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Document: Study Protocol

Official Study Title: Project 2VIDA! COVID-19 Vaccine Intervention Delivery for Adults in Southern California

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UCSD Human Research Protections Program
New Social and Behavioral Sciences Application
RESEARCH PLAN

1. PROJECT TITLE

2VIDA!: SARS-CoV-**2** **V**accine **I**ntervention **D**elivery for **A**dults in Southern California

2. PRINCIPAL INVESTIGATOR, FACULTY ADVISOR, SUPERVISOR

Britt Skaathun, PhD (Principal Investigator) – Assistant Professor, Department of Medicine.

3. FACILITIES

UCSD, Department of Medicine, Division of Infectious Diseases and Global Public Health– The UCSD investigators and research staff for this project have offices on the main UCSD campus in La Jolla, CA, where project coordination and data analysis will occur. Staff will have no access to identifiable data or contact with research participants at this location. All other research activities will be conducted within the San Ysidro Health (SYH) facilities (see below).

San Ysidro Health (SYH) – San Ysidro Health (SYH) is a Federally Qualified Health Center (FQHC) founded in 1969 in San Ysidro, California. With clinics located less than one mile north of the US-Mexico border, a staff of over 1,300 employees and an annual patient population of over 94,000 individuals, SYH is one of the largest community health centers in San Diego County and is currently one of the largest safety net providers in the county's South Region. All data collection, adaptation, and piloting activities of the proposed project will occur within the context of San Ysidro Health facilities as determined by the needs of the study and recommendations from sexual and reproductive health specialists, the Center for Research and Health Promotion, community partners, including but not limited to, San Ysidro Health specialty sites

4. ESTIMATED DURATION OF THE STUDY

5 years

5. SPECIFIC AIMS (2 paragraphs maximum)

As of January 2021, the World Health Organization (WHO) reports that 90 million cases of COVID-19 (SARS-CoV-2) have been confirmed and have resulted in more than 1.9 million deaths globally.[1] Currently, the United States (U.S.) is the country with the largest number of infections and deaths due to COVID-19, with a total of 26 million infections and 454,596 deaths.[2] Furthermore, early findings that have examined COVID-19 demographics show that racial and ethnic minorities in the U.S. are bearing a disproportionate number of COVID-19 cases and deaths. Recent data from the Centers for Disease Control and Prevention (CDC) indicate that COVID-19 hospitalization rates among African American (AA) and Latinx people were both 4.7 times the rate of non-Hispanic white people[3]. While there's no evidence that people of color (POC) have genetic or biological factors that make them more likely to be affected by COVID-19, they are more likely to have underlying health conditions, live in multi-generational homes and densely populated areas, limited access to healthcare, and be essential workers,[4] All of these factors contribute to higher rates of infection and adverse COVID-19 outcomes. Although COVID-19 preventive behaviors such as mask wearing, and social distancing have been shown to be effective in curbing the spread of the virus, acceptance and uptake of COVID-19 vaccines will be instrumental to ending the pandemic. However, public confidence in vaccination is fragile, especially among racial and ethnic minorities, likely due to historical racism in health care and human rights violations in research.[5] COVID-19 vaccination programs will only succeed if there is widespread belief that available vaccines are safe and effective and that policies for prioritizing their distribution are equitable and evidence-based. To this end we have formed an intervention working group comprised of representatives from community and academic organizations including San Ysidro Health and UC San Diego, to address challenges in COVID-19 vaccination among Latinx and African American (AA) communities in Southern California. We have developed *2VIDA! (SARS-CoV-**2** **V**accine **I**ntervention **D**elivery for **A**dults in Southern California)* a multilevel intervention to address individual, social, and contextual factors related to access, acceptance, and uptake of the COVID-19 vaccine among Latinx and AA adults in San Diego. *2VIDA!* builds on our previous community-based participatory research (CBPR) efforts and was developed as a pilot clinical program in one of SYH community health centers. Through this proposal we seek to evaluate this program and its effects in increasing access, acceptance and uptake of the COVID-19 vaccine by scaling-up across 3 communities in South San Diego. *2VIDA!* centers on conducting COVID-19 Individual awareness and education, COVID-19 linkages to medical and supportive services, and COVID-19 Community Outreach and Health Promotion in the intervention sites (Phase 1); and offering the COVID-19 vaccine to Latinx and AA adults (≥16 years old) in SYH community health centers (CHC) and

mini-vaccination stations in communities highly impacted by the pandemic and identifying individual and structural barriers to COVID-19 immunization (Phase 2). Specific aims include:

Aim 1. To evaluate the preliminary impact of *2VIDA!* compared to the standard-of-care for COVID-19 vaccination services among Latinx and AA adults ≥16 years (N=1000) in San Diego. We will use a 2-armed randomized controlled trial (RCT)* where Latinx and AA adults ≥16 years or older from six participating community health centers (CHC) and surrounding communities will be assigned to the *2 VIDA!* intervention (n=3 CHC; N=500 participants) or to the control site (e.g., standard of care) (n=3 CHC; N=500 participants). Data will be collected on a) sociodemographic characteristics; b) characteristics associated with social marginalization; c) access to and utilization of health care; d) vaccination history, interest, hesitancy and uptake; e) perceptions of the COVID-19 vaccine (e.g., fears, myths, etc.); f) general health; and h) trust in government, research, and social agencies, i) satisfaction with 2VIDA!; at baseline and 4-week follow-up. We hypothesize that at follow-up, compared to control participants, *2VIDA!* participants will:

H.1 have increased knowledge about the COVID-19 vaccine (including medically accurate information, benefits, and risks);
H.2. more likely to receive the COVID-19 vaccine;
H.3. more likely to complete vaccine series (based on Centers for Disease Control and Prevention [CDC] recommendations).[1]

Aim 2. **To assess feasibility, acceptability, and intervention effects of *2VIDA!*** To assess feasibility and acceptability, we will utilize quantitative methods to track recruitment, condition assignment, participant retention, intervention implementation, and potential threats (e.g., contamination). We will also utilize qualitative methods to assess acceptability via focus groups with participants to understand potential for broad implementation (e.g., what components did they receive of the intervention, client satisfaction, linkage to COVID-19 services). To assess intervention effects, we will examine participant vaccination rates/completion across both groups.

*Please note that only one community health center out of their 25 clinics is currently delivering *2VIDA!* as a clinical program and all of their clinics are offering the vaccine on site (no mini-vaccination stations). For the purposes of this research, we will randomize 6 community health centers and their surrounding communities that are predominantly Latinx and AA to receive either *2VIDA!* or the standard of care for vaccine delivery (i.e. no components of *2VIDA!* will be deployed). In order to avoid contamination, the community health center where the *2VIDA!* was developed (i.e., Chula Vista) and is currently being implemented as a clinical program will be excluded from this study. Additionally, SYH is currently offering the vaccine at their community health centers, however, there is low vaccine uptake, therefore we believe this study will help increase interest in the vaccine and address vaccine hesitancy by working with the community.

6. BACKGROUND AND SIGNIFICANCE (2-3 paragraphs maximum)

As of November 27, 2020, the CDC reported that more than half of COVID-19 cases in the U.S. (55.6%) have been among Latinx and African American (AA) individuals, despite the fact that these groups comprise less than a third of the total U.S.[2] COVID-19 has disproportionately affected racial/ethnic minority and underserved individuals, particularly AA and Latinx communities**.** Compared to non-Hispanic White persons, age-adjusted death rates were 2.8 times higher among AA and Latinx persons.[3] Further, preliminary data show that diabetes, hypertension, and obesity increase a patient's risk for severe COVID-19 disease and mortality.[7] AA and Latinx have a disproportionately high prevalence of such comorbidities. The disproportionate burden of chronic medical conditions is compounded by lower access to healthcare.[8] Latinx and AA have significantly lower rates of insurance and they also tend to live in areas where medical care is of poor quality or is underserved.[4] Similarly, before the pandemic, poverty rates in the U.S. were higher among Latinx (19%) and AA (22%) compared to whites (9%) having less financial capacity to make healthful decisions.[9] Minority groups also comprise a disproportionate percentage of workers in essential industries (e.g., caregivers in nursing homes, transportation, food service) during the pandemic, involving interaction with the public and exposure to the virus. These occupational hazards are compounded by the fact that only 55% of essential workers in the food service industry have access to paid sick leave. Lastly, living conditions in some minority communities further increased risk for COVID-19 infection and/or transmission. Communities with higher racial and ethnic minority populations have higher housing density, more housing insecurity, air pollution, and more multigenerational households that makes social distancing harder. Therefore, all of these important medical, social, economic, environmental, and political contexts that predate[10] the pandemic or have been exacerbated by the pandemic, contribute to disproportionate infections and deaths among Latinx and Black individuals in our country.[4]

The current COVID-19 response is failing the needs of minority populations because it models what has been done for other health conditions – interventions have not been designed for, or tested in, racial and ethnic minorities.[11] Of the 350,000 people who registered online for a coronavirus clinical trial, 10% are AA or Latinx.[12] That's less than a third of the total U.S. population these two groups account for (31.9%).[13] Efforts to ensure equitable design, implementation, and effectiveness of interventions to prevent and treat COVID-19 are urgently needed. These efforts should include the design of interventions that respond to the culture, history, values, and needs of Latinx and AA communities. This is crucial given that testing, sheltering in place, and physical distancing are not an option for many. Furthermore, preventive interventions, testing, and vaccines should be deployed where minority populations live and work, along with strategies to facilitate adoption and implementation in settings that serve these populations. The proposed study is significant in that it has been developed and designed by and for racial and ethnic minorities (the PI is Latinx and was born and raised in Southern California) and will be tested in three communities in Southern California that have been severely affected by the pandemic and are predominantly Latinx and AA.

