

Redwine/Stern RADx-UP Protocol

Title: Social, Ethical, and Behavioral Implications (SEBI) Research on COVID-19 Testing and Vaccine Uptake among Rural Latino Migrants in Southwest Florida

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STUDY SITE

University of South Florida

PRÉCIS

Study Title: Social, Ethical, and Behavioral Implications (SEBI) Research on COVID-19 Testing and Vaccine Uptake among Rural Latino Migrants in Southwest Florida

Objectives

AIM 1: To work with our community partner, HSC and promotoras to engage rural Latinx migrant and immigrant communities in southwest Florida in formative research methods including focus group discussions and surveys. We propose to identify multilevel barriers, facilitators and attitudes (informed by existing COVID-19 and other health relevant measures) that predict willingness/intention to obtain COVID-19 testing and/or a future vaccine. We will also query respondents on, key messages, messengers and communication channels that hold the most salience, to inform development of community-based prevention marketing. Focus group interviews and survey responses will inform Aim 2.

AIM 2: Develop an integrated strategy that is multi-level and responsive to addressing social determinants of health (SDOH) for increasing COVID-19 testing and vaccination uptake. Community-based activities and communication materials will be developed based on Aim 1 findings. We propose to explore the viability of the products with the community using charlas (informal group conversations), in addressing the emergent barriers and facilitators to COVID-19 testing and vaccination.

Design and Outcomes

Data will be collected in three phases.

Phase I. Four qualitative focus groups with men and women from four rural cities in Hillsborough County, FL to gather information on individual attitudes, and multilevel facilitators and barriers (social, cultural and behavioral) that influence willingness/intention to seek COVID-19 diagnostic testing and eventual vaccines.

Phase II. Surveys will be administered by promotoras to residents that will comprise existing questionnaires on attitudes, facilitators and barriers, key messages, messengers, and communication channels regarding COVID-19 testing and vaccination. Exploratory moderators (e.g. sex, age and country of origin) will be investigated.

Phase III. We will collaboratively (HSC Director, USF marketing and research investigators, and

promotoras) develop integrated marketing strategies to produce communication materials, media campaigns and HSC community-based programs. Feedback on the formulated social marketing products will be obtained through group charlas facilitated by promotoras and USF research staff.

Duration

Total duration of the study is two years. Year one will consist of Phases I and II and Year two will consist of Phase III.

Sample Size and Population

Participants in the study will be men and women over the age of 18 years across Latinx ethnic groups (e.g. Mexican, Northern triangle) from rural areas in Hillsborough County, FL. Phase I focus groups will consist of between 32 – 40 individuals in 4 focus groups. Phase II will include 500 adults completing surveys. Phase III will include 50 individuals who will attend charlas.

1. STUDY OBJECTIVES

Aim 1a. Qualitative focus groups (4-groups; n = 8-10 per group) with men and women across ethnic groups (e.g. Mexican, Northern triangle), SES, acculturation level and age will be facilitated by USF research staff and promotora partners. Four rural cities in Hillsborough County, FL with high Latinx populations are targeted. These cities vary in Latinx cultural composition and each focus group will comprise participants from a different city to obtain inclusive information about individual attitudes, and multilevel facilitators and barriers (social, cultural and behavioral) that influence willingness/intention to seek COVID-19 diagnostic testing and eventual vaccines. Findings will inform Aim 2 and will be shared with other NOSI recipients.

Aim 1b. Surveys will be administered by promotoras to residents (N = **500**), and will comprise existing questionnaires¹⁻⁷ that will be selected and adapted based on Aim 1a. Attitudes, facilitators and barriers, key messages, messengers, and communication channels will be used to predict *willingness/intention* to obtain COVID-19 testing and vaccination among our Latinx population, as well as whether they have received *actual testing*. Exploratory moderators (e.g. sex, age and country of origin) will be investigated.

Aim 2a. We will collaboratively (HSC Director, USF marketing and research investigators, and promotoras) develop integrated marketing strategies with the goal of making them culturally and linguistically sensitive to Florida's rural Latinx population. Products will include communication materials, media campaigns and HSC community-based programs designed for this population.

Aim 2b. Feedback on the formulated social marketing products from Aim 2a will be obtained through group charlas (6 – 7 groups of survey participants, total n = **50**), facilitated by promotoras and USF research staff. Charlas will focus on determining the most effective message tailoring and delivery, communicators for message delivery, and appropriate channels for health communication message delivery for COVID-19. Strategies will inform a future dissemination and implementation study in rural Latinx communities to evaluate their effectiveness in improving COVID-19 testing and eventual vaccination. These findings may be generalized to other rural Latinx communities across the USA for the present and future pandemics.

