Study Protocol

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: July 26, 2022

Research Plan

IMPORTANT: When completing this outline, please use the **Research Plan Guidance** for the content necessary to develop a comprehensive yet succinct Research Plan. Using the guidance to complete this outline will help facilitate timely IRB review.

Study Title: Creating a Sustainable Infrastructure for SARS-COV-2 Testing at Syringe Exchange Programs
Protocol Number: 11162020.013

A. Introduction and Background

People who inject drugs (PWIDs) are a socially vulnerable population and are exposed to risk factors including unstable housing and underlying medical conditions such as human immunodeficiency virus (HIV), tuberculosis (TB), and viral hepatitis that put them at increased risk for severe COVID-19 symptoms, including death. PWIDs also experience barriers such as a history of stigmatization and discrimination by health care systems and exposure to misinformation about testing that reduces access to health care services and testing. Because timely receipt of services relative to symptoms onset is critical for positive health outcomes and to reduce SARS-CoV-2 transmission, lack of testing has significant implications for PWID, highlighting an urgent need to increase testing uptake among this population. Despite this, PWIDs have been an underserved population in the context of the current pandemic; thus, little is known about the prevalence of COVID-19 and the acceptability and possible reach of testing for COVID-19 among PWIDs. To address this gap, this study leverages a current partnership with HIV Alliance (HIVA) in Oregon and our Community and Scientific Advisory Board to support implementation and sustainability of a COVID-19 testing program. Specifically, we will use community-based participatory approaches to develop, implement, and evaluate a COVID-19 testing program offered through HIVA's Syringe Services Programs (SSP), a natural point of care for PWIDs. Moreover, SSPs may offer a natural venue for dissemination and delivery of a vaccine, once available. The COVID-19 testing program will include procedures for sample collection, transmission of specimens to the University of Oregon CLIA-certified laboratory, and results reporting. For aim 1, we will assess the testing and vaccine program utilization. For aim 2, we will develop and test a brief motivational enhancement intervention to optimize testing utilization among PWIDs. Using a randomized control trial design, we will evaluate intervention effects on utilization of COVID-19 testing resources. For aim 3, we will collect data from syringe exchange staff and key volunteers on program acceptability, feasibility, appropriateness, adoption, and implementation barriers and facilitators related to the testing program and intervention. The current project has the potential to enhance COVID-19 testing access and reach among a significantly underserved population who experience multiple risks that make it difficult to prevent SARS-CoV-2 exposure and transmission and who are at increased risk for severe COVID-19 symptoms, if they were to contract the disease.

B. Specific Aims/Study Objectives

We will accomplish our goals to increase testing capacity and utilization of testing resources for PWIDs by accomplishing the following specific aims:

Aim 1: Use a community-based participatory approach to collaborate with HIVA to build their capacity to implement a sustainable COVID-19 testing program that will include procedures for sample collection, transmission of specimens to the University of Oregon CLIA-certified laboratory, and results reporting, and assess testing utilization to understand the reach of the program.

Aim 2: Develop a brief one-session intervention (i.e., Connect2Test) that incorporates ecological assessment and motivational interviewing and that can be implemented during syringe exchange services. We will use a randomized control trial design to evaluate whether the Connect2Test intervention increases the likelihood of COVID-19 testing and retesting in comparison to a control condition. We will also test whether social determinants of health (SDOH) linked to COVID-19 moderate intervention effects.

Aim 3: Assess implementation outcomes associated with COVID-19 testing and the Connect2Test intervention. We will collect qualitative and quantitative data from HIVA staff and key volunteers to examine acceptability, appropriateness, feasibility, adoption, and sustainability of the testing program and

Connect2Test intervention and identify implementation barriers and facilitators that can be used to adapt the testing and Connect2Test for scale-up.

We are also testing the following aims as a result of obtaining Phase II funding which mirror the aims from Phase I (listed above) but adds an evaluation of vaccination uptake and tests the combination of contingency management (CM) :

Aim 1: Collaborate with HIVA to sustain the SARS-CoV-2 testing program established at SEPs during Phase I and develop infrastructure and processes to implement a COVID-19 vaccine program at SEPs, and assess if testing program reach is sustained from Phase I to Phase II and assess the vaccination program's reach.
Aim 2: Use a community-based participatory research approach to adapt the Connect2Test intervention developed in Phase I and conduct an evaluation of the adapted intervention.

2a: Adapt Connect2Test to 1) address the continued necessity of SARS-CoV-2 testing in the context of vaccine accessibility and vaccine hesitancy, 2) enhance vaccine uptake, and 3) enhance acceptability, appropriateness, and feasibility of the intervention based on lessons learned during Phase I.

2b: Conduct a 2-arm randomized control trial to evaluate the comparative effectiveness of CM alone (arm 1) versus CM plus the adapted Connect2Test intervention (arm 2) on SARS-CoV-2 testing and COVID-19 vaccination uptake.

Aim 3: Evaluate the implementation of CM and Connect2Test including: 1) an assessment of reach, acceptability, appropriateness, feasibility, fidelity, penetration, and sustainability, and 2) a cost-effectiveness analysis of CM versus CM + Connect2Test.

C. Methods, Materials and Analysis

Overall Study Design: This study involves development and implementation of a COVID-19 testing and vaccination program embedded in HIV Alliance's (HIVA) Syringe Service Programs (SSP) at 10 sites across Oregon (Aim 1). We will evaluate testing and vaccination utilization rates as our outcome for Aim 1. Across all sites, for Aim 1, we to administer approximately 150 tests per week for a total of 15,600 tests over the study period. We will also administer a total of 1,200 vaccines during the study period. Some of these individuals will be repeat testers and vaccinators. For Aim 1, we will compute the ratio of total persons tested and vaccinated/total persons attending syringe exchange who were offered testing or vaccination to assess testing and vaccination program reach. We will use data collected during testing and vaccination intake, "Testing Intake Form", processed by our study team's data scientist which includes name, date of birth, and contact information. We will collect test results from the UO COVI9-19 MAP laboratory. Following testing and vaccination, HIVA SSP clients will have the opportunity to take a follow-up survey, "Aim 1 Post-Testing Survey". At the time of testing or vaccination, the HIVA testing facilitator will invite clients to complete the testing intake and obtain informed consent and authorization for sharing protected health information. Consent, information sharing authorization, and the testing intake and consent will be completed electronically. The "Aim 1 Post-Testing Survey" will be collected either electronically either on Qualtrics or through a secure data collection tool provided by the CDCC or via paper and pencil. Research assistants will administer the "Aim 1 Post-Testing Survey".

