

Cover Page

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Project Title:	Enhancing SARS-CoV-2 Rapid Testing Acceptance in Latinx Communities
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Consent for Research Participation

Project Organizer: Oregon Saludable: Juntos Podemos

Project Title: Enhancing SARS-CoV-2 Rapid Testing Acceptance in Latinx Communities

Sponsor: National Institutes of Health

Researcher(s): Dave DeGarmo, Leslie Leve, Jorge Ramírez García, Ellen McWhirter, University of Oregon

Researcher Contact Info: 541-650-2562 | osjp@uoregon.edu

You are being asked to take part in a research study. Below is information about this research. Please let us know if you have any questions.

Who is leading this research?

Dr. Dave DeGarmo, a professor and faculty member at the University of Oregon is leading this research with Dr. Leslie Leve, who is also a professor at the University of Oregon. They are asking for your consent to participate in this study.

This study is one of many studies that is part of a larger group of studies designed to increase COVID-19 testing in communities. This project is organized by Oregon Saludable: Juntos Podemos (OSJP) and funded by the NIH. The NIH stands for the National Institutes of Health. The NIH supports health research, including the RADx-UP program. RADx-UP stands for Rapid Acceleration of Diagnostics - Underserved Populations. RADx-UP is a COVID-19 research program.

What is the purpose?

The purpose of this study is to see if we can improve health behaviors among people who come to events where we are distributing free COVID-19 rapid testing kits. We would also like to see if talking about personal experiences changes how people think and behave.

Who can participate?

You are being asked to participate because you're attending today's Mexican Consulate event. To participate, you must be 18 years of age or older and have not joined the study before.

What does it mean to take part in a research study?

Research studies include only people who agree to be in them. Before you decide to be in this study, you should read this whole form and ask questions so we can answer them. Being in research is your choice. You do not have to be in this study and whatever you decide is ok. If you decide to be in this study, you can change your mind and leave the study at any time by telling the research team. You can choose to skip any question you choose not to answer.

What do I need to do for this study?

If you join this study, we will gather data (information) from you. Examples of the data that we will collect may include, but are not limited to:

- Your name and contact information
- Race, ethnicity, gender, or languages spoken

- Medical history
- Your health insurance status, disabilities, or job
- COVID-19 symptoms, test results, vaccination, and treatments
- Your schooling, family, home, and social life

We will ask you to participate in two surveys over the course of about 1 month. The surveys you will ask questions about you and your health behaviors.

TODAY'S SURVEY: You are being asked to take part today by completing a survey that takes about 30-45 minutes. You can complete it on paper, have it read to you, use a study iPad, or use your own device by scanning a QR code. You would receive a \$30 gift card for participating in the survey.

SURVEY IN 1 MONTH: We may ask you to complete another survey in about 1 month. You will tell us in the survey today how you would like us to contact you for the survey in 1 month. You can choose to receive the survey in a few different ways. You can choose to receive a link by text or email, to complete it by phone with a staff member, or we can mail it to you with a pre-paid return envelope. You will receive \$30 gift card for completing this second survey, which will take about 30-45 minutes to complete. You can choose in the survey if you want to receive your \$30 gift card by mail or by email. We may also contact you via email, text, phone or mail about your participation in this study. There is a risk that people around you will learn that you are in the study because of this communication. Please let us know if there are ways we should not contact you.

The site where you receive free COVID-19 rapid testing kits will have staff members talking with people about health behaviors. The goal of this conversation is to improve health behaviors and reduce the spread of COVID-19. Conversations with the staff members will last around 5-15 minutes.

What are the benefits to me?

You may benefit from sharing your thoughts and experiences and improving your health behaviors and reducing the spread of COVID-19.

Are there any risks to me?

The risks to you are very small. You could feel uncomfortable answering questions about stressful things that happen to you. There is a possible risk that someone might see your information when they do not have permission.

What will happen to all the information?

We will use the information you provide to answer research questions about improving health behaviors to reduce the spread of COVID-19. Researchers will write papers to share in scientific journals or in reports to community organizations. You will never be identified in any of these reports. A description of this clinical trial will be available on www.clinicaltrials.gov. This website will not include information that can identify you. You can search this website at any time.

Duke was chosen by the NIH to hold the data from all RADx-UP studies. Duke will keep your data securely. This means with extra protection. Researchers will use the data to learn more about COVID-19.

Duke will build two RADx-UP databases. Databases are systems that hold electronic information.

The first database will only hold data that can easily identify you. These data are called identifiable data. Examples include your name, address, email, and phone number, among others.

- Duke will not share your identifiable data with others.
- Your data will be stored securely. Only study staff approved by a research ethics committee will be able to see your data.
- You will initial below if you would like to share identifiable data with Duke. This will allow researchers in the future to contact you about other kinds of research studies.

The second database will not hold data that can easily identify you. It will hold all of your other data.

- Your data will be assigned a study code. Your data will only be identified in this database by this study code.
- Your data may be linked with other data using your zip code. This linked data will tell us more about the area where you live.
- We will transfer these data to a secure NIH database. These data will not be able to identify you.
- Other researchers may use these data for future studies.
- We will not ask your permission before sharing these data because they are non-identifiable.

How will you keep my information safe?

We will keep information and the surveys we collect during this study locked up. We will do everything we can to make sure nobody will know who you are except the people doing the research. We will enter and store your personal information on secure computers. We can use or share your information in ways that nobody can tell it came from you. If you say it's okay, we will share your identifiable information with the Duke Clinical Research Institute (DCRI). If you do not want to share your information with the DCRI, you can still take part in our study.

Your privacy is important. We will take great care to protect your privacy. But, privacy cannot be guaranteed. Below are a few steps we will take to protect your privacy.

- Data will be collected via secure applications.
- Data will be stored on secure computer systems.
- Paper data will be stored in secure, locked areas.
- We will limit and keep track of who can see your data.
- Your data will be protected by a password and multi-factor authentication.
- We will take steps to protect your data from others that should not be able to see it.
- We will not share data that can identify you.

Are there exceptions to confidentiality?

Everything you say will be kept confidential, unless there is a risk that you may hurt yourself or there is a risk that someone else may get hurt. Then we would need to tell someone. This project has a Certificate of Confidentiality (CoC) from the NIH. A CoC protects your identifiable data from all legal proceedings. Data from this study that identifies you will not be shared outside this research unless you consent. No one can be forced to share your identifiable data for a lawsuit. This is true even if there is a court order.

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact Sarai Villalobos at 541-650-2562 or osjp@uoregon.edu



You may also contact the Office for Research Protections at (541) 346-2510 if you have questions about your rights as a person in a research study or have any concerns related to the research.

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions about my participation. I understand that I can ask more questions at any time.

I am 18 years of age or older. I understand that by signing below, I volunteer to take part in this research. I understand that I am not waiving any legal rights. I will receive a copy of this consent form.

Yes, I agree to participate _____ (sign)

No, I do not agree

CAN WE SHARE YOUR INFORMATION WITH THE DCRI?

I agree to let Duke University collect my identifiable information. This includes name, address, and contact information.	<input type="radio"/> Yes, I agree _____ (initials) <input type="radio"/> No, I do not agree _____ (initials)
I agree to let the DCRI collect my zip code .	<input type="radio"/> Yes, I agree _____ (initials) <input type="radio"/> No, I do not agree _____ (initials)
I agree to be contacted for future research.	<input type="radio"/> Yes, I agree _____ (initials) <input type="radio"/> No, I do not agree _____ (initials)