JHM IRB - eForm A – Protocol

- **Use the section headings to write the JHM IRB eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
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1. Abstract

Latinos in the US are three times more likely to be hospitalized and more than twice as likely to die from COVID-19 than non-Hispanic (NH) whites.[1-3] In communities disproportionately affected by COVID-19 and where vaccination coverage is suboptimal, testing and isolation remain critical to slow the spread of the virus and the emergence of more aggressive variants. For many low-income Latinos, access to conventional healthcare facility-based testing is hampered by lack of health insurance, difficulty in navigating the health system, immigration status, language barriers, stigma, lack of trust in healthcare institutions, and other social, economic, and cultural concerns. Home-based self-testing (HST) could achieve higher testing uptake by removing many of these barriers and identifying individuals who need to self-isolate to prevent onward transmission. However, information is limited about the optimal approaches for distributing COVID-19 HST to at-risk individuals and the usability and acceptability of these tests among low-income Latinos. In addition, due to the autonomous nature of HST, there is concern that testing could become decoupled from real-time instruction and timely linkage to care or preventive and other social services. To address this gap, we will expand "Vive Sin Duda" to implement and evaluate innovative implementation strategies to increase reach, access, and uptake of COVID-19 HST among low-income Latinos in Maryland. We will implement and evaluate two COVID-19 HST distribution approaches: 1) Network-based; and 2) Social marketing. We will also incorporate data-driven iterative changes to optimize a community health worker (CHW)-led short message service (SMS) platform to support HST and linkage to COVID-19 care, vaccination, and other services (e.g., cash and food assistance). Primary and secondary outcomes include: 1) Reach and uptake of HST; and 2) Linkage to care for those who test positive or vaccination for unvaccinated people who test negative.

Research hypotheses include:

Hypothesis 1: Uptake of HST will be higher through network-based than social marketing distribution.
Hypothesis 2: Network-based HST distribution will reach individuals with a higher positivity rate and greater vulnerability than social marketing distribution.
Hypothesis 3: Participants who use CHW-led SMS support will be more likely to use HST and better link to COVID-19 care or vaccination than those who don't use CHW-led SMS support.

Findings from this project will provide important new information that can improve access and uptake of innovative COVID-19 testing technology. This project also will fill critical knowledge gaps to guide the translation of evidence-based interventions into widespread adoption by RADx-UP consortium members.

2. **Objectives** (include all primary and secondary objectives)

Objective 1: Determine the optimal distribution strategies for reach and uptake of HST among low-income Latinos.
Objective 2. Optimize CHW-led SMS platform on adherence to HST protocol and linkage to COVID-19 care or vaccination.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

The CDC estimates that in 2020 there was a 54% excess mortality among Latinos compared to 12% among non-Hispanic whites and that deaths from COVID-19 occurred at younger ages among Latinos [4]. The COVID-19 pandemic has been particularly difficult for low-income Latino immigrants. Evidence shows the heightened risk of infection among undocumented and limited English Proficiency (LEP) Latinos due to lack of eligibility for unemployment benefits or stimulus checks, the need to work in high-risk essential jobs, and crowded housing conditions [5,6]. In communities disproportionately affected by COVID-19 and where vaccination coverage is suboptimal, testing and isolation remain critical to slow the spread of the virus and the emergence of more aggressive variants. Home-based self-testing (HST) can be an empowering and innovative way to reach those who have limited access to healthcare facility-based COVID-19 testing and those at high risk of COVID-19 infection. HST can offer a potentially far-reaching and convenient approach and enable more frequent testing by removing many testing barriers associated with in-person testing, such as anxiety about anticipated stigma, disclosure, and logistic considerations, such as testing locations and times.

As of February 7, 2022 16 at-home test kits for COVID-19 have received Emergency Use Authorization (EUA) by FDA. Although more test options are commercially available and the US government continues its efforts on expanding the market for HST, several barriers remain. The supply chain continues fall short and the cost of these kits could pose barrier to their usage, especially for large low-income households. The recent federal distribution of free home tests only allocated two tests per household and initial instructions were provided only in English.