Aim 1, Step 1 (Testing or vaccination Facilitator, Consent and HIPAA Authorization): Participate in testing or vaccination and receive $10 to get tested or vaccinated and share testing information.
Aim 1, Step 2 (Research Assistant, no additional consent): Participate in "Aim 1 Post-Testing Survey" and get $20 for completing the 20-min survey.

Data from steps 1 and 2 will be shared with the RADx-UP CDCC as required by our funder. The information that will be shared is summarized in the consent form.

For Aim 2, we will use a brief motivational enhancement intervention (Connect2Test) to increase testing and vaccination program utilization and use a randomized control trial (RCT) design to evaluate if this intervention increases COVID-19 testing and vaccination utilization, in comparison to a control condition. Procedures are subsequently outlined as the vary between Phase I and Phase II. Specifically, Phase I was implemented and tested with research staff but for Phase II, recruitment and consent will be facilitated by research staff but intervention delivery will be facilitated by syringe exchange staff and volunteers.

The Connect2Test intervention is designed to be approximately 2-5 minutes and focuses on using motivational interviewing skills to facilitate uptake of COVID-19 testing and vaccination. Specifically, strategies include asking for permission to share information, using open-ended questions, reinforcing change talk, and

using reflections to check for understanding. In Phase II, the syringe exchange staff or volunteer will initiate the conversation using an open-ended question and then have an informal conversation with participants using the skills they learned in MI training with Dr. Anne Marie Mauricio.

For Aim 3, we will collect survey and interview data on implementation experiences from HIVA staff and volunteers.

The research will occur at HIVA SSP sites across the state of Oregon. HIVA will be responsible for coordinating training activities for HIVA staff and UO will be responsible for training HIVA staff on-site and virtually. HIVA will meet with the UO implementation team (Cioffi, Mauricio, Tavalire) at least monthly (but more frequently to start).

Research Procedures:

Phase I Testing Program: Aim 1. At the time of testing, the HIVA testing facilitator will invite clients to share their intake data with the study team and obtain signed informed consent. The testing intake data will be collected by HIVA regardless of the research. Consents will be available on site for clients to read and copies will be available for their records. Signatures will be collected electronically.

After testing (either the same day or at a future date), a research assistant will have a list of people who have been previously tested and provided consent for the Testing Follow-up Survey. Only these individuals will be able to participate. They may also participate if they were tested the same day the research assistant was on site. They will provide either an electronic data collection tool or paper and pencil surveys to be read by the clients. If clients cannot read, the survey may be read to them by a member of the research team. If the survey is read aloud, it will be done in a space away from other clients to maintain privacy.

Phase II: Aim 1. In Phase I, we demonstrated close collaboration with HIVA to establish a SARS-CoV-2 testing program as mentioned in *Phase I, Testing Program: Aim 1*. This program and research are on-going and will remain unchanged. In addition to testing, given the ever-changing nature of the pandemic and need to offer COVID-19 vaccinations to the intended population quickly, we will assist HIVA in setting up vaccination infrastructure.

Phase I, Connect2Test Evaluation: Aim 2: We will use community-based participatory approaches to develop a brief one-session intervention that will include an ecological assessment, feedback, and motivational interviewing, called Connect2test. While Connect2Test draws from principles used in the Family Check-Up, such as ecological assessment, feedback, and motivational interviewing, the Connect2test intervention is unique from the Family Check-Up. We will use a randomized control trial (RCT) design to evaluate if Connect2test increases COVID-19 testing utilization, in comparison to a control condition. The RCT in Aim 2 will be conducted at the six syringe exchange sites in Lane County.

Following client participation in syringe exchange services, clients will be invited to participate in the RCT by a research staff. Clients that agree to participate will complete signed informed consent programmed in Qualtrics and consented participants will be randomized to the intervention or control condition by Qualtrics. All participants will complete a study questionnaire (in Qualtrics) that includes both the Connect2Test Assessment questions and Common Data Elements questions. For clients randomized to the intervention, the Connect2Test Assessment questions will be used to guide the Connect2Test motivational interviewing intervention component. The consent and all surveys/assessments will be administered via an iPad. Recruitment script and consent are included with protocol. In most cases, clients will self-administer the survey; however, if they cannot read, the survey may be read to them. If the survey is read aloud, it will be done in a space away from other clients to maintain privacy. In total, surveys/assessment should take approximately 15 minutes to complete. Participants will receive a blank paper copy of the consent. Clients randomized to the intervention condition will participate in the Connect2Test motivational interviewing intervention component, which should take approximately 5 minutes. The motivational interviewing intervention component, which will be offered by a clinician on the research team, will be facilitated by a personalized feedback form that summarizes Connect2Test assessment data and that is auto-generated on the iPad that the client used to complete the Connect2Test assessment. After completing the motivational interviewing intervention component with the research team member, clients will be offered COVID-19 testing. Clients in the control condition will be invited to participate in testing after completing the survey. A research

team member will assess Connect2Test fidelity on a randomly selected 20% of testing days. The clinician offering the intervention will also self-report on fidelity. We will use testing utilization (yes/no) as our outcome to evaluate intervention effects. Data from the CDE survey and the HIVA intake form will be leveraged to evaluate moderators of intervention effects.

