Creating a Sustainable Infrastructure for SARS-COV-2 Testing at Syringe Exchange Programs

Informed Consent for Research Participation
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Title: Creating a Sustainable Infrastructure for SARS-COV-2 Testing at Syringe Exchange Programs

Sponsor: National Institutes of Health

Researcher(s): University of Oregon

Researcher Contact Info: Dr. Camille Cioffi
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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 increase COVID-19 testing among syringe exchange clients and to understand characteristics of person who may choose to get tested and factors that motivate persons to get tested. This project is a "RADx-UP" program. RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is funded by the National Institutes of Health. The purpose of RADx-UP is to understand how to help more people at risk for or with COVID-19.
- **Duration.** It is expected that your participation will take approximately 20 minutes.
- **Procedures and Activities.** You will be asked to complete a survey and answer some questions about yourself. These questions will include basic information such as your name and date of birth and will also include information about COVID-19, including test results, your medical history and health, if you have or have not had vaccines and why, your education, family, home, relationships, and social life. Participation may also involve completing a brief intervention during your time at the syringe exchange today.
- **Risks.** Risks to you include possible violation of confidentiality or loss of privacy. Although these risks are unlikely, confidentiality and privacy can never be fully guaranteed.
- **Benefits**. Some of the benefits that may be expected include contributing to understanding about why people chose to get tested for COVID-19.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Who is conducting this research?

The University of Oregon is partnering with the HIV Alliance to conduct this research. The University of Oregon is asking for your consent to this research. The study is funded by the National Institutes of Health (NIH). 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.

What happens if I agree to participate in this research?

If you agree to be in this research, you will answer some research-related questions during your time at the syringe exchange today. These questions will ask you for basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information. Questions will also ask you information about COVID-19, including information about any symptoms and test results, your medical history, if you have or have not had vaccines and why, and about your health, education, family, home, relationships, and social life. Additionally, University of Oregon would like to use these data and your HIV Alliance intake data for research. If you choose to have a COVID-19 test today, we would also like to use data from your test, including your results, for a research purpose. You will be asked to sign a separate HIPAA Authorization to release the testing information to the UO researchers for research purposes. Participation may also involve completing a brief intervention during your time at the syringe exchange today. If you chose to participate, we will also share your data with the National Institutes of Health (NIH), who will use the data to understand how to help more people at risk for or with COVID-19. In addition to

gathering some of the data from you directly, NIH may gather some information about you from other sources, such as the Centers for Medicare and Medicaid Services. Detailed information about University of Oregon sharing your data with the NIH and how NIH will use the data is detailed below. Participation is voluntary and your decision to not participate will not affect any services that you receive at the syringe exchange program. If you chose not to participate, there will be no penalty or loss of benefits to which you would otherwise be entitled. We will tell you about any new information that may affect your willingness to continue participation in this research.

What happens to the information collected for this research?
Information collected for this research will be used to help understand why people chose to get tested for COVID-19. Researchers will use the data to learn more about COVID-19 or other diseases and conditions. As described in more detail below, if you chose to participate, we will share your data with the National Institutes of Health (NIH), who will share it with the Duke Clinical Research Institute (DCRI) to combine and store the data collected from everyone taking part in RADx-UP studies. Your information may be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others. The DCRI or NIH may contact you for future research studies. The University of Oregon, NIH, and DCRI will keep your data secure. Your data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data will be able to see this information.

After your data are collected, it will be de-identified. You will be assigned a study code, after which you will only be identified in this database by this study code. After identifiers are removed from the identifiable private information that you provide, your de-identified information will be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative. Your name will not be used in any published reports, conference presentations. We may publish/present the results of this research. However, we will keep your name and other identifying information confidential. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. If you participate in this study, you may discontinue participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

How will my privacy and data confidentiality be protected?
The University of Oregon and National Institutes of Health will make every effort to keep your data confidential. We will take measures to protect your privacy. Your data will be stored on secure, password protected file servers at the University of Oregon, the Duke Clinical Research Institute (DCRI), or the National Institutes of Health (NIH). Only members of the research team at these sites will have access to your data. Although we may collect identifying information such as name, birthdate, or address, this information will not be stored with any other data. Your data will be de-identified before it is stored. Any results of this research that are made public will be in aggregate form only and never include information such as name, birthdate, or address.

Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected. Individuals and organizations that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information and other data that you provide. These individuals and organizations include the Institutional Review Board at the University of Oregon who reviewed this research, the DCRI, or the NIH. Identifiers will be removed from identifiable private information collected in this research. After removal of identifiers, the information may be used for future research or distributed to another investigator for future research without obtaining additional consent.

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 of participating in this research include confidentiality and privacy can never be fully guaranteed, despite the precautions we are taking to protect your information. Risks to you include possible violation of confidentiality or loss of privacy. Although these risks are unlikely, confidentiality and privacy can never be fully guaranteed, despite the precautions we are taking to protect your information.

What are the benefits of participating in this research?
You may or may not benefit from participating in this research. Your participation in this study will help us understand why people chose to get tested for COVID-19. Benefits of participation include contributing to understanding about why people chose to get tested for COVID-19.

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.

Will I be paid for participating in this research?
You will receive a $20 gift card for participating in this research.

Who can answer my questions about this research?
Dr. Camille Cioffi is the contact person for this research. If you have questions or concerns related to this research study, you can contact Dr. Camille Cioffi at ccioffi@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

NATIONAL INSTITUTES OF HEALTH RADX-UP INFORMED CONSENT FOR DATA SHARING

WHAT IS THE NIH AND RADX-UP?
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 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, 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.

WHAT WILL YOU ASK OF ME?
If you decide to join this study, we will gather data (information) about you. We will gather some of the data from you directly. We may gather some of the data from other places, such as the Centers for Medicare and Medicaid Services.

Examples of the information that we may collect from you or other places include, but not limited to:

- We may ask you for basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information.
- We will ask you information 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.
- We will ask you information about your health, education, family, home, relationships, and social life, among others.
- We may ask you to fill out questionnaires, surveys and other forms in order to collect the information above.

WHAT WILL YOU DO WITH MY DATA?
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 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).
The first 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 may be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- The DCRI will keep information that can identify you in order to contact you for future research studies if your research team provides these data. If your research team does not provide these data , 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 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.

HOW WILL YOU PROTECT MY PRIVACY?

Your privacy is **very** important to us. We will take great care to protect your privacy. However, 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.
- When your data are shared with other researchers, they will not have information that can identify you.
- 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.

STATEMENT OF CONSENT

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.

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.
I consent to participate in this study.

Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signature (to be completed at time of informed consent)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

Name of Research Team Member	Signature of Research Team Member	Date