Cover Page

Official Title: Scaling Up SARS-CoV-2 Testing to Serve Latinx Communities

Brief title: COVID-19: Healthy Oregon (Oregon Saludable): Together We Can (Juntos Podemos) (OSJP)

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Consent for Research Participation

Title:	Scaling Up SARS-COV-2 Testing to Serve Latinx Communities: Individual Surveys to Assess Health Behaviors (Oregon Saludable: Juntos Podemos/OSJP)
Sponsor:	National Institutes of Health
Researcher(s):	Leslie Leve, William Cresko, David DeGarmo, University of Oregon
Researcher Contact Info:	541-346-9530 kelseyvb@uoregon.edu

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research is to test whether a promotores intervention can improve health behaviors among community members who receive COVID-19 testing.
- **Duration.** It is expected that your participation will last 1 month. During the 1 month, you will be asked to participate in two surveys lasting 30 minutes each and may also be invited to participate in an intervention. If your site was selected for the intervention, you will have the opportunity to talk with a promotor to learn about health behaviors to reduce the spread of COVID-19.
- **Procedures and Activities.** You will be asked to complete a survey that includes information about your contact information and health behaviors. We will ask you to complete the survey once at the beginning of the study and once about one month later. The site where you receive testing at may be randomly assigned to provide an in-person promotor intervention to provide information about health behaviors. Being part of this intervention would include engaging with a promotor to learn more about health behaviors to reduce the spread of COVID-19. A goal of the intervention is to see if this intervention will improve health behaviors to reduce the spread of COVID-19.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include psychological and social discomfort as well as a risk of breach of confidentiality.
- **Benefits**. Some of the benefits that may be expected include are sharing your thoughts and experiences and improving your health behaviors.
- **Eligibility**. In order to participate, you must be 18 years of age or older and have not previously enrolled in the study.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

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Who is conducting this research?

Dr. Leslie Leve, a professor and faculty member at the University of Oregon is conducting this research in collaboration with Dr. David DeGarmo and William Cresko, who are professors 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 specifically designed to increase COVID-19 testing in communities. This project is organized by Oregon Saludable: Juntos Podemos (OSJP).

The larger group of studies are funded by NIH. The NIH stands for the National Institutes of Health. The NIH is part of the United States Department of Health and Human Services. The NIH's purpose is to find new knowledge that will lead to better health for everyone. The NIH funded (provided support) for this program, which is called the RADx-UP program.

RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. If you join RADx-UP Program, we will gather some data (information) about you. We will combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

Why is this research being done?

The purpose of the research is to understand if a promotor intervention improves health behaviors to reduce the spread of COVID-19. You are being asked to participate because you are attending the event today. About 3600 people will take part in the OSJP research study.

What happens if I agree to participate in this research?

If you agree to be in this research, your participation will include completing a 30 minute survey now and again in one month. A research assistant will ask you two questions to determine if you are eligible to participate. You must be 18 years of age or older to participate. You are not eligible to participate if you have previously enrolled in our study.

- The survey today will be completed on either your personal device, on paper, or on a sanitized tablet provided by the research team.
- To take the survey in one month, we will text, email, mail, or call you for the survey. You can select your preferred method of receiving the follow-up survey in the survey you complete today.
- Surveys will include general information about you (such as your name, date of birth, address, contact information, race, ethnicity and gender) and your health beliefs, behaviors, relationships, and social life, among others.
- Surveys will ask about COVID-19, including information about any symptoms (a change in your health) and test results. We will ask about your medical history and if you have or have not had vaccines and why.
- You can decline to answer any questions.

You may be at a site that was randomly selected to include an intervention which will be a five-minute or less health information delivered by a promotor while you are at the testing site today.

The site you are being tested at has been randomly selected for one of two groups- either the individuals being tested will receive the promotor health information or you will receive a pamphlet about health behaviors.

We will tell you about any new information that may affect your willingness to continue participation in this research.

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 website at any time.

What happens to the information collected for this research?

Information collected for this research will be used to understand whether a promotor intervention may be effective for improving health behaviors to reduce the spread of COVID-19. Information may be published in scientific journals or shared in reports to community organizations.