Any client can receive COVID-19 testing, regardless of their participation in the research.

Clients using HIVA's syringe exchange services provide their unique HIVA ID. This unique identifier is used to link data for persons who are repeat users of HIVA's services. We will use the unique ID to link HIVA intake, CDE data, and UO's CLIA laboratory data (i.e., testing utilization) for the purpose of evaluating effects of Connect2Test on testing utilization and the moderating effects of SDOHs (assessed using the CDEs and HIVA intake data).

At the time of consent, a research team member will ask clients to complete a HIPAA Authorization form (which will be programmed in Qualtrics with the consent and survey) for the purpose of releasing their testing utilization data to the UO research team. UO's COVID-19 MAP will only give the research team access to testing utilization data for HIVA IDs for whom we have a HIPAA authorization and consent. The client will also be given a blank paper copy of the HIPAA Authorization form for this study.

During the course of the RCT, clients will only be invited to participate in the study once. Participation in the study will be tracked by research staff. Regardless of whether clients consent to participate in the study, they will be offered an opportunity to get tested every time they visit the exchange.

Data Analysis: We will use a randomized control trial to evaluate whether Connect2Test increases COVID-19 testing utilization. We will also test whether SDOH moderate intervention effects. We will use chi-square tests to examine whether the expected rates of testing utilization vary by condition. We will use logistic regression to examine whether SDOHs moderate intervention effects.

Phase II, Aim 2: For Aim 2, we will adapt the ME Connect2Test intervention that we developed during Phase I and examine whether the adapted Connect2Test augments the effects of Contingency Management on SARS-CoV-2 testing and vaccination utilization.

Staff and volunteer co-creation. An essential component of intervention development is co-creation with HIV Alliance syringe exchange staff and volunteers. As part of co-creation, staff and volunteers will also be trained in intervention delivery to prepare for the randomized trial where they will be the interventionists. The training and co-design process will be completed in two 3-hour sessions. The first part will include foundational motivational interviewing skills and research ethics training. As part of the first training, staff and volunteers will provide input on talking points in line with motivational interviewing principles. The second part will be training on the specificized intervention after incorporating staff and volunteer feedback. It will also include training on research protocols for randomization (e.g., research assistants will invite participation, consent participants, and identify participants to receive the intervention then syringe exchange staff will deliver the intervention to clients who are randomized to intervention). Staff and volunteers will receive $75 for participation in each part of the co-design process ($150 total). We will assess pre-post gains in knowledge and self-efficacy(See MI pre-post survey). Each survey will take approximately 5 minutes to complete.

Intervention testing. **For Aim 2**, we will use a randomized control trial (RCT) design to evaluate if this intervention in conjunction with contingency management increases COVID-19 testing and vaccination utilization, in comparison to contingency management (CM) alone. Aim 2 will be implemented at HIV Alliance syringe exchange sites. During client participation in syringe exchange services, clients will be invited to participate in the RCT by the research team member on site. Clients that agree to participate will complete signed informed consent programmed in Qualtrics; consented participants will complete a brief survey (Aim 2 Brief Client Survey) and be randomized by Qualtrics to the Connect2Test + CM condition or to CM alone. At the time of consent, research staff will ask clients to complete a HIPAA Authorization form for the purpose of sharing their testing and vaccination utilization data as well as test result with the UO research team. The HIPAA Authorization form will also be programmed in Qualtrics. Research staff will discretely inform syringe exchange staff/volunteers whether the client has been assigned to Connect2Test + CM so the staff/volunteer will know whether to deliver the intervention. Clients in the CM only condition will be invited to participate in testing and vaccination after completing syringe exchange. Clients in the Connect2Test + CM condition will receive the brief intervention, which involves an approximately 5-minute conversation guided by motivational

interviewing processes, and then be invited to participate in testing and vaccination. The syringe exchange staff/volunteer delivering the intervention as well as the research staff assisting with Aim 2 will also complete a checklist to document intervention delivery.

We will use data collected during testing and vaccination intake, "Testing Intake Form", processed by our study team's data scientist which includes name, date of birth, and contact information. We will collect test results from the UO COVI9-19 MAP laboratory. At the time of testing or vaccination, the HIVA testing facilitator will invite clients to complete the testing intake and obtain informed consent and authorization for sharing protected health information, intake data and test results.

All individuals who participate in Aim 2 will be invited to complete an additional longer survey (i.e., "Post-Testing Survey"; 20 minutes) that includes common data element (CDE) questions. This survey will be completed during a future visit to syringe exchange or via e-mail, phone, text, or Facebook.
The target sample size for the RCT in Aim 2 is 350 unique individuals. The RCT will be initiated once IRB approval is received and we anticipate it will take approximately 3-4 months to reach the target sample size. Aim 2 data will be shared with the RADx-UP CDCC as required by our funder. The information that will be shared is summarized in the consent form. We plan to enroll 350 participants.

Data Analysis: We will use a randomized control trial to evaluate whether Connect2Test + Contingency Management increases COVID-19 testing utilization in comparison to contingency management alone. We will also test whether SDOH and key motivational variables (collected via Aim 2 Brief Client Survey) moderate intervention effects. We will use chi-square tests to examine whether the expected rates of testing utilization vary by condition. We will use logistic regression to examine whether SDOHs moderate intervention effects.

Phase I, Assess implementation experiences from HIVA staff and volunteers: Aim 3. HIVA staff and volunteers will be invited to participate and complete consent via email. Staff/volunteers who consent to participate will be invited to complete a survey. In the consenting process, participants will provide their name and signature. Participants will also provide an e-mail so we can send them a $50 gift card for their participation. However, names will be replaced with a unique participant ID and consent information, name, and e-mail will be stored separately from the data. Following survey completion, staff and volunteers will be invited to participate in a 30-45 minute qualitative interview to understand barriers and facilitators to implementation of testing and Connect2Test. This process may occur up to two times per staff and key volunteer. Qualitative interview data will be audio-recorded and names will not be used in the interview to protect anonymity of responses. Audio recordings will be transcribed for coding. Participants' names will be used to link their survey and their audio transcript so we can know participants to whom we should send a gift card for their participation. After this, a unique ID will be assigned to participants' survey data and audio transcript to link these and then identifiers (name and email) will be permanently deleted. The audio transcription of the interview will be stored on a secure server, prior to being transcribed, and will be destroyed immediately following transcription. All staff and volunteer data will be presented in aggregate so that responses can never be linked to a particular staff or volunteer.

