

Cover Page

Document:	Study Protocol
Document Date:	2025-02-04

Project Title:	Enhancing SARS-CoV-2 Rapid Testing Acceptance in Latinx Communities
Identifiers:	NCT05910879
Unique Protocol ID:	STUDY00000790
Secondary ID:	1U01MD018311-01

Research Plan

IMPORTANT: When completing this outline, please use the [Research Plan Guidance](#) for the content necessary to develop a comprehensive yet succinct Research Plan. Using the guidance to complete this outline will help facilitate timely IRB review.

Study Title: Enhancing SARS-CoV-2 Rapid Testing Acceptance in Latinx Communities

Protocol Number: STUDY00000790

Principal Investigator: Dave DeGarmo

A. Introduction and Background

There remains a critical need to understand and address barriers to testing among vulnerable populations. Consistent evidence from national initiatives have shown that Latinx individuals are underrepresented at SARS-CoV-2 testing sites, suggesting that we need to better understand psychosocial and behavioral barriers. They are more likely to test positive when testing, with representative data showing that for every 1 percent increase in underrepresentation of Latinx persons in testing, a state's mortality rate is 1.04 percentage points more over-representative compared to non-Latinx COVID-19 mortality rates. Further compounding challenges for Latinx communities is mounting evidence demonstrating the deleterious effects of racial and ethnic discrimination on mental and physical health, which has only been exacerbated by the COVID-19 pandemic.

The ongoing Oregon Saludable: Juntos Podemos (OSJP, Healthy Oregon: Together We Can) project was developed to directly address the COVID-19 related health disparities among Latinx communities through community engagement funded by Phase I and II of the RADx-UP initiative. This project is organized by the University of Oregon's Oregon Saludable: Juntos Podemos (OSJP) project. This project is funded by the NIH's RADx-UP (Rapid Acceleration in Diagnostics (in) Underserved Populations) consortium and its Coordination and Data Collection Center (CDCC). The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies. The DCRI is acting only as a data repository as chosen by the NIH, and will not be engaging in this particular research project.

In this Phase III study, we build on our successful Phase I and Phase II partnerships with Latinx-serving community-based organizations and our established Community Scientific Advisory Board (CSAB) to employ a data-informed approach for implementing preventive interventions designed to advance health equity and ameliorate health disparities among vulnerable populations. Based on identity-stress and stereotype threat models for racial and ethnic minorities, we will further tailor the *Promotores de Salud* COVID-19 evidence-based health promotion intervention we developed in Phase I, and further adapted in Phase II, to experimentally evaluate a brief behavioral self-affirming implementation intention (SAII) intervention; an approach that is evidence-based for increasing acceptance of health messaging, increasing intentions to change, increasing health promoting behaviors, and decreasing psychological distress.

We hypothesize (a) the SAII will increase SARS-CoV-2 rapid testing, testing and vaccine acceptance, and health outcomes through enhancing health promotion messaging, reducing stigma, and affirming self-perceptions; and (b) the SAII will serve as a buffer that moderates (lowers) negative effects of COVID-19-related stressors and discrimination on testing and health outcomes. This community-engaged research addresses foci of the funding announcement, "the urgent need for social, ethical, and behavioral implications (SEBI) research to understand and reduce barriers to COVID-19 testing, as well as COVID-19

disparities that arise from barriers to testing among underserved and vulnerable populations.” We will conduct our activities at events sponsored by the Mexican Consulate throughout the state of Oregon.

B. Specific Aims/Study Objectives

The key targets of the SAI intervention will be structural social determinants of health (i.e., discrimination and mistrust) as barriers to testing acceptance. Our assessment infrastructure will be fully established with the RADx-UP Coordination and Data Collection Center (CDCC). We will employ our demonstrated survey collection strategies to accomplish the following specific aims in partnership with our existing relationships with the state health authority and our community partners:

Aim 1. Pilot test rapid SARS-CoV-2 test distribution and an English and Spanish version of the SAI intervention. In the first quarter of Year 1 we will tailor and pilot the existing “ultra-brief” SAI intervention to be offered in Spanish and English. We will consult our established community partners and CSAB to develop manualized protocols and train research study team to administer an oral version of SAI that can be readily applied by our research team and does not require English language proficiency or literacy. Our research team will also be trained to distribute SARS-CoV-2 rapid test kits. The purpose of Aim 1 will be to assess if the new protocol has acceptable levels of usability with this population.

