during the design phase in aim 1.

C. Potential Benefits of the Proposed Research to Research Participants and Others

Participants may benefit from receiving health information and referral services. Stakeholders may not directly

benefit from participating in the study. However, they will gain knowledge on the development of the intervention and eventually adopt this or a similar health unit model. Organizations may also increase their reach to Hispanic populations through participation in this study.

D. Importance of the Knowledge to be Gained

Considering the high risk of [redacted] in Hispanics and [redacted] communities and the lack of access to screening services, this study will provide important information on the development of mobile health approaches specifically designed for Hispanic populations. This study will result in a scalable intervention with potential to improve access to [redacted] preventive services for [redacted] Hispanics in [redacted]. It will also test an implementation system that can potentially be adapted and applied in similar populations in the [redacted] and potentially the US.

Section 4 - Protocol Synopsis (Study 1)

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

Type	Name	Description

4.1.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ❍ No

4.1.e. Intervention Model

4.1.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description

4.3. Statistical Design and Power

4.4. Subject Participation Duration

4.5. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? ❍ Yes ❍ No

4.7. Dissemination Plan

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			