Phase II, Aim 3: Similar to *Phase I, Aim 3*, we will conduct interviews and surveys with HIV Alliance staff. However, we will expand Aim 3 in Phase II to also interview clients, observe interventionists, and review administrative data from HIV Alliance. We plan to develop these materials and will submit an amendment prior to implementation.

Table 1: Implementation Outcomes

	Assessment	Source	Participants
Reach	HIVA SEP clients utilizing testing and vaccination examined by demographic variables compared to overall HIVA SEP clients	Administrative data from HIVA	HIVA Administrative staff
	Information about barriers and facilitators to client engagement	Interviews & surveys	HIVA SEP Participants and HIVA Staff

Acceptability, Appropriateness, & Feasibility	HIVA SEP clients and HIVA staff perceptions of acceptability, appropriateness, and feasibility of CM and Connect2Test implementation to affect SARS-CoV-2 testing and vaccination, including the satisfaction with the service, implementation supports (e.g., training), fit, usefulness, practicability, readiness	Interviews & surveys	HIVA SEP Participants and HIVA Staff
Adoption	Utilization of outlined implementation protocols at each site, number of client encounters and SARS-CoV-2 testing and vaccination services		HIVA Staff
Fidelity	Adherence to Connect2Test implementation protocol	Observer and self-report ratings	Research Team
Cost	Cost effectiveness of Connect2Test and CM relative to CM only	Administrative data	HIVA Administrative Staff
Penetration & Sustainability	Intentions of organization to adopt Connect2Test and CM after study completion	Interviews	HIVA Leadership

Testing and Vaccine Hesitancy Client Interviews: Vaccine hesitancy is being collected as part of the Aim 1 testing survey. To augment quantitative data, client interviews will be conducted to inform future work related to testing in the presence of vaccines.

The interviews will be 1-on-1 interviews that will take place in an outdoor, secluded section of one of six approved syringe exchange locations, including the HIV Alliance office. The location will be away from any needle exchange workers or clients to maintain the privacy of the participant. After obtaining informed consent, the research assistant will begin interviewing the participant. The interviews will take 20 – 30 minutes. During the interview, the research assistant will ask the participant to share what factors contribute to their delay or refusal to receive vaccination services. The researcher will also ask them to share if they have any personal experiences that have contributed to their hesitancy toward COVID-19 vaccines. Finally, they will ask if the participant has any insight as to how COVID-19 vaccination services at HIV Alliance may better serve the PWID community.

With the permission of the participant, the research assistant will audio-record the interview to be analyzed and partially transcribed for coding later. The transcription will be done automatically using a component of NVIVO software. NVIVO is a data analysis software commonly used by qualitative public health researchers. During the research, the name of the participant will not be disclosed to protect the anonymity of responses. The research assistant will, however, obtain an HIV Alliance ID that is a unique ID used by HIV Alliance to track a participant's acquisition of syringe exchange services. This information must be obtained to link the participant's COVID-19 survey responses to their interview responses. However, all identifying information will be removed from the data as soon as possible and all data will be de-identified. The interview data will be stored on the Prevention Science Institute server, accessed by the University's VPN. All data will be aggregated prior to presentation to ensure individual responses cannot be traced back to any participant.

After the interview process has concluded, interviews will be transcribed, and responses will be coded in NVIVO.

Given the nature of this study and the increased risk of severe COVID-19 symptoms among PWIDs, both the participant and the research assistant will be masked for the entirety of the

recruitment, informed consent, and interview processes. All surfaces will be sanitized with disinfectant wipes at the end of every interview.

Attached is a copy of the proposed interview script that will be used, titled “Client Interviews”. The number of client interviews will not exceed 60.

D. Research Population & Recruitment Methods

Study Population: The study population will be people who inject drugs (PWID) and use HIVA’s SSP services in Oregon. We anticipate the sample characteristics to be comparable to demographics for individuals who typically participate in syringe exchange. Specifically, we expect 6% Hispanic and 94% non-Hispanic, with 85% of individuals identifying as White in both ethnic groups and the remaining 15% identifying as African American, Asian, Pacific Islander, American Indian/Alaska Native, or more than one race. Only individuals 18 and older will be eligible to participate in testing, vaccination, and the intervention study. All study and intervention materials will be available in English. Although all participants regardless of language spoken will be invited to test and vaccinate; only participants who speak English will be eligible for the RCT (Aim 2), as Connect2Test materials will only be available in English. For Phase II, We anticipate approximately 3800 unique participants will be included in Aim 1 and approximately 350 unique participants will be included in Aim 2. All HIVA SSP clients (up to testing capacity, i.e., 150 per week) will have access to and be invited to test. We expect an excess of male participants (i.e., 60%), based on the demographics of persons who use syringe exchange services. Across all sites, we expect to offer testing to 3800 unique individuals in Year One and to administer approximately 150 tests per week. For Phase II, Aim 2, we anticipate recruiting up to 20 HIVA staff and volunteers to participate in the training sessions and MI pre-post survey.