Aim 2. Conduct a clustered randomized trial (CRT) testing a health equity effectiveness hypothesis. We will use a 2-group × 2-time (pre-post) design to randomly assign 600 participants sampled from Mexican Consulate event attendees to either an SAI + Promotores de Salud condition or to a control condition (Promotores de Salud only) and test (a) hypothesized main effects of the SAI intervention on testing and vaccine acceptance and health outcomes, and (b) hypothesized buffering effects of COVID-19 stressors and discrimination on testing and health outcomes.

C. Methods, Materials and Analysis

Overall Study Design: The research strategy involves a data-informed approach for the study design, with the primary aim of testing a SAI intervention hypothesized to reduce barriers to SARS-CoV-2 testing. In Aim 1 we will tailor and pilot a brief intervention (SAI) designed to increase health messaging uptake and rapid testing acceptance for a vulnerable population – Latinx individuals. The SAI is an “ultra-brief” exercise, where participants are asked to formulate an if-then plan with one preferred self-affirmation-inducing cognition: “If I feel sad, threatened, or uneasy by something, then I will think...”. Respondents then select one of four responses, “a)...think about things I value about myself, b)...remember things that I have succeeded in, c) ...think about what I stand for, or d)...think about things that are important to me”. After selecting response, participants fill in up to three blank sentences in response to the stem “If....”. Coupling with the “If-Then” structure of implementation intentions makes self-affirming cognitions accessible once a person’s self-system is threatened and involves focusing on valuable aspects of self to restore or sustain self-integrity in real time and in a timely manner. Therefore, a SAI is a specific mode-of thought-inducing plan (i.e., self-affirmation-thought-inducing) developed to address mental health and emotion regulation issues in response to threats. The SAI has traditionally been completed using a written affirmation procedure, however, we are piloting this in an oral collection method (i.e., verbally describing a personal experience). Together with our CSAB, we will tailor the extant SAI intervention to be offered in Spanish and English. Our study team will first practice the SAI intervention with members of our bilingual bicultural research team ($n = 5$). Our research team will then pilot the SAI intervention with participants at Mexican Consulate events ($n = 20$). The investigative team will examine the length of SAI intervention delivery, any comprehension or translation challenges, and cultural appropriateness to iteratively refine the SAI protocols for the Latinx population before we begin the CRT. We will iteratively discuss the pilot experiences with our CSAB and incorporate their input. SAI

Intervention tailoring will first focus on a culturally competent adaptation of the SAll. Cultural adaptation of any evidence-based program, brief or intensive, requires systematic modification to consider language, behavioral traditions, and context that are compatible with and relevant to a focal population's shared values and beliefs. This primarily involves adequate translation and backtranslation for meaning and cultural acceptance. Secondly, it involves assuring culturally adequate administration protocols. In consultation with our established community partners and CSAB, we will then develop manualized protocols and train the research team to administer an oral version of SAll that does not require English language proficiency or literacy. In addition, we will train the research team on the use and distribution of SARS-CoV-2 rapid testing kits. Both the rapid testing distribution and the SAll will be examined for usability and acceptability in a sample of 20 Latinx community members attending the MC event.

In Aim 2 we will experimentally evaluate the effectiveness of SAll using a 2-group $\times$ 2-time (pre-post) clustered randomized trial. We will randomly assign 600 participants sampled from Mexican Consulate event attendees to either an SAll + Promotores de Salud condition or to a control condition (the Promotores de Salud only).

The proposed project leverages the testing event model approach we established in Phase II with the Mexican Consulate, to approach individuals while they were attending the Consulate for other services. We can leverage this successful outreach and engagement model for this population to now distribute rapid tests and collect new data using the RADx-UP common data elements—both of which are essential given the newer and continuous evolution of the stages of the COVID-19 pandemic-endemic. We will maintain our ongoing collaborations with our CSAB, the OHA, and the Mexican Consulate as integral partners in the research. This will help ensure that we are meeting the state's needs, while simultaneously increasing the likelihood of sustainability of the intervention and rapid test kit distribution model after any federal grant funding has ended.