2. BACKGROUND AND RATIONALE

2.1 Background

The Latinx population in Florida account for approximately 30% of all COVID-19 cases and hospitalizations.⁸ Most Latinx individuals in Florida live in rural areas and work as migrant farmworkers.⁹ These rural families have high rates of underlying medical conditions, limited access to health care, and live in circumstances that interfere with implementation of community mitigation measures,^{10, 11} all potentially leading to increased risk of COVID-19 exposure, morbidity and mortality. Our community partner, the Hispanic Services Council (HSC) hires and trains local promotoras de salud (Spanish term for community health workers)¹² to deliver programs (education, health and civic engagement) to Latinx immigrant families in Southwest Florida. In only the past 2-years the HSC and their promotoras reached over **5,900** local families. The HSC has also worked with agencies, including the Florida Department of Health, where promotoras collected health information in focus groups, surveys and charlas (informal workshops) from **500+** Latinx residents in Southwest Florida (e.g. Voices, Health Department studies). At the beginning of the COVID-19 pandemic, HSC promotoras contacted **317** Latinx immigrants from Southwest Florida to provide information on food pantries, social services and health materials. We will build on our ongoing partnership with HSC and the promotoras (R34AT010661-01) to collect data using mixed methods (qualitative and quantitative) to assess factors that influence the ability and willingness of Latinx immigrant families to get tested and/or vaccinated for COVID19. Findings will guide development of community-based prevention marketing products to improve COVID-19 testing and vaccination uptake in this population. In partnering with and sharing information with other NOSI grantees we can expand the effort to increase testing for COVID-19 and eventual vaccination across diverse communities to eradicate the virus in the USA.

2.2 Study Rationale

The rationale of the current study is to collect data to provide information on barriers and facilitators for COVID-19 testing and vaccinations. Findings from the proposed study can lead to strategies/products that can be widely disseminated (e.g. integrated into the HSC curriculum offerings to ensure sustainability in the community). This data will be added to the RADx-UP consortium data set to develop the best methods of increasing COVID-19 testing and vaccine uptake.

3. STUDY DESIGN

3.1 Aim 1 Methodology (to be completed year 1). We will work with our community partner, HSC, and promotoras to examine the multilevel barriers and facilitators at the individual, interpersonal and community levels that predict willingness/intentions to obtain COVID-19 testing and/or a potential vaccine among southwest Florida rural Latinx migrant and immigrant communities.¹³

Aim 1a. Focus Groups: Four groups, n = 8-10 per group will be facilitated by USF trained research staff and promotora partners across ethnic groups (e.g. Mexican, Northern triangle), SES, acculturation level, and age. To maximize comparisons across NOSI datasets and studies, and facilitate data integration, we will obtain feedback on and employ tools that promote the collection of comparable data on SDOH from the PhenX Toolkit [<https://www.phenxtoolkit.org/index.php>] and the NIH Public Health Emergency and Disaster Research Response (DR2) COVID-19 & SDOH Data Collection Instrument Repository [<https://dr2.nlm.nih.gov/>]. We plan to utilize *COVID-19 Community Response Survey* to obtain information on demographics, chronic conditions, knowledge and attitudes, housing and family structure, and psychological function. However, given the limited availability of measures to

assess COVID-19 *testing and vaccine intentions and behaviors*, we drew from the cross-cultural HIV literature to identify measures of facilitators and barriers that may be relevant to rural Latinx migrants' testing intentions and behaviors. To assess attitudes, barriers and facilitators to COVID testing, and vaccination, focus groups will review questions from surveys on COVID-19 testing, facilitators and barriers, and marketing and provide feedback on their salience and relevance to testing and vaccination behaviors in this population. Focus group feedback will be used to adapt existing measures to ensure that our measures are sufficiently refined and optimized to target these attitudes and behaviors in the rural Latinx migrant community. Focus groups will last no longer than two-hours and participants will be compensated for their time. Focus groups will be facilitated by promotoras (trained by our bilingual project coordinator) and a bilingual RA to elicit feedback via structured interviews developed for the project. RA's and promotoras will be trained to use both verbal and non-verbal communication strategies to elicit information from participants until saturation of responses is reached. Focus groups and charlas will be recorded, then transcribed into Spanish, and then translated into English using the GMR transcription services company (see Budget Narrative) and then back translated into Spanish and reconciled when necessary. These tapes will then be coded for emergent themes by two masked study staff to establish inter-coder reliability and consistency. The grounded theory method¹⁴ will guide coding and theme identification of facilitators and barriers that we will then evaluate and incorporate into surveys and questionnaires used to address Aim1b. Similar methods are employed for our parent R34.

Training, Supervision and Fidelity Checks. 1) Training in Cultural Competence. All USF staff will be trained to understand the importance of being culturally competent, with an emphasis on the importance of family preferences and cultural relevance.^{15, 16} 2) Monitoring fidelity. Reliable delivery of the project is assured by: a) having a clear, detailed interview guide; b) facilitator training; and c) frequent communication between the promotoras, the MPI's and project coordinator. d) Promotoras will participate in a two-day training prior to the start of the project, will participate in weekly reviews and supervision; and 3) Quality assurance measures will be used to verify that the focus groups are delivered as planned. Briefly, a) promotoras will complete a <2min checklist documenting delivery of content, b) Quality Assurance raters (RAs during sessions and co-I, Rodriguez post-sessions) will review all group sessions, using the Fidelity of Implementation Rating System,¹⁷ checklist. c) Both verbal and non-verbal cues are rated in the assessment of participant responsiveness. Stern (MPI) has extensive experience in communication coding^{18, 19} d) Any deviation identified from the standard protocol will result in retraining staff to meet protocol criteria.

Aim1b. Survey Assessments:¹⁻⁷ Assessments will be comprised of existing surveys that are adapted to target the Aims of the present study (informed by Aim 1a), and will be composed of questions on attitudes, barriers and facilitators of COVID-19 testing and vaccination (when available), as well as queries about key messages, messengers, and communication channels relating to COVID-19 testing and vaccines. We are particularly interested in which factors strongly predict our primary outcomes of willingness/intention to obtain COVID-19 testing for themselves and their children.