Recruitment Procedures:

For Phase I & II, Aim 1, data from all syringe exchange service participants across 10 HIVA syringe exchange sites will be included in this study. HIVA SSP clients will also be invited to complete a “Common Data Elements” survey for the funder, National Institutes of Health. At the time of testing or vaccination, the HIVA testing facilitator will invite clients to complete the survey and obtain signed informed consent. The Data Manager will create a running list with client names and date of birth of individuals who have consented to participate in the follow-up survey. Clients who wish to participate will either provide their name and date of birth and the research assistant will verify their previous participation, or the client will consent as part of the testing process the same day and the testing team will verbally let the research assistant on site know that the client has signed consent to participate. Clients who share their intake information will receive a $10 gift card for their participation. Clients who complete the follow-up survey will receive a $20 gift card for their participation.

For Phase I & 2, Aim 2 syringe exchange clients, a research staff person will invite syringe exchange service participants to participate in the study when they visit the exchange for services (see Recruitment script). The research staff will inform clients about the opportunity to participate in the research study and obtain signed informed consent. At the time of consent, research staff will ask clients to complete a HIPAA Authorization form for the purpose of releasing their testing and vaccination intake data and test result to the UO research team. The HIPAA form will also be programmed in Qualtrics. UO’s COVID-19 MAP will only give the research team access to test results data for HIVA IDs for whom we have a HIPAA authorization and consent. Clients will be given a blank consent and HIPAA form. During the course of the RCT, clients will only be invited to participate in the study once. Research staff will document participation to target recruitment of unique individuals visiting the exchange. Regardless of whether clients consent to participate in the study, they will be offered an opportunity to get tested or vaccinated every time they visit the exchange. The RCT in Aim 2 will be conducted any HIV Alliance syringe exchange site. Clients will receive a $10 gift card for their participation in the study to be given after completing the Brief Client Survey. All individuals who participate in Aim 2 will be invited to complete an additional longer survey (i.e., 20 minutes) that includes common data element (CDE) questions and “Aim 2 Brief Client Survey” at a future date approximately 3 weeks from the date of enrolling in Aim 2. Clients will be given an appointment reminder card with their 3 week return date and a phone number to reach research staff. This survey will be completed during a future visit to syringe exchange or via e-mail, phone, text, or Facebook. Clients can show up at a syringe exchange event or call the number on their appointment card to make alternate arrangements to complete the survey. We will also

attempt to contact participants if they are unable to make their scheduled appointment and will provide reminder messages. Participants will receive a $20 gift card for completing this survey. For clients who complete the survey remotely, we will make arrangements with them to disburse payment by meeting at a syringe exchange site, another public location, or mailing it to them.

Staff and volunteer co-creation. Staff and volunteers will be recruited to participate via email from HIV Alliance staff. Participation in co-design is mandatory for syringe exchange staff and optional for syringe exchange volunteers. HIV Alliance will let staff and volunteers know of the training opportunities. While at the training, the research team will recruit staff and volunteers to participate in the research pre-post survey. Participation in the pre-post survey will be optional and part of the research. Staff and volunteers will receive $75 for participating in each day of training (3-hours each, 6 hours total) for a total of $150. They will be receive compensation regardless of their participation in the survey.

For Phase I & II, Aim 3, we will also collect survey and interview data on implementation experiences from HIVA staff and volunteers. We anticipate staff and volunteers to be 13% Hispanic and 87% non-Hispanic, with 87% of individuals identifying as White in both ethnic groups and the remaining 13% identifying as African American, Asian, Pacific Islander, American Indian/Alaska Native, or more than one race. We anticipate 75% of staff and volunteers to be female. We anticipate up to 50 people will participate in the survey and interview data collection. Emails with informed consent for Aim 3 and survey link will be sent to staff and volunteer by HIVA. All staff and volunteers interested in participating will be invited to participate. We will collect names for consenting purposes and email addresses for sending $50 gift card. If staff and volunteers choose to participate, after completing informed consent, they will be able to proceed to the survey. Following the survey, participants will be asked to select a time to schedule a 30-45 minute zoom or phone interview. Staff and volunteers will receive a $50 gift card for their participation in the survey and interview each time they participate.

Information on additional Aim 3 procedures for Phase II will be submitted in a future amendment.

Testing and Vaccine Hesitancy Client Interviews: The recruitment process for this research will be verbal. The primary sampling procedure will be convenience sampling with participants in HIV Alliance's COVID-19 testing services. The research assistant will ask that staff at the COVID-19 testing table of syringe exchange refer individuals who have completed surveys that indicate the participant has not been vaccinated to them. For the purposes of this study, only individuals who have not received any COVID-19 vaccinations will be selected for interviews. The research assistant will use the attached "Client Interviews recruitment script" to inform participants about the background, goals, and procedures of the project. If the individual is interested in being interviewed, they will be invited to read the informed consent form provided to them and will then the researcher will obtain informed consent. If the individual suggests that they are not available to be interviewed at the time in question but are interested in being interviewed at a later date, they will be invited to contact the research assistant to schedule another meeting time. The research assistant will then schedule a time to interview them at one of the six approved syringe exchange locations during syringe exchange hours. Individuals that participate in this study will received a $20 gift card as compensation for their time. The number of client interviews will not exceed 60.

E. Informed Consent Process

Phase I & II, Aim 1. To assess the Aim 1 outcome, proportion of HIVA syringe exchange clients being tested or vaccinated, no individual level data is being collected by the research team. We will compute proportions based on aggregate weekly syringe exchange and testing data. At the time of testing, the HIVA testing facilitator will invite clients to share their testing data and obtain signed informed consent for sharing testing data and the follow-up survey. Consents will be read by the clients and signed on Qualtrics then the intake survey will be read to the client as part of testing intake. The testing research staff will also clarify that the information that the participant includes in the follow-up CDE survey will be used by National Institutes of Health (NIH) and Duke Clinical Research Institute (DCRI), however identifying information will not be shared. To ensure only clients who have consented to participate take the follow-up survey, the data manager will create a list with name and date of birth and the research assistant on site will check the list when a participant comes to take the follow-up survey after the participant provides their name and date of birth. For clients who wish to participate on the same day after they complete testing, the testing team will verbally let the research team know that the client has signed their consent (the research surveys will be conducted physically adjacent to the testing tent). Clients will be reminded that they previously consented to participating

in a research study when they were tested and remind them that participation in the follow up survey is voluntary.

