Informed Consent Form

Official Title: Motivational Enhancement to Augment Contingency Management for SARS-CoV-2 Testing and Vaccination Utilization Among Syringe Exchange Clients
NCT number: NCT05534061
Document Date: August 8, 2022

Informed Consent for Research Participation

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: Camille Cioffi, PhD
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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. You will not lose any services or benefits if you decide not to participate or stop participation.
- **Purpose**. The purpose of this research is to increase COVID-19 testing and vaccination among syringe exchange clients and to understand factors that increase the choice to get tested or vaccinated. 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.** Your participation will take approximately 5 minutes to complete a brief survey and you may also complete a brief intervention that involves having a 5-minute conversation with a syringe exchange staff or volunteer today. You may also complete a longer 20-minute survey at a future date approximately 3 weeks from today. This longer survey has questions that ask about basic information such as your race, ethnicity, and age and will also include information about COVID-19, your medical history and health, if you have or have not had vaccines and why, your education, family, home, relationships, and social life. You would receive a $10 gift card if you chose to complete the brief survey and participate in the brief intervention. You would receive a $20 gift card if you also chose to complete the longer survey at a future date.
- **Procedures and Activities.** You will complete a brief 5-minute survey with questions that ask you to describe how you feel and think about COVID-19 testing and vaccination and you may participate in a brief intervention that involves having a 5-minute conversation with a syringe exchange staff or volunteer during your time at the syringe exchange today. If you participate in testing or vaccination, you will authorize the sharing of your testing and vaccination intake data and your test results. You will also be asked to complete a longer survey at some date in the future approximately 3 weeks from today. We will reach out to you to ask you to complete this other survey during a future visit to syringe exchange or by e-mail, phone, text, or Facebook. This data will also be shared with researchers.
- **Risks.** The only risk to participating in this research would be disclosure of your information. However, because of the precautions we are taking to protect your information, these risks are unlikely.
- **Benefits**. Some of the benefits that may be expected include contributing to understanding about factors that motivate people to get tested or vaccinated for COVID-19.
- **Alternatives.** The alternative to participation is to get tested or vaccinated for free and not share your intake information and test result with researchers. If you choose not to participate, you would not receive a gift card.

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 participate in this research, you will complete a very brief survey during exchange today and you may

participate in a brief intervention that will involve having a 5-minute conversation with a syringe exchange staff or volunteer during your time at the syringe exchange today. You will also be asked to complete a longer 20-minute survey at a future date approximately 3 weeks from today that has questions that ask about basic information such as your race, ethnicity, and age and will also include information about COVID-19, your medical history and health, if you have or have not had vaccines and why, your education, family, home, relationships, and social life. You will also be sharing your survey responses with researchers. You will be given an appointment reminder card today with the date 3 weeks from now to return to syringe exchange and complete the longer survey. Alternatively, you can call the number on the card to schedule a different way to complete the survey (email, phone, text, etc). If you participate in testing or vaccination, you will also complete testing and vaccination intake forms, which will include some basic information about you including your name and date of birth, contact information, demographics, testing and vaccination, and you will share your testing and vaccination intake data as well as your test results with researchers. If you chose to participate in this study, we will also share your de- identified 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. 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 thatyou receive at the syringe exchange program. If you chose not to participate, it will not change your ability to receive services or other benefits that you would usually be able to receive.

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 or vaccinated 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. 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, you will be assigned a study code; you will only be identified in this database by this study code. 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. Any results of this research that are made public will be in aggregate form only and never include information that can link back to you. 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?
Your data will be de-identified meaning that any personal information that could be used to identify you will be separated from your survey data, testing data, and vaccination information where only research team members who need to link your data or follow-up with you for the follow-up survey will have access to them. Your identifiers will only be used to link your data over time and afterwards removed and stored until all data collection is complete up to one year. They will be destroyed at the earliest opportunity once all data has been linked and prepared. The University of Oregon and National Institutes of Health will make every effort to keep your data secure. 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. Any results of this research that are made public will be in aggregate form only and never include information that can link back to you. Despite the precautions we are taking, we can never fully guarantee that your de-identified will never be disclosed, though these risks are highly unlikely.

Individuals and organizations that conduct or monitor this research may be permitted access to and inspect the research records. These individuals and organizations include the Institutional Review Board at the University of Oregon who reviewed this research, the DCRI, or the NIH. Your de-identified 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 only risk to participating in this research would be disclosure of your information. However, because of the precautions we are taking to protect your information, these risks are unlikely.

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 or vaccinated for COVID-19. Benefits of participation include contributing to understanding about why people chose to get tested or vaccinated 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, and you have the right to choose not to participate this study activity at any time. You may withdraw your data by contacting our research team. 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 $10 gift card today for completing a brief survey and agreeing to possibly participate in a brief intervention **and a $20 gift card for completing an additional longer survey approximately 3 weeks from today**. The $20 gift card will be given to you after completing the longer survey in person, or we will arrange with you the best way to send or give you the card if you complete the survey remotely.

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 of Diagnostics - 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 may ask you to participate in a brief intervention that involves having a conversation with a syringe exchange staff or volunteer. We will ask you to complete a survey about you. We will gather some of the data from you directly. We will gather some of the data from other places. Examples of the information that we may collect from you now or later include, but are not limited to:

- We will ask you for basic information such as your name, date of birth, race, ethnicity, gender, language, health insurance status, disability, job, and household information.
- We will ask you information about COVID-19 that may include, but will not be limited to: information about any symptoms (a change in your health), contact information, test results, vaccination, and treatments. If you had a positive COVID-19 test. We will ask about your medical history, including if you have or have not had vaccines and why, among others.
- 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?
Your research data will be hosted on data servers at Duke University. However, the space where your data is stored will only be accessible by 1) project staff at University of Oregon who are IRB approved to work on this study and 2) Duke staff who need access to the system for system maintenance. We will keep your data securely (which means with extra protection) on the servers. Some data [including/not including identifiers] will be transferred to the Duke Clinical Research Institute (DCRI) RADx-UP databases described below. 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 as well as other diseases and conditions.

The 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 a database (systems that hold electronic information). The database will not hold information that can easily identify you. It will hold all the 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 not be able to 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 collected via protected, secure applications and 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 and multi-factor authentication.
- 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.

COLLECTED VIA QUALTRICS: INDICATED BELOW FOR ILLUSTRATIVE PURPOSES
PARCIPANTS WILL BE OFFERED A COPY OF THE CONSENT FORM FOR THEIR RECORDS

(Check box) Participant does not consent (gift card will not be provided, signature box is skipped).

_____	_____	_____
Name of Adult Participant	Signature of Adult Participant	Date