Only the principal investigators for this project and research assistants who need to have your information to contact you will have on-going access to your personal information. There may be others that will have access to your identifiable data. These organizations are listed in this consent document. You can discontinue participation at any time, and if after participation you decide that you want your information withdrawn from the study, and future studies, you can notify the research team and your wishes will be honored. However, once the code linking names and numeric identifies is destroyed, it may not be possible to remove specific information.

OSJP will store any information about your personal identity (e.g., names, dates of birth) separate from the other information you provide during this study. We will keep your identifiable information until the study ends, and then we will destroy it. Your identifiable information will not be used in our analyses, publications, presentations, or other reports.

Data from this study, with all personally identifiable information removed ("de-identified data"), will also be stored in a secure, web-based database. The Oregon Saludable: Juntos Podemos (OSJP) will make sure that only researchers who have training in human research ethics and are given access to these data.

The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies. The DCRI will build two RADx-UP databases (systems that hold electronic information). We will keep your data securely (which means with extra protection), along with the data from all the other people who take part in the RADx-UP Program. Researchers will use the data to learn more about COVID-19 or other diseases and conditions.

The first DCRI database will only hold information that can identify you (called identifiable information). Examples are your name, address, email, and gender.

- These data will be kept at the DCRI. The DCRI will not share these data with the NIH.

- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.

- Only if you agree, by initialing below, the DCRI will keep information that can identify you in order to contact you to invite you to participate in future research studies. If you do not agree, this information will stay with your study team, as applicable.

- These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data at the DCRI will be able to see this information.

The second DCRI database will not hold information to identify you. It will hold all the non-identifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- When using the data from this second database, researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.
- You cannot have your data removed from the repository since there may not be a way to identify you after it has been provided.

How will my privacy and data confidentiality be protected?

Your privacy is very important to us. We will take measures to protect your privacy including using a secure server to store data and a secure wifi connection. However, we can only secure the wifi we are using so your wifi will also need to be secure to ensure your information is protected when you are sharing it with us. We will take measures to protect the security of all your personal information including your name, date of birth, and diagnoses. Despite these precautions to protect the confidentiality of your information, there is always a chance that, even with our best efforts, your identity and/or information collected during this study may be accidentally released or seen by unauthorized persons. Here are a few steps we will take:

- Data will be stored on protected, secure computer systems. We will limit and keep track of who can see these data.
- Anyone who can see these data will have to use a password.
- We will take steps to protect your information from others that should not be able to see it.
- Identifiers will be removed from identifiable private information collected in this research. After removal of identifiers, the information will be used for future research and may be distributed to another investigator for future research without obtaining additional consent.
- Each participant will be assigned a unique numeric identifier, so your name does not appear anywhere with the information that they provide.

There is an exception to maintaining confidentiality, due to learning the participant is in danger of being hurt or hurting someone else.

The project investigator and other study investigators and research assistants have access to the data collected for research purposes. In addition, individuals that conduct or monitor this research, such as the UO and the IRB, may access and inspect the research records but that names will not be associated with the questionnaire responses or other data. Individuals and organization that conduct or monitor this research maybe permitted access to and inspect the research records. This may include access to your private information. These individuals and organizations include: The Institutional

Review Board (IRB) that reviewed this research; The National Institute on Drug Abuse, and the National Institutes of Health. If any of these agencies have access to identifiable personal information, they are required to adhere to confidentiality procedures.

This project has a Certificate of Confidentiality from the United States government. Certificates of Confidentiality protect your privacy by blocking the release of identifiable, sensitive research information to anyone not connected to the research except when you agree, or in a few other specific situations.

What are the risks if I participate in this research?

The risks or discomforts of participating in this research include psychological risks such as feeling uncomfortable with the questions asked or self-esteem about your health behaviors and social risks such as feeling uncomfortable answering questions about your personal experiences. Additionally, there are risks to privacy and confidentiality previously mentioned.

Our staff will contact you by text, email, postal mail, or phone to send you the follow-up survey in about one month. You can select your preferred method of receiving the follow-up survey in the survey you complete today. They may also contact you via email, text, or post mail to send you compensation for participating. 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 we should not contact you using in a particular way to minimize this risk.

What are the benefits of participating in this research?