Leveraging our existing community steering committee, testing and vaccination clinics, and a team of bilingual and bicultural CHWs, we are well-poised to implement proposed HST strategies to promote the reach and uptake of HST and linkage to services among the most vulnerable Latinos in Maryland.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

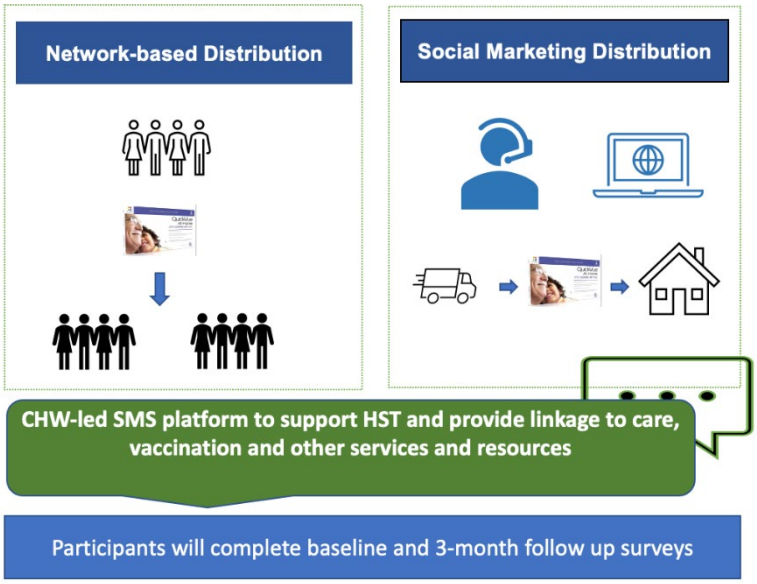
We will implement and evaluate network-based and social marketing distribution strategies of COVID-19 HST and optimize a CHW-led SMS platform to support HST and linkage to COVID-19 care, vaccination, and other services among low-income Latinos in Maryland.

We will compare the two COVID-19 HST distribution strategies: 1) Network-based strategy where we will recruit and train individuals ("indexes") to distribute COVID-19 HST kits to network members ("peers"); and 2) Social marketing where individuals can request HST kits on our project website sinduda.org or by calling a bilingual phone line. We will also optimize a CHW-led SMS platform to support HST and linkage to COVID-19 care, vaccination, and other services. All participants will complete baseline and 3-month follow-up surveys. Primary and

secondary outcomes include: 1) Reach and uptake of HST; and 2) Linkage to care for those who test positive or vaccination for unvaccinated people who test negative.

HST kits will be distributed with a flyer with a brief description of the study, including details on incentives and study contact information. We will use self-test kits authorized by FDA Emergency Use Authorization (EUA). The QuickVue® At-Home OTC COVID-19 Test and the InteliSwab COVID-19 Rapid Antigen Test are antigen-based test that has received a EUA from the US FDA for individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two (or three) days, with at least 24 hours (and no more than 36 hours) between tests. These tests are authorized for nonprescription home use with self-collected (unobserved) direct anterior nares specimens (NS) from individuals aged 14 years and older or with adult-collected anterior NS samples from individuals aged 2 years or older.

Figure 1. Phase 1 Study Design



Network-based Distribution

Recruitment: We will implement a network referral method with an initial selection of "indexes" recruited from the community (See *Study Flow*). Index participants will be asked to participate in study activities and refer five non-household adult peers in their network who will, in turn, be invited to participate in study activities and refer up to five peers (i.e. become indexes). Index participants will also receive a box with 5 tests which they can use themselves and/or among household members. To recruit non-household peers, they will receive 5 coupons to distribute to peers who can redeem them to request kits (with 5 tests) and participate in the study. An RA will provide brief training in person or by phone on different strategies to distribute coupons and refer peers to the study. (See *Recruitment Script).* With monitoring recruitment, the number of coupons allowed to be distributed per participant may increase or decrease at the discretion of the study investigators. Participants will receive automated text notifications to remind them to distribute coupons or to notify them of when they have reached their recruitment limit (see *Notifications).*

Recruitment of peers will use e-coupon codes that can be texted to invite them to the study. Each text coupon contains a unique identifier code that anonymously links the index to the peer recruit and which is used for subsequent data analysis (see *Coupon).* This code must be provided by the peer for entry to the study. Study staff will enter the unique code into the study data system to identify whether the coupon ID had been previously submitted.

