

**PROTOCOL TITLE:** Community-Engaged Research on COVID-19 Testing Among Underserved and/or Vulnerable Populations

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## **I. ABSTRACT**

The SARS-CoV-2, also known as COVID-19 pandemic has caused disastrous and unprecedented public health and economic consequences in the U.S., seriously affecting Americans' physical and mental health. Death rates attributable to COVID-19 among minority populations are several folds higher than among predominantly White counties. South Florida and specifically Miami-Dade County has been an epicenter of the COVID-19 pandemic, where non-Hispanic Blacks and Latinos are overrepresented in COVID-19 related hospitalizations and deaths. Pervasive structural inequities and social determinants of health are the main cause of health disparities due to a complex interaction of multiple factors including individual and societal risk factors. Understanding the impacts of these factors on health and social consequences of the pandemic has broad policy implications, especially for the acceptance of testing and future vaccines. This research will address the impact of COVID-19 on vulnerable minority populations and examine (1) the barriers to testing and uptake of future vaccines, (2) effectiveness of community engagement to increase the uptake of COVID-19 testing in the underserved communities, (2) acceptability, sensitivity and specificity of using less invasive testing methods compared to nasopharyngeal swabs, and (3) assessment of barriers and potential strategies to engage community members and community organizations in COVID-19 testing and vaccine deployment. We propose to conduct community-engaged research studies in collaboration with community-based partners to (a) determine barriers to testing, and uptake of future vaccines, including health literacy, stigma, drug use and financial burden associated with testing, follow-up care, feasibility of effective self-isolation if positive, and perceived effectiveness of testing and vaccination, (b) assessment of the acceptability of extensive community outreach and deployment of a mobile COVID-19 testing unit to geographical areas occupied by underserved and vulnerable populations in close proximity to our community partner, Borinquen Health Care Center (BHCC), and (c) compare the acceptability, sensitivity, and specificity of alternative approaches to obtain samples, including medically administered nasopharyngeal swabs, saliva, and self-swabbing options sampled simultaneously. The goal is to improve understanding of COVID-19-related health disparities, enhance access, effectiveness, and implementation of COVID-19 testing in vulnerable and/or underserved populations and to mobilize the community to develop culturally-appropriate strategies to mitigate the COVID-19 epidemic and increase acceptance of future vaccines. The potential for evidence-based approaches to address COVID-19 disparities will be facilitated by our community-based partners that have the resources to provide community engagement, follow-up care, and public health mitigation for cases who test positive; the PI who manages a CLIA-certified laboratory at the university and a research team experienced in recruiting and retaining >1,000 study participants from the same vulnerable and underserved populations.

## **II. BACKGROUND AND SIGNIFICANCE**

COVID-19 is an unparalleled pandemic in modern times. As of November 3, 2020, more than 9.2 million Americans have tested positive for COVID-19 and more than 230,000 died from the disease.<sup>1</sup> In addition, the

socioeconomic impact in trying to contain the pandemic has been enormous, with more than 40 million Americans unemployed, deepening the inequities among the marginalized communities. As of November 3, 2020, Florida has been disproportionately affected with 821,123 cases, 49,889 hospitalizations, and 16,922 deaths overwhelming the capacity of the systems. The majority of these cases occurred in Miami-Dade County in South Florida, which was one of the epicenters of the infection.<sup>2</sup> The COVID-19 crisis has heightened the underlying disparities in health, healthcare access, living conditions, financial insecurity, and other social determinants of health (SDoH) that have long been documented among racial/ethnic minorities and make them more susceptible to disease.<sup>3</sup> The most pervasive disparities and the highest mortality rates in the US have been observed among African American and Latino individuals who also have disproportionate burden of underlying comorbidities that are considered risk factors for COVID-19 outcomes, including diabetes, cardiovascular disease, asthma, HIV, morbid obesity, liver and kidney disease. African American and Latino populations carry greater disease burden due to higher poverty rates, limited health care access, higher rates of jobs in service industries where they are less able to work from home, subsequently having increased exposure risk.<sup>4,5</sup> Crowded living conditions, poverty, and dependence on public transportation prevent physical distancing without the ability to isolate in a safe home, or work remotely with full digital access and ongoing income while quarantining.<sup>6</sup> Unemployment, food insecurity and unstable or substandard housing conditions may further perpetuate racial disparities in COVID-19 outcomes.<sup>7,8</sup>

Increasing testing capacity among the underserved population is critical as these minorities are more exposed due to disparities in SDoH.<sup>9</sup> Increased testing is important for identifying infections and contact tracing to reduce the spread of transmission. In addition, obtaining accurate information on the spread of COVID-19 among vulnerable groups is important for decision-makers and public health workers at local, state, and national levels. Using this information, sound decisions can be made about allocation of personal protective equipment (PPE), mitigation efforts, and, ultimately, vaccine procurement and prioritization. The immediate effectiveness of various public health interventions in limiting virus spread can be assessed and compared, and the true case fatality rate of SARS-CoV-2 infections can be determined.

The proposed research is significant because, (1) as the number of cases and the rate of morbidity and mortality are increasing in Miami-Dade County, now one of the epicenters of the pandemic in the U.S., testing, contact-tracing, and preparing the population for the rapid deployment of a vaccine are the most effective strategies to contain the epidemic, in addition to convincing Americans that current face coverings, social distancing, and hand hygiene are effective and should be embraced. (2) Florida International University (FIU) with its community partners (NeighborhoodHELP (NHELP) and Borinquen Health Care Center (BHCC)) is exceptionally well-situated to address the goals of this proposal because of its commitment to community service and research, its network of linkages with community organizations, the diverse backgrounds, race and ethnicity of the faculty, staff and students, a deep reach into Miami-Dade County's underserved populations, its cadre of professionals with expertise in these areas, and its laboratory and testing infrastructure that will assure the success of this research. (3) Our community partners, NHELP and BHCC serve the census tracts in Miami-Dade with the highest COVID-19 positivity rates.<sup>10</sup>

### **III. STUDY AIMS**

Specific Aim 1: Convene a Scientific Advisory Board (SAB) to guide the science of the project. In collaboration with NeighborhoodHELP (NHELP), a community outreach program, convene a Community Advisory Board (CAB) to identify and interview community leaders and key informants about barriers to COVID-19 testing and future vaccinations among residents in the targeted communities. Using this information, a culturally appropriate survey will be designed. **(PHASE 1)**

Specific Aim 2: Administer a culturally appropriate survey, using information derived from the CAB and key informants, specifically tailored to non-Hispanic Black and Latino residents. The survey will include items about

knowledge, attitudes, and beliefs about COVID-19 testing and vaccination, individual-level barriers such as drug use, stigma and financial burden, and structural barriers such as lack of transportation and places to self-isolate. **(PHASE 2)**

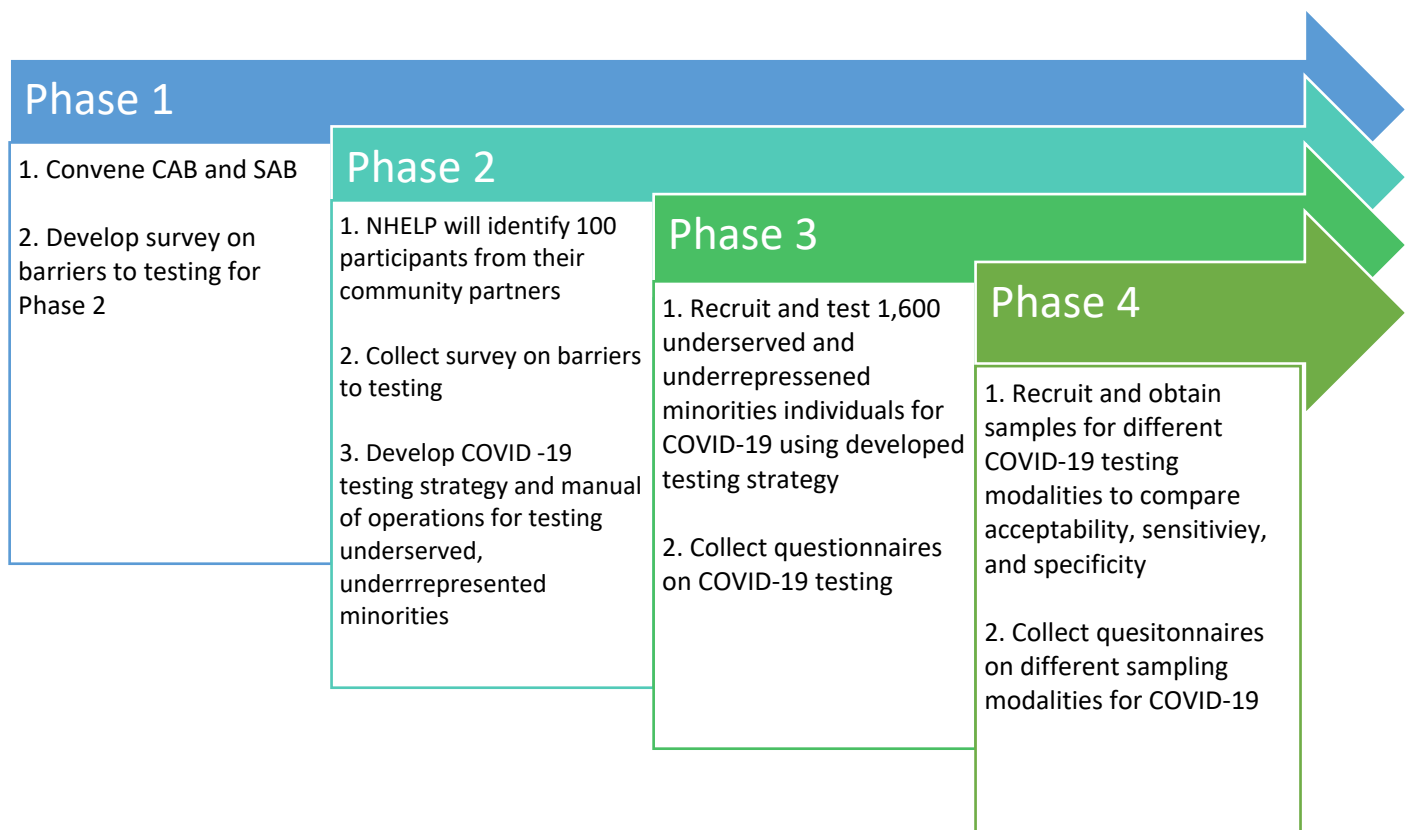
**Specific Aim 3:** To assess the reach of added community outreach and deployment of a mobile COVID-19 testing unit to geographical areas occupied by underserved and vulnerable populations in close proximity to our community partner, Borinquen Health Care Center (BHCC). The uptake of testing will be compared to that of the free-standing BHCC. Cases will be referred as appropriate to BHCC for follow-up and to the Florida Department of Health (DOH) for contact tracing. A survey will be conducted to assess acceptability of the mobile testing unit and whether participants would have gotten tested otherwise, as well as relevant questionnaires provided by CDC and the RADx-UP Social, Ethical and Behavioral Implications program. **(PHASE 3)**

**Specific Aim 4:** Compare the acceptability, sensitivity, and specificity of alternative approaches to obtain samples, including medically administered nasopharyngeal swabs, saliva, and self-swabbing options sampled simultaneously. **(PHASE 4)**

## IV. STUDY DESIGN

### a. STUDY PHASES

The study protocol currently covers Phases 1 and 2 of the planned research activities. These phases will be used to provide guidance on the development of Phases 3 and 4 activities, procedures and protocols. As the activities and milestones are completed for Phases 1 and 2, the study protocol will be updated to reflect the latest developments through the work of the study investigators, SAB, CAB and community partners.



### a. EXPERIMENTAL DESIGN OF THE STUDY (PHASE 1 AND PHASE 2)

The proposed work will be conducted in collaboration with community partners to leverage community resources and local service delivery settings to address the needs of multiple stakeholders to enhance COVID-19 testing. Approaches such as team science communication, community-engaged research, participatory action research, lay-person science, and related frameworks will be used to engage stakeholders and vulnerable populations throughout the research process.

The framework for this research we will use the Population Health Framework (PHF)<sup>11-13</sup> to develop questionnaires that assist in understanding barriers and facilitators to increase uptake of testing in the community and develop education and dissemination materials to engage the population in conjunction with the Coordination and Data Collection Center (CDCC) and the Social, Ethical and Behavioral Implications (SEBI) of COVID-

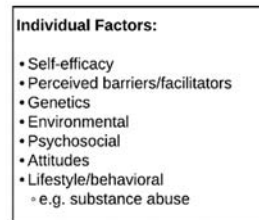


Figure 1: Conceptual Framework

19 testing. According to the PHF, individual and contextual factors and the interaction between them may produce varying levels of risk for adverse outcomes, in this case becoming positive for COVID-19. More specifically, using this framework, this proposal aims to simultaneously evaluate (1) individual factors (self-efficacy, perceived barriers and facilitators for testing, attitudes and beliefs about the risk of acquiring COVID-19, its severity, the importance of testing and future vaccination, and the willingness to engage in social distancing, masking and hand hygiene), (2) contextual factors (socioeconomic, occupational history, past exposures, access to health services and testing), (3) principal covariates, such as demographic variables (age, gender, race), self-perceived health status and co-morbid conditions, and (4) measurable outcomes of uptake of testing in the community, acceptability of alternative sampling methods, and sensitivity/specificity of different testing protocols (Figure 1). The individual factors will be measured by the demographic and health questionnaire which includes co-morbidities and health beliefs and attitudes. The contextual factors will be measured by the PhenX SDoH toolkit in collaboration and with the guidance provided by the Coordinating and Data Collection Center (CDCC). We will also work with the funded RADx-UP Social, Ethical and Behavioral Implications program grantees and other RADx-UP field sites. Outcomes will be measured with culturally-appropriate, tailored questionnaires based on input from key informants in the community and by comparing our testing data with that of BHCC.

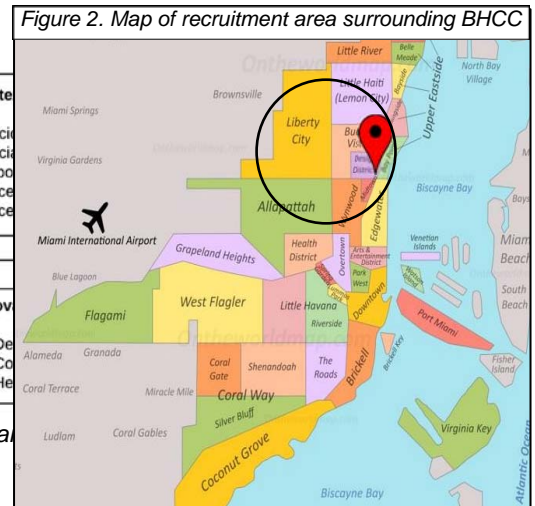


Figure 2: Map of recruitment area surrounding BHCC

### b. STUDY POPULATION GENERAL DESCRIPTION (PHASE 2)

The study population will be community-dwelling adults from vulnerable and underserved areas in Miami-Dade County, recruited through the collaboration with our community-based partners.

Our community partner, the Borinquen Health Care Center serves more than 43,000 patients in the most underserved zip codes of Miami-Dade, where minorities are concentrated. Please see the map (Figure 2)—the pointer is on BHCC and the surrounding areas are the poorest zip codes occupied by minorities. This area will be our target testing locations. We will also leverage the Miami Adult Studies on HIV (MASH) cohort resources for this endeavor, an urban, economically disadvantaged Black and Hispanic middle-aged and older adult cohort from South Florida, the groups most affected by HIV in the US.<sup>14</sup> The MASH cohort is part of a NIDA-funded consortium, the Collaborating Consortium of Cohorts Producing NIDA Opportunities (C3PNO), providing data and linking with 9 other cohorts.

There are only 25 county drive-throughs, 6 walk-up, and 6 homebound federally qualified community testing sites listed in all of the Miami-Dade County of 2.8 million people.<sup>15</sup> There are additional testing sites requiring a proof of health insurance (Urgent Care clinics, drug stores). Moreover, there are limited sampling kits available with people waiting 10-12 hours to be tested. Labs are unable to return results for up to two weeks or more.<sup>16</sup> There are fewer testing stations and less staff in areas primarily inhabited by racial minorities, showing deep disparities in testing availability. Consequently, people of color, especially Blacks and Latinos, are more likely to experience longer wait times in >100° F weather, lack of personal vehicles, and understaffed testing stations.<sup>17,18</sup>

### ***c. SAMPLE SIZE DETERMINATION AND POWER ANALYSES***

#### **PHASE 1**

Not Applicable

#### **PHASE 2**

We propose to randomly select and survey 100 participants of NeighborhoodHELP program to assess barriers to testing and understating of test results. A sample size of 100 produces a two-sided 95% confidence interval +/-10% around the estimate when the sample proportion is assumed at 0.5.

## **V. STUDY PROCEDURES**

#### **PHASE 1**

##### ***a. COMMUNITY ADVISORY BOARD***

A community advisory board will be led by Drs. Brown and Garba from the Florida International University NeighborhoodHELP program. They will work to include the following individuals from the community that may provide the necessary guidance for the development of the study outreach protocols and activities. The community advisory board will include:

1. (2) Health care professionals such as primary care physician, nurse or social worker
2. (2) Religious leaders
3. (2) community leaders
4. (2) Individual living with HIV and individual living without HIV currently receiving care from community centers

##### ***b. SCIENTIFIC ADVISORY BOARD***

The Scientific Advisory Board will be convened and will be chaired by Dr. Campa, an experienced researcher from the R. Stempel College of Public Health and Social Work, and composed of individuals with expertise in epidemiology, infectious disease, behavioral science and biostatistics. The Board will meet before the start of the study to review the study design and the justifications, and quarterly thereafter to evaluate the science, the appropriateness of the study design and on continuing basis, the milestones set out in this protocol. The Scientific Advisory Board includes the following members:

Adriana Campa, PhD (Chair)

R. Stempel College of Public Health & Social Work, Florida International University

Cristina Palacios, PhD

R. Stempel College of Public Health & Social Work, Florida International University

MaryJo Trepka, MD, MSPH

R. Stempel College of Public Health & Social Work, Florida International University

Zoran Bursac, PhD

R. Stempel College of Public Health & Social Work, Florida International University

Eneida Roldan, MD, MPH, MBA

Herbert Wertheim College of Medicine, Florida International University

Yolangel Hernandez-Suarez MD, MBA

Herbert Wertheim College of Medicine, Florida International University

### **c. *COMMUNITY ENGAGEMENT***

The following activities will be conducted through the networks of the NHELP, guidance provide by the Community Advisory Board (CAB) and oversight of the Scientific Advisory Board (SAB):

- (1) Outreach activities to establish and strengthen working relationships with community-based organizations (CBO)s that serve the target populations.
- (2) Create networks to increase participation of hard-to-reach minorities to support the aims of the proposed research; facilitate study participants' referrals for services provided by our community partner program.
- (3) Engage community leaders through their participation in a CAB in the development of strategies to increase testing rates for COVID-19 in hard-to-reach underserved populations and for deploying future vaccines, as well as the design, implementation, and dissemination of results of the proposed research.
- (4) The CAB, comprised of community stakeholders, will assist in identifying barriers to testing, monitoring, evaluating, and facilitating the activities, and increasing community awareness of the goals, partnerships, and achievements of this research.
- (5) The SAB will oversee the development and implementation of strategies to achieve the aims of this study, and it will be led by Dr. Adriana Campa.

The Community Partner Program encourages trust between researchers and the community, relying on continuous communication and exchanges between FIU investigators, CBOs, and community stakeholders. This relationship helps to overcome mistrust and engage community members, which is critically important for increasing the uptake of COVID-19 testing and uptake of future vaccines that is meaningful, effective, and culturally appropriate.<sup>19-21</sup> This program will also facilitate the science-to-practice transfer of culturally relevant and evidence-based COVID-19 prevention interventions. Although our scientific knowledge regarding effective interventions in COVID-19 is now nascent, new, population-specific discoveries need to be urgently applied to reduce the health and socioeconomic impact of the pandemic. With regard to COVID-19, testing in the community is vital to identify where resources should be allocated, and measures of social distancing implemented. In addition, the increased burden of COVID-19 among Hispanics/Latinos and African-Americans needs to be understood.

The engagement activities will seek to enhance bidirectional linkages with CBOs and provide participants with the opportunity to contribute to the design, implementation, and dissemination of our research results. Creating and maintaining a CAB to collaborate with the FIU investigators will be the most pressing activity. The proposed plan will devote much of its efforts to building and enhancing partnerships with affected minority communities and the CBOs representing them, through fostering equitable, transparent, inclusive, and meaningful community collaborations. Through empowerment, inclusion, and trust, as well as including key

CBO leaders on the CAB, it is anticipated that these CBOs will build the capacity to successfully and sustainably reduce the COVID-19 epidemic devastating our community.

The community engagement will be conducted by NHELP which has developed a unique engagement approach to promote sustainable relationships with stakeholders and members of the vulnerable and disadvantaged population. The outreach workers were hired from the underserved minority communities they serve and speak the language (English, Spanish, Creole). They have knowledge of, and shared living experiences with the target communities and can relate and communicate with members of these communities in a culturally sensitive manner. They also have knowledge of the local resources that can be leveraged to address the social needs of the community.

The NHELP outreach team will identify, establish, and maintain partnerships with community stakeholders including adult daycare centers, faith-based organizations, government agencies, social service providers, and other CBOs with which the team has ongoing collaboration. The community partners will refer underserved individuals to the program and outreach workers will enroll individuals into the testing initiative; the members of the community will also be referred to other specific programs to address their social needs as needed. The outreach team maintains monthly contact to continue nurturing the established relationships and keep the communication lines open to ensure continuous access to these individuals for repeated testing and referrals.

In summary, the engagement activities proposed will extend and strengthen the partnerships between FIU investigators and the underrepresented minority communities in Miami-Dade, bringing together investigators and community stakeholders to solve some of the most pressing problems of this county. In addition, through engaging communities and their CBOs, we aim to improve the health and well-being of South Florida residents at-risk of COVID-19 and its sequelae by facilitating massive testing and preparing the grounds for rapid deployment of future vaccines.

NHELP will conduct community engagement activities with multiple community organizations to organize and conduct a series of COVID-19 education sessions either remotely with Zoom or socially distanced and face-masked meetings about the benefits of testing. The CAB and community leaders will be 1) informed about the study, its purpose, and the potential benefits of participation to the community; 2) sharing ideas and soliciting theirs on the best ways to mobilize members of the community to increase COVID-19 testing and vaccination uptake within their communities; 3) discuss community partners' perspectives on barriers to testing, and for future vaccination against COVID-19; 4) ask community partners and other stakeholders to refer community members to the study.

During the meetings with the stakeholders we will examine factors at multiple levels, including policies, community-level factors, interpersonal/family and individual variables that maximize the impact on population morbidity and mortality. Topics will include strategies to increase effective communication with community to reduce misinformation, promote testing uptake, increase referral to services, and improve follow up. Thus, the community relationships and cultural knowledge will drive testing implementation strategies. NHELP has already earned the trust and respect of the community. Employing culturally appropriate engagement and tapping community-held knowledge about best practices to reduce testing barriers to scale-up testing and use future vaccines in the underserved communities ensures long-term sustainability.

## **PHASE 2**

### ***a. PARTICIPANT SELECTION PROCEDURES***

To understand the barriers to COVID-19 testing, a random sample of 100 adults from the population that NHELP regularly serves will be surveyed with questionnaires developed with information derived from key informants from the CAB about barriers for COVID-19 testing and uptake of future vaccines. The NHELP outreach staff will recruit individuals from their networks and provide them with a flyer that will include our contact information.

### **Eligibility Criteria**

#### **Inclusion Criteria:**

1. Adult, age 18 or older
2. Able to provide informed consent
3. Willing to provide questionnaires via telephone

Exclusion Criteria:

1. Child, age 17 or younger
2. Unable and/or unwilling to provide informed consent
3. Unable and/or unwilling to provide questionnaires via telephone