Phase I & II, Aim 2: Clients attending the syringe exchange will be invited to participate in the RCT by a research staff. Clients who agree to participate will provide signed informed consent via Qualtrics, and participants that consent will be randomized to the intervention or control condition via Qualtrics. At the time of consent, the research staff will review the consent with the participant before they sign it to ensure that the participant is clear about data will be obtained by National Institutes of Health and Duke Clinical Research Institute versus the UO. Specifically, the UO will collect identifying information like including name and date of birth to improve the ability to link data over time and will also collect contact information. The research staff will clarify that the information that the participant shared with the UO research team will be used by National Institutes of Health (NIH) and Duke Clinical Research Institute (DCRI), however identifying information will not be shared with NIH or Duke. At the time of consent, the research team member will ask clients to complete and a HIPAA Authorization form (also in Qualtrics) for the purpose of releasing their testing and vaccination intake data and test results to the UO research team. Clients will be given a blank paper copy consent and HIPAA form. For follow-up surveys, clients will be reminded that they previously consented to participating in a research study when they were tested and remind them that participation in the follow up survey is voluntary.

Staff and volunteer co-creation. For pre-post training surveys consent forms for HIVA staff and volunteers will be provided on Qualtrics. The informed consent will explain the project, their rights, and how the data will be used in the future. Staff and volunteers will be assured that their participation in the study is voluntary and that if they choose to participate, they can change their minds at any time. They will be informed about potential benefits and harm. Staff and volunteers will be informed that their data will only be presented in aggregate. Staff and volunteers will provide signed informed consent before participating. Participants will be able to download from Qualtrics and save a copy of the consent for their records. It will be clear that they will receive compensation for attending training, regardless of their participation in the survey.

Phase I & II, Aim 3: Survey and interview data from HIVA staff and volunteers. For survey and qualitative interview data on implementation experiences from HIVA staff and volunteers, consent forms for HIVA staff and volunteers will be provided on Qualtrics. The informed consent will explain the project, their rights, and how the data will be used in the future. Staff and volunteers will be assured that their participation in the study is voluntary and that if they choose to participate, they can change their minds at any time. They will be informed about potential benefits and harm. Staff and volunteers will be informed that their data will only be presented in aggregate. Staff and volunteers will provide signed informed consent before participating. Participants will be able to download from Qualtrics and save a copy of the consent for their records. In addition to asking for consenting purposes, we will ask for an email address for sending them a $50 gift card. The consent explains that we will use names to link survey and audio transcript data. In the consent, we also indicate that after sending the gift card and linking audio and survey data, a unique ID will be assigned to survey data and audio transcript and then identifiers (name and email) will be permanently deleted.

Emails with the consent and survey will be sent to staff and volunteer by HIVA. If staff and volunteers choose to participate, after reviewing and signing informed consent, they will be able to proceed to the survey; after completing the survey they will have the opportunity to schedule a time for a qualitative interview. In the consenting process, participants will provide their name and signature. However, names will be replaced with a unique participant ID and consent information will be stored separately from the data. Qualitative interview data will be audio-recorded but names will not be used in the interview to protect anonymity of responses. Audio recordings will be transcribed for coding. Participants' names will be used to link their survey and their audio transcript so we can know participants to whom we should send a gift card for their participation. After this, a unique ID will be assigned to participants' survey data and audio transcript to link these and then identifiers (name and email) will be permanently deleted. The audio transcription of the interview will be stored on a secure server, prior to being transcribed, and will be destroyed immediately following transcription. All staff and volunteer data will be presented in aggregate so that responses can never be linked to a particular staff or volunteer.

Additional consent procedures will be added in a subsequent amendment for new research activities.

Testing and Vaccine Hesitancy Client Interviews: The research assistant will provide a printed copy of the "client interviews informed consent document" for the individual to read. The research assistant will request that the individual does not sign the consent form until they have had a conversation with the research assistant regarding the form's contents. After the individual has finished reading the document, the research assistant will go over every element with them and will administer several comprehension checks to ensure there is a mutual understanding of what will be asked of them during the interview. During the process of obtaining informed consent, the research assistant will also ensure that the participant understands that their interview responses may also be shared with HIV Alliance and a research team at the Prevention Science Institute. Specific attention will be drawn to the fact that their participation in the study will have no bearing on their ability to access HIV Alliance resources. Once the research assistant feels confident that the participant understands the entirety of the document, they will ask them to sign the final page and the interview will proceed. The research assistant will remind them that they are welcome to ask questions at any point during the interview process or after the interview has completed.

F. Provisions for Participant Privacy and Data Confidentiality

Table 2. Identifiable information table

Component	Source	Purpose
Phase II, Aim 1 Testing	HIV Alliance Intake, created and prepared for MAP to process samples by Fernandes (only individuals who consent to sharing are retained for study purposes)	Linking data over time to ensure participants have previously consented when conducting the follow-up survey, ability to re-contact for follow-up survey
Phase II, Aim 1 Testing Result	MAP	Linking data over time to ensure participants have previously consented when conducting the follow-up survey, satisfying funding requirements
Phase II, Aim 1 Vaccination	HIV Alliance Intake only for people who consent created and managed by Fernandes	Linking data over time to ensure participants have previously consented when conducting the follow-up survey, ability to re-contact for follow-up survey
Phase II, Aim 1 Follow-up Survey	RA administered survey	Linking data over time, required by the funder to collect but not to share (funding could be removed if not collected)
Phase II, Aim 2 Staff and Volunteer	RA administered survey	Linking pre-post data over time (completed)
Phase II, Aim 2 Intervention Enrollment	RA administered survey	Linking data over time to ensure participants have previously consented when conducting the follow-up survey, ability to re-contact for follow-up survey
Phase II, Aim 2 Intervention Follow-up Survey	RA administered survey	Linking data over time, required by the funder to collect but not to share (funding could be removed if not collected)
Phase II, Aim 2 Testing	HIV Alliance Intake, created and prepared for MAP to process samples by Fernandes (only individuals who consent to sharing are retained for study purposes)	Linking data over time to ensure participants have previously consented when conducting the follow-up survey, ability to re-contact for follow-up survey