Procedure: After providing informed consent, indexes will be mailed the HST kit and receive text notification upon delivery. Additional notifications will remind participants to use the kit and encourage them to contact the Sin Duda team with questions. Participants can report the result of their test through our HIPPA-compliant SMS platform WelTel.[11] If indexes test positive, we will follow the triage protocol, including symptoms risk factors for severe disease, that we've already implemented for community testing. The CHW will connect them to existing resources

and to a clinical provider. If indexes are tested negative, the CHW will offer assistance for vaccine registration if indexes have not been vaccinated.

Indexes will also complete a survey and receive brief training on different strategies to distribute coupons. Informed by the Information-Motivation-Behavioral Skills model (IMB),[7] the brief training is designed to motivate indexes to promote evidence-based information on the COVID-19 home-basted testing and work with their peer networks to increase HST acceptance and uptake in the community. Index participants will be reimbursed $20 for each peer who uses the coupon to order a HST kit and enrolls in the study. Indexes will be followed up in 3 months with a brief survey on their experiences of distributing HST. Peers who receive the HST with a project flyer will be asked to distribute coupons to their peers and complete a baseline and 3-month follow-up survey to assess the HST uptake, barriers, and facilitators of HST use.

Social Marketing Distribution

Recruitment and eligibility criteria: HST will be promoted using a social marketing strategy through our existing partnerships with key social media presences in Maryland's Latino community. This approach has successfully recruited diverse samples of Latinos and promoted our community COVID-19 testing events during the RADx-UP Phase 1 project.[9,10] Social marketing promotion is geotargeted to both urban and rural areas in Maryland. Study banners, messages, and broadcasts use diverse images of Latinos and provide a link to our project website sinduda.org. This website was developed as part of our RADx-UP Phase 1 project to facilitate access and reach of our community-based COVID-19 testing events, as well as expedited linkage to care services and/or CHW support, and includes a bilingual hotline number. We will use a similar iterative process that includes feedback from the Community Steering Committee and focus groups with the target population across the state to design and refine the HST request page. Based on the effective "Vive Sin Duda" model, this COVID-19 HST page will center on bilingual mobile-friendly content that addresses the community-identified concerns and provides an option to request COVID-19 HST directly via the page or by calling the Esperanza hotline number. Individuals can request HST kits when they meet the following eligibility criteria: 1) being age 18 years or older, 2) being Hispanic/Latino, and 3) living in Maryland.

Procedure: Individuals can request up to test kits on the sinduda.org project website or call the bilingual hotline. Individuals will provide web-based or oral informed consent and complete a risk assessment survey online or over the phone. Individuals will be asked to provide their full name, mailing address, phone number, and email address. They will be invited to complete a follow-up survey 3-month after requesting the HST kits to assess the HST uptake, barriers, and facilitators of HST use.

CHW-led SMS Platform

Individuals who receive the HST kits may sign up for the CHW-led SMS platform by scanning a QR or calling the study phone number. We will integrate HST support to an existing WelTel SMS [11] platform offered by our team is currently using for community outreach and COVID-19 vaccine appointment reminders. Informed by IMB,[7] preliminary data, and best practices from the team, we will incorporate data-driven iterative changes to develop and refine a library of text message content tailored to different needs by the testers (**Table 1**). These text messages, available in English and Spanish, will provide simple and easy-to-understand information about COVID-19 HST and vaccine and other COVID-19 prevention options and will promote personal and social motivations for COVID-19 HST proper use. The library of text messages will be constantly refined and expanded when new themes emerge during the course of the study. These text messages will be personalized so that it is evident that the CHW sends them.