Surveys will be administered by promotoras to Latinx residents living in our four target cities in Southwest Florida. Surveys will primarily be administered in participant's homes, by phone or by computer/virtual platform, e.g., Zoom. Our prior experience²⁰ has informed us that many of our target Latinx participants are unable to read or write in Spanish. To standardize procedures, promotoras will read each question to participants to ensure that they clearly understand what is being asked. For the various modes of data collection (in person vs phone vs virtual), promotoras will use tablets with cellular capability to read the consent, each survey question

and then record participants' responses directly into REDCap surveys. These surveys will determine the multilevel multidomain factors predictive of willingness/ intention for engaging in COVID-19 testing and potential vaccination (n = **500**).

The adapted measures for COVID-19 testing-uptake regarding attitudes, intentions, and behaviors, as well as a future vaccine, will first be assessed for basic psychometric structure. Second, attitudes, barriers, and facilitators will be investigated as predictors of participants' COVID testing behaviors, as well as their testing and vaccine intentions. Additional multilevel information will be collected and will be used descriptively, as well as covariates in the statistical models predicting intentions and behaviors. Survey questions will address multiple factors that influence ability, willingness/intention to use COVID-19 diagnostic services and eventual vaccines such as, **Individual:** age, high-risk comorbidities, insurance status, health literacy, etc.; **Interpersonal:** number of people in the household, household member diagnosed with COVID, household members being tested for COVID, etc.; **Community/Societal:** number of cases in the community/state, community testing initiative.

3.2. Aim 2 methodology (to be completed year 2). We will use CBPM to develop integrated strategies to increase COVID testing uptake and future vaccinations, based on findings from Aim 1. CBPM is a dynamic process that comprises multiple steps. The first several steps of CBPM are captured in Aim 1, which uses preliminary evidence to define the behavior focus (testing and vaccination) and target population (rural Latinx community) and formative research to examine facilitators, barriers, attitudes and preferences for information channels. Aim 2 focuses on the next steps of social marketing, which are to develop strategies to promote COVID-19 testing and vaccination uptake, and to obtain feedback on these strategy ideas from members of the target population. This feedback will inform a **future** large-scale dissemination and implementation project that examines the effectiveness of CBPM products on COVID-19 testing and potential vaccination behaviors in the community (final steps of a social marketing project).

Aim 2a. Community participation is a central principle of CBPM. Research findings from Aim 1 will inform the facilitators that we can incorporate into our social marketing strategies to promote COVID-19 testing and vaccination uptake. The team will develop various messaging and marketing strategies to overcome the individual, interpersonal, and community barriers that we identified. Significant predictors of intention for undertaking COVID-19 testing and/or vaccine will specifically be targeted and organized in a social marketing strategy plan. We will also investigate whether demographic, structural and other factors identified in Aim 1 impact how the products are interpreted and received. The marketing strategy development process involves having researchers engage in small group meetings with HSC leaders and promotoras to make marketing decisions that correspond with each component of the strategic plan. This plan consists of several components -- products, pricing, placement, and promotional strategies

Integrated social marketing strategy will include: 1) a detailed profile of the target population subgroups – consisting of demographic information, cultural practices, and communication and messages preferences; 2) potential products (key messages, posters, flyers, educational materials, social media posts etc. and activities based on the target population's communication and message preferences; 3) core benefits that will be offered to them; 4) how best to position testing and vaccination for the target population; 5) strategies for lowering barriers; 6) strategies for mobilizing partners; 7) spokespersons, information channels and message design guidelines for promoting COVID-19 testing and vaccination.

Social marketing components and strategy development		
Marketing component	Definition	Current study

Product	Behaviors that we are asking the target audience to adopt	COVID-19 testing and vaccination
Price	Perceived costs or other barriers	Barriers identified from Aim 1
Place	Places and times in which the target audience makes decision; dissemination system(s) most efficient in reaching the target audience; structural/environmental changes	Facilitators and other determinants identified from Aim 1 & strategies developed from Aim 2a
Promotion	Communication channels; promotional techniques best fit the key messages	
People	Target audience, and promising people/organizations with which to join forces to implement the social marketing strategy	Latinx, HSC leaders, and promotoras

Social Marketing Product prototype and material development: Based on the integrated social marketing strategy and plan, samples of flyers, posters, and educational materials on COVID-19 testing and potential vaccination will be created. Other potential structural/environmental changes to support testing availability and transportation will be addressed in the

informational materials that can be presented to the community members (Aim 2b). Social media campaign examples and posting schedules will be outlined in the informational materials, and small-scale prototypes of large advertisement board posters, radio public service announcements samples, and engaging informational Spanish language video clips will be created.

The social marketing strategy will result in the development of a COVID-19 testing and vaccination campaign that will focus on constructs most relevant to the rural Latinx immigrant responses (e.g. health and well-being of the family, community, ability to work and provide food and shelter for themselves and family).

Aim 2.b. Charlas for Pretesting the social marketing strategies, messages, and materials.