Randomization: The study design randomization will occur at the **event** level such that all events will be randomized for half to receive Promotores de Salud plus the SAll intervention, and half to be randomized to receive the Promotores de Salud only. Mexican Consulate (MC) events are two-day events typically held on Saturdays and Sundays. We will randomize by day of event for each newly scheduled event. As in the wait-listed control event randomization in Phase I, the study design randomization is not directly shared with the participant because the randomization occurs by event, as opposed to randomization by participant. The event will already be assigned to the condition of providing the Promotores de Salud vs. the Promotores de Salud + SAll. Rather, all participants in either condition are invited to participate in the survey, the Promotores, and the SAll (if relevant) with all procedures explained and opportunity provided for questions *prior* to consenting.

In collaboration with the Mexican Consulate, research team members will attend MC mobile events. Members of the Latinx community typically attend MC mobile events in order to secure services, such as obtaining a passport or ID card. In addition, vaccination clinics are often held in conjunction with the MC mobile events.

Research team members will attend the MC mobile events, invite MC attendees to participate in the research study and complete a survey, offer the Promotores de Salud, and SAll intervention to all attendees (if event is assigned to the intervention condition), and distribute rapid tests to them. When receiving their rapid tests, participants will also receive a Post-Enrollment Letter that contains contact information for our research team, a reminder about being recontacted in 30 days for the follow-up (T2) survey, a link to the study website, and information about the Rapid Test Kits (e.g. instructions, reading

results, reporting results, and kit expiration dates). The intervention version of the letter also contains a list of the topics from the SAI intervention. The RA will check the option selected by the participant during the SAI intervention to serve as a reminder of the discussion.

- Promotores de Salud only
 - Basic flyer and conversation to promote healthy behaviors
 - Post-Enrollment Letter (control version)
- Promotores de Salud and self-affirming implementation intention (SAII) intervention
 - Basic flyer and conversation to promote healthy behaviors
 - Self-Affirmation Implementation Intentions interview
 - Post-Enrollment Letter (intervention version)

Data Points to assess test the main effects of the intervention on testing and vaccine acceptance and health outcomes, and buffering effects of COVID-19 stressors and discrimination on testing and health outcomes includes collection of **individual level survey data** ($n = 600$) and anonymous pilot data ($n = 20$).

1. Anonymous pilot data

A random set of individuals attending an MC event will be asked to participate in the anonymous interview for piloting purposes. Participants who verbally agree to this component will be directed to meet with a study staff member, who will verbally consent the participant using the consent script.

2. Individual level survey data

- a. Surveys will contain information including demographic information, including address, phone number, and email. Surveys will also include Tier 1 and Tier 2 RADx-UP CDCC required Common Data Elements (CDEs). The baseline survey (T1) will be collected in-person at MC events. These data will be collected using an electronic survey that participants can complete on their smartphone, or using an iPad provided on site, or on paper. If the participant prefers or as is needed, the survey items will be read by a field team member, who is bicultural and bilingual. Surveys will be available in Spanish and in English.
- b. Individuals who are willing to participate in the T1 survey will be asked in the T1 survey how they prefer to complete the follow-up (T2) survey. They will be able to select to receive a text message with a follow-up survey link, email with a follow-up survey link or a paper survey by postal mail with a pre-paid envelope to return the survey, one month later. For participants who prefer, the one-month survey will be conducted by telephone. Each survey will take approximately 30 minutes to complete. The T2 survey will contain most of the same CDEs as the T1 survey, with the exception that items that are not expected to change in 30 days will not be asked again (e.g., birth date, education level).
- c. All participants will be asked to provide consent to participate in the research survey.
- d. Baseline (T1) recruitment and survey data will be collected in-person at testing sites, requiring direct interaction with participants.
- e. Participants at events assigned to the intervention condition will be asked to complete the Self-Affirmation Implementation Intentions interview. Participants who consent to participate in the study and agree to this component will be directed to meet with a study staff member at an MC event after they complete the T1 survey. A study staff member will verbally consent the participant before conducting the interview.