Acceptance and uptake of COVID-19 vaccines will be instrumental to ending the pandemic, however, public confidence in vaccination is fragile, especially among racial and ethnic minorities. A recent nationally representative longitudinal study found that the public's likelihood of getting a COVID-19 vaccine declined from 74% in early April to 56% in early December 2020, despite the press releases in November 2020 of a high vaccine efficacy for 2 vaccines in phase 3 trials and the surge in cases during this timeframe.[14] Likewise, self-reported likelihood of getting COVID-19 vaccination was lower among women, AA individuals, and those with lower educational backgrounds. Similarly, other studies have indicated that Latinx are less likely to trust the vaccine and that there is skepticism among Latinx communities across the country[15] due to unequal access to health care, the lack of reliable information (especially in Spanish), coupled with disinformation.[16] These findings highlight the mistrust between racial and ethnic minorities and public health officials, likely due to historical racism in health care and implicit bias.[5] This is concerning due to their disproportionately higher burden from COVID-19 disease and because high levels of vaccination are necessary to reach herd immunity and control the pandemic. These findings emphasize the need for interventions that address these barriers and rebuilt trust in our communities of color. The proposed study is significant in that it will conduct extensive individual and community level awareness, education, outreach and health promotion that center on providing COVID-19 medically accurate and culturally competent information (in English and Spanish at 8th grade level) in order to empower our communities of color.

7. PROGRESS REPORT/PRELIMINARY STUDIES

N/A

8. RESEARCH DESIGN AND METHODS (1 page maximum)

2VIDA! is informed by the National Institute on Minority Health and Health Disparities (NIMHD) research framework[17] and the principals of Community Based Participatory Research (CBPR)[18] as it seeks to understand and address health disparities from a multilevel approach by examining individual, social, and contextual factors related to access to, and acceptance of, the COVID-19 vaccine. CBPR offers an opportunity to emend health disparities in our communities of color. It requires an equitable involvement of researchers and the members of a community that are affected in all aspects of a research process, aiming to improve health, generate knowledge and effect social change. Utilizing the principles of CBPR, we aim to reduce such disparities in health literacy and access to COVID-19 vaccine by addressing the specific challenges of the Latinx and AA communities in Southeast San Diego with practical, sustainable, culturally appropriate solutions that utilize the community's strengths, and testing the effectiveness of the intervention by utilizing rigorous research methods. Based on CBPR and the NIMHD framework, we expect *2VIDA!* to improve health literacy, acceptance and uptake of COVID-19 vaccine among Latinx and AA adults in the three target CHC and surrounding communities.

Description of Intervention. We will use a 2-armed randomized controlled trial (RCT)* where Latinx and AA adults ≥16 years or older from six participating community health centers (CHC) and surrounding communities will be assigned to the *2 VIDA!* intervention (n=3 CHC; N=500 participants) or to the control site (e.g., standard of care) (n=3 CHC; N=500 participants) (Figure 1). The two major components of the 2VIDA! intervention are outlined below:

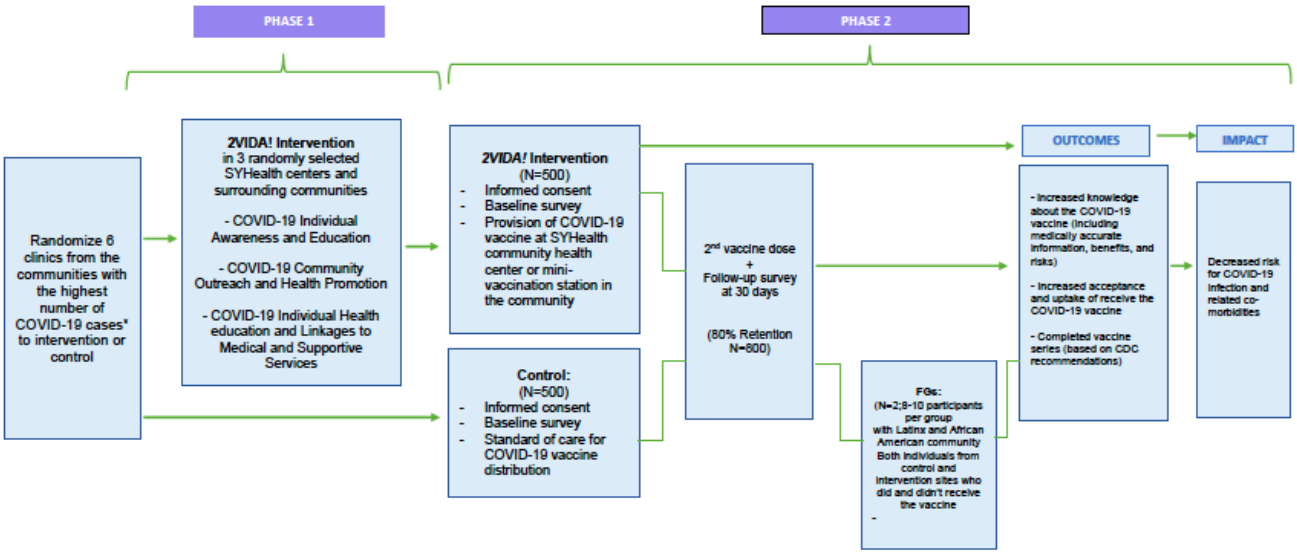
PHASE I. COVID-19 Individual Awareness and Education, Community Outreach and Health Promotion, and Individual Health Education and Linkages to medical and Supportive Services in Latinx and Black communities.

- **COVID-19 Individual Awareness and Education. *** The *2VIDA!* CBPR working group has developed culturally competent COVID-19 educational and outreach materials (available printed and electronically) in English and

Spanish that are written at the 8th grade level (the average reading level of adults in the United States) that peer-health educators will distributed to community members during their visits to the participating SYH community centers, door-to-door, local supermarkets (SYH has a partnership with Northgate Gonzales Market), and community-based organizations (CBO's) in the selected communities. These materials have general information on COVID-19 as well as educational information and resources regarding COVID-19 prevention, symptoms, testing, contact tracing, COVID-19 vaccine (how it works, technology used, administration [2-dose series and importance of vaccine completion], safety concerns, benefits, risks, dispelling common misconceptions and misinformation, potential side effects and what to do), and other topics identified based on community needs. This information will be updated monthly to ensure the most up to date information. The goal is to distribute approximately 20,000 educational and outreach materials across the three randomly selected communities.

- **COVID-19 Community Outreach & Health Promotion**. Peer-health educators will work with local CBO's and facilitate a combination of live broadcast sessions, pre-recorded webinars, social media posts, and other outreach activities in English and Spanish reaching community members with information on the above COVID-19 related topics as well as other identified needs such as what to do if a family member is infected and where you can get the COVID-19 vaccine. The goal of this research activity is to reach 10,000 viewers (per session) in the various social media platforms in the three randomly selected communities.
- **COVID-19 Individual Health Education & Linkages to Medical and Supportive Services.** For the purposes of this research, SYH will establish a COVID-19 Resource Center within the participating health centers in the three randomly selected communities (intervention sites only) providing individual COVID-19 related health education and linkages to medical and supportive services for patients and community members in need of additional education and support regarding COVID-19 disease and COVID-19 vaccine.

