

**Cover Page for ClinicalTrials.gov**

**Document:** Informed Consent Form

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

**NCT number:** NCT05022472

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## 2VIDA! Digital Survey Consent Form – English



You are being invited to participate in a research study titled *2VIDA!* This study is being done by Dr. Argentina Servin from the University of California, San Diego (UCSD) and Dr. Fatima Muñoz from San Ysidro Health (SYH). You were selected to participate in this study because you are an individual 16+ years or older living in San Diego that is eligible to receive the COVID-19 vaccine. We will recruit 1000 individuals to participate in this study.

The purpose of this research study is to understand the barriers that Latinx and African American communities are facing to accessing the COVID-19 vaccine as well as inform the Latinx and African American community about the risks and benefits of the COVID-19 vaccine by providing medically accurate information and places where individuals can receive additional information and if they are interested, receive the vaccine at a location close to home or work. If you agree to take part in this study, you will be asked to complete a survey today on a tablet. This survey will ask about the difficulties that Latinx and African American communities are facing to get medically accurate information about the COVID-19 vaccine, and it will take you approximately 20 minutes to complete. Further, if you are interested, you may be eligible to receive the COVID-19 vaccine during your visit today. Choosing to participate or not participate in this survey research project will not impact your ability to receive the COVID-19 vaccine. You do not have to complete this survey to receive the COVID-19 vaccine.

There may or may not be any direct benefit to you from this research. The investigators may also learn more about the difficulties our communities are facing to access COVID-19 resources and utilize this information to improve information and access to the COVID-19 vaccine.

There are risks associated with this research study. One possibility is the loss of confidentiality as a result of participating in this study. Only the primary researchers and their assistants will have access to your information. We will not share your information with anyone but the study team. You will be given a participant number/code ID number to avoid having your name written on any documents. All of your personal information will be kept on a password protected secure server at UCSD that only research staff of our project are able to access. Research records will be kept confidential to the extent allowed by law and may be reviewed by the UCSD Institutional Review Board, the San Ysidro Health Review Board and the National Institutes of Health (NIH). Your participation is voluntary, and you may ask to end the survey at any time.

This research is covered by a Certificate of Confidentiality from NIH. Researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research *unless* there is a federal, state, or local law that requires disclosure (such as to report child abuse, elder abuse, intent to hurt self or others, or communicable diseases), you have consented to the disclosure, including for your medical treatment; or it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institute on Minority Health and Health Disparities which is funding the project or for information that

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must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA). You should also understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the research to release it.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

Another potential risk is nervousness or discomfort of having to complete a survey or at the prospect of receiving the COVID-19 vaccine (e.g., swelling or pain in the injected area). We have a group of physicians and nurses on staff that can answer all your questions in regard to the survey and/or COVID-19 vaccine (e.g., risks, benefits, side effects).

Further, if you are injured as a direct result of participation in this research, the University of California San Diego (UCSD) will provide any medical care you need to treat those injuries. The University of California San Diego will not provide any other form of compensation to you if you are injured. You may call the UCSD Human Research Protections Program Office at +001-858-246-HRPP (+001-858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems. UCSD will only be responsible for injuries which are directly related to study participation and caused by UCSD employees performing research activities within the course and scope of their UCSD employment.

Because this is a research study, there may also be some risks that we don't know of and can't know at this time. You will be informed of any important new findings. Other than your time, there are no costs to you for participating in this study. Likewise, it is also important to mention that due to the nature of this study, the researchers may also withdraw you from the study at any time without your consent.

You will receive a \$20 VISA gift card to thank you for your time in completing the survey today. Additionally, when you complete the second survey in 21 days, when you return for your second dose of the COVID-19 vaccine, you will receive an additional \$20 VISA gift card to thank you for your time in completing that survey. If you chose a one dose vaccine, you will receive an email or text message with a link to complete a 5-min survey in 21 days. If you have difficulties using technology or don't have access to a smartphone or computer someone from our research team can assist you over the phone to help you complete the follow-up survey. After you complete the survey, you will receive a link for a \$20 VISA gift card. You will receive this compensation even if you choose not to answer all the questions. There will be no cost to you for participating in this study.

Your participation in this study is completely voluntary and you can withdraw at any time by simply exiting the survey. Choosing not to participate or withdrawing will result in no penalty or loss of benefits or health care to which you are entitled. You are free to skip any question that you choose.

If you have questions about this project or if you have a research-related problem, you may contact the researcher(s), Dr. Argentina Servin at (619) 576-7211 or Dr. Fatima Muñoz at (619) 662-4100 (extension: 2933) . If you have any questions concerning your rights as a research subject, you may contact the UCSD Human Research Protections Program Office at 858-246-HRPP (858-246-4777).

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By clicking “You agree” below you are indicating that you are at least 16 years old, have read this consent form, and agree to participate in this research study. Please let us know if you would like to email this consent to yourself or have us print a copy for your records.

You  
Agree

You Do  
Not Agree