D. Research Population & Recruitment Methods

This research study builds on existing partnerships with the Mexican Consulate (MC) and our Community and Scientific Advisory Board (CSAB), both of which were established and nurtured in Phase I and II of this work. As noted in the letter of support from MC, we have established a strong and trusted working relationship with them and they are supportive of our distribution of rapid tests and the Promotores de Salud + SAIL intervention at their mobile events (for Aim 2). The MC is also supportive of our pilot activities, to refine the intervention (for Aim 1).

1. Anonymous pilot data

For Aim 1, we will first practice the SAIL with our bilingual, bicultural research team ($n = 5$) by having the research team practice with each other. Next, we will draw pilot participants from MC events ($n = 20$). Members of our research team will approach individuals attending an event and will first confirm they are over the age of 18. If they are over 18, the research team will invite them to: 1) complete the ultra-brief SAIL interview, 2) receive the Promotores de Salud and healthy behaviors flyer, and 3) receive free COVID-19 rapid testing kits. We will invite approximately 20 individuals to participate in the brief anonymous interview with a research team member at an MC event. No individually identifiable data will be collected. Individuals that agree to pilot these activities will be given a \$10 gift card, as a thank you for their time. An oral script will be used to outline these activities, and will provide information about the purpose of the interview. Anonymous interview data will provide staff with experience and feedback to assist investigators with refining the ultra-brief SAIL intervention. These anonymous interviews will not be used as research data, and are only to provide staff feedback on the SAIL.

2. Individual level survey data

For Aim 2, members of our research team will approach individuals attending an event and confirm their eligibility using a recruitment screener to determine their eligibility (see Recruitment Script). Information collected during the recruitment screening will be collected verbally and not recorded as data. If individuals are eligible, the research team will invite them to: 1) complete the research survey; 2) receive the Promotores de Salud, and 3) receive free COVID-19 rapid testing kits. If the event is assigned to the Intervention Condition, the participants will also receive the ultra-brief SAIL.

Participants will receive \$30 for participating in the T1 research survey. The research survey asks participants about the best methods of contacting them for the T2 survey, approximately 30-days later. Depending on participant preference, bilingual/bicultural research team members will use text messages, phone calls, and/or physical mail to reach out to invite participants to complete the T2 survey. Participants will be offered \$30 for T1 survey and \$30 compensation for the T2 survey.

Inclusion criteria includes:

1. Individuals are age 18 years and older
2. Individuals are attending a MC event

Exclusion criteria includes:

1. Individual is unable to understand Spanish or English at a 5th grade level (participants who cannot read will have the consent form read to them)
2. Individual discloses that they previously enrolled in the research project

We anticipate 600 adult individuals will provide survey data. Recruitment will occur at the Mexican Consulate events, by the study research team. A standardized recruitment script (see recruitment information document) will be used. Participants will be compensated with a \$30 gift card for each

survey they complete (one at baseline (T1), one at one month follow-up (T2), for a total of \$60 in gift card remuneration available).

E. Informed Consent Process

1. Anonymous pilot data

Participants will be consented verbally utilizing the attached recruitment and consent script.

2. Individual level survey data

For Aim 2, we will use a standardized consent form to consent participants 18 and older at MC events. All individuals will read the consent form and will be asked if they have any questions. Individuals over 18, who cannot read at a 5th grade level will have the consent form read to them. Children will never be used as translators. At the time of consent, the research study team will review the consent form with the participant before they sign it to ensure that the participant is clear about data will be obtained by NIH and DCRI versus the UO.

Participants will be assured that their participation in the study is voluntary and that if they choose to participate, they can change their minds at any time. They will be informed about potential benefits and harm. They will be informed that their decision about whether to participate will not alter the medical care, or social services they will receive at any time from the county partners and that they will not be denied services of any kind. Participants will be asked to sign an informed consent form that explains the project, their rights, and how the data will be used in the future. A phone number and email address linking participants to Spanish-speaking and English-speaking members of the research team will be provided so participants can contact project staff if they have any questions about the consent form. The study research team will be trained in recruitment procedures and have specialized training in how to handle any exceptions. We have used similar consent procedures in many prior intervention research studies and have successfully recruited large numbers of participants in community agencies.