PHASE II. To evaluate the preliminary impact of *2VIDA!* compared to the standard-of-care for COVID-19 vaccination services among Latinx and AA adults >16 years (N=1000) in San Diego. During Phase 2 we will offer the COVID-19 vaccine at the participating SYH community health centers and mini-vaccination stations that will be set-up in these communities (only intervention sites) as part of the intervention efforts (i.e., research activities) to increase access and uptake of the COVID-19 vaccine. We have identified various open spaces (e.g., public parks) in these communities to set-up the vaccination stations. SYH is currently offering the vaccine in their facilities as part of their standard of care. It is available to everyone who is eligible according to the state guidelines and does not depend on participating in this study. However, as part of *2VIDA!* we will add these mini-vaccination stations to increase access to the vaccine (e.g., open after 5:00pm and on the weekends). Furthermore, data will be collected to assess individual, social, and contextual factors related to access, acceptance, and uptake of the COVID-19 vaccine including: a) sociodemographic characteristics; b) characteristics associated with social marginalization (e.g., homelessness, food insecurity); c) access to and utilization of health care; d) vaccination history, interest, hesitancy and uptake; e) perceptions of the COVID-19 vaccine (e.g., fears, myths, etc.); f) general health; and h) trust in government, research, and social agencies; i) satisfaction with *2VIDA!* at baseline and 4-week follow-up. The survey will last approximately 20 minutes and will be self-administered in both English and Spanish. Following the survey participants will be offered the COVID-19 vaccine and the SYH staff will help them set-up an online appointment onsite for the 2nd dose (1 month follow-up) and will be asked to complete a 5 min survey during the follow-up visit. SYH has trained medical staff and a strict protocol for the storage, handling, and application of the vaccine. UCSD staff will not be involved in this process. Furthermore, participants will be asked to provide separate written consent in order to receive the vaccine that will be conducted by SYH staff. Additionally, two focus groups (FGs) will be conducted with members of Latinx and AA communities (n=8-10 participants per group) to obtain feedback on implementation and ways to improve future sustainability and scalability for future vaccination efforts among vulnerable underserved communities. FGs will be transcribed and reviewed for themes specific to *2VIDA!* including personal and structural barriers to medical accurate information and the COVID-19 vaccine, benefits, challenges, feasibility, and scalability.



Mini-vaccination stations. We will set-up mini-vaccination stations in the parking of three public parks in the selected intervention sites to support the SYH community health centers. We will set-up signs with the *2VIDA!* project for participants to identify (e.g., same logo and illustrations used during Phase 1) and tent-lined lanes for eligible recipients to drive up. Research assistants will confirm eligibility with potential study participants via verbal assessment of the following inclusion criteria: 1) age 16 years or older; 2) identify as Latinx and/or AA; 3) biologically male or female; 4) be a resident of one of the three communities selected for the intervention (National City, Lincoln Park, Logan Heights, Valencia Park, San Ysidro); 5) literate in English or Spanish); 6) no known history of severe allergic reactions to any components of the vaccine; 7) no history of immune disease; 8) not be pregnant; 9) no plans to move from the area in the following 30 days; 10) able to provide voluntary informed consent; and 11) able to provide complete contact information for themselves (email and phone number) and two additional contact individuals for follow-up. Inside their car they will complete the 10-15 min. survey, receive the COVID-19 vaccine, and pull aside for a 15-minute observation period. We will also set-up additional tents with portable chairs at least 6 feet apart for participants who do not own a vehicle and want to receive the vaccine at the mini-stations. The stations will be opened Monday-Sunday from 7:00am-7:00pm based on the recommendations from our community partners (e.g., some individuals work early/late shifts). We will have two options for the vaccine – a one shot or a two-shot vaccine and the participants will select what type of vaccine they prefer. The vaccines will be available on a first come first-serve basis. For individuals who select a two-shot vaccine, the study staff will schedule the appointment for the participants on site when they receive the 1st dose of the vaccine (as they are waiting during observation period) and give them the date (confirmation). We will use the NextGen program to schedule the follow-up appointments for these participants. For participants who select a one-shot vaccine, they will be reminded that they will receive a text message and/or a link via email (based on their preference) to complete a follow-up survey in 4-weeks. Participants who select a two-shot vaccine will be asked to complete the follow-up survey (4-weeks) when they return for their second shot (during the observation period). We have noticed that percentage of our population has low digital literacy levels and/or limited access to internet or digital technologies which has made enrollment and follow-up challenging. In order to address these barriers, we are proposing to utilize Computer Assisted Telephone Interviewing (CATI)[20] and videoconferencing and screen sharing (VCSS).[21] Both tools have been successfully used for many years in public health as well as by our community partner (SYH) on other similar federal-funded research projects. During enrollment, we would provide the participants with the option to complete the follow-up survey utilizing CATI or VCSS if they require assistance or have limited access to digital technologies. If they chose CATI or VCSS, following the completion of the follow-up survey we would send the incentive via a unique link similar to the follow-up for other participants. The entire team has been trained on these two platforms and would only be used for follow-up. Additionally, SYH will create a temporary patient ID for them and enter them in the system to schedule their second appointment. This is the software program that SYH is currently utilizing to follow-up for vaccine appointments. We believe that utilizing SYH existing infrastructure will allow sustainability and scalability of *2VIDA!* The participants who select a two-shot vaccine will receive an email or automated

text reminder (based on their preference) 24 hours before their scheduled appointment for the 2nd dose. If a participant does not show-up to their appointment for the 2nd dose, we will contact the references that they provided (2 contacts) and reschedule their appointment. This is not an activity routinely done for COVID-19 vaccination efforts by SYH. This is only for *2VIDA!* participants and these tracking mechanisms have been effective in reducing attrition rates in our previous research efforts working with similar populations. Lastly, having participants scheduled for 2nd dosage will allow us to know how many vaccines we need to have available per day following the initial roll-out and avoid any shortages and/or unused dosages. We will follow the same process as with the first dosage, participants will drive up to the tent-lined lanes and inside their car or in tents and chairs (if they come by foot) they will complete the 5 min. survey, receive the 2nd shot of the COVID-19 vaccine, and pull aside for a 15-minute observation period.

The overall goal of this study is to provide medically accurate information and resources on COVID-19 and barriers to accessing the COVID-19 vaccine to increase acceptance, uptake and series completion among predominantly Latinx and African American communities that have been severely impacted by the pandemic. Therefore, individuals who do not meet the eligibility criteria to participate in this research project but are interested in receiving the COVID-19 vaccine will have access to receive the vaccine (just the same as study participants) at the mini-vaccination station or at the participating SYH community health center. We will also follow the same scheduling procedure for non-eligible participants. During the observation period after receiving the vaccine (15 minutes) SYH staff will schedule their appointment for the 2nd dose using the NexGen program at the mini-vaccination station or the SYH community health center that is most convenient for them. This will enable us to provide the ineligible individuals access to the vaccine and have sufficient amounts of the 2nd dose. We will follow the same process for an individual who received the 1st dosage of the vaccine at one of the control sites is seeking to receive the 2nd dosage of the vaccine at the intervention site or mini-vaccination station for non-research purposes.

Lastly, because SYH is currently receiving the vaccine from both the state and the federal government, we don't anticipate any future events where individuals will be unable or receive the vaccine. As of December 2020, when SYH began administering the vaccine, there has only been one incident where the vaccines were not available due to the winter storms that caused a delay in the transportation of the vaccines to the state of California. At that time individuals were rescheduled for another day and everyone received the vaccine. In the event that individuals for both research or non-research purposes are unable to receive the vaccine for any reason directly or indirectly due to this research project, we will reschedule their appointments at their earliest convenience to either the mini-vaccination station or the participating SYH community health center that is closest to them to ensure everyone has access to the vaccine.

Focus Groups (FG). Two separate FGs (one in English and one in Spanish) will be conducted (n=2; 8-10 participants per group) following the implementation of *2VIDA!* with members of the Latinx and AA community in San Diego to understand the socio-structural barriers to COVID-19 information and resources (e.g., testing) and vaccine uptake (e.g., medical mistrust, discrimination, stigma, transportation, access to vaccination site, lack of insurance) as well as acceptability of the *2VIDA!* intervention. Participants will be recruited from six SYH community health centers (from both intervention and control sites) that are located in the communities with the highest cases of COVID-19. Eligibility criteria includes: 1) identify as Latinx or African American, 2) 16 years of age or older, 3) reside in one of the target communities (National City, Lincoln Park, Logan Heights, Valencia Park, San Ysidro), 4) literate in English or Spanish, 5) able to provide written and informed consent (including permission to record FG session). We will recruit equal number of Latinx and AA participants for each session, as well as equal number of individuals who both have and haven't received the vaccine as part of *2VIDA!* to provide an in-depth discussion and have a better understanding of the community needs. The FGs will take place based on the time/date that is most convenient for the community members. Each FG will take place in the private conference room located in the clinics, will follow a semi-structured open-ended guide, last between 60-90 minutes and be facilitated by a moderator (Dr. Servin) and note-taker (who also records each session). This data will allow us to identify structural barriers, acceptability, and feasibility of *2VIDA!* on COVID-19 vaccination uptake.