Pretesting is an essential activity to confirm that the target audience finds activities, messages, and materials understandable, relevant, persuasive, and appealing. After the marketing plan has been designed, prototype materials and messages will be developed (Aim 2a.). We will then obtain feedback on the formulated social marketing products from charlas. Utilizing charlas for obtaining feedback on social marketing products are a culturally accepted practice that allows community members/stakeholders to participate in community decisions. Promotoras, along with Dr. Pasha and a bilingual RA will facilitate the charlas to obtain feedback on social marketing products. The focus of these charlas will be to determine the most effective messages: tailoring and delivery, optimal communicators of message delivery, and appropriate channels for health communication message delivery. Strategies can then inform future dissemination and implementation studies in rural Latinx communities to improve testing and vaccine behaviors now and for future pandemics.

Sampling: Pretesting is an iterative process. A randomly selected subgroup of Aim 1b survey participants (n=50; groups of 6 to 7; approximately 8 charlas or two from each of the four target cities) will be selected and stratified by age, sex and city origin. Results from each round will be used to make improvements that are tested in the next round until saturation is reached.

Data Collection Techniques: Charlas will be facilitated by bilingual USF researchers (trained by Dr. Pasha) and promotoras. Sessions will be audio-recorded and trained bilingual USF research assistants will take notes. The first iteration will focus on comprehension, appeal, persuasion, and relevance. The second round will focus on believability, appropriateness, and on cultural acceptability and ensure that previous revisions are working as intended. All charlas will be transcribed and translated using the GMR transcription services company and then coded by

masked assistants. We will evaluate whether there were any noteworthy differences across subgroups of Latinx participants.

Decision Making Process: After each charla, USF researchers will conduct decision making meetings with the HSC leaders to discuss feedback from charlas and compare meeting notes from multiple RAs and other documents (e.g., participant worksheets). Discussion will be continued until a consensus is reached on which marketing products will be kept or excluded and how revisions will be made. We will ensure to include various levels (i.e., individual, interpersonal, and community) from the NIMHD research framework.

Development of Final Social Marketing Products: Based on the results from charlas and decision-making process, the final social marketing products will be selected. A report on these products and a detailed implementation and dissemination plan will be documented for further testing in a future investigation.

Study population and location

Eligible individuals will be Latinx men and women (at least 35%-40% men) who are > 18 years

City/County	Latino %	Below Poverty Line %	Obesity Latino %
Wimauma/Hillsborough	73.4	36.9	30.3
Dover/Hillsborough	70.6	50.1	
Plant City/Hillsborough	29.3	19.9	
Ruskin/Hillsborough	38.6	19.8	
Florida	23.6	16.3	26.4

of age, living in one of the four communities, Dover, Wimauma, Plant City and Ruskin, FL and have the ability to understand and provide consent for participation in the study. These communities are primarily rural, with Latinx migrants living below the poverty line.

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Eligibility/ Ineligibility criteria

- Participants identify as Latino and are at least 18 years old; there is no upper age limit although age will be a factor considered in all analyses
- Participants must be able to speak and understand Spanish and be able to follow basic instructions in Spanish. Because promotoras will be conducting all focus groups and charlas in Spanish, and most suveys in person or over the phone/Zoom, there is no eligibility criteria for writing.

4.2 Study Enrollment

Several approaches for recruitment are used in each of our community sites (Dover, Plant city, Ruskin and Wimauma). The director of the Hispanic Service Council (HSC) promotora program will identify bilingual promotoras to hire and to work with us on this project. These promotoras will then identify potential participants via several methods: 1) recruit from existing HSC educational programs in the targeted communities; 2) recruit from ongoing HSC education Charlas (talking circles) programs; 3) Promotoras, as active community members, who continually utilize social networks for all HSC programs and are currently doing this for the parent project, ADAPT+ and will do the same for the supplement; 4) Flyers will also be distributed throughout the communities via local community events, at low-income housing complexes and local stores, churches and community centers; 5) "Word of mouth" via social networking events also will be utilized. As clearly outlined in the preliminary data section of the application, HSC promotoras have been highly successful in recruiting participants for all projects. They were able to reach over 300 Latino families in less than one month, to assess

with their needs at the very beginning of the COVID-19 crisis. We expect to have little difficulty in recruitment. USF-based bilingual study staff will work with the promotoras to follow-up with interested participants and explain the study details and obtain consent.

5. STUDY PROCEDURES

5.1 Schedule of Procedures

Task	Year 1 (11/1/20-10/31/21)												Year 2 (11/1/21-10/31/22)											
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Secure IRB approval and Develop database forms																								
Finalize Translating measures and developing the focus group interview guide into Spanish for Aim 1A																								
Hire all promotoras and study staff																								
Train promotoras to lead focus groups for Latino adults for Aim 1A																								
Aim 1A) Conduct 4 Focus groups in 4 different communities and analyze information																								
Identify and modify all surveys based on Aim 1A findings; Transcribe and translate all focus group information using GBR services;																								
Train promotoras to administer surveys (Aim 1B) and recruit Latino adults in the target communities																								
Aim 1B) conduct surveys in person face to face, via phone or zoom (N = 500)																								
Aim 2A) review all findings from Aim 1 and develop educational and social marketing strategies																								
Train promotoras to lead Aim 2B charlas (informal groups)																								
Aim 2B) conduct 8 informal charlas to evaluate the strategies developed in Aim 2A																								
Transcribe and translate all charlas and code and analyze the information to develop dissemination strategies																								
Transcription, Coding, Data Entry & Maintenance																								
Data Analysis & Interpretation																								
Prepare Manuscripts & dissemination Grant application																								

Focus groups will be performed

Consenting Procedure and enrollment

Enrollment for the present study is defined as both signing a consent form and meeting the eligibility criteria.