You may or may not benefit from participating in this research. However, there are potential benefits. You may enjoy the opportunity to reflect on your experiences. You may see improvements in your health behaviors. You will also be contributing to research on providing supports to community members who engage in COVID-19 testing. There may be risks that are currently unforeseeable.

What are my responsibilities if I choose to participate in this research?

If you take part in this research, you will be invited to complete two surveys and if assigned to the intervention group, you will be invited to engage in a promotor intervention about health behaviors.

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon or the people responsible for collecting samples and reporting results.

You can inform a staff member at any time that you no longer want to participate in the study, and you can request a staff member to remove any information already collected. You have the right to choose not to participate in any aspect of the study or to completely withdraw from continued participation.

Will it cost me money to take part in this research?

It will not cost you money to take part in this research. You may be referred to additional support/services. Any services you are referred to are not part of this research and may have a cost. These costs would be your responsibility.

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Will I be paid for participating in this research?

You will be compensated $30 for each survey you complete.

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

Kelsey Van Brocklin
(541) 346-9530
kelseyvb@uoregon.edu

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510

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STATEMENT OF CONSENT (to Participate in Research)

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

You must be 18 years of age or older to take part in this research study. I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

- o Yes, I consent to participate in this study

  _____(sign) _____(date)

- o No, I do not consent to participate in this study.

Can the UO laboratory share your information with us?

We would also like to link your protected health information to the survey data you are providing today. We are asking that you sign below to give your consent to the University of Oregon COVID-19 MAP laboratory to disclose the health information collected in connection with your COVID-19 test, including your test results, to the research team collecting your survey data (Drs. Leslie Leve, William Cresko, and David DeGarmo).

By signing below, I acknowledge that I am 18 years of age or older and am authorizing and consenting to the release of my health information, specifically the intake information I provided with my sample and my COVID-19 test result as described herein. Unless revoked in writing this authorization will remain in effect indefinitely. The research team may re-disclose some of my de-identified protected health information, however, the HIPAA Privacy Rule does not apply to the re-disclosure. To revoke this authorization, contact UO MAP at 541-346-6553 or osjp@uoregon.edu.

o Yes, I agree to have my survey data connected to the intake data collected during my testing today.

_____(sign)

_____(print)

o No, I do not agree to have my data connected

Can we share your information with the DCRI?

I agree to let the DCRI collect the following identifiable information: name, address, contact information, and date of birth, as stated above.

o Yes, I agree _____(initials)

o No, I do not agree

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Assent for Research Participation

For Teens 15-17

Title:	Oregon Saludable: Juntos Podemos / OSJP *Scaling Up SARS-COV-2 Testing to Serve Latinx Communities: Individual Surveys to Assess Health Behaviors*
Sponsor:	National Institutes of Health
Researcher(s):	Leslie Leve, William Cresko, David DeGarmo, University of Oregon
Researcher Contact Info:	541-346-9530 kelseyvb@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.

What is the purpose?
The purpose of this study is to see if we can improve health behaviors among people who come to our COVID-19 testing events.

Who can participate?
You are being asked to participate because you're attending today's COVID-19 testing event. To participate, you must be 15 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?
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. 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 COVID-19 testing may have community members talking with people about health behaviors. The goal of this conversation is to improve health behaviors to reduce the spread of COVID-19. Conversations with the community members will last around 5-10 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.

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 will give your samples a secret ID number and place them in locked storage to use in research later on. 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.

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 from the United States government. This is to help us protect your privacy. The researchers can use this Certificate to refuse to give information about you.

Who can answer my questions about this research?
If you have questions, concerns, or have experienced a research related injury, contact Kelsey Van Brocklin at 541-346-9530 or kelseyvb@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.

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STATEMENT OF ASSENT

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 15 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 assent form.

o Yes, I agree to participate _____(sign)

o No, I do not agree

Can we share your information with the DCRI?

I agree to let the DCRI collect the following identifiable information: name, address, contact information, and date of birth, as stated above.

o Yes, I agree _____(initials)

o No, I do not agree

Can the UO laboratory share your information with us?

Can the University of Oregon COVID-19 MAP laboratory share your health information collected in connection with your COVID-19 test, including your test results, with the research team collecting your survey data?

o Yes, I agree to have my survey data connected to the intake data collected during my testing today.

_____(sign)

_____(print)

o No, I do not agree to have my data connected