Data Analysis. We will approach overall data analyses using a multivariate repeated measures design (i.e., doubly multivariate) to assess mean differences in treatment and control groups on our primary (acceptance of COVID-19 vaccine and vaccine series completion) and secondary outcome variables (increased knowledge of COVID-19 vaccine, increased

access to COVID-19 vaccine, vaccine hesitancy). Additional measures at baseline and follow-up will be used as covariates (e.g., outreach and health communication, vaccine hesitancy or mistrust). Mean differences, both within and between treatment and control groups as well as group by treatment interaction effects will be analyzed. The targeted sample size is sufficient to detect a small effect size (.20) with power = .90 at alpha = .05 accounting for moderate participant attrition. Descriptive Statistics. To describe the overall sample regarding demographics, structural and individual barriers, and potential covariates of intervention effects at baseline, prevalence statistics and means and standard deviation will be provided for all baseline variables; Cronbach's alpha of .70 will be required to be considered reliable. Baseline Analyses to Detect Differences Between Treatment Groups. Chi-square analyses and paired t-tests will be used to detect differences in demographics, knowledge of COVID-19 vaccine, access to COVID-19 vaccine, acceptance of COVID-19 vaccine and series completion, COVID-19 resource-seeking behaviors and linkage into care between intervention and control groups. Demographic variables included in these analyses will be age, gender, race/ethnicity, education, household income, marital status, and having insurance. Those variables differing across treatment groups at the $p<.20$ level will be included in subsequent adjusted outcome analyses. For the qualitative data analysis, final translated electronic transcripts will be imported into Dedoose. Analysis will be done through identification of recurrent themes following Crabtree and Miller's 5 step "interpretive process."[19] First, transcripts will be read to identify common themes, codes will be developed and ~10% of data will be double coded and inter-rate reliability assessed. Coded text will be extracted and organized and read to identify emergent themes.[65] Matrices will be created to compare codes by themes (e.g., medical mistrust, discrimination, stigma, transportation, access to vaccination site, lack of insurance). Data will be utilized to refine *2VIDA!*, assess acceptability, and inform future vaccination efforts among underserved communities.

*****Please note that only one community health center out of their 25 clinics is currently delivering *2VIDA!* as a clinical program and all of their clinics are offering the vaccine on site (no mini-vaccination stations). For the purposes of this research we will randomize 6 community health centers and their surrounding communities that are predominantly Latinx and AA to receive either *2VIDA!* or the standard of care for vaccine delivery (i.e. no components of *2VIDA!* will be deployed). In order to avoid contamination, the community health center where the *2VIDA!* was developed (e.g., Chula Vista) and is currently being implemented as a clinical program will be excluded from this study.

9. HUMAN SUBJECTS (2 paragraphs maximum)

Human subjects will be involved according to the study design and data collection activities detailed in Aims 1-3. All data collection will proceed under the direction of Dr. Servin from UCSD and Dr. Muñoz from SYH in accordance with the current standards of human subjects research taking place in SYH community health centers as outlined in state of California law. Additionally, Dr. Servin will oversee all analyses and protection of subjects in coordination with Dr. Muñoz and members of the CBPR working group. Dr. Talavera (Co-Investigator and licensed physician) from SYH will oversee implementation of the COVID-19 vaccine based on the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) recommendations and guidelines.[1,7]

All participants will be notified of potential risks and risk mitigation via informed digital consent for the survey (e.g., tablets) and written paper consent (for the focus groups conducted by UCSD personnel and the vaccine that will only be conducted by trained SYH registered nurses). The written paper consent process for the vaccine will be conducted by SYH staff as they will administer the vaccine, not UCSD staff. Those agreeing to participate will be escorted to a private room within the participating SYH community centers or in their cars or tents (if they come by foot) at the mini-vaccination stations and will provide informed digital consent for the survey (e.g., tablet) and complete the survey via a tablet (self-administered). Participants will have the option to email themselves the consent form or we can print it for them on site. As previously mentioned, we will set-up mini-vaccination stations in the parking of three public parks in the selected intervention sites and tent-lined lanes for eligible recipients to drive up. Participants will be inside their car and wearing a mask at all times during the consent process. Inside their car they will complete the 10-15 min. survey, receive the COVID-19 vaccine, and pull aside for a 15-minute observation period. We will also set-up additional tents with portable chairs at least 6 feet apart for participants who do not own a vehicle and want to receive the vaccine at the mini-stations. Although the mini-vaccinations will be in open public spaces (e.g., local park) because the set-up between the vaccine stations will be at least 6 feet apart, we expect this will allow for privacy for those that come by foot or do not own a vehicle. However, those participants who feel uncomfortable will be invited to the health center to complete the consent process and survey in a private room. All participants will be assigned a unique identifier to link initial survey and follow-up survey (when they

receive the 2nd dose). The baseline survey will take approximately 20 minutes and the follow-up survey last 10 minutes, both will be self-administered (tablet). The research staff will be available in case the participants don't understand a question or need help with any aspect of the survey. We will also have Wi-Fi hotpot and mobile printers on site at the mini-vaccination stations for participants who would like to take a copy of the digital consent form and access to printers in the participating health centers. Following survey completion, participants will be eligible to receive the COVID-19 vaccine if they provided written informed consent (paper). Although participants would have already been screened for eligibility, the research assistants from SYH will confirm again that they do not have any known history of severe allergic reactions to any components of the vaccine, no history of immune disease, and not be pregnant. As previously mentioned, individuals may also receive the vaccine even if they choose not to participate in the study. Registered nurses from SYH will proceed to apply the COVID-19 vaccine and as previously mentioned, will observe the participant has no reaction for 15 minutes. SYH will follow strict vaccination protocols (based on the FDA and CDC COVID-19 recommendations and guidelines) [1,7] and will report all vaccine administration errors, all serious adverse events following administration of the COVID-19 Vaccine to the IRB and to the Vaccine Adverse Event Reporting System (VAERS) and Dr. Servin will report to the IRB and NIH if warranted. Likewise, if an individual who received the 1st dosage of the vaccine at one of the control sites is seeking to receive the 2nd dosage of the vaccine at the intervention site or mini-vaccination station, they will be placed on a wait-list and contacted by our study staff towards the end of the day if there are available dosages due to the no-shows. Alternately, if they don't wish to be on the wait list we can schedule an appointment for them to the SYH community health center location that is most convenient for them.

The written paper consent process for the focus groups will be conducted by UCSD staff the day of the FG prior to beginning the session. As previously mentioned we will conduct two separate FGs (one in English and one in Spanish) following the implementation of *2VIDA!* with members of the Latinx and AA community in San Diego to understand the socio-structural barriers to COVID-19 information and resources (e.g., testing), vaccine uptake (e.g., medical mistrust, discrimination, stigma, transportation, access to vaccination site, lack of insurance), and acceptability of the *2VIDA!* intervention. Research assistants will recruit eligible participants from both intervention and control sites that are located in the communities with the highest cases of COVID-19. As previously mentioned, each FG will take place in the private conference room located in the clinics, will follow a semi-structured open-ended guide, last between 60-90 minutes and be facilitated by a moderator (Dr. Servin) and note-taker (who also records each session).

10. RECRUITMENT

Six SYHealth community health centers across San Diego County have been selected based on their serving predominantly Latinx and AA client population and having the Zip codes with the highest number of COVID-19 cases in the County. These clinics are located in National City, Logan Heights, Lincoln Park, Valencia Park and San Ysidro. Each clinic will be randomly selected and randomized evenly to either the intervention or control conditions, using computer-generated randomization plans prepared using SAS statistical software under the direction of the lead study statistician. Clinic-level randomization was selected to minimize between-arm contamination of intervention and control conditions**.** Participants from both intervention (n=500) and control sites (n=500) will be recruited using reactive recruitment, including the use of community partner social media platforms, and flyers distributed in the SYH target health centers and high traffic, readily visible areas, where eligible participants are likely to see them (e.g., grocery stores, local CBO's, parks, barber shop, cafés, food banks, gyms, local restaurants). Flyers will include study information and contact information for study staff. Likewise, the project staff publicized the rapid vaccine effort (e.g., mini-vaccination stations) by posting flyers that noted locations, dates, and times of vaccine distribution, and through presentations about the project at community meetings. Project staffing, training, and support, including the selection of nurses and outreach staff (e.g., peer-health educators and research assistants) with complementary research skills and personal knowledge of the community will be key to the success of the project. Two bilingual Latinx (one male and one female) and two AA (one male and one female) outreach workers trained in research ethics and protocols, and familiar with this population will approach individuals who appear to be eligible (Latinx and AA adults ages 16 years or older) at the SYH community centers and mini-vaccination stations in the participating communities, confirm eligibility, and describe the study to those eligible. Research staff will update time logs and continuously update our sampling frame until recruitment is finalized. The reason for refusal or ineligibility will be recorded. Extensive efforts will be made to have an equal representation of Latinx and Black community members and at least 40% women.