For Aim 1a, our bilingual RA will obtain consent from each participant in writing prior to beginning the focus group. For Aim 1b, prior to administering the questionnaires/surveys individually, consent will be obtained in accordance with IRB regulations by having the participant electronically sign the consent on the tablet, if participating via in person, on their own computer if via zoom and verbally, if by phone.

For Aim 1b, in the cases where in-person consenting takes place, participants will be asked to sign the consent electronically using the tablet purchased for the project, using REDCap forms, ensuring password protection. All promotoras will be provided with tablets with cellular capacity, and will have the participant read/follow along while the promotora reads aloud the contents of the REDCap consent form and obtain electronic signatures. Consent forms will be in Spanish, written at a 4th or lower grade reading level, clearly stating our project's goals and emphasizing that we are not conducting any individual level diagnostic testing. Consent forms will stress that the study is entirely voluntary and will indicate that participants can change their mind at any time about participating in the study. This method of obtaining electronic signatures indicating consent will have been approved by USF IRB prior to the start of the project. This signature will be deemed as voluntary consent to begin the study – after which, promotoras (who would have obtained human subjects training prior to the start of the project) will begin

reading aloud each question of the surveys and then recording participants' responses into the REDCap program on the tablet.

6. STATISTICAL CONSIDERATIONS

Preliminary Analyses. Preliminary analyses will include descriptive statistics to characterize the sample, including age, country of origin, and sex. For all analyses, missing data and variability in responses will be examined. Data will be screened for both missing and outlier scores on measures following procedures suggested by Tabachnick and Fidell ²¹, with appropriate measures taken to reduce outlier influence (e.g., median ± 2 inter-quartile ranges). If distributions are non-normal, effects will be estimated using the appropriate technique. Bivariate correlations will provide information on associations between variables of interest. Existing measures of testing and vaccine attitudes, intentions, and behaviors will be adapted based on a content analysis of the focus group feedback.

Aim 1a. Discussions will be coded by two RAs to identify existing items that needs to be modified, items that are perceived as irrelevant, and content that need to be added to the measures to ensure they reflect multilevel factors.

Aim 1b. To investigate the impact of attitudes, barriers, and facilitators on COVID-19 testing intention and behavior, and vaccine intention, first exploratory factor analyses will be conducted to identify the factor structures of the adapted measures. Global fit statistics (X^2 , SRMR $< .08$, RMSEA $< .06$, CFI $> .90$), eigen values, and parallel analyses will be used to determine the appropriate number of factors. Factor loadings $> .40$ will be interpreted as the primary factor loading. If items demonstrate loadings of < 0.40 onto any factor or items significantly cross-load onto multiple factors (either a gap between significant loading and non-significant loading $< .20$ or a gap between significant loading and significant loading $< .30$; Brown, 2015), these items will be removed from the model and the EFA will be re-run until all included items load at ≥ 0.40 onto a single factor and the global fit statistics demonstrate acceptable fit. Internal consistency of the factors will be calculated after the factor structures are identified.

Once the factor structure is identified, subscales for attitudes, barriers and facilitators will be included as independent variables in multiple linear and logistic regression models. Dependent variables will include willingness to obtain COVID-19 testing (continuous variable), intention to obtain COVID-19 testing (continuous variable), willingness to obtain COVID-19 vaccine (continuous variable), intention to receive COVID-19 vaccine (continuous variable), and actual COVID-19 testing behavior (tested/not tested – binary variable). Covariates will include age, sex and country of origin. In addition, dominance analyses (Budescu, 1993) will be conducted to examine relative importance of the attitudes, behaviors, and facilitators to identify which factors may be the most appropriate to target to increase COVID-19 testing behavior and vaccine uptake (when available) in the rural migrant Latinx population.

6.1 Outcomes

Aim 1a. Focus Groups: To maximize comparisons across NOSI datasets and studies, and facilitate data integration, we will obtain feedback on and employ tools that promote the collection of comparable data on SDOH from the PhenX Toolkit

[<https://www.phenxtoolkit.org/index.php>] and the NIH Public Health Emergency and Disaster Research Response (DR2) COVID-19 & SDOH Data Collection Instrument Repository

[<https://dr2.nlm.nih.gov/>]. We plan to utilize *COVID-19 Community Response Survey* to obtain information on demographics, chronic conditions, knowledge and attitudes, housing and family structure, and psychological function. However, given the limited availability of measures to assess COVID-19 *testing and vaccine intentions and behaviors*, we drew from the cross-cultural

HIV literature to identify measures of facilitators and barriers that may be relevant to rural Latinx migrants' testing intentions and behaviors. To assess attitudes, barriers and facilitators to COVID testing, and vaccination, focus groups will review questions from surveys on COVID-19 testing, facilitators and barriers, and marketing and provide feedback on their salience and relevance to testing and vaccination behaviors in this population. Focus group feedback will be used to adapt existing measures to ensure that our measures are sufficiently refined and optimized to target these attitudes and behaviors in the rural Latinx migrant community. Focus groups will last no longer than two-hours and participants will be compensated for their time.

Aim 1b. Surveys: Surveys will be modified according to Aim 1a feedback regarding the salience, cultural fit, and applicability of the instruments. For example, COVID-19 testing attitudes survey will be optimized from surveys on HIV testing attitudes and discussed in focus groups.