Phase II, Aim 2 Testing Result	MAP	Linking data over time to ensure participants have previously consented when conducting the follow-up survey, satisfying funding requirements
Phase II, Aim 2 Vaccination	HIV Alliance Intake only for people who consent created and managed by Fernandes	Linking data over time to ensure participants have previously consented when conducting the follow-up survey, ability to re-contact for follow-up survey

1. Privacy
Common data elements survey data from syringe exchange participants will be provided to the Coordination and Data Collection Center (CDCC). Data will only be shared with CDCC if syringe exchange participants consent to participate in the study. Data from all syringe exchange participants that consent to the study will be shared. Common data elements data will be shared using secure processes and procedures as designated by the CDCC. No data from HIVA staff and volunteers will be shared. The research team will not have access to HIVA SSP client protected health information, other than the data described in the methods, materials and assessment section.

2. Data Disposition
For all identifiable data, consents and HIPAA Authorization are programmed with the survey questions but identifying information (names on consent/HIPAA) will stripped from the data at earliest opportunity. All data will be retained and stored for the duration of record storage but will be de-identified with a "code key" following study completion by assigning a new ID to the data. This code key will be kept separate from the data and the de-identified data on the secure file server at the Prevention Science Institute and destroyed within 1 year of study completion to ensure all data are cleaned and there is no loss of linked data. Data will be maintained by the research study team. Data will be transmitted between the research team and UO COVID-19 MAP lab and between the research team and HIVA using encrypted, secure email. Data will only be transmitted for participants for whom the research team has consent and HIPAA authorization for sharing of testing data.

3. Confidentiality
Data will be de-identified meaning anything used to identify someone will be stored in a separate secured data file that is only accessible by the data manager to link study records and individuals who need to recontact the participant for the follow-up survey. Identifiers will be stored for 1-year after data collection is complete which is the earliest opportunity for being destroyed to ensure all data files are complete and accurately linked and then destroyed. UO's COVID-19 MAP will only give the research team access to testing data for people for whom we have a HIPAA authorization and consent. All research survey data and audio files will be stored at the Prevention Science Institute using standard security techniques (password protected file folders on the University's Prevention Science Institute secure server). Data from Qualtrics will only be accessed using secure wifi.

Storage of data will be stored electronically on a private server and will be directly uploaded only while using secure wifi. If the data must be transferred, they will be transferred using a secure client server. Study researchers and the students they supervise may be granted access to the de-identified data after signing a data use agreement, in order to complete analyses. Records will be kept for up to 3 years after the study has been completed.

Research funded by NIH automatically has a Certificate of Confidentiality associated with it. This is added protection against forced disclosure of research information in circumstances of subpoena.

G. Potential Research Risks or Discomforts to Participants

Potential Risks: Potential risks and discomforts involved in participation include (1) possible violation of confidentiality. This risk are unlikely but possible.

Minimizing Potential Risk 1: *Possible violation of confidentiality.* All records obtained from participants will be kept strictly confidential. To ensure strict confidentiality, any additional data will be coded with HIVA ID.

The protocol involves intervention. The intervention includes an intervention that aims to increase testing and vaccination utilization. This will involve a brief assessment and conversation with syringe exchange staff or volunteers. This research does not pose any additional risk over the services provided as usual.

The funding agency required a Data Safety Monitoring Plan for this research at the time of funding proposal. A copy of the DSMP submitted to the funder is attached.

There is no established Data and Safety Monitoring Board/Committee (DSMB/C) as noted in the DSMP.

H. Potential Benefits of the Research

The overall risk involved in the project is relatively minor, given the goals of the research. Participants would face similar levels of risk -or higher - visiting a clinic or other outdoor testing or vaccination event in order to be tested or vaccinated for COVID-19. Participants will benefit by receiving a free SARS-CoV-2 diagnostic test and educational information that could improve their health behaviors and reduce transmission of SARS-CoV-2 in their communities and around Oregon. Others in the community would benefit if participants are identified as positive who previously did not know they were infectious and if participants actively alter their health behaviors, whether infectious or not.

This study has the potential to identify a strategy that could effectively optimize access and reach for testing and vaccination for SARS-CoV-2 infection among a hard-to-engage, underserved population at high risk for SARS-CoV-2 transmission and severe illness, if infected. Additionally, through this work, we plan to offer testing and vaccination to 3800 persons in year one, after which HIVA will continue to administer testing and vaccination, adding to the total testing, vaccination, and surveillance efforts in the United States and our understanding of the disproportionate spread within - and burden felt by - these historically underserved communities.

I. Investigator Experience

1. Investigator Qualification

MPI: Beth Stormshak, PhD., Dr. Stormshak is the Department Head of the Counseling Psychology and Human Services department in the College of Education. Dr. Stormshak's research focuses on understanding risk factors in early and middle childhood associated with the development of problem behavior in late adolescence, including substance use and delinquency. Her primary research focus includes testing the efficacy of family-centered interventions, such as the Family Check-Up, that reduce the later risk of problem behavior. She also studies the process of dissemination of evidence-based interventions into real world community settings and has developed an online version of the Family Check-Up for wide-scale dissemination. She has worked collaboratively with a variety of service providers, including elementary and middle schools in the state of Oregon as well as community mental health agencies.