Additionally, two separate FGs (one in English and one in Spanish) will be conducted (n=2; 8-10 participants per group) following the implementation of *2VIDA!* with members of the Latinx and AA community in San Diego to understand the socio-structural barriers to COVID-19 information and resources (e.g., testing) and vaccine uptake (e.g., medical mistrust, discrimination, stigma, transportation, access to vaccination site, lack of insurance) as well as acceptability of the *2VIDA!* intervention. Participants will be recruited from six SYH community health centers (from both intervention and control sites) that are located in the communities with the highest cases of COVID-19. Participants will be recruited using selective sampling, a non-probability sample that is selected based on characteristics of a population and the aims of the proposed research and is acceptable for the proposed qualitative research.[22] The research assistants will recruit Latinx and AA adults by two mechanisms: 1) from the waiting room of the community health centers (both control and intervention sites) and when they come to the clinic or mini-vaccination site to complete their 2nd dose of the vaccine and if interested in participating scheduling an appointment for them to come into the community health center to learn more about the study. We will use a standard recruitment script and research assistants will confirm eligibility with potential study participants via verbal assessment of the following inclusion criteria: 1) identify as Latinx or African American, 2) 16 years of age or older, 3) reside in one of the target communities (National City, Lincoln Park, Logan Heights, Valencia Park, San Ysidro), 4) literate in English or Spanish, 5) able to provide written and informed consent (including permission to record FG session). We will recruit equal number of Latinx and AA participants for each session, as well as equal number of individuals who both have and haven't received the vaccine as part of *2VIDA!* to provide an in-depth discussion and have a better understanding of the community needs. Each FG will take place in the private conference room located in the clinics, will follow a semi-structured open-ended guide, last between 60-90 minutes and be facilitated by a moderator (Dr. Servin) and note-taker (who also records each session). This data will allow us to identify structural barriers, acceptability and feasibility of *2VIDA!* on COVID-19 vaccination uptake.

11. COMPENSATION FOR PARTICIPATION

When this work was first submitted, working group members decided that providing a reimbursement for completing the survey may not be well received in our target communities given they will complete at the same time they receive the COVID-19 vaccine, and this could be misinterpreted as being paid to receive the vaccine and would be morally flawed. This decision was made based on community leaders and CBO's recommendations. However, since then many organizations including the local government now offer an incentive for receiving the vaccine. Therefore, we propose to provide participants with a $20 VISA gift card for completing the baseline survey and an additional $20 VISA gift card for completing the follow-up survey (4-weeks). For those individuals who already completed a baseline and follow-up survey prior to the approval of this amendment, we propose to send them a link (similar to the You Call the Shot program) for a $40 VISA gift card participating in the study.

Participants from the focus groups (n=2; 8-10 participants per group) will be compensated via $20 VISA gift cards for their time and transportation. Working group members decided that providing a reimbursement for participating in the focus groups would be acceptable as it will be done at a separate time from when they are offered the COVID-19 vaccine.

12. INFORMED CONSENT

At recruitment, research assistants will confirm eligibility with potential study participants via verbal assessment of the following inclusion criteria: 1) age 16 years or older; 2) identify as Latinx and/or AA; 3) biologically male or female; 4) be a resident of one of the three communities selected for the intervention (National City, Lincoln Park, Logan Heights, Valencia Park or San Ysidro); 5) literate in English or Spanish); 6) no known history of severe allergic reactions to any components of the vaccine; 7) no history of immune disease; 8) not be pregnant; 9) no plans to move from the area in the following 30 days; 10) able to provide voluntary informed consent; and 11) able to provide complete contact information for themselves and two additional contact individuals (for follow-up 2nd vaccine shot). These data will be recorded in the form of a Client Recruitment Log. Although pregnancy is not a contraindication for COVID-19 vaccination, working group members decided that vaccination of pregnant women may not be well received in our target communities. This decision was also made based on community leaders and CBO's recommendations. Research assistants will record data regarding eligibility and reasons for non-participation where applicable. We are requesting a waiver of parental consent for subjects enrolled in the study who are ages 16-17. We request that minors who are 16-17 are able to provide assent for themselves as this study poses minimal risk to the subjects. The biggest risk is the loss of confidentially and appropriate measures will be taken by the research personnel to ensure all data is kept confidential. These include assigning a unique study ID to each participant, only sharing data with approved research personnel, and keeping all data on a password protected device.

However, parental consent will be requested by our community partners (SYH) before they apply the vaccine. Furthermore, participants who refer low digital literacy levels and/or limited access to internet or digital technologies will be informed about the option to conduct the follow-up survey via Computer Assisted Telephone Interviewing (CATI) or videoconferencing and screen sharing (VCSS). Those agreeing to participate will be escorted to a private room within the participating SYH community centers or in their cars or tents (if they come by foot) at the mini-vaccination stations and will provide informed digital consent (e.g., tablet) and complete the survey via a tablet (self-administered). We will set-up mini-vaccination stations in the parking of three public parks in the selected intervention sites and tent-lined lanes for eligible recipients to drive up. Participants will be inside their car and wearing a mask at all times during the consent process. Inside their car they will complete the 10-15 min. survey, receive the COVID-19 vaccine, and pull aside for a 15-minute observation period. We will also set-up additional tents with portable chairs at least 6 feet apart for participants who do not own a vehicle and want to receive the vaccine at the mini-stations. Although the mini-vaccinations will be in open public spaces (e.g., local park) because the set-up between the vaccine stations will be at least 6 feet apart, we expect this will allow for privacy for those that come by foot or do not own a vehicle. However, those participants who feel uncomfortable will be invited to the health center to complete the consent process and survey in a private room. All participants will be assigned a unique identifier to link initial survey and follow-up survey (when they receive the 2nd dose). The baseline survey will take approximately 20 minutes and the follow-up survey last 10 minutes, both will be self-administered (tablet). The research staff will be available in case the participants don't understand a question or need help with any aspect of the survey. Following survey completion, participants will be eligible to receive the COVID-19 vaccine if they provided written informed consent. Although participants would have already been screened for eligibility, the research assistants will confirm again that they do not have any known history of severe allergic reactions to any components of the vaccine, no history of immune disease, and not be pregnant. Further, SYH staff will have parents to provide consent for their children (16–17-year-old) to receive the vaccine. Registered nurses from SYH will proceed to apply the COVID-19 vaccine and as previously mentioned, will observe the participant has no reaction for 15 minutes. SYH will follow strict vaccination protocols (based on the U.S. Food and Drug Administration[7] and Centers for Disease Control and Prevention recommendations and guidelines)[1] and will report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death following administration of the COVID-19 Vaccine to the IRB and to the Vaccine Adverse Event Reporting System (VAERS). The same procedure will be followed for the 2nds dose of the vaccine. Additionally, a detailed protocol has been developed by SYH for this intervention to handle adverse events, although none have occurred so far in the application of the COVID-19 vaccine to front line healthcare providers. Staff members have assigned specific responsibilities (e.g., if warranted, nurses will administer epinephrine or Benadryl and maintain an airway; outreach workers would call 911 and wait for the ambulance). The medical director of the study on behalf of SYH, Dr. Talavera who is a licensed physician, will be on call at all times, and a licensed nurse will manage all aspects of the COVID-19 vaccination phase.

As previously mentioned, two separate FGs (one in English and one in Spanish) will be conducted (n=2; 8-10 participants per group) following the implementation of *2VIDA!* with members of the Latinx and AA community in San Diego to understand the socio-structural barriers to COVID-19 information and resources (e.g., testing) and vaccine uptake (e.g., medical mistrust, discrimination, stigma, transportation, access to vaccination site, lack of insurance) as well as acceptability of the *2VIDA!* intervention. Participants will be recruited using selective sampling, a non-probability sample that is selected based on characteristics of a population and the aims of the proposed research and is acceptable for the proposed qualitative research.[20] Research assistants will confirm eligibility with potential study participants via verbal assessment of the following inclusion criteria: 1) identify as Latinx or African American, 2) 16 years of age or older, 3) reside in one of the target communities (National City, Lincoln Park, Logan Heights, Valencia Park, San Ysidro), 4) literate in English or Spanish, 5) able to provide written and informed consent (including permission to record FG session). The written paper consent process for the focus groups will be conducted by UCSD staff the day of the FG prior to beginning the session. Each FG will take place in the private conference room located in the clinics, will follow a semi-structured open-ended guide, last between 60-90 minutes and be facilitated by a moderator (Dr. Servin) and note-taker (who also records each session). This data will allow us to identify structural barriers, acceptability, and feasibility of *2VIDA!* on COVID-19 vaccination uptake.

13. ALTERNATIVES TO PARTICIPATION

The alternative to participation is non-participation.

14. POTENTIAL RISKS

Potential risks for study participation in the focus groups and survey include loss of confidentiality as a result of participating in this study. It is possible that participants may disclose confidential information about themselves. In order to provide participants with as much opportunity as possible to control access to information about themselves, recruitment and consent procedures will include thorough explanation of the purpose of the study, what participation entails, risks and benefits of participating in the study. Participants will also be told explicitly that participation is voluntary, consent can be withdrawn at any time during the study, and that there are no consequences for withdrawing from the study. Furthermore, a policies and procedures manual for the project will specify immediate data monitoring and response. Participants will be informed during the consent procedure that confidentiality may be breached under certain circumstances (i.e. they are a danger to themselves or others). In cases where a breach of confidentiality is necessary, project staff will be instructed to report to the project coordinator, who will file an incident report with Dr. Servin within 24 hours. The incident report requires a detailed account of the problem, date of occurrence, date it came to the PI's attention, impact on participant and corrective action taken. Dr. Servin will report adverse events to the UCSD IRB to make a determination if the event was related to research, directly or indirectly, and, if so, require revisions of protocol or consent, as applicable, and re-review of these procedures by the IRB with copies to the Office of Human Subjects for any necessary further action. Project staff hired through UCSD will be required to obtain ethical training through the CITI program (i.e., Social-Behavioral course) so that they are aware of the responsible conduct of research, and the types of adverse events that may warrant a breach of confidentiality. Monitoring of potential adverse effects or serious problems will be given high priority by project staff and researchers. All project staff will receive verbal and written instructions pertaining to the rules governing the maintenance of confidentiality upon completion of the study or if they leave the study before its completion. As previously mentioned, we are using an existing program to schedule participants follow-up appointments for the 2nd dose (NextGen) is currently being utilized by SYH because it is a safe and secure resource. NextGen sends automated reminders masking the direct line's outgoing and incoming phone numbers for text messaging and email reminders. Although there is no link between identity and the data (i.e., the unique code linking the surveys does not link to identifying information) this research is protected by the NIH Certificate of Confidentiality (CoC). The CoC will protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research.