Potential Questionnaires for Aim 1b Survey	
Testing Attitudes	1. HIV testing attitudes ¹ 2. Vaccination Attitudes Examination ²
Facilitators/Barriers:	3. Facilitators and Barriers Related to Voluntary Counseling and Testing for HIV ³ 4. COVID Community Response Survey, module 4 (DR2)
Marketing:	5. COVID-19 Experiences (COVEX) – (section-9) ⁴
Demographics/other measures	6. Stephenson Multigroup Acculturation Scale (SMAS) ⁵ 7. COVID Community Response Survey (modules 1 - 5, demographic + psychosocial) 8. COVID19 Impact on Health and Wellbeing Survey (Spanish, 5 item) (DR2) 9. 3-item Health Literacy Questionnaire (Spanish) ⁶

6.2 Data Analyses

Aim 1.a. Focus Groups. Focus groups and charlas will be recorded, then transcribed into Spanish, and then translated into English using the GMR transcription services company (see Budget Narrative) and then back translated into Spanish and reconciled when necessary. These tapes will then be coded for emergent themes by two masked study staff to establish inter-coder reliability and consistency. The grounded theory method ¹⁴ will guide coding and theme identification of facilitators and barriers that we will then evaluate and incorporate into surveys and questionnaires used to address Aim1b. Similar methods are employed for our parent R34.

Aim 1.b. Surveys. To investigate the impact of attitudes, barriers, and facilitators on COVID-19 testing intention and behavior, and vaccine intention, first exploratory factor analyses will be conducted to identify the factor structures of the adapted measures. Global fit statistics (χ^2 , SRMR < .08, RMSEA < .06, CFI > .90), eigen values, and parallel analyses will be used to determine the appropriate number of factors. Factor loadings > .40 will be interpreted as the primary factor loading. If items demonstrate loadings of < 0.40 onto any factor or items significantly cross-load onto multiple factors (either a gap between significant loading and non-significant loading <.20 or a gap between significant loading and significant loading < .30; Brown, 2015), these items will be removed from the model and the EFA will be re-run until all included items load at \geq 0.40 onto a single factor and the global fit statistics demonstrate acceptable fit. Internal consistency of the factors will be calculated after the factor structures are identified. Once the factor structure is identified, subscales for attitudes, barriers and facilitators will be included as independent variables in multiple linear and logistic regression models. Dependent variables will include willingness to obtain COVID-19 testing (continuous variable), intention to obtain COVID-19 testing (continuous variable),

willingness to obtain COVID-19 vaccine (continuous variable), intention to receive COVID-19 vaccine (continuous variable), and actual COVID-19 testing behavior (tested/not tested – binary variable). Covariates will include age, sex and country of origin. In addition, dominance analyses (Budescu, 1993) will be conducted to examine relative importance of the attitudes, behaviors, and facilitators to identify which factors may be the most appropriate to target to increase COVID-19 testing behavior and vaccine uptake (when available) in the rural migrant Latinx population.

Aim 2.b. Marketing Strategies and Charlas.

Charlas for Pretesting the social marketing strategies, messages, and materials.

Pretesting is an essential activity to confirm that the target audience finds activities, messages, and materials understandable, relevant, persuasive, and appealing. After the marketing plan has been designed, prototype materials and messages will be developed. We will then obtain feedback on the formulated social marketing products from charlas. Utilizing charlas for obtaining feedback on social marketing products are a culturally accepted practice that allows community members/stakeholders to participate in community decisions. Promotoras, along with

Data Collection Techniques: Charlas will be facilitated by bilingual USF researchers (trained by Dr. Pasha) and promotoras will use think-aloud techniques and probing questions^{22, 23} to explore charla participant responses to proposed materials, messages, and activities. Charlas sessions will be audio-recorded and trained bilingual USF research assistants will take notes during the sessions. The first iteration will focus on comprehension, appeal, persuasion, and relevance. The second round will focus on believability, appropriateness, and on cultural acceptability and ensure that previous revisions are working as intended. Charlas will be transcribed and translated using the GMR transcription services company and then coded by masked assistants. Although we anticipate few variations across cities, we will evaluate whether there were any noteworthy differences across subgroups of Latinx participants.

Decision Making Process: After each charla, USF researchers will conduct decision making meetings with the HSC leaders to discuss feedback from charlas and compare meeting notes from multiple RAs and other documents (e.g., participant worksheets). Discussion will be continued until a consensus is reached on which marketing products will be kept or excluded and how revisions will be made. We will ensure to include various levels (i.e., individual, interpersonal, and community) from the NIMHD research framework.

Development of Final Social Marketing Products: Based on the results from charlas and decision making process, the final social marketing products will be selected. A report on these products and a detailed implementation and dissemination plan will be documented for further testing in a future investigation.