***b. STUDY ASSESSMENT AND ACTIVITIES***

**Consent Process**

A verbal informed consent will be used for this study. Two team members will contact the participant to provide telephone verbal consent. The first team member will review the consent and the second team members will confirm that the consent was provided and act as a witness for the process. Both team members will document their efforts on RedCap. Each consenting participant will have a screening appointment, and eligible participants will be recruited into the study by a personal interview with the Outreach Specialist through telephone. The risks and benefits of the study will be explained and at the end of the interview and explain that participation is voluntary and may be discontinued at any time. Capacity to provide informed consent will be determine if the individual is able to demonstrate understanding of the benefits and risks of, and the alternatives to participating in the study, demonstrate appreciation of those benefits, risks, and alternatives explained, show reasoning in making a decision, and communicate their choice. If it is deemed that the participant cannot demonstrate capacity to provide informed consent, the individual will not be enrolled into the study or a legal guardian will provide consent for participation. Consenting team members will provide a detailed explanation of the research study using the consent form as a guide, by explaining the purpose, procedures, risks, compensation, reimbursement, benefits, alternatives, confidentiality, and other pertinent facts regarding the study. They will allow the participant to have time to ask questions. Both team members will document their efforts on RedCap.

**Questionnaires**

After informed consent has been obtained and documented the outreach staff will proceed to interview the participant to collect data from the planned questionnaires. Questionnaires will be provided to 100 individuals from the community. These questionnaires will include demographics, health literacy, drug use, stigma and financial burden associated with testing, follow-up care, feasibility of effective self-isolation if positive, and perceived effectiveness of testing and vaccination. Guided by the Conceptual Framework Based on Population Health that includes (1) individual factors (self-efficacy, perceived barriers and facilitators for testing, attitudes and beliefs about the risk of acquiring COVID-19, its severity, the importance of testing and future vaccination, and the willingness to engage in social distancing, masking and hand hygiene), (2) contextual factors (socioeconomic, occupational history, past exposures, access to health services and testing), (3) principal covariates, such as demographic variables (age, gender, race), self-perceived health status and co-morbid conditions, and (4) measurable outcomes of uptake of testing in the community, acceptability of alternative sampling methods, and sensitivity/specificity of different testing protocols (Figure 1), questionnaires will be developed or adapted as needed to address the barriers and facilitators for COVID-19 testing. New strategies to increase uptake of COVID-19 testing and future vaccines will be developed based on the community stakeholders' recommendations and the results of the survey of the community members. The investigators of this proposal with the Scientific and Community Advisory Boards, key community stakeholders, and NHELP



will meet regularly to develop these strategies and evaluate their effectiveness every three months. Consultation with the RADx-UP CDCC and SEBI will be sought in finalizing the questionnaires for this phase of the planned research study.

## **Data Collection and Data Management**

Questionnaires will be administered by telephone in the preferred language (English, Spanish, Creole) of the participant and the answers will be recorded via RedCap software. It is estimated that the interview will take about 45 minutes. The participants will receive a \$30 incentive for their participation and safety measures are already in-place at our research clinic to provide these incentives in-person.

For data management we use the REDCap software system, and SAS for data analyses. The database tracks and links baseline and follow-up data by respondent for longitudinal studies. The database undergoes regular quality control, comprised of rules and staff training for completion of data forms, including skipped questions, missing data and refusals, 100% double-entry, validation rules and error checks. Statistical summaries are generated for enrollment. Secure data transfer system via a secure web-based data upload system has been developed with permission-based logins by authorized staff, and logs for the dates of uploads are maintained. All data files are protected by passwords. Backups of all files and programs occur daily.

These activities will inform the activities of Phase 3, which includes deployment of a mobile COVID-19 testing unit to geographical areas occupied by underserved and vulnerable populations. Additionally, these activities will also inform Phase 4 activities that will include a comparison of the acceptability, sensitivity, and specificity of alternative approaches to obtain samples, including medically administered nasopharyngeal swabs, saliva, and self-swabbing options sampled simultaneously.

## **VI. ANALYSES PLAN**

### **PHASE 1**

Not Applicable

### **PHASE 2**

Analysis of collected surveys will consist of descriptive statistics such as means with standard errors and proportions with standard errors, in order to estimate 95% confidence intervals. Comparison by the result of the COVID test will consist of two-sample t-test and chi-square test for continuous and categorical variables respectively. Any exploratory modeling will involve either linear or logistic regression depending on the outcome of interest, with limited covariates due to relatively low total number.

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