Research Protocol and Consent Forms
Supported Employment COVID-19 Rapid Testing for PWID
ID: STUDY00000657
Approval Date: 6/27/2023

PROTOCOL

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: Supported employment to create a community culture of SARS-CoV-2 rapid testing among people who inject drugs: PeerConnect2Test

Protocol Number: STUDY00000657

Principal Investigator: Camille Cioffi

A. Introduction and Background

This project uses a novel approach to adapt to the changing pandemic context; facilitation of rapid testing by people who inject drugs (PWID) via a supported employment program that trains PWID as peer health workers (PHW). PWID are vulnerable to contracting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and to the effects of the disease caused by SARS-CoV-2, coronavirus disease 2019 (COVID-19) due to structural disadvantage, health vulnerabilities, