UCSD Human Research Protections Program
New Biomedical Application
RESEARCH PLAN

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1. PROJECT TITLE

COVID-19 Testing in Underserved and Vulnerable Populations Receiving Care in San Diego Community Health Centers

2. PRINCIPAL INVESTIGATOR

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3. FACILITIES

Moores Cancer Center is the primary site. The study includes a subcontract to Health Quality Partners (HQP) of Southern California and participation of 3 San Diego community health centers (CHC) for testing and data collection.

4. ESTIMATED DURATION OF THE STUDY

Three years from the time of initial funding (11/2020).

5. LAY LANGUAGE SUMMARY OR SYNOPSIS (no more than one paragraph)

As of November 1, 2021, the 2019 novel coronavirus disease (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has caused ~5 million deaths worldwide,[1] including ~745,000 in the United States (U.S.). Pronounced inequities and disparities in COVID-19 related illness and death have been reported among Black and Hispanic individuals in the U.S. Furthermore, testing challenges to date are evident, particularly among underserved populations. The goal of this community-engaged proposal is to develop, test, and evaluate a rapid, scalable capacity building project to enhance COVID-19 testing among underserved and COVID-19 vulnerable individuals in regional CHCs in San Diego County. In collaboration with our CHC partners, we will assess feasibility and acceptability of rapid at-home COVID19 testing and reporting of test results among men and women 21 years of age and older. Participants will be provided with the opportunity to offer testing to their household members regardless of symptoms. We will assess testing acceptance and ask participants to report test results. Participants will be invited by clinic staff during a clinic visit or at community events sponsored by the CHC. We will also assess feasibility and acceptability of testing in study participants' household members. We will further gather patient, provider, CHC leadership, and community stakeholder insights to establish best practices for future scale-up of COVID-19 testing sustainability and vaccination.

6. SPECIFIC AIMS

Aim 1. Assess acceptability and feasibility of rapid at-home COVID19 testing and reporting of test results among individuals seeking care at participating CHCs. We will also assess feasibility and acceptability of study participants offering testing to household members regardless of symptoms.

Feasibility will be assessed by the proportion of participants who agree to undergo testing and to report test results. *Acceptability* will be assessed by participants undergoing testing and providing test results.

Feasibility of testing of household members will be assessed by participants' willingness to offer and support testing of eligible household member(s). *Acceptability* will be assessed by the proportion of household members who undergo testing and reporting results.

Aim 2. Gather patient, provider, CHC leadership, and community stakeholder insights to establish best practices for future scale-up of COVID-19 testing sustainability and vaccination.

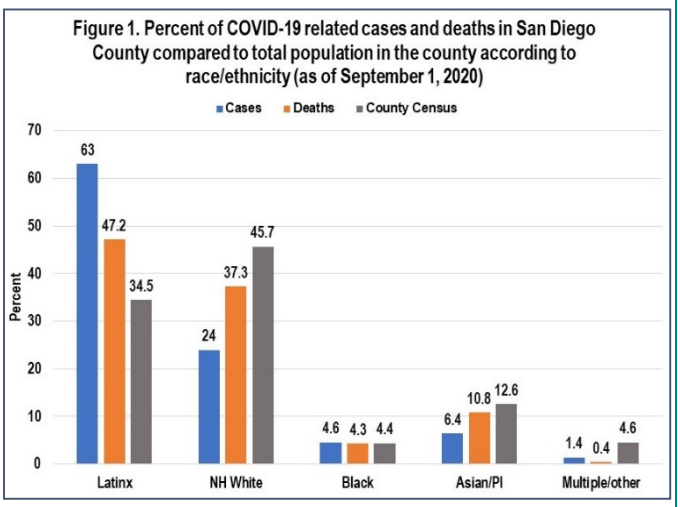
We will use an implementation science mixed-methods approach to evaluate COVID-19 testing strategies, materials and outcomes. We will gather information on implementation and sustainability facilitators and barriers from patients, providers, CHC leaders, and key community stakeholders. CHCs use a patient center medical home (PCMH) approach that helps ensure quality, accessible, whole-person care and active patient involvement that contributes to optimal health outcomes and sustained care. We hypothesize that when coupled with high-risk patient descriptors, PCMH characteristics and other contextual factors, will contribute to understanding the

acceptability of COVID-19 testing and future vaccination.

7. BACKGROUND AND SIGNIFICANCE

COVID-19 Profile and Disparities

As of November 1, 2021, the 2019 novel coronavirus disease (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has claimed nearly 5 million lives worldwide,[1] including ~745,000 in the United States (U.S.). Pronounced inequities and disparities in COVID-19 morbidity and mortality have been reported among Black and Latinx individuals in the U.S,[2,3] largely due to comorbid conditions, social determinants of health,[4,5] and structural racism.[6] As of November 1, 2021, California has reported ~4.9 million confirmed cases of COVID-19 and 72,1420 deaths.[7] San Diego County, the most populous U.S.-Mexico border county in the country, reported 370,488 cases and 4,218 deaths as of October 29, 2021.[8] Latinx communities have experienced the greatest burden of COVID-19 disease in San Diego County. As shown in **Figure 1**, Latinx individuals represent 63% of cases and 47% of deaths (60% of hospitalizations) related to COVID-19, yet this ethnic group makes up 34.5% of the county population. The figure reflects data from September 1, 2020. Although the number of cases and deaths has increased, the differences by racial/ethnic group remain largely unchanged: Hispanics in San Diego County continue to bear the largest burden of the infection and deaths. <u>These data underscore the need for continued targeted efforts in Latinx individuals, a priority population in our testing research project.</u>



According to the Kaiser Family Foundation, [9] although 66% of the total population in the U.S. have received at least one dose of a COVID-19 vaccine, coverage remains uneven across the country. As of October 25, 2021, White people accounted for the largest share (60%) of people who are unvaccinated, while Black and Hispanic people remain less likely to have been vaccinated, leaving them at increased risk, particularly as variants spread.

Testing can Save Lives but Challenges are Evident

COVID-19 testing, including asymptomatic individuals, is essential to contain the spread of infection.[8] Effectively implementing recommended public regimens could help limit disease spread and reduce reliance on costly measures, such as stay at home orders and shutting down businesses. This strategy must include rapid return of test results given that the peak asymptomatic contagious period may only be one week. However, national survey data show that: [11] 1) Most people (63%) are not getting results within the optimal 1-2 days (median wait time in California is 4 days); 2) 21% of individuals receive test results too late (5+ days) for controlling disease spread. Most concerning is <u>longer testing return times for Black (5 days) and Latinx (4.6 days) individuals compared to whites (3.9 days)</u>, meaning that containment strategies will be less effective in these groups.

Experts have noted that COVID-19 testing will continue to be important, even as more people get vaccinated. This is due in part to the fact that SARS-CoV-2, the virus that causes COVID-19, continues to mutate. Furthermore, as we approach flu season, testing will be needed for symptomatic individuals given the similarity in the symptoms. At-home tests offer advantages due to their access and convenience. In light of the fact that a high proportion of the population is fully vaccinated, testing recommendations from the Centers for Disease Control and Prevention include getting tested if individuals have symptoms of COVID-19 or have a close contact with someone who has COVID-19.[12] In addition, testing is also recommended for not fully vaccinated individuals who must travel.[13] Questions remain, however, as to the acceptability of this testing

modality, including: 1) Who are likely to undergo testing? 2) What are the reasons for testing? 3) Are tested individuals willing to report results to their provider or county agency? 4) Will test positive individuals quarantine? In addition, in large households, who are at higher risk of infection, [14] it is important to assess the acceptability of testing multiple household members.

8. PROGRESS REPORT

Not applicable

9. RESEARCH DESIGN AND METHODS

Community Partner Program and Study Setting

The proposed testing project will leverage existing community health center (CHC)-academic partnerships under the NCI-funded Accelerating Colorectal Cancer Screening and Follow-up through Implementation Science (ACCSIS) Cancer Moonshot grant (UG3CA233314), whose goal is to improve colorectal cancer (CRC) screening among medically underserved populations. This partnership include UCSD and Health Center Partners (HCP) and its subsidiary, Health Quality Partners (HQP). HCP/HQP is a non-profit consortium of 16 CHCs that provide primary care to meet the health needs of communities in Southern California. HCP members collectively operate over 160 clinic sites that include urban, rural, agricultural worker, and US-Mexico border populations, and serve over **858,000 vulnerable patients with 3.6 million patient visits** each year. CHCs have been at the front lines of health care in the nation's poorest neighborhoods for decades. High risk asymptomatic patients served by these centers are not getting proper testing, include essential workers, and could contribute to further spread of the virus. For these reasons, HCP/HQP, our community partner, approached the academic partner with interest in submitting this application.

Participating CHCs. CHC participation involved a process of several presentations that outlined the concept and deliverables and elicited feedback from the medical directors, providers, and staff. Following these, three CHCs indicated interest and capacity to participate: Neighborhood Healthcare (Neighborhood) and Vista Community Clinic (Vista) and La Maestra Community Health Centers. As of June 17, 2021, La Maestra Health has separated from the study. For the amended study, only Neighborhood Healthcare (Neighborhood) and Vista Community Clinic (Vista) will participate.

Study Methodology

AIM 1*: Assess feasibility and acceptability of rapid at-home testing and reporting of test results among individuals seeking care at participating CHCs. We will also assess feasibility and acceptability of study participants offering testing to household members regardless of symptoms.*

We will include symptomatic and asymptomatic individuals, age 21 years and over, who come to the participating CHC clinic site or clinic mobile unit. Our two participating CHCs will also reach out to non-CHC patients who come to their community vaccine clinics. Clinic staff will approach eligible participants to inform them of the study and invite them to participate and ask participants to consider offering the home test to members of their household who are older than 2 years of age

COVID-19 Testing

Individuals who attend a clinic visit will be provided with information on the study and invited to participate. Individuals who agree to participate will receive kits for two COVID tests. They will also receive two test kits for each eligible household member. We will use an over-the-counter (OTC) commercially available rapid antigen testing kit. The specific kit will depend on commercial availability. Individuals who undergo testing will be able to do so in the privacy of their own home, following specific kit instructions. Results will be available 10-15 minutes after collecting a sample. Possible kits provided to the participants include Quidel QuickVue At-Home OTC test, Binax NOW, Flowflex and others. These OTC home tests are FDA authorized for nonprescription home use with self-collected (unobserved) direct anterior nasal swab specimens.

Participants will be provided with an educational handout indicating potential situations when they and eligible family members may consider testing, including: 1) COVID-19 symptoms; 2) travel; 3) family gatherings; 4) contact with infected individual; 5) contact with someone at high risk (such as older individual and immune compromised individual). Participants will be encouraged to test more than once as these scenarios arise, or anytime they are worried about COVID infection. Directions from the test kit manufacturer will be reviewed with participants at enrollment.

We will also assess feasibility and acceptability of COVID-19 testing of study participants' household members who are older than 2 years of age (OTC tests are not approved for younger children). The enrolled participants will share the test kits, and testing information described above with household members, including how to test, when to test, and report testing results for household member through completing an online anonymous survey or calling designated study line at UCSD (described in Data Collection, Harmonization and Reporting Section below).

Data Collection, Harmonization and Reporting.
There are two surveys for participants: the first is an enrollment survey completed by participants at the participating health center or mobile unit at the time of enrollment; the second is a post-COVID test survey completed after each test using a QR code or written link to an anonymous survey using the participant code given by the health center at the time of consent. The post-COVID test survey can be accessed each time when there is a COVID test result to report.

From the enrollment survey we will collect the following data: Age, sex, race and ethnicity, access to health services, income, employment status, education, English proficiency, food insecurity, gender identity, health insurance, COVID-19 illness history, COVID-19 vaccination status, experience and barriers of past COVID-19 testing and knowledge and attitude to COVID-19 testing and vaccination. We will also include household size, foreign-born status, and job type, given that these factors contribute to higher infection rates in Latinx communities,[6] as well as trust in healthcare and discrimination, which are important for our Latinx population.

From the post-COVID test survey we will collect data specific to the OTC at-home testing, including:

1. Members of household that undergo testing, including age, sex, race/ethnicity and COVID-19 and flu vaccination status.
2. If multiple household members tested at the same time.
3. Date of testing of each individual.
4. Reason for testing: a) travel; b) family gatherings; c) contact with infected individual; d) symptoms; e) other.
5. Self-reported testing results.
6. Actions taken by the patient and household members undergoing testing if tested positive, including: a) undergoing isolation; b) calling the clinic; c) reporting to the county; d) missing work or school.

Primary Study Endpoints.
Feasibility will be assessed by the proportion of participants who agree to undergo testing and to report test results. *Acceptability* will be assessed by the proportion of participants who undergo testing and provide test results.
Feasibility of testing for household members will be assessed by the participant's willingness to offer and support testing of eligible household member(s). *Acceptability* will be assessed by the proportion of household members who undergo testing and report results.

Sample Size and Study Power.
The study is not designed to test any specific hypothesis, but rather to provide assessment of feasibility and

acceptability of at-home testing kits, which could guide efforts to optimize testing methods of valuable in addressing future pandemics. The primary goal of this study is to deliver as many tests as possible to help limit the spread of COVID-19 in underserved communities. Therefore, the number of study participants was driven by budget and number of eligible participants who are willing to participate. Our goal based on funds available for testing is to enroll 5,000 participants. Assuming an average of 1 members per participant's household undergoing testing, our predicted total number of tests delivered is 10,000.

Statistical Analysis.
In our primary analysis, we will calculate the proportion of individuals who agree to undergo COVID testing and to report test results among all individuals to whom clinic staffs reach out. We will also calculate the proportion of participants who complete at least one test and provide test results. Similarly, we will also calculate the proportion of participants who offer and support testing to eligible household member(s) among all participants and the proportion of household members who complete at least one test and report results. We will describe the demographic and clinic characteristics among those who agree to undergo testing and to report test results and those who complete at least one COVID test and report results. If possible, we will include vaccination status in the analysis.

AIM 2: *Gather patient, provider, CHC leadership, and community stakeholder insights to establish best practices for future scale-up of COVID-19 testing sustainability and vaccination.*
We will use a mixed-methods approach to evaluate our COVID-19 testing strategies, materials and outcomes (acceptability, feasibility, appropriateness, sustainability). We will gather information on implementation and sustainability facilitators and barriers from individuals receiving/declining testing Using structured interviews and a coded directed content analysis approach to analyze transcripts, we will collect comparable information for feasibility, acceptability, appropriateness, and sustainability for select providers (1 per clinic), chief medical officers in 2 participating CHCs, and 3 key community stakeholders. Dr. Nodora has experience with relevant implementation science frameworks and qualitative analysis methods and is conducting comparable assessments for both ACCSIS and a similar CRC screening study in the three participating CHCs. Measures include survey items guided by the Practical, Robust Implementation and Sustainability Model (PRISM) and (Reach Effectiveness, Adoption, Implementation and Maintenance) RE-AIM framework [15, 16] and include the Feasibility of Intervention Measure (FIM), Acceptability of Intervention Measure (AIM), and Intervention Appropriateness Measure (IAM).[17]

10. HUMAN SUBJECTS

Participating CHCs

Table 1 shows patient and CHC characteristics of active patients (those with at least one clinic visit in the prior year). There is substantial racial/ethnic representation, including a large Latinx (~55%) and non-English speaking population (~50%).

Table 1. Patient and Community Health Center Characteristics

Characteristic	Neighborhood	Vista
No. of clinics	9	11
Adult active patients*	32,506	39,720
Age 21 - 64 years	28,105	36,300
Age ≥ 65 years	4,401 (14%)	3,420 (9%)
Latinx	15,260 (47%)	20,380 (51%)
Non-Latinx White	10,750 (33%)	16,503 (42%)
Black/African American	751 (2%)	1,205 (3%)
Asian or Pacific Islander	1,230 (4%)	1,636 (4%)
Non-English speaker	14,189 (44%)	14,219 (36%)
Uninsured	5,200 (16%)	12,710 (32%)
Medicaid	24,379 (75%)	22,640 (57%)
Medical Conditions**		
Obese (BMI ≥ 30 kg/m²)	8,589 (26%)	13,932 (35%)
COPD	955 (3%)	1986 (5%)
Chronic kidney disease	76 (<1%)	543 (1%)
Serious heart conditions***	2925 (9%)	516 (1%)
Type 2 diabetes	8,488 (26%)	4,814 (12%)
Cancer	162 (<1%)	169 (<1%)
Immunocompromised****	57 (<1%)	37 (<1%)
Sickle cell disease	423 (1%)	1 (<1%)
>1 medical condition	3,901 (12%)	520 (13%)

*Patients with at least one clinic visit in the prior year from 3/1/2019 to 02/29/2020; **Not mutually exclusive; ***heart failure, coronary artery disease, or cardiomyopathies; ****Due to solid organ transplant.

Inclusion Criteria

Eligible participants will include symptomatic and asymptomatic men and women 21 years of age and older, who attend a clinic visit at participating CHCs or mobile unit sponsored by the CHC. *Household members* will include individuals greater than 2 years of age who reside in the home address of the participant (based on minimal age of home testing kits). They do not have to be a patient of the participating CHC.

Exclusion Criteria

Under age 21 for participants and younger than 2 years for the household member; inability to complete anterior nasal swab sampling for COVID-19 testing.

Study participants

The primary goal of this study is to deliver as many tests as possible to help limit the spread of COVID-19 in underserved communities. Based on our budget and number of eligible participants who are willing to participate, we estimate to recruit 5000 participants and 5000 household members (with one member per participant's household) who will undergo testing.

11. RECRUITMENT AND PROCEDURES PREPARATORY TO RESEARCH

1. Recruitment

Community Health Centers (CHC) participation in this application involved a process of several presentations that outlined the concept and deliverables and elicited feedback from the CMOs, providers, and staff. Following these, three CHCs indicated interest and capacity to participate: Neighborhood Healthcare (Neighborhood), Vista Community Clinic (Vista), and La Maestra Community Health Center (La Maestra). La Maestra subsequently opted not to be part of the study and was dropped on June 17, 2021.

We will include symptomatic and asymptomatic participants, age 21 years and over. CHC staff will approach eligible participants attending a clinic visit or mobile unit sponsored by the CHC to describe the study and invite them to participate. If they agree to participate, they will provide informed consent and be provided with a number of OTC tests equal to 2 tests per household member, in addition to their own.

3. Single IRB plan

We will comply with the NIH policy on the use of a single Institutional Review Board by using the UC San Diego (UCSD) Human Research Protections Program (HRPP) as the single Institutional Review Board to conduct the ethical review required by HHS regulations for the Protections of Human Subject Research. The subcontract institution at Health Quality Partners agrees to rely on the ethical review of UCSD, and prior to initiating the study will sign authorization/reliance agreements. UC San Diego will maintain the authorization/reliance agreements and will regularly communicate with the other sites in term of IRB updates, renewals, and any other IRB issues should they arise.

12. INFORMED CONSENT

There will be three separate consent procedures for the study.

1. **A waiver of informed consent for recruitment and at-home testing**

We will request a waiver of informed consent for recruitment and at-home testing. Our rationale for waiver of informed consent request is as follows

The study is minimal risk**,** for several reasons:

- Study participants will be contacted and offered an over-the-counter (OTC) commercially available at-home rapid antigen testing kit.
- The research purpose of the study is to assess feasibility and acceptability of rapid at-home COVID-19 testing and reporting of test results among underserved and vulnerable populations. The at-home COVID-19 testing per se as standard of care is not part of research questions in this study.
- The at-home COVID-19 tests are FDA authorized for nonprescription home use with self-collected (unobserved) direct anterior nasal swab specimens. It is safe and not invasive. Individuals who undergo testing will be able to do so in the privacy of their own home.

The waiver will not adversely affect the rights and welfare of the subjects**,** for several reasons:

- Subjects will maintain their autonomy. Specifically, they will be invited to participate, they may choose or not choose to complete the test.
- The study will not interfere with any usual medical care, regardless of their participation of the study.
- Waiver of consent for study participation is not expected to decrease rates of participating and testing completion.
- COVID-19 testing is standard of care. Completion of COVID-19 testing is considered a sign of positive health welfare. Indeed, requiring consent could actually have a negative impact on welfare. In this underserved and vulnerable community that has already experienced disproportionate health and economic impacts from COVID-19 pandemic, requiring a consent might place a burden on patients and reduce the chances of access to and uptake of COVID-19 testing.

It is impractical to do the study without the waiver**,** for the following reasons:

- Requiring consent will change the focus of the study. If informed consent is required, the study population will be biased, and likely include participants who are more motivated to complete the test.
- Requiring consent will require contacting almost 5,000 participants before they receive any testing. This would cost more money than is allowed for in the study budget and would result in a smaller number of tests we could offer and compromise testing capacity as our primary goal is to deliver as many tests as possible to help limit the spread of Coronavirus diseases in this underserved communities.

Overall, the waiver is being requested for the testing because waiving the informed consent is not only the most scientifically valid approach for the study, but also the most ethical because it will:

- Maximize participation in COVID-19 testing. As explained above, requiring consent might actually reduce the number of patients who participate in testing. In this way, a waiver might actually be more beneficial than it is risky.
- Provide scientific advantage of observing as close to real-world impact of the planned strategies on an unbiased sample of patients.
- Practically allow the study to be conducted.

2. **Informed consent for data collection for index participants via medical record (EHR query), enrollment survey and post-COVID test survey**

We will obtain written informed consent for data collection including the participant enrollment survey and

post-COVID test survey. The consent will also request permission for trained CHC staff to abstract several data variables (e.g., demographics, COVID-relevant health conditions) from the participant's electronic health record. The enrollment survey will be administrated at the time of distribution of tests in CHC clinics either in offices or mobile/community. The survey can be self-administered or via interview by experienced and trained research staff. The post-COVID test survey will be self-administered. Participants will be provided a QR code or written link to access and complete the post-COVID test survey each time after they conduct a test. Participants can also call UCSD study coordinator to complete the post-COVID test survey

3. A waiver of informed consent for minimal data collection from participants' household members

- The study is minimal risk as stated above.
- Only minimal, de-identifiable data will be collected from a household member, specifically including age, sex, race/ethnicity, at-home testing results and reason for testing.
- Requiring a consent might place a burden on a household member and reduce the chances of uptake of COVID-19 testing. Indeed, requiring consent could actually have a negative impact on welfare of household members as completion of COVID-19 testing is considered a sign of positive health welfare.
- It would be impossible to conduct the study if we have to obtain informed consent from the other household members for the minimal data collection.

13. ALTERNATIVES TO STUDY PARTICIPATION

The alternatives to participation in this study are: To not participate in the study.

14. POTENTIAL RISKS

There is minimal risk to human subjects. Study participants are not randomized to any therapeutic intervention, We will use our team's extensive knowledge and experience with existing protocols from our ongoing ACCSIS colorectal screening mailed stool testing intervention as models for the COVID-19 testing project, which have been culturally adapted and tailored for CHC patients. Data collected as part of this research will be obtained through review of medical records/EHRs collected as part of usual medical care as well as interviews with patients, survey of participants, and surveys with health care providers and other CHC system personnel. The proposed research will leverage existing community-academic partnerships under the NCI-funded Accelerating Colorectal Cancer Screening and Follow-up through Implementation Science (ACCSIS) in Cancer, in which we have data infrastructure in place to efficiently set up our Data Reporting Unit. Data acquisition, collection, curation, and dissemination will be conducted in accordance with guidance from the Coordination and Data Collection Center (CDCC). Formal agreements will also be in place for data sharing.

15. RISK MANAGEMENT PROCEDURES AND ADEQUACY OF RESOURCES

Risks related to the study include the following:

i. Loss of confidentiality or privacy due to disclosure of research data, including protected health information: Loss of confidentiality or privacy could lead to physical, psychological, social, legal, or financial harms due to the personal nature of the data used. The seriousness of loss of privacy or confidentiality would be substantial. However, the likelihood of loss of confidentiality or privacy, and subsequent harms, is low due to the study procedures we have planned to protect research data. For example, only study-related personnel will have access to protected health data, only non-identifiable coded data will be transferred from the CHC systems to academic collaborators, and all study related data will be saved electronically on a password protected server with access to the study related folder only granted to study personnel, or in locked filing cabinets in a locked office with limited access. Furthermore, the study will be protected by a Certificate of Confidentiality.

ii. Anterior nasal swab sampling may cause some discomfort. However, it is considered safe and not very invasive. Since the participants are self-swabbing, they will be able to control and make decisions about

the swabbing.

iii. The interview instruments and questions contain information regarding social determinants of health, health behavior and other topics possibly related to COVID-19 testing and infection. This has the potential for embarrassment for the patient as a result of discussing the topic with the study staff. There is also the potential for inconvenience on the part of the participants as a result of participation in study interviews.

vii. COVID-19 testing result of being positive may potentially cause anxiety and feeling ashamed in some patients due to social stigma of being infected. It could also bring difficulties and challenges to the life of those underserved participants as infected individual may have to take time off work, conduct self-quarantine and share testing results with family and contacts.

Protection against risk

Protection of privacy and data security

A key issue to consider that pertains to COVID-19 testing is the protection of participant confidentiality and privacy. We will work with our Advisory Board members, our community collaborators, stakeholders to ensure that the implementation of the study will be conducted in an ethical and socially responsible way and will not add extra distress on this underserved and/or vulnerable populations that have already experienced health disparities including COVID-19 burden. We will use our team's extensive knowledge and experience with existing protocols from other research that our team is involved in at the CHCs. Our experienced and trained research and clinical personnel are available to ensure that participants' worry or anxiety related to COVID-19 testing will be addressed and minimized.

We will further accomplish the following steps to protect patients' confidentiality and privacy and data security.

- Limiting access to research data to study related personnel
- Using de-identified passcodes for all electronic surveys.
- Storing all electronic data on a password protected research drive within a secure research server
- Storing all paper records in a locked filing cabinet within a locked office
- Only sharing coded data for analysis purposes with UCSD, CHCs and HQP
- IRB required training for research personnel will be kept current for all study personnel
- Names will not be recorded or kept in analytic datasets
- Only de-identified and aggregated data will be used for study presentations and publications

If the study team becomes aware of any unanticipated adverse events, the IRB will be informed promptly, and a plan to address the adverse event will be proposed. Responsibility for supervising implementation of the plan lies with the PIs.

We have adequate resources to support our risk management procedures, including study team members and co-investigators. **Dr. Hill** is a licensed physician and will provide medical oversight to the study. The study will follow the standard internal referral mechanisms set forth in the CHC systems, which provide a comprehensive spectrum of primary care services.

In the event of concern for loss of confidentiality and/or disclosure of research related data to unauthorized personnel, the PIs and research team will review the event immediately, and within 1 business day inform the UCSD and CHC system Human Subjects (IRB) Subcommittees

In the event of any adverse event, we will report it to the UCSD and CHC system Human Subjects, IRB Committees to plan corrective action, and also initiate actions to prevent further research related risks.

16. PRIVACY AND CONFIDENTIALITY CONSIDERATIONS INCLUDING DATA ACCESS AND MANAGEMENT

16.1. Adequacy of Protection against Risks

Recruitment and informed consent

We will seek a waiver of informed consent for recruitment and at-home testing. Our rationale for waiver of informed consent request is as follows

The study is minimal risk**,** for several reasons:

1. Study participants are not randomized to any therapeutic intervention.

2. Home testing is widely available in the community.

3. Anterior nasal swab sampling for home testing is a standard diagnostic testing for COVID-19. It is safe and not very invasive. Participants may only feel some discomfort.

4. Testing community members is part of a recommended public regimen to limit the spread of COVID-19.

The waiver will not adversely affect the rights and welfare of the subjects**,** for several reasons:

1. Subjects will maintain their autonomy.

2. Even if given home kits for testing, they may choose or not choose to complete the testing.

3. The study will not interfere with any usual medical care, either in patients invited or not invited for testing.

4. Waiver of consent for study participation is not expected to decrease rates of participating and testing completion.

5. Completion of COVID-19 testing is considered a sign of positive health welfare. Indeed, requiring consent could actually have a negative impact on welfare. In this high-risk patient population, requiring a consent might place a burden on patients and reduce the chances of access to and uptake of COVID-19 testing.

Data collection and informed consent

We will obtain written informed consent for data collection before the participant enrollment survey is administered. We will abstract several data variables from the EHR.

16.2. Data Safety Monitoring Plan

A Data Safety and Monitoring Board (DSMB) is not be needed for this study. A DSMB is typically required for "studies where the effect of health-related intervention on outcomes in human subjects is greater than minimal risk". The study participants are not randomized to any intervention, but will participate by undergoing COVID-19 home testing and filling out surveys. Anterior nasal swab home testing is a standard diagnostic testing for COVID-19. It is safe and not very invasive.

Consortium Data Reporting Unit

Data acquisition, collection, curation, sharing, and dissemination will be conducted in accordance to guidance from the Coordination and Data Collection Center (CDCC) as we do for our ACCSIS project, which involves the same academic and community partners in RADx UP. We have infrastructure in place to quickly set up our Data Reporting Unit and efficiently and rapidly report data to the CDCC using similar protocols as for ACCSIS, where we have formal data sharing agreements that include the CHC organizations. HQP will work with CHCs to develop data queries to identify and monitor study participants. Participant's level data will be extracted from the CHC EHR into Excel and transferred on a weekly basis from the health centers to UCSD using a Secure File Transfer Protocol. Once CHC data are received, they will be validated and imported into the database. The database will be used to store and track participant data and produce data monitoring and other reports. Common Data Elements selected to collaborate with other RADx-UP sites will be included in the database as well as data needed to implement the study activities (delivery and tracking of testing kits, study IDs, test completions, reminders, post-COVID testing survey completions, etc.). We will designate Dr. Jian Shen as project data steward to work with CHC and HQP to ensure timely and proper operation for reporting to the CDCC.

Monitoring Accuracy and Integrity of the Data

Data management will be an on-going activity designed to ensure the highest quality data possible. Activities include data-coding, computer data entry, data quality control and tracking, data confidentiality and development of data files for statistical analysis. Prior to data entry, forms will be examined for completeness and accuracy. A tracking system will be developed to ensure all forms have been administered to participants. Completed forms will be entered into the database using a double data entry verification system. All identified errors will be resolved using the original hard data. All corrected fields will be noted for a detailed audit trail. Forms will be kept in locked files at the CHC. Subjects will be assigned study ID numbers to be linked with CHC medical record numbers on data management and data analysis files. No identifiable information will be used in reports. Data entered and stored will be periodically archived on the secure UCSD server. Analyses will be carried out using SAS by the study statistician (Dr. Jian Shen) who will receive a deidentified dataset from CHC.

17. POTENTIAL BENEFITS

Potential Benefits of the Proposed Research to Research Participants and Others

Pronounced inequities and disparities in COVID-19 morbidity and mortality have been reported among Black and Hispanic individuals in the U.S. Importantly, it is estimated that approximately 40 to 45% of reported cases occur among asymptomatic individuals. COVID-19 testing, including asymptomatic individuals, together with rapid turnaround of tests results, is essential to containing the spread of the infection. However, national survey data show that most (63%) people are not getting results within the 1-2 days, which is optimal to aid contact tracing (median wait time in California is 4 days) and 21% of individuals receive test results too late (5+ days) to be of any significant assistance in helping to control the spread of COVID-19; 3). Even more concerning is that waiting times are longer for African Americans (5 days) and Hispanic Americans (4.6 days) compared to white respondents (3.9 days). Our proposed community-engaged project is to develop, test, and evaluate a rapid, scalable capacity-building project to enhance SARS COVID-19 testing and follow up and to ensure that COVID-19 vulnerable and underserved health disparity populations have optimal access to and uptake of the latest testing technology.

This study will help to better understand the barriers to home testing, and the actions that are taken as a result of obtaining home testing results. Home testing is one important strategy for COVID-19 prevention and mitigation.

18. RISK/BENEFIT RATIO

The benefits of COVID-19 testing among symptomatic and asymptomatic individuals which is essential to contain spread of the disease far outweighs the risks of loss of confidentiality that might be a risk. In addition to measures stated in section 15 to minimize those risks, we will work with our Advisory Board members, our community collaborators, stakeholders to ensure that the implementation of the study will be conducted in an ethical and socially responsible way and will not add extra distress on this underserved and/or vulnerable populations that have already experienced health disparities including COVID-19 burden. This will ensure a favorable risk/benefit ratio.

19. EXPENSE TO PARTICIPANT

There will be no expense to participate in this study.

20. COMPENSATION FOR PARTICIPATION

The index participant will receive a $20 incentive at the time of enrollment for the enrollment survey they complete, and $5 incentive for each post-COVID testing survey they complete, up to five surveys. Therefore, each index participant can potentially receive $45 in incentives. Household members will receive a $5 incentive only for the post-COVID testing survey they complete, up to five surveys. Therefore each household member can potentially receive $25 in incentives.

21. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES

The study will be protected by a Certificate of Confidentiality. All members of the research team have up to date CITI certification and the professional background to conduct the current study.

The proposed testing project will leverage existing community-academic partnerships under the NCI-funded Accelerating Colorectal Cancer Screening and Follow-up through Implementation Science (ACCSIS) Cancer Moonshot grant (UG3CA233314, **Dr. Martinez**, contact PI), whose goal is to improve colorectal cancer (CRC) screening among populations medically underserved populations. The application organizational structure includes a study team that includes three Principal Investigators (MPIs) and a community partner co-investigator. Aside from the MPIs, the organizational structure also includes a Scientific and Community Advisory Board, which will meet on a quarterly basis.
The team has considerable expertise in: 1) conducting multilevel interventions; 2) cancer disparities research; 3) working in multidisciplinary community-academic teams; and 4) leading large consortia. The duties and responsibilities of the MPIs are noted below.
Administrative and fiscal operations will be overseen and coordinated by **Drs. Jian Shen and Bilge Pakiz**. Dr. Jian Shen will function as the study coordinator and oversee regulatory aspects of the study and conduct data analysis. Dr. Pakiz will oversee fiscal details and work with Dr. Shen on the regulatory aspects.