Participants will be presented with the consent to participate in the survey. The informed consent will document the participants agreement to participate in the T1 and T2 survey, agreement to receive the Self-Affirmation Implementation Intentions interview (if applicable). An informed consent form will be posted on a Federal Web site (e.g., clinicaltrials.gov) after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

F. Provisions for Participant Privacy and Data Confidentiality

As a requirement from our funder, Aim 2 de-identified data will be provided to the Coordination and Data Collection Center (CDCC). This is referred to as a RADx-UP database in the consent. Data will not be identifiable and will be shared using secure processes and procedures as designated by the CDCC.

1. Privacy: During the intervention, it will be up to participants to disclose vulnerable information about their previous experiences. Though recruitment will occur in public spaces, as is common at MC events, efforts will be made to ensure that participants will be recruited, consented in a private environment (e.g., behind a partition, facing away from others, in their vehicle, etc).

- a. **Anonymous pilot data:** Participants will not be asked to provide any identifiable information during the anonymous participant interview. In addition, efforts will be made to ensure participant confidentiality.
- b. **Individual level survey data:** Participants will only disclose contact information they feel comfortable disclosing, which may include email, phone number, or physical address.

2. Data Disposition:

- a. **Anonymous pilot data:** This component does not include the collection of individual identifiers.
- b. **Individual level survey data:** For Aim 2, identifiable participant information will be collected in Qualtrics or on paper. Following data collection, identifiable data will be removed, and a unique identifier assigned for all analyses. Only participants who provide consent to share identifiable data with DCRI will have their identifiable data shared with them. Disposition of email, phone number, or physical address will include keeping these data separate from the client survey data for analysis. The SAll intervention does not include the collection of individual identifiers.

Confidentiality:

- a. **Anonymous pilot data:** This component does not include the collection of individual identifiers.
- b. **Individual level survey data:** All research survey data will be stored at the Prevention Science Institute. Participants can choose to complete surveys via Qualtrics or on paper. Electronic data will be stored using standard security techniques (password protected file folders on the University's Prevention Science Institute secure server). Data from Qualtrics will only be accessed using secure wifi. Any sharing of survey data will occur on shared drive (such as One Drive) that is password protected. Storage of data will be stored electronically on a private server and will be directly uploaded only while using secure wifi. If the data must be transferred, they will be transferred using a secure client server.

Paper data will be transported to the Prevention Science Institute after T1 data collection or after T2 surveys are returned by mail. Data collected during a phone interview with the participant is entered directly into Qualtrics. Data and records are identified with a participant number only. The electronic data files and any paper and pencil originals are not identified by name. Participants will be asked to provide their mailing address information in our online surveys to confirm where they would like us to mail their subject payment(s) and/or assessment materials, however, the address information participants provide will be removed from data files by our study's Data Manager during the data cleaning and processing stage prior to sharing data with investigators for analyses.

In addition to our study's database and data storing procedures within the UO, data collected for the RADx-UP project that will be shared with the RADx consortium will be uploaded through a secure client server and maintained by staff at the DCRI. Identifiable data will be shared with DCRI when permission is given in the informed consent form. Participants are given the option to share identifiable information with the DCRI on the informed consent form. Agreeing to share identifiable data with the DCRI is not a requirement for participants to be enrolled in the study. The DCRI manages data from all studies participating in the RADx Program. The DCRI maintains data in two separate databases, one that contains identifiable information and one contains de-identified information.

The only individuals with access to identifiable participant information on Qualtrics or paper will be those who have the appropriate human subjects training who need access to the data to complete their assigned role on the research team. The code and key with participant contact information will be retained in a locked file on the Prevention Science Institute (at

University of Oregon) server with permissions granted to only to the study project coordinator and data manager.

Research funded by NIH automatically has a Certificate of Confidentiality associated with it. This is added protection against forced disclosure of research information in circumstances of subpoena.

Study researchers and the students they supervise may be granted access to de-identified data after signing a data use agreement, in order to complete analyses. Records will be kept for up to 3 years after the study has been completed.

G. Potential Research Risks or Discomforts to Participants

Information risks, psychological risks, and social risks may occur as the result of participating in this study. Social risks may occur as a result of receiving services in public. Specifically, participants might feel uncomfortable engaging in the intervention if they do not have a private space to participate.

Psychological risks may occur such as guilt or loss of self-esteem while receiving the health intervention. It is likely that the intervention will improve sense of responsibility to engage in health behaviors without inducing guilt and improve self-esteem but not everyone receives treatment uniformly. Participants will be encouraged to seek services if they are in need of additional support.

The protocol involves intervention. The intervention aims to understand and reduce barriers to COVID-19 testing, as well as COVID-19 disparities that arise from barriers to testing among underserved and vulnerable populations. The research team will provide health information which includes information from the Centers for Disease Control that has been vetted by county public health professional and will conduct the SAIL interview (if applicable). This research does not pose any additional risk over the services provided as usual since some communities provide similar interventions.

The funding agency required a Data Safety Monitoring Plan for this research at the time of funding proposal. A copy of the DSMP submitted to the funder is attached.

There is no established Data and Safety Monitoring Board/Committee (DSMB/C) as noted in the DSMP.

1. Anonymous pilot data

There are no physical risks for the individuals who choose to complete the anonymous interview, however, some participants may experience discomfort when asked behavior related questions. Participants who feel uncomfortable during any part of the interview have the option to skip any question.

2. Individual level survey data

Information risks include loss of privacy and/or breach of confidentiality. Since electronic data will be collected using only private wifi (except when participants are not connected to secure wifi if they use their own device) and will be stored on a secure server, it is unlikely that loss of privacy will occur. T1 survey data collected on paper will be transported to the Prevention Science Institute following collection at an MC event. T2 survey data collected on paper will be returned by mail to the Prevention Science Institute. All paper data is kept in secure, locked areas. All risks will be communicated in the informed consent process.

H. Potential Benefits of the Research

The overall risk involved in the project is relatively minor, given the goals of the research. Research participants will benefit by receiving free SARS-CoV-2 rapid tests and educational information that could improve their health behaviors and reduce transmission of SARS-CoV-2 in their communities and around Oregon. Thus, others in the community would benefit from general participation if participants are identified as positive who previously did not know they were infectious, and if participants actively alter their health behaviors, whether infectious or not.

Individuals may receive benefits from participating in this research such as improvements in health behaviors and reduced likelihood of contracting and spreading COVID-19.

By participating in this research, the research team will be able to learn whether the Promotores de Salud component and (SAll) intervention would be generally useful over just the Promotores de Salud.

I. Investigator Experience

1. Investigator Qualifications

- **PI: David DeGarmo, Ph.D.**

DeGarmo is a Research Professor at the University of Oregon Prevention Science Institute and the Department of Counseling Psychology and Human Services. DeGarmo has extensive experience leading and evaluating federally funded clinical trials. He was MPI of the RADx-UP Phase I project (P50 DA048756-S2: Leve, Cresko, DeGarmo) and is currently MPI of the RADx-UP Phase II 'Optimizing SARS-CoV-2 Testing and Promotores Interventions to Serve Latinx Communities' 3P50DA048756-03S3 (Leve, Cresko, DeGarmo). DeGarmo is also MPI of the 'Investigating the impacts of COVID-19 School Closures on Long-Term Adjustment in Youth with or at Risk for 1R01HD108887-01 (McIntyre, DeGarmo) and PI of the UO Data Science Core for the P50 DA048756-01 (Leve) centers of excellence Center on Parents and Opioids. His expertise and work focus on intervention design and evaluation. Relevant for the current project, Dr. DeGarmo has conducted research on health equity intervention, stress and discriminatory sequelae and buffers for Latino/a/x families and Mexican Immigrants (DeGarmo, De Anda, Cioffi et al., 2022; Parra-Cardona, Fuentes-Balderrama, Vanderziel et al., 2022; De Anda, Budd, Halvorson et al., 2022; DeGarmo & Martinez Jr, 2006). Also relevant, DeGarmo has conducted programmatic research in measuring and evaluating identity stress, identity salience and behavioral interactions (DeGarmo, Jones, & Rains, 2019; DeGarmo, 2010; DeGarmo, Reid, Leve et al., 2010, DeGarmo & Forgatch, 2002). DeGarmo is former director of the Center for Assessment, Statistics and Evaluation (CASE) at the University of Oregon and have coauthored more than 40 efficacy and effectiveness evaluations, and currently teaches prevention science methodology in the College of Education including multilevel modeling, structural equation modeling, and adaptive intervention design and evaluation.