Table 1. Content Delivered via CHW SMS Platform

Type of message	Details
HST instruction	Video, infographics, and text
Reminder of test	QuickVue® At-Home or InteliSwab OTC COVID-19 Test requires testing twice over two (or three days) with at least 24 hours (and no more than 36 hours) between tests. An automatic reminder message will be sent to testers.
Verification of test results	For testers who report their result(s) digitally through sending the image, a CHW will verify the reported result within 24 hours of the reporting. The CHW will record their interpretation and send a notification back to the participant informing them of the team's interpretation of the results. The team will not be blinded to the participants' interpretation of the result. In instances of discrepancy (e.g., participant interprets test strip as negative and trained human reviewer interprets test strip as positive), second trained staff will verify the result.
Linkage to services and resources	If the participant or the CHW interprets the test strip as "positive" for SARS-CoV-2, the participant will receive a telephone call and text with detailed instruction for self-isolation. The CHW will connect the participant to existing resources at the time (e.g., cash assistance and food delivery if available) and to a clinical provider (e.g., Dr. Page, PI) based on triage protocol (symptoms risk factors for severe disease) - what we already do for community testing.
Vaccine appointment, reminder, and follow-up messages	CHWs will facilitate COVID-19 vaccine appointments to eligible unvaccinated participants and send a message two days before any scheduled appointments. Participants also receive a reminder message if they have missed an appointment. Participants receive up to three messages following a missed appointment to encourage them to follow up. After the participant is vaccinated, a CHW will send check-in messages to see if the participant has any concerning side effects or has any questions.
Expiration date alert	Participants will get an alert two weeks prior to the expiration of their unused QuickVue® At-Home OTC COVID-19 Test and will be offered the opportunity to order a new kit if needed.
Two-way messages	Two-way messaging is designed to maintain contact with the participant, provides a means of engagement, and serves as a probe to ensure that the participant's concerns need to be addressed. These are automated weekly "check-in" messages after participants receive the test kits. The participant gets a request to "reply 1 if you're good or 2 if you need to talk." If the participant responds "2," CHWs will receive an alert to call the participant after receiving the notification. If the participant does not respond to the check-in message within 24 hours, the participant will receive the message a second time. If the participant has not replied to either message after 48 hours, CHWs will receive an alert to call the participant.
Stop option	Participants can text STOP at any time if they no longer wish to receive SinDuda messages

Quality Assurance/Control (QA/QC)

We will use the highly structured protocols we have developed for monitoring fidelity of intervention delivery. CHWs/interventionists will meet at least twice weekly with the supervisor to ensure coordination. A random sample of 10% of the communications with participants on the SMS platform will be evaluated for fidelity and quality across various indicators. Indexes and testers receiving SMS support will rate the content with a brief 5-item measure on knowledge gained and usefulness and clarity. CHWs/interventionists will be given regular feedback from the supervisor; those whose ratings are <90% will be re-trained until they pass the assessment. The follow-up survey includes a set of global ratings of the program and open-ended questions on what the participants liked and disliked about the project. This will help us identify the intervention's core elements for possible future replication.

Phase 2

During Phase 2, we will conduct a qualitative examination with key stakeholders regarding implementation determinants specified within the CFIR.[60] In addition, we will evaluate several key implementation outcomes in the RE-AIM framework,[19] which assesses program elements that can improve the sustainable adoption of effective evidence-based interventions.

We will conduct qualitative interviews regarding implementation determinants specified within the CFIR[60] with two types of stakeholder: 1) *Interactors* (n=20 individuals representing various

community organizations, local health departments, and CHWs): Interactor interviews can provide practical, detailed information about the dynamics of interactions between Latinos and service/social organizations or health care settings. The interview process will cover a range of topics, based on the participant's background, to explore barriers and facilitators to broad-scale implementation of the implementation strategies tested in this proposed study 2) *Individual Key Informants* (n=40; 20 testers from the network-based distribution [10 index participants and 10 alter participants] and 20 testers requesting HST from social marketing [10 who requested HST kits through the website and 10 through the hotline]). Interviews will examine the experiences of different distribution strategies, individual experience of HST, and the CHW-led SMS platform.

b. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies. Please note: Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016. If this situation applies, Section 36, question 6 in the application will need to be answered "Yes" and "Hopkins Faculty" should be selected in question 7. No other documents are required.

n/a

c. Study duration and number of study visits required of research participants.