Many people can experience a slight nervousness or discomfort at the prospect of being interviewed or expressing their opinions in a group discussion. The focus group questions asked to the participants may be embarrassing and upsetting, as they reflect upon their thoughts about COVID-19 and the vaccine. Asking about their behaviors or beliefs could be a sensitive matter. RAs will stress to everyone who chooses to participate that they should feel free to decline to answer any question they wish and may terminate the FG or interview at any time. Seriousness, respect, and professionalism will be emphasized during the training of and supervision of the RAs. Nonetheless, it is possible that some participants may become anxious, depressed, sad, or angry due to this content, and there is a small possibility that this may result in becoming a risk to themselves or someone else. Training of RAs will include participant debriefing to detect these issues. If such issues arise, research staff will offer the participant the opportunity to speak with a trained SYH behavioral health professional. If needed, the SYH counselor will escort or refer the client to longer term behavioral health services. Our previous work in similar contexts using similar items has elicited no such responses.

Additional potential risks for study participation include a slight nervousness or discomfort at the prospect of receiving the COVID-19 vaccine (e.g., swelling or pain in the injected area) and having to complete a survey. Dr. Servin will supervise overall data collection and outreach efforts to accomplish the study objectives. SYH and Dr. Talavera (Co-Investigator and licensed physician) will oversee implementation of the COVID-19 vaccine based on the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) recommendations and guidelines.[1,23] Since enrollment will occur at participating SYH community centers and mini-vaccination stations, the researchers will follow the data safety protocols as outlined by SYH. In accordance with these guidelines, at the time of enrollment to the RCT, all patients will be assigned a unique study ID to link their responses across time. Quantitative survey data collected via tablet computers will include no personal identifiers, only the unique study ID of participants. Furthermore, registered nurses from SYH will proceed to consent for and apply the COVID-19 vaccine and will observe the participant has no reaction for 15

minutes. SYH will follow strict vaccination protocols (based on the FDA and CDC recommendations and guidelines)[1,7] and will report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death following administration of the COVID-19 Vaccine to the IRB and to the Vaccine Adverse Event Reporting System (VAERS). Additionally, a detailed protocol has been developed by SYH to handle adverse events related to the COVID-19 vaccine, although none have occurred so far in the application of the COVID-19 vaccine. Staff members have been assigned specific responsibilities (e.g., if warranted, nurses will administer epinephrine or Benadryl and maintain an airway; outreach workers would call 911 and wait for the ambulance). The medical director of the study on behalf of SYH, Dr. Talavera, will be on call at all times, and a licensed nurse will manage all aspects of the COVID-19 vaccination phase. Additionally, project staff, will be responsible for immediately reporting any breaches of protocol, breakdowns in the consent process, violations of confidentiality of the data, complaints by participants or any serious problems or adverse events to the project coordinator who will file an incident report with Dr. Servin. Dr. Servin will collect any incident reports and communicate serious problems or adverse events to the UCSD HRPP, who will report to NIH if warranted.

Lastly, based on the intervention components and objectives, we do not foresee an increased risk of an individual receiving the 1st dose but not the 2nd dose as a result of participating in this project. The different *2VIDA!* individual and community research activities centered on providing health literacy and addressing vaccine hesitancy, as well as the reminders and tracking mechanisms in place (i.e., providing two additional contacts), we believe that participants from this research projects will be more likely to receive the 2nd dosage.

15. RISK MANAGEMENT

Multiple precautions will be taken to minimize the risk that research participants will become emotionally distressed and to support any participants who experience emotional distress despite these precautions. Prior to beginning the FG or interviews, participants will be reminded that some sensitive questions will be asked, that they are free not to answer any question and may terminate their participation at any point without any penalty. Our staff will be trained in accordance with the World Health Organization (WHO) guidelines for conducting research on sensitive subjects to be aware of signs that a participant is becoming distressed or fatigued due to participation in data collection. If this occurs, verbal support will be provided support and encouragement that they are free to decline such questions, such as "I know these can be difficult questions, and you can skip a question or stop the interview if you are uncomfortable for any reason." Upon the participant's completion of the interview or at their termination of involvement, the participant will be debriefed and screened for emotional distress: "These questions can make some people feel sad, anxious, or angry. How are you feeling now?" In addition to debriefing, all participants will be provided with service information for a variety of community resources, including mental health and social support services. No such adverse events have occurred in Dr. Servin's previous projects that have employed these procedures with adults within similar contexts.

Any research involvement involves some risk of loss of confidentiality. Extensive measures will be taken to protect the confidentiality of the study participants and minimize any risk of a breach. All personal data collection will be conducted in private settings. Additionally, participants will be represented via a unique identifier for purposes of re-contact; contact/tracking information that include personal identifiers (i.e. first names, Google Voice number) will be linked with these unique identifiers on a list kept on a secured server in a password protected file, accessed only by the Research Coordinator and site Co-I at SYH. Only SYH research staff will have access to this list, and solely for identifying participants for scheduling their time for study participation. Clients unique IDs, and Google Voice number will be deleted immediately after completion of the data collection (i.e., after the 4-week follow-up). Audio-recordings from focus groups will be moved daily onto a secure UCSD server that is password-protected and backed-up daily and will be destroyed immediately after transcription is complete. Transcripts will not include personal identifiers and the document connecting personal identifying information to the list of unique survey identifiers will be destroyed as soon as data collection is completed. Additionally, research assistants and SYH clinical staff will be required to maintain confidentiality of all research participants and will be required to sign a pledge agreeing to do so upon joining the research project. They will not be permitted to report on anyone's data or participation in this study.

All the FG participants will be asked to sign a written confidentiality agreement before participating in the session to ensure participants do not share with others outside the group what was discussed and by whom during the FG. Additionally,

during the FGs all participants will be requested to only refer to others using a pseudo name. Research assistants (RAs) will explain that confidentiality is critical to the safety and ability to share freely for all participants in the group. RAs will also remind participants that they may choose to not identify themselves or the experiences they share (for example, say that a friend had a particular experience even if it was their own experience). No identifiers will be recorded in transcripts.

Every effort will be made to minimize participants' risk of a loss of confidentiality. All research and SYH staff will be required to maintain confidentiality of all research participants and will have signed a pledge to do so upon joining the research project. If any privacy or data security arrangement is violated, either through physical tampering or breach of confidentiality, the individual making the discovery will immediately notify Dr. Servin and the SYH research team. Dr. Servin will immediately report this breach to the UCSD IRB. Dr. Servin and SYH will take immediate efforts to identify the breach, remedy it, and terminate employment of anyone directly causing it. Participants' names and other identifying information will not be used in any reports or publications.

There are some circumstances in which confidentiality will be breached by the researchers. If the participant directly informs research staff of his/her intentions of homicide or suicide, the researcher will immediately contact authorities (police or mental health) to help address the issue. However, as part of informed consent we will let all participants know this, and we do not directly assess these issues via our data collection processes. These issues have not arisen, to our knowledge, in the past across similar projects in similar contexts. Finally, if any participant reports being hurt by another person or harming another person, SYH, as mandated reporters, will contact local law enforcement. We will also inform participants of this during the informed consent process, and before data collection begins.

Data and Safety Monitoring Plan: Data and safety monitoring of study participants will focus on two major safety aspects: 1) assurance that no harm comes to participants as a result of research participation and 2) assurance that all data collection from this study maintains the privacy of research participants. Major mechanisms of precaution include the use of confidential and anonymous data. Data provided to UCSD from surveys and FGs will include no personal identifiers. Survey data and audio-recordings of FGs maintained for this study will only be labeled with unique participant identifiers; no names or other identifiers will be stored with any data collected. Only participants' first names and the Google Voice number associated with their account will be saved during the recruitment and scheduling process for the 2nd dose of the vaccine. Once the applicable data collection activity is complete, these will be immediately and permanently deleted.

All physical data collected (i.e., audio files from FGs) from this study will be transcribed and translated from Spanish to English without personal identifiers prior to electronic storage, coding, management, and analysis. Original copies of audio files that may include personal identifiers will be destroyed after transcription and/or translation are complete. Prior to translation, audio files will be secured by immediately uploading them to an encrypted server and password protected file on a UCSD computer and the audio file from the recording device will be deleted. Audio recordings of FGs will be de-identified in the process of transcription and the audio file will be deleted after it has been transcribed and verified.