MPI: Anne Mauricio, Ph.D., Mauricio is an Associate Research Professor and a Family Intervention Scientist at the University of Oregon. She has 18 years of experience collaborating with Latinx communities to develop, implement, and evaluate culturally competent evidence-based interventions, and she has been PI or Co-I on several grants focused on implementation of evidence-based interventions in real-world practice. She is also a licensed psychologist with experience working with Latinx families and children in community mental health settings and training and supervising clinicians in the delivery of culturally competent interventions.

Co-I: Leslie Leve, Ph.D., Leve is the Alumni Faculty Professor in the College of Education at the University of Oregon. She has extensive expertise in directing and managing multicomponent and multi-site projects, including her role as Principal Investigator of an ECHO cohort award from NIH which contains three cohorts of families, coordination with her cohort co-investigators across the U.S., and coordination with the larger ECHO consortium of more than 30 awardees. She co-chaired the Data Sharing working group for ECHO and serves on its Return of Results workgroup. On her P50 Center of Excellence award, she directs the Administrative Core, and received a HEAL supplement to focus on web-based platforms for the prevention of substance use in adolescent and young adult populations. Both ECHO and HEAL have extensive data harmonization and data sharing requirements, which Leve's projects have fully met. She holds national and local leadership roles

that require outstanding research and leadership skills, including her past role as President of the Society for Prevention Research, and her current roles as Associate Vice President for Research at the University of Oregon and Associate Director of the Prevention Science Institute. She is an accomplished scholar, with over 170 peer reviewed publications focused on research in partnership with community social service organizations and has been an investigator on dozens of NIH grants.

Co-I: Camille Cioffi, Ph.D., Cioffi is a Research Associate at the Prevention Science Institute at the University of Oregon. She has experience in providing leadership and support to multicomponent and multi-site projects, including her role on the CPO, coordination for Dr. Leve's ECHO cohort award from NIH, and Oregon Suicide Prevention and Response for Youth (OSPREY). On the CPO, she has worked closely with community-based agencies to establish research to practice partnerships and has provided support on the administrative core to improve coordination between the center components which includes service on the data science core and science communication committee. Cioffi has worked extensively with the MPIs for this project engaging in weekly meetings with each of the PIs in her various roles. In addition to her role on the CPO and OSPREY, she is presently assisting Drs. Leve and Cresko on the University of Oregon on the COVID-19 Monitoring and Assessment Program as the project Community Liaison, which has included assistance coordinating the implementation of testing sites in Lane County and Marion County. Along with her publications on public health research and implementation science, her commitment to bridging the gap from research to practice is exemplified in her involvement with the federal Research-to-Policy Collaboration, service to Oregon Health Authority collaborations, and co-instruction of Implementation Science coursework.

Co-I: Hannah Tavalire, Ph.D., Tavalire is a Research Associate in the Prevention Science Institute at the University of Oregon. She currently serves as the Scientific Coordinator for the COVID-19 Monitoring and Assessment Program (COVID-19-MAP), working closely with community partners in Lane and Marion Counties to facilitate testing and collect research samples. Tavalire has also served on working groups and task forces as part of an ECHO cohort award and in the Data Science Core of Leve's P50 Center of Excellence award. She has expertise in infectious disease biology, genomics, and has led several field research teams, including a current SARS-CoV-2 testing team.

(Phase 2) Co-I Dr. Jeff Gau, project methodologist, has expertise in the design and analysis of experimental and quasi-experimental research in public health, including advanced statistical modeling of longitudinal and multilevel data and missing data analysis. Dr. Gau will supervise all data analyses and conduct data analyses. Dr. Gau will also supervise the project data manager, Llewellyn Fernandes.

2. Roles and Research Duties

The Principal Investigator will assume responsibility for all scientific, administrative, financial, and operational aspects of the project.

Co-Investigators will:

- assist the PIs with administrative functioning of the overall project
- assist in facilitating the community-based participatory approach
- support the project's collaboration with key community stakeholders and interface with county collaboratives
- interface with funded RADx-UP Social, Ethical and Behavioral Implications program grantees (SEBI, NOT-OD-20-119) and other RADx-UP field sites to support novel research on social, ethical and behavioral implications of testing in underserved and/or vulnerable populations
- contribute to activities to support implementation of the proposed interventions
- oversee the implementation and improvement science methodology employed to address the study aims
- assist in administrative and communication aspects of the testing project between working groups and help coordinate with the CDCC
- serve as data analytic support
- serve as a consultant on data processes and data modeling
- play a leadership role in the design, optimization, and implementation of data science tools and approaches.

Research Assistants will support the implementation of testing sites throughout Oregon and will provide implementation support to HIVA collaborators. RAs will also collect individual data on intervention

effectiveness and common data elements and assist with data analyses and dissemination activities. RAs are TBD thus none are listed in the present application.

For Aim 1, the graduate student research assistant, Maryanne Mueller, will deliver the intervention to syringe exchange clients. She will be trained and supervised by Dr. Anne Mauricio. Mueller is a student in the Couples and Family Therapy program and has had training in similar strengths-based approaches. Dr. Mauricio will provide motivational interviewing training and scripts to facilitate the brief intervention with clients. Dr. Mauricio will provide opportunities for practice and feedback.

For Aim 2, Dr. Mauricio will provide motivational interviewing training to HIV Alliance staff and volunteers to facilitate their delivery of Connect2Test with clients. Dr. Mauricio will provide opportunities for practice and feedback.

3. Training and Oversight

Co-investigators and research assistants will perform research activities within the scope of their training.

Training for research assistants and HIVA testing facilitators who collect data from participants will be provided by the research team. Training will include how to sanitize devices used for data collection, relevant human subjects training, and standardized processes and procedures for data collection.

HIV Alliance staff will participate in an alternative human subjects training plan for these individuals. Specifically, a researcher with human subjects training will provide human subjects training during the training already being conducted by the research team. All HIV Alliance staff will be added to the research plan and will complete Individual Investigator Agreements (IIA)s if they are not affiliated with the UO. Alternative training procedure and training dates will be documented in the research records.