7. DATA COLLECTION AND QUALITY ASSURANCE

7.1 Training and Fidelity

The RAs and promotoras will be trained by and maintain consistent contact regarding recruitment with the MPI's. Study fidelity/standardization of study implementation will be ensured via the following strategies: 1) Prior to beginning the study, all promotora group leaders

will participate in training led by the MPI's, project coordinator and the director of the promotoras at Hispanic Services Council (HSC). Research Staff will be training in Cultural Competence, with an emphasis on the importance of family preferences and cultural relevance.^{15, 16}

Monitoring fidelity. Reliable delivery of the project is assured by: a) having a clear, detailed interview guide; b) facilitator training; and c) frequent communication between the promotoras, the MPI's and project coordinator. d) Promotoras will participate in a two-day training prior to the start of the project, will participate in weekly reviews and supervision; and Quality assurance measures will be used to verify that the focus groups are delivered as planned. Briefly, a) promotoras will complete a <2min checklist documenting delivery of content, b) Quality Assurance raters (RAs during sessions and co-I, Rodriguez post-sessions) will review all group sessions, using the Fidelity of Implementation Rating System,¹⁷ checklist. c) Both verbal and non-verbal cues are rated in the assessment of participant responsiveness. Stern (MPI) has extensive experience in communication coding^{18, 19} d) Any deviation identified from the standard protocol will result in retraining staff to meet protocol criteria.

7.2 Data Management

Dr. Rancourt, our data manager has the experience and expertise in managing large data sets and will serve as our Data Manager for the study and statistical analyses. She has expertise in advanced longitudinal data analysis, including latent group curve and multilevel modeling. She will oversee the building of the data base with the assistance of the project coordinator and research assistants. Dr. Gray (Co-I) has experience in multi-site, complex intervention projects, and will assist Dr. Rancourt in evaluating and analyzing data, particularly qualitative data and aspects relating to public health and social marketing, and measurement. We will use Research Electronic Data Capture (**REDCap**), which is a secure web application *for building and managing online surveys and databases*, designed to collect ("capture"), store, secure, organize, and analyze data. Projects funded under the three NOSIs will serve as one consortium of interlinked community engaged research projects across the United States to understand COVID-19 health disparities, and to deploy implementation strategies to improve the reach, acceptance, uptake, and sustainability of COVID-19 testing. Therefore, we plan to actively coordinate and share data with other grantees. In line with this goal we propose to develop and maintain a secure database, where participant confidentiality is protected. We will streamline the data collection and entry process to eliminate duplicative efforts. The database will be created and maintained using cloud computing with Box, which is supported by USF. Box is useful because it conforms to HIPAA (Health Insurance Portability and Accountability Act) requirements, has a large storage capacity, syncs files with local computers, and shares files with partners across institutions.

Authorized users will be granted access to this password protected secured database. Multiple users concurrently may add, edit, and query data remotely through REDCap. This will be done by using forms that contain textboxes, radio buttons, check boxes, and labels, **whereby study elements can be shared** across HIPPA compliant networks.

- Data Entry- a) we will use direct entry as well as b) data entry from paper forms when e-forms are unavailable. The platform is designed to capture information efficiently and accurately and allows the provision of oversight by permitting the data manager to set and flag in 'real time' unrealistic values for each variable so that mis-key data entry errors are severely limited. An additional independent staff member will review the initial

data entry and bring any discrepancies to the attention of the data manager who will make the decision as to what value(s) should be entered.

- Data Editing- the data manager will review the data on a quarterly basis to identify out-of-range and missing entries and logical inconsistencies and correct any errors. Additionally, he will use this opportunity to provide feedback to the data entry staff so as to reduce the likelihood of similar errors in the future.
- Data Tracking-the data manager will track status of enrollment, and questionnaires/forms completed. A table will be created for each participant within one week of study visit to quickly assess whether there are missing data and notify study coordinators so the data can be obtained.
- Updating-the data manager will be responsible for overseeing data correction by staff that he designates as having the authority to make such changes. Data changes that are more than a simple correction of data that was mis-entered will be entered into a log that includes a description of the change, reason for change, date, and initials of staff member making the change.
- Data Conversion- REDCap is able to convert the data sets between different formats such as comma separated variables (CSV), SAS or SPSS. Data conversion better facilitates the exchange of data sets for multi-site investigators who may use different software for data management and analysis.
- Reporting-in a password protected file on a password protected fileserver, the data manager will maintain a master log of all enrolled subjects, their demographic data, and study status for ease of reporting. This master log of participants will be updated weekly.
- Statistical Analysis Support- data entry will be performed using REDCap. As such, data will be ready for regular inspection by the data manager and analysis when the time comes.

Data Coordinating and Data Quality Control

Coordination and support of database development and maintenance. The waves of large volumes of data will require continuous monitoring and maintenance of the database. Accrual reporting, automated interim data quality checks will be performed regularly. Participant confidentiality and privacy regulations, will be protected. Specific data management functions will include: (i) data management SOPs (ii) build and validate data entry screens (iii) define, program and validate edit checks (iv) enter and verify data (v) resolve and handle data discrepancies (vi) coordinate and submit annual reports (vii) NIH cumulative enrollment reports (viii) perform quality assurance (QA) checks on database and (ix) audit database.

Reporting and Data Validation: Built into data system will be automatic checks for inconsistent, illogical or missing data. When inconsistencies are found, an error message will arise. Furthermore, upon data entry, the system will recognize the missing data elements and prompt the data entry personnel to explain why the data is missing. If the data manager cannot read a field, or the data seem illogical or obviously incorrect, a notification will be sent to the data manager.

Study Monitoring: We will monitor and track in real-time, missing data, logic checks, spellings, and incorrect terminologies/acronyms. The coordinators and data managers will make corrections and resolve data entry issues more efficiently, maximizing monitoring visits. For example, if there are missing or out-of-range data, the data management staff has the

explanation in electronic format prior to the visit, and out of range, or inconsistent data issues will already have been resolved via the query process. They can also have the authorization to "lock" the form to prevent the site, prior to authorization, from changing data after the monitoring visit.