Study Duration: 3 years
Number of visits: Participants in Phase 1 will have two visits (one at enrollment and a follow up survey at 3 months). Participants in Phase 2 will have one visit for in-depth interview.

d. Blinding, including justification for blinding or not blinding the trial, if applicable.

n/a

e. Justification of why participants will not receive routine care or will have current therapy stopped.

n/a

f. Justification for inclusion of a placebo or non-treatment group.

n/a

g. Definition of treatment failure or participant removal criteria.

n/a

h. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

n/a

i. If biological materials are involved, please describe all the experimental procedures and analyses in which they will be used.

n/a

5. Inclusion/Exclusion Criteria

Eligibility criteria for Phase I:

1. age 18 years or older and
2. Hispanic/Latino and
3. Living in Maryland.

Exclusion Criteria:

1. Previously participated in study
2. Lacks capacity to consent

Eligibility criteria for Phase 2:
1. Age 18 years or older
2. Worked with Latino communities (interactor) or participated in Phase I (key informant)

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used.
b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.
c. Justification and safety information if non-FDA approved drugs without an IND will be administered.

n/a

7. Study Statistics

a. Primary outcome variables: .
    1. Reach of distribution strategies
        a. Number of HST distributed via different distribution strategies, number of HST kits used via different distribution strategies, characteristics of indexes and individuals who request the HST kits, characteristics of testers.

b. Secondary outcome variables:
    1. Linkage to services: Post-test service utilization, including COVID-19 care, vaccination, and other social services.
    2. SARS-CoV2 positivity rate

c. Statistical plan including sample size justification and interim data analysis.

Key metrics will include testing uptake, positivity rates, linkage to COVID-19 care or vaccination, and characteristics (i.e., vulnerability) of testers. Chi-square tests for categorical and t-tests for continuous variables will be used to compare characteristics of testers between network-based and social marketing distributions and testers with SMS support and those without SMS support.

Latent Class Analysis. We will use latent class analysis (LCA) to characterize different levels of vulnerability and the extent to which they vary between HST distribution strategies. LCA allows us to assess whether measured social determinants of health (SDOH) are associated with an individual's membership in an inferred group.[89] LCA takes a person-centered approach by identifying subgroups of individuals with different patterns or profiles of vulnerability, investigating whether these groups' characteristics vary between network-based and social marketing distribution strategies. More specifically, LCA will be conducted to identify sub-groups of participants based on their reported SDOH indicators. To determine the number of sub-groups (or classes), a series of models will be fitted with increasing class numbers until the model that best fit the data was identified. Substantive evaluation and model fit statistics, including the Bayesian Information Criteria (BIC), Akaike's Information Criteria (AIC), and sample size adjusted BIC, will be used to evaluate model fit. All models accounted for clustered data, and missing data will be imputed using the missing data function of Mplus. Latent class regression will be used to assess the association between latent class membership and HST distribution strategies. The analysis includes bivariate and adjusted models. Mplus will be used

for latent variable models, and Stata will be used for exploratory statistics and regression models.

Mediators and Moderator Analysis. We will also conduct a series of analyses to identify key mediators and moderators associated with COVID-19 HST uptake. For example, we will hypothesize that individual perceived costs and benefits of the COVID-19 HST will mediate the relationship between social norms and COVID-19 HST update. The mediation will be tested using the "Sobel" method via guidelines proposed by MacKinnon.[90] Mediator models attempt to identify explanatory variables (i.e., perceived costs and benefits of COVID-19 HST) through which an independent variable (i.e., social norms) affects an outcome variable (i.e., COVID-19 HST uptake).[91] Therefore, a basic mediation model proposes that the predictor is associated with the mediator (path "a") and that the mediator is associated with the outcome variable (path "b") and that the combination of these two pathways is statistically significant. Mediated effects will be estimated by calculating the product of the unstandardized betas that represent path "a" and path "b" (a × b). Approximate Z scores for each mediated effect will be estimated by dividing the product by its standard error.[92,93] Finally, multivariate mediator models using regression will be estimated, controlling for significant covariates. We will also hypothesize that social support will moderate the relationship between the perceived risk of COVID-19 and the COVID-19 HST update. Moderation will be tested using standard procedures outlined by Aiken and West[94] and Cohen et al.[95] The interaction term will be calculated by multiplying the moderator (e.g., social support) with the predictor (e.g., perceived risk of COVID-19). Significant interactions will be examined by estimating the relationship between the predictor (e.g., perceived risk of COVID-19) and the outcome variable (e.g., COVID-19 HST update) at different levels of the moderator (e.g., social support).