All research staff collecting and translating or transcribing data from this study will sign an agreement in which they agree to maintain absolute confidentiality of all participants within this research project. All survey and FGs data analyses will occur at UCSD; electronic files will be kept on an encrypted shared project drive within UCSD's protected network. Data files on the online server and at UCSD are backed up every night to minimize the likelihood of lost files. As described above, all data with personal identifiers or that link data to personal identifiers will be destroyed as soon as it is no longer needed, i.e., after transcription or translation, or after completion of 2nd dose/follow-up survey data collection.

Additionally, to minimize any potential risks, all research staff under the direction of Drs. Servin and Muñoz will attend a three-day training where they are trained in supportive techniques and procedures to protect the confidentiality of participants, to ask sensitive questions without judgment, and to assess participants for signs of distress during and upon completion of the survey and receiving the vaccine. If a participant is upset or distressed at any point during data collection, the research staff are trained to offer the opportunity to speak privately with an on-site SYH counselor trained in the provision of brief mental health counseling; the counselor will refer participants to follow-up services if longer-term

assistance is needed. Lastly, a policies and procedures manual for the project will specify immediate data monitoring and response. Participants will be informed during the consent procedure that confidentiality may be breached under certain circumstances (i.e. they are a danger to themselves or others). In cases where a breach of confidentiality is necessary, project staff will be instructed to report to the project coordinator, who will file an incident report with Dr. Servin within 24 hours. The incident report requires a detailed account of the problem, date of occurrence, date it came to the PI's attention, impact on participant and corrective action taken. Dr. Servin will report adverse events to the UCSD IRB to make a determination if the event was related to research, directly or indirectly, and, if so, require revisions of protocol or consent, as applicable, and re-review of these procedures by the IRB with copies to the Office of Human Subjects for any necessary further action. Project staff hired through UCSD will be required to obtain ethical training through the CITI program (i.e. Social-Behavioral course) so that they are aware of the responsible conduct of research, and the types of adverse events that may warrant a breach of confidentiality. Monitoring of potential adverse effects or serious problems will be given high priority by project staff and researchers. All project staff will receive verbal and written instructions pertaining to the rules governing the maintenance of confidentiality upon completion of the study or if they leave the study before its completion.

16. POTENTIAL BENEFITS

The results of this study will inform local and national scale-up efforts of interventions designed to address vaccine hesitancy and increase access, acceptance, uptake and series completion of the COVID-19 vaccine among Latinx and AA adults in the U.S. Even if the intervention proves ineffective at increasing access, acceptance, uptake, and series completion of the COVID-19 vaccine among Latinx and AA communities, this information is valuable to the development of more effective models in the future and to inform efforts to ending the pandemic. Based on the study design and the nature and severity of COVID-19 infection, the potential knowledge gained from this study outweighs any potential risk and will have an impact on the health of Latinx and AA communities in San Diego that have been severely impacted by the pandemic.

17. RISK/BENEFIT ASSESSMENT

Based on previous research and efforts towards the COVID-19 vaccine development and subsequent FDA Emergency Use Authorization, we know that there is a demonstrated benefit of receiving the COVID-19 vaccine and addressing vaccine hesitancy among racial/ethnic minorities that have been severely impacted by the pandemic is critical. Health benefits are hypothesized and determining this is the purpose of the research study. Study participants will receive COVID-19 Individual Awareness & Education, COVID-19 Community Outreach & Health Promotion, COVID-19 Individual Health Education & Linkages to Medical and Supportive Services and provision of COVID-19 vaccine at participating SYH community centers and mini-vaccination stations in the communities where they live. Due to the severity of COVID-19, the high rates of infection and deaths among AA and Latinx communities and the current low uptake of the vaccine (only 14% of Latinx and 3% of AA have received at least one dose of a coronavirus vaccine compared to 60% of White individual)[10,11] we believe that the *2VIDA!* intervention is promising and the AA and Latinx communities will benefit in receiving the intervention – which centers on providing medical education and increasing access to the vaccine.

18. QUALIFICATIONS, TRAINING, CULTURAL LITERACY AND ROLES OF THE PI AND RESEARCH TEAM

Britt Skaathun, PhD, MPH (Principal-Investigator). Dr. Skaathun is an Assistant Professor in the IDGPH at UCSD and an epidemiologist whose research examines the intersection of social environment factors, venues (both physical and virtual), and networks, and how they can be considered simultaneously to maximize the uptake of biomedical interventions by populations experiencing high rates of infectious diseases. She utilizes a combination of methodologies, including epidemic modeling, social network analysis, and cost-effectiveness methods to produce evidence-based results that inform intervention and policy in diverse contexts. Dr. Skaathun's efforts are paramount to the implementation, analysis, and dissemination of findings regarding effectiveness and implementation of 2VIDA! at scale.

Davey Smith MD, MAS (Co-Investigator). Dr. Smith is a Professor of Medicine and Chief of the IDGPH at UCSD. Dr. Smith has a broad background in clinical infectious diseases, clinical trials, health disparities, virology diagnostics, and

molecular virology. Dr. Smith has extensive experience leading and participating in large projects, including large multinational projects, including multinational trials in the AIDS Clinical Trials Group (ACTG) and the San Diego Center for AIDS Research (CFAR). These experiences will serve the proposed intervention well for its successful completion. Since the outbreak of SARS-CoV-2 in 2019, Dr. Smith has been actively engaged in the international effort to find safe and effective treatments as well as cost effective daily screening tools to detect SARS-CoV-2 among asymptomatic healthcare workers. As Co-Investigator for the proposed study, Dr. Smith will provide expertise on the framework, implementation strategies, study design, and evaluation for wide dissemination of the proposed study.

Jamila K. Stockman, PhD, MPH (Co-Investigator). Dr. Stockman is a Vice Chief and an Associate Professor in the IDGPH and the Director of the Disparities Core at UC San Diego's Center for AIDS Research. Dr. Stockman is an epidemiologist by training and her research focuses on the intersecting epidemics of intimate partner violence and sexual violence, HIV acquisition and transmission, and substance abuse among marginalized populations. She is working to advance understanding of the underlying immunological and physiological mechanisms linking these epidemics and develop interventions that provide maximal reductions in HIV, substance abuse, and violence against women. Currently, she conducts her work in the US, US-Mexico border region, Latin America, and Caribbean. In addition to her research, Dr. Stockman actively collaborates with local public health departments and community-based organizations to ensure ethical and cultural appropriateness of her research among members of the community.

Brittany Wood, MPH (Data Analyst). Brittany is a Research Data Analyst in the IDGPH. She received her Bachelor of Arts in Sociology with a minor in Counseling and Social Change from San Diego State University. She also received her Master of Public Health degree with a concentration in Epidemiology from San Diego State University. She currently works with Dr. Jamila K. Stockman on the THRIVE, ESSENCE, and Connect the DOTS studies. Brittany's interests center around health disparities research, particularly among women and LGBTQ populations. From her work in previous research labs, she is experienced with data management, data cleaning, statistical analysis, and scientific writing.

Ricardo Vera-Monroy, MS (Data Management). Ricardo is a bilingual research associate with the Center on Gender Equity and Health & the Department of Medicine at UCSD, where he has worked in various domestic and international research projects focused on sex-trafficking, gender-based violence and HIV prevention and underserved and marginalized populations such as youth-at-risk and Female Sex Workers. His work primarily focuses on creating and managing data collection systems as well as assisting with data management and analysis.

Sophie O'Bryan, BS (Research Project Coordinator). Sophie is a Research Project Coordinator with the IDGPH. She received her Bachelor of Science in Biology and Biotechnology from Tufts University in 2019. After working as a Clinical Research Coordinator at Well Cornell Medicine for two years she joined our team. Sophie is dedicated to promoting health equity through providing access to comprehensive and non-judgmental healthcare for all. Before joining the iSTRIVE research lab, she volunteered with Planned Parenthood, campaigning for accessible sexual and reproductive healthcare and strengthening her commitment to patient advocacy. She is motivated to continue to eliminate health disparities through conducting innovative research and uplifting the voices of underserved communities.

Raquel Rocha, IMG (Research Assistant). Raquel is a bilingual International Medical Graduate (IMG) with training in preventive medicine and infectious diseases. Raquel has a strong interest in addressing health disparities and enjoys being in the community and conducting CBPR. She will provide support for data collection efforts.