María Elena Martinez, MPH, PhD, Principal Investigator (PI). Dr. Martinez, Professor of Public Health at UCSD and Lead PI of the parent grant will serve as contact PI of the current project, per the NOSI guidelines. In this role, she will have primary responsibility for all correspondence with NIH. She will also oversee all administrative components of the project, including oversight of the subcontract with HQP/HCP. Drs. Martinez, Nodora, and Hill will share responsibility for the scientific direction, governance, fiscal management, and reporting requirements of the project. Dr. Martinez has extensive experience in accomplishing such tasks by serving on several MPI studies, including large consortia as well as the parent grant. Dr. Martinez will be available to serve on consortium working groups as they develop.

Jesse Nodora, DrPH, Principal Investigator (PI). Dr. Jesse Nodora is Associate Professor of Public Health at UCSD, will be responsible for coordinating the work with the CHCs, while working through the community partner organization, Health Quality Partners/Health Center Partners (HQP/HCP). He will also be responsible for gathering progress reports and for organizing PI and other project meetings. Dr. Nodora has extensive experience working with CHCs in the San Diego region. He is co-investigator in the ACCSIS parent grant, where he is responsible for implementation science assessment. As the new ACTRI Director of Community Engagement, he will facilitate community-engaged research and capacity-building on both academics and community stakeholders. Together with Dr. Hill, he will oversee the Scientific and Community Advisory Board, with the primary responsibility being the community members. He will share scientific leadership of the project with the other MPIs. Dr. Nodora will be the key contact investigator for the Coordination and Data Collection Center (CDCC) by serving on the consortium steering committee and working groups as they develop.

Linda Hill, MD, **Principal Investigator (PI)** Dr. Hill, Professor of Public Health at UCSD, is a practicing clinician and clinical and community-based researcher. She will share responsibility for the scientific leadership of this project with Drs. Nodora and Martinez. With her clinical expertise, including providing care in a CHC in the region (not a part of this testing project), Dr. Hill will guide the clinical aspects of study related testing and follow up. She will be responsible for overseeing COVID19 testing capacity operation at UCSD to ensure timeliness and efficiency. She will coordinate and oversee the Scientific and Community Advisory Board along with Dr. Nodora. Dr. Hill will be available to serve on consortium working groups as they develop.

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23. FUNDING SUPPORT FOR THIS STUDY

This study will be federally funded by National Cancer Institute (NCI). The UCSD ePD number is 201505

24. BIOLOGICAL MATERIALS TRANSFER AGREEMENT

Not Applicable

25. INVESTIGATIONAL DRUG FACT SHEET AND IND/IDE HOLDER

Not Applicable

26. IMPACT ON STAFF

Not Applicable

27. CONFLICT OF INTEREST

Not Applicable

28. SUPPLEMENTAL INSTRUCTIONS FOR CANCER-RELATED STUDIES

Not Applicable

29. OTHER APPROVALS/REGULATED MATERIALS

Community health center (CHC) participation involved a process of several presentations that outlined the concept and deliverables and elicited feedback from the medical directors, providers, and staff. Following these, three CHCs indicated interest and capacity to participate, including Neighborhood Healthcare (Neighborhood) Vista Community Clinic (Vista), and La Maestra CHC (La Maestra), and provided letters of support. As of June 17, 2021, La Maestra Health has separated from the study. For the amended study, only Neighborhood Healthcare (Neighborhood) and Vista Community Clinic (Vista) will participate. The UCSD researchers and the community affiliates will make sure the following will be in place:

- Protecting the confidentiality of data during collection, transmission, and storage, which will be primarily executed by the CITI trained UCSD study coordinator.
- Address data security by confirming the existence of firewalls to protect patient records.
- Ensuring informed consent is obtained and documented from each participant in compliance with federal regulations and local IRB approvals. This will be completed by the CITI trained UCSD coordinator.
- Tracking, reporting and maintaining documentation of all serious adverse events and unanticipated problems and disseminating the information to sites. There is a very low likelihood of SAEs for the current study as it includes no invasive procedures.
- Providing periodic updates to affiliated investigators on participant enrollment, general study progress, and relevant scientific advances.
- Assuring that all relevant IRB correspondence (continuing review and amendments) and study status changes are communicated to all sites. The study coordinator will provide copies to each site.
- Securing compliance at external sites that are not adhering to the current version of the research protocol and/or good clinical research practices & Terminating the involvement, if necessary, of non-compliant investigators and reporting such action to the IRB.
- The study will be implemented primarily by the UCSD PI and the study coordinator at each site, in conjunction with the staff on site, which will provide a primary layer of certainty that the above items will be implemented.

30. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT

Not Applicable