- **Co-I: Leslie Leve, Ph.D.**

Leve is the Lorry Lokey Professor of College of Education at the University of Oregon. She has extensive expertise in directing and managing multicomponent and multi-site projects, including her role as Principal Investigator on RADx Phase I and Phase II awards. In addition, she is Principal Investigator of an ECHO cohort award from NIH which contains three cohorts of families, coordination with her cohort co-investigators across the U.S., and coordination with the larger ECHO consortium of more than 30 awardees. She co-chaired the Data Sharing working group for ECHO and serves on its Return of Results workgroup. On her P50 Center of Excellence award, she directs the Administrative Core, and received a HEAL supplement to focus on web-based platforms for the prevention of substance use in adolescent and young adult populations.

RADx, ECHO, and HEAL all have extensive data harmonization and data sharing requirements, which Leve's projects have fully met. She holds national and local leadership roles that require outstanding research and leadership skills, including her past role as President of the Society for Prevention Research, Associate Vice President for Research at the University of Oregon, and Associate Director of the Prevention Science Institute. She is currently Department Head for the Counseling Psychology and Human Services department. She is an accomplished scholar, with over 200 peer reviewed publications focused on research in partnership with community social service organizations and has been an investigator on dozens of NIH grants.

- **Co-I: Ellen McWhirter, Ph.D.**

McWhirter is the Ann Swindells Professor in Counseling Psychology and director of the Spanish Language Psychological Services and Research (SLPSR) Specialization at the University of Oregon. Her scholarship on Latinx adolescent career development, critical consciousness, and risk and protective factors is particularly salient to her roles on this grant. Her contributions include 59 refereed publications, 13 book chapters, and 2 books as well as 140 refereed or invited presentations. A Fulbright Scholar (Universidad de Chile, Santiago, Chile, 2004), her integration of research with service has been recognized with national and university awards. In conjunction with her scholarship, her roles on the executive board of Center for Latina/o and Latin American Studies (CLLAS) and the University of Oregon (UO) Dreamers Working Group, and more than a decade of evaluation work with the César E. Chávez Leadership Conference, provide a strong network of connections with Oregon Latinx communities.

2. Roles and Research Duties

Principal Investigator will assume responsibility for all scientific, administrative, financial, and operational aspects of the project.

Co-Investigators will:

- assist the PI with administrative functioning of the overall project
- assist in facilitating the community-based participatory approach
- support the project's collaboration with key community stakeholders
- interface with funded RADx-UP Social, Ethical and Behavioral Implications program grantees (SEBI, NOT-OD-20-119) and other RADx-UP field sites to support novel research on social, ethical and behavioral implications of testing in underserved and/or vulnerable populations
- contribute to activities to support implementation of the proposed interventions
- assist in administrative and communication aspects of the testing project and help coordinate with the CDCC

The study research team will support the implementation of events throughout Oregon in partnership with the Mexican Consulate. The study research team will also collect individual survey data.

3. Training and Oversight

Co-investigators and the study research team will perform research activities within the scope of their training.

Training for the study research team will be provided by the project coordinator. Training will include how to sanitize devices used for data collection, relevant human subjects training, and standardized processes and procedures for recruitment, obtaining consent, and data collection. The

study research team will complete the study Promotores de Salud training and specific SAI intervention training.

3. Translator

At least two people who are proficient in Spanish will review all written study materials before providing materials to participating county health departments and community-based organizations.