7.3 Quality Assurance

Quality assurance measures are used to verify that all components of the project is delivered as planned. a) Following each focus group session (Aim 1A) and charlas group (Aim 2B), promotoras will complete a brief (<2 min) checklist to document the occurrence of planned activities and content. These facilitator forms are a useful way to continuously remind facilitators of the protocol and interview guide. b) Participants also will complete a session checklist after each focus group or charlas session that addresses issues of likeability, acceptability, and usefulness of the group and group leaders. c) Co-I Rodriguez will serve as our primary Quality Assurance Rater. She will complete quality assurance rating forms to provide written documentation, using an observer checklist that will determine adherence to the interview guide. d) Any deviation identified from the standard protocol will result in retraining staff to meet protocol criteria.

7.3.a. Monitoring of data and protocol compliance. Quality assurance will be conducted by the MPIs on randomly selected patient records per quarter from accruals registered in the preceding quarter. The quality assurance/protocol compliance process for case review audits includes review of:

- Eligibility and consent form
- Intervention administration
- Adverse event documentation and reporting
- Overall quality and completeness of the data including database entry

7.3.b. Protocol Deviations

A log for recording protocol deviations will be kept by research staff and reviewed monthly by the MPIs and DSMO. Deviations will be routinely reported to the USF IRB. Protocol deviations include, but are not limited to the following:

- Failure to obtain Informed Consent
- Failure to keep IRB approval up to date
- Outcome measurement not performed

8. PARTICIPANT RIGHTS AND CONFIDENTIALITY

8.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document (Appendix A and B) and any subsequent modifications will be reviewed and approved by the USF IRB.

8.2 Informed Consent Forms

For Aim 1a, our bilingual RA will obtain consent from each participant in writing prior to beginning the focus group. For Aim 1b, prior to administering the questionnaires/surveys individually, consent will be obtained in accordance with IRB regulations by having the participant electronically sign the consent on the tablet, if participating via in person, on their own computer if via zoom and verbally, if by phone.

For Aim 1b, in the cases where in-person consenting takes place, participants will be asked to sign the consent electronically using the tablet purchased for the project, using REDCap forms, ensuring password protection. All promotoras will be provided with tablets with cellular capacity, and will have the participant read/follow along while the promotora reads aloud the contents of the REDCap consent form and obtain electronic signatures. Consent forms will be in Spanish, written at a 4th or lower grade reading level, clearly stating our project's goals and emphasizing that we are not conducting any individual level diagnostic testing. Consent forms will stress that the study is entirely voluntary and will indicate that participants can change their mind at any time about participating in the study. This method of obtaining electronic signatures indicating consent will have been approved by USF IRB prior to the start of the project. This signature will be deemed as voluntary consent to begin the study – after which, promotoras (who would have obtained human subjects training prior to the start of the project) will begin reading aloud each question of the surveys and then recording participants' responses into the REDCap program on the tablet.

8.3 Participant Confidentiality

Each participant will receive a subject number upon entering the study. All participant files will be identified by this number, with all identifiers removed. Survey data will be populated into REDCap when surveys are being completed. In the event paper surveys are completed, technicians will enter data into the database according to the subject number. Access to the computers and the data files will be restricted by password codes. The study coordinator will maintain a confidential list associating subject number with participant name and identifying information stored in a password protected file on an encrypted file server. All research study personnel will have human subjects training certification as required by USF. De-identified hardcopy data will be stored in locked file cabinets in and de-identified electronic data will be stored on the USF encrypted servers and the RADx-UP servers.

In the event of a real or suspected breach of security, the USF IRB will be notified immediately.

Data will only be destroyed according to USF IRB guidance.

9. RADx-UP Data Sharing Plan

We will share all data with the RADx-UP Consortium. We are committed to disseminating and sharing our findings with colleagues and our target population through several platforms. Several strategies for dissemination of our findings will be employed. 1) We will share our findings with participants and other community members at local community centers. 2) We will share our findings at grand round lectures, or the equivalent. 3) We will present our findings at local, regional, national and international forums/conferences on a regular basis. 4) We will also disseminate our findings in a timely manner through publication in peer-reviewed journals and press releases. 5) All final peer-reviewed manuscripts that arise from this grant application will be submitted to the digital archive PubMed Central. Wherever applicable, data will be deposited to appropriate public repositories.

We will share final data in accordance with NIH policy. Identifiers will be removed from the data. To fully protect the human participants, we will make an evaluation of each data request to ensure that special circumstances do not exist that would permit anyone to deduce the identification of individuals from the remaining data. If such a case exists, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for a commitment to: (1) using the data only for research purposes and not to identify any individual participant, (2) securing the data using appropriate computer technology, and (3) destroying or returning the data in the time specified by the USF IRB after analyses are completed. We plan to provide a complete and final study protocol of this project with the 12-month progress report. The protocol will include the study aims (primary, secondary and exploratory), the hypotheses that we are testing (i.e., target benchmarks), the study population, and the complete methodology. In addition, we will include definitions of all outcomes measured in the project, the timeline, and the planned analyses. Included with the analysis section will be data definitions, any codes utilized, and the specific plans for data analyses.

10. SUPPLEMENTS/APPENDICES

Appendix A: Informed Consent Form

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