Fatima Muñoz, MD, MPH (Co-Investigator). Dr. Muñoz is the Director of Research and Promotion at SYH. She has extensive experience engaging a variety of public health issues and building strong bridges between public health leaders on both sides of the U.S.-Mexico border region. Her research emphases include HIV prevention and treatment, chronic disease, cervical and breast cancer, tuberculosis, substance use, and the impact that bi-national access to care has on health policy. This research has involved the use of community-based participatory research (CBPR) models with a specific emphasis on marginalized populations and vulnerable groups. Dr. Muñoz will be responsible for initial meetings and set up of research activities taking place under the proposed project. She will assist in gathering required information to set up sub-award at SYHealth, facilitating meeting space for planning meetings, gathering all required information for IRB submission and planning project activities. Dr. Muñoz will provide expertise, oversight and leadership at SYH on all aspects of the study (along with Dr. Servin, PI) and will also be responsible for serving as a liaison between the project and SYH providers.

Gregory Talavera, MD, (Co-Investigator). Dr. Talavera is a practicing physician at SYH and the Medical Director for the South Bay Latino Research Center (SBLRC). He is bilingual bicultural physician scientist with more than 30 years in clinical practice, epidemiology and disparities research most of which has focused on psychosocial, clinical and behavioral dimensions of chronic disease prevention and control. Dr. Talavera practices ambulatory family medicine in the communities where this study will occur. He has an intimate knowledge of the health and welfare of the Latinx and AA adults as well as the social context in which this occurs. As a licensed physician at SYH in ambulatory family medicine and with over 30 of experience in public health and direct patient care, Dr. Talavera (Co-Investigator) will oversee implementation of the COVID-19 vaccine based on the FDA and CDC guidelines.

San Ysidro Health (SYH) is a non-profit Federally Qualified Health Center (FQHC) committed to providing high quality, compassionate, accessible and affordable health care services, with a mission to improve the health and well-being of the communities we serve with access for all. Originally established along the border in 1969 by seven women in search of medical services for their children, SYH is now one of the most trusted and leading providers of comprehensive safety net primary health care and support services across San Diego County. SYH primarily serves the *South Bay Region* (61% Latino), with recent expansion into 6 clinics and 1 community center in the *East County Region* (28% Latino). SYH serves a predominantly racial and ethnic minorities (85%), with high rates of poverty (69% live below the federal poverty level), uninsured individuals (21%) and families with low educational attainment and non-English speaking heads of households. As the largest community partner on this proposal, SYH will build upon existing experience with, and trust established in the local Latinx and AA communities to guide the data collection efforts of *2VIDA!* health promotion and education outreach efforts, establishment of the mini-vaccination stations and COVID-19 vaccine delivery. As a practicing licensed physician at SYH and with over thirty years of experience in public health and direct patient care, Dr. Talavera (Co-Investigator) will oversee implementation of the COVID-19 vaccine based on the FDA and CDC guidelines. Dr. Muñoz will supervise overall data collection and outreach efforts along with Dr. Servin (PI) to accomplish the study objectives.

19. FUNDING FOR THIS PROJECT

National Institute on Minority Health and Health Disparities (NIMHD).

20. CONFLICT OF INTEREST

Neither the PI nor any key personnel associated with this study have any financial interests or other "conflicts" related to this study.

21. BIBLIOGRAPHY (1 page maximum)

1. Centers for Disease Control and Prevention (CDC). Vaccine recommendations and guidelines of the ACIP: COVID-19. Available from: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html. Accessed on Dec 28, 2020.
2. World Health Organization (WHO). Weekly epidemiological update – 12 January 2021. 2021. Available from: https://www.who.int/publications/m/item/weekly-epidemiological-update---12-january-2021.
3. Johns Hopkins University Center for Systems Science and Engineering (JHU CSSE). COVID-19 data repository by the center for systems science and engineering (CSSE) at Johns Hopkins University. Available from: https://github.com/CSSEGISandData/COVID-19. Accessed Jan 11, 2021.
4. Centers for Disease Control and Prevention (CDC). Infographic presenting table of COVID-19 cases, hospitalizations, and deaths, by race/ethnicity. 2020. Available from: https://www.cdc.gov/coronavirus/2019-

ncov/community/health-equity/racial-ethnic-disparities/infographic-cases-hospitalization-death.html#:~:text=As%20of%20November%2027%2C%202020,higher%20among%20Black%20or%20African. Accessed on Feb 5, 2021.
5. Hooper MW, Nápoles AM, Pérez-Stable EJ. COVID-19 and racial/ethnic disparities. JAMA. 2020;323(24):2466-2467. doi:10.1001/jama.2020.8598
6. Scharff DP, Mathews KJ, Jackson P, Hoffsuemmer J, Martin E, Edwards D. More than Tuskegee: understanding mistrust about research participation. *J Health Care Poor Underserved*. 2010;21(3):879-897. doi:10.1353/hpu.0.0323
7. U.S. Food & Drug Administration (FDA). FDA guidance on conduct of clinical trials of medical products during COVID-19 pandemic, guidance for industry, investigators, and Institutional Review Boards. 2020. Available from: https://www.hhs.gov/ohrp/sites/default/files/fda-covid-guidance-2apr2020.pdf. Accessed on Jan 8, 2021.
8. Wagner GA, Pacold ME, Kosakovsky Pond SL, Caballero G, Chaillon A, Rudolph AE, Morris SR, Little SJ, Richman DD, Smith DM. Incidence and prevalence of intrasubtype HIV-1 dual infection in at-risk men in the United States. J Infect Dis. 2014 Apr 1;209(7):1032-8. doi: 10.1093/infdis/jit633. Epub 2013 Nov 22. Erratum in: J Infect Dis. 2014 Oct 1;210(7):1166.
9. Munawwar A, Singh S. Human Herpesviruses as Copathogens of HIV Infection, Their Role in HIV Transmission, and Disease Progression. J Lab Physicians. 2016;8(1):5-18. doi:10.4103/0974-2727.176228
10. Recht H and Weber L. As Vaccine Rollout Expands, Black Americans Still Left Behind. Kaiser Health News. 2021. Available at: https://khn.org/news/article/as-vaccine-rollout-expands-black-americans-still-left-behind/. Accessed on Jan 31, 2021.
11. Nicquel Te. White people are getting vaccinated at higher rates than Black and Latino Americans. https://www.cnn.com/2021/01/26/us/vaccination-disparities-rollout/index.html. Accessed on Jan 27, 2021.
12. COVID-19 Prevention Network. 3 reasons to continue COVID-19 vaccine research. Available from: https://www.coronaviruspreventionnetwork.org/covid19-vaccine-continuation/.
13. United States (U.S.) Census Bureau. 2019. Population by race in the U.S., 2019 American Community Survey 1-Year Estimates. Available from: https://data.census.gov/cedsci/profile?q=United%20States&g=0100000US. Accessed on Jan 15, 2021.
14. Szilagyi PG, Thomas K, Shah MD, Vizueta N, Cui Y, Vangala S, et al. National trends in the US public's likelihood of getting a COVID-19 vaccine—April 1 to December 8, 2020. JAMA. 2021;325(4):396-398. doi:10.1001/jama.2020.26419
15. Malani P, Singer D, Solway E, Kirch M, Kullgren J. Older adults' perspectives on a COVID-19 vaccine. University of Michigan National Poll on Healthy Aging. 2020. Available at: https://www.healthyagingpoll.org/report/older-adults-perspectives-covid-19-vaccine.
16. Rodriguez-Diaz CE, Guilamo-Ramos V, Mena L, Hall E, Honermann B, Crowley JS, et al. Risk for COVID-19 infection and death among Latinos in the United States: examining heterogeneity in transmission dynamics. Ann Epidemiol. 2020;52:46-53.e2. doi:10.1016/j.annepidem.2020.07.007
17. National Institute on Minority Health and Health Disparities (NIMHD). NIMHD research Framework. 2017. Available from https://www.nimhd.nih.gov/about/overview/research-framework.html. Accessed on Dec 20, 2020.
18. Wallerstein N, Duran B. Community-based participatory research contributions to intervention research: the intersection of science and practice to improve health equity. Am J Public Health. 2010; 100(Suppl 1): S40–S46. doi: 10.2105/AJPH.2009.184036.
19. Crabtree BF and Miller WL. Doing Qualitative Research. Thousand Oaks, Calif. 1999. Sage Publications.
20. Kirk M, Tribe I, Givney R, Raupach J, Stafford R. Computer-assisted telephone interview techniques. Emerg Infect Dis. 2006 Apr;12(4):697; author reply 697-8. doi: 10.3201/eid1204.050756. PMID: 16715578; PMCID: PMC3298272.
21. Doyle C, Jackson D, Loi S, Malta S, Moore K. Videoconferencing and telementoring about dementia care: evaluation of a pilot model for sharing scarce old age psychiatry resources. Int Psychogeriatr. 2016 Sep;28(9):1567-74. doi: 10.1017/S1041610216000740. Epub 2016 May 18.PMID: 27189501
22. Gentles SJ, Charles C, Ploeg J, McKibbon K. Sampling in Qualitative Research: Insights from an Overview of the Methods Literature. *The Qualitative Report*. 2015; *20*(11), 1772-1789.

23. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers) Emergency use authorization (EUA) of the Pfizer-Biontech COVID-19 vaccine to prevent Coronavirus disease 2019 (COVID-19). 2021. Available from: https://www.fda.gov/media/144413/download.