Official Title: Identifying and addressing critical social, ethical, and behavioral factors associated with COVID-19 testing and vaccination among Spanish speakers

NCT05302908

IRB Approved Date: 05/20/24

ADVOCATE HEALTH Wake Forest University School of Medicine

Division of Public Health Sciences

Department of Social Sciences and Health Policy

IDENTIFYING AND ADDRESSING CRITICAL SOCIAL, ETHICAL, AND BEHAVIORAL FACTORS ASSOCIATED WITH COVID-19 TESTING AND VACCINATION AMONG SPANISH SPEAKERS

Informed Consent Form to Participate in Research

Post-Intervention Interview - *Navegante*

Scott D. Rhodes, PhD, MPH, Principal Investigator

1. Summary

You are invited to participate in a research study. The purpose of this research study is to better understand the factors that influence COVID-19 testing and vaccination among Spanish-speaking Latines communities and test the *Nuestra Comunidad Saludable* program. You are invited to be in this phase of the study because you have participated as a *Navegante* in this intervention program.

Your participation in this phase of the study will involve an interview that will last about 60 minutes. All research studies involve some risks. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life. You may or may not benefit from participation in this phase of the study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Your alternative is to not participate in this study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator, Dr. Scott D. Rhodes. His contact information is [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted].

2. Introduction

You are invited to be in a research study. Studies help researchers learn new information that may help other people in the future. You are being asked to be in this phase of the study because you have participated as a Navegante in the *Nuestra Comunidad Saludable* program. Your

participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask the researchers to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

Your participation in this phase of the study will take place via telephone or web-conferencing platforms.

3. Why Is This Study Being Done?

The purpose of this research is to better understand the factors that influence COVID-19 testing and vaccination among Spanish-speaking Latine communities and test *Nuestra Comunidad Saludable*, a program to increase COVID-19 testing and vaccination within these communities.

4. Who is Sponsoring this Study?

This study is being sponsored by the National Institutes of Health (NIH). The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

5. How Many People Will Take Part in the Study?

A total of 10 individuals will take part in this study who participated as *Navegantes* during the program.

6. How Long Will I Be in the Study?

Your participation in this phase of the study will be during one interview which will last about 60 minutes.

7. What Is Involved in the Study?

If you choose to participate, you will be asked to participate in an interview via telephone or web-conferencing platforms. We will ask you questions about your experiences as a *Navegante* in the *Nuestra Comunidad Saludable* program, your experiences promoting COVID-19 testing and vaccination among Spanish-speaking Latines in your communities, and your experiences with other health services and support from family, friends, and community. The information you share with us will help to improve healthcare access for Spanish-speaking Latines in North Carolina. There are no wrong answers. As part of these interviews, you will be audio recorded. This is done because what you have to say is important and to enable study staff to accurately transcribe the interviews. You understand that you may request the recording be stopped at any time during the course of the research study. If you ever want the audio recorder turned off, just let the researchers know and they will do that. You can also withdraw your consent to use and disclose the audio recording before it is used. You should also understand that you will not be able to inspect, review, or approve the audio recordings before they are used in this study. The audio recordings will be destroyed once their use in this study is finished.

8. Will I receive the results of the study?

Research results that are not clinically relevant will not be disclosed to you.

9. What are the risks of the study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life. However, talking about life experiences and health can sometimes be uncomfortable. **You will never be required to discuss anything that makes you feel uncomfortable.** You should discuss the risks of being in this study with the study staff.

Taking part in this research study may involve providing information that you may consider confidential or private. Efforts, such as coding research records, keeping research records secure, and allowing only authorized people to have access to research records, will be made to keep your information safe.

10. Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be a direct benefit to you. We hope what is learned from this study will benefit you and other people in the future. The benefits of taking part in this study may be more access to culturally appropriate materials and increased community awareness about COVID-19 and local resources.

11. What Other Choices Are There?

You do not have to participate in this study. This is not a treatment study. Your alternative is to not participate in this study.

12. What Are the Costs?

There are no costs to you for taking part in this study. All study costs will be paid for by the study.

13. Will You Be Paid for Participating?

You will receive $60.00 to complete the interview.

14. Will Your Research Records be Confidential?

Your participation in this research and any study records created about your participation will be kept as confidential as possible. The overall results of this study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be shared unless you give your permission or are required by law to protect you or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your

identity.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

15. What if I am harmed from being in the study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life.

16. WHO WILL SEE MY PROTECTED HEALTH INFORMATION?

Who may have access to my information:	***Purpose:***
Any sponsor, including future sponsors, of the study and anyone working on behalf of a sponsor or future sponsor	To oversee the study and make sure the information is correct.
Consultants and employees of Advocate Health – Wake Forest University School of Medicine, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research	To make sure applicable laws are being followed.

Protections (OHRP), or similar government agencies in the US and other countries).	
Organizations that grant accreditation to hospitals and research programs.	For Advocate Aurora Health to remain accredited.
Monitors, auditors, IRB, or other regulatory agencies may be granted direct access to your medical record.	To verify clinical trial procedures or data.

By signing this form, you are giving the researchers permission to use and share your personally identifiable health information.

Please note that the study staff may also share personal information about you if required by law (for example, if the study staff suspects that you are going to harm someone or yourself, reporting of communicable disease (HIV, hepatitis, tuberculosis, etc.). If you have questions about this, please ask the study staff.

How will my information be used for this study?
You must authorize the use and sharing of your information by signing this form or you cannot be in the study.

The study principal investigator and study staff will collect, use, and share identifiable health information about you for the following reasons:

- to conduct this research study.
- to review the study, and to check the safety and results of the study.
- to seek government approval of an investigational study drug, vaccine, device, or product if such was involved in the trial.
- to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

- information collected about you during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number, demographic information, information about health attitudes and behaviors, and/or other identifying information.

How will my information be kept confidential?
We will keep your personal health information as confidential as possible. We will store records in a cabinet in a locked office or on a password-protected computer. Your identity will be

protected as required by law and according to any policies described in the study consent form. Researchers may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually, the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead, a code number is used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves the organization, we cannot control how it is used, and the law may not require other groups to protect the privacy of your information.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally will have access to your health information.

How do I cancel my authorization?

You can cancel your authorization to use and share your information at any time by writing a letter to the principal investigator. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

Dr. Scott D. Rhodes

If you cancel your authorization, no new information will be collected without your permission. The study staff will still be able to use and share the information that has already been collected to maintain the integrity of the study.

When will my authorization expire?

This authorization to use and share your information expires at the end of the research study when data analysis is complete, and study records have been destroyed.

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

17. What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or

loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

You may be asked to complete a survey about your experiences participating in a research study.

18. Whom do I call if I have questions or problems?
For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Scott D. Rhodes at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact [redacted]

You will be given a copy of this consent form.

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one, or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By providing consent, I am not releasing or agreeing to release the investigator, the sponsor, the institution, or its agents from liability for negligence.