Qualitative Analysis (Phase II) All transcripts will be analyzed using template analysis, a type of thematic analysis employing both *a priori* and emergent themes. [96] We will create the initial templates, akin to "codebooks," based on the CFIR domains and constructs. Coding will occur in an iterative fashion, with the templates being expanded and refined. Data analysis will begin after the first interviews are transcribed. "Final" templates will be applied to all interview data using Atlas.ti qualitative coding software.

d. Early stopping rules.

None

3. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

There are no direct medical risks associated with participation in the study. There is a risk to confidentiality in the use of the WelTel SMS platform.

b. Steps taken to minimize the risks.

Our team has extensive experience of working with underserved and vulnerable populations including Latino and immigrant communities. We have developed numerous protocols to ensure that risks are minimized during recruitment and assessment activities. Participants are informed that they may withdraw from the study at any time if they feel uncomfortable. All individuals involved in human subjects research are supervised by the PI and the Study Coordinator and receive individualized quality assurance reports on a bi-weekly basis. In addition, monthly supervision meetings are held with recruitment and assessment staff to discuss quality assurance and human subjects' protections.

Risks to confidentiality will be minimized by storing all data in encrypted format on an WelTel server that is password protected. WelTel is a secure, web-based, digital health application that utilizes multi-modal, including 2-way SMS for communication (supports multilingual) outreach to support patient engagement and integrated virtual care. The system is patient-centered to ensure equitable access and improves clinical efficiencies by using automated messaging, reminders, and alerts that allow care providers to deliver precision care and improve health system resource allocation. PHI and account data is encrypted using AES-256 and encryption keys are managed solely by WelTel and not accessible by hosting firm. All communication traffic to hosted server is encrypted using HTTPS-TLS1.2 WelTel Incorporated has a signed BAA with AWS and uses only the HIPAA compliant AWS servers dedicated to healthcare. Only authorized study personnel will have access to this data. A triple level of data encryption will be used to ensure confidentiality of data and HIPAA-compliance. Electronic research data will be exported from WelTel to central storage (JHU) via secure, encrypted transmission.

All project members are required to complete the Protection of Human Subjects Computer-based Training and Education program, which was developed in response to the National Institutes of Health directive requiring training on Human Subjects Protection. Utmost care will be taken when contacting participants about enrollment, participation and study compensation. Study staff will only talk to the participant directly unless the participant has authorized staff to leave a message. Participants provide identifiable information which will be kept in the password-protected Locator Information & Participation Database.

c. Plan for reporting unanticipated problems or study deviations.

Unanticipated problems will include adverse events (AEs) and serious adverse events (SAEs). The research staff will report problems or study deviations to the PIs during weekly meeting. SAEs will be reported to the PI within 24 hours orally or by email. Breaches of confidentiality would also be considered an adverse event.

The PI will report unanticipated problems or study deviations that involve risks to participants or others promptly to the JHM IRB in accordance with Organization Policy. Minor problems and protocol deviations (which pose no risk to subjects or others) will be reported in annual protocol continuing review.

SAEs are based on the FDA definition and defined as those that result in death, are life-threatening, result in hospitalization or prolongation of existing hospitalization, a persistent or significant disability, a congenital abnormality or birth defect. Other injuries or medical events may be considered to be serious adverse events when, in the opinion of a physician, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the above outcomes.

Participants will be reminded to report any physical or social harm to the study staff immediately, so that participants may receive counseling or other assistance. When an adverse event is reported to the study staff, the staff investigates the details of the event and reaches a determination as to whether occurrence of the event was related to participation in the study.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

No legal risks are expected.

e. Financial risks to the participants.

No financial risks are expected.

4. Benefits

a. Description of the probable benefits for the participant and for society.

Potential indirect benefits include social and healthcare service referrals, where staff will make appropriate referrals for COVID-19 care or vaccine, and social services in their area. Another potential benefit is that participants may experience the altruistic benefit of participating in a study that contributes to health of Latino communities.

5. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

Individuals will receive $30 for each survey completion. Index will receive $20 for a successful HST distribution to an alter. Individuals will receive $50 for in-depth interview.

6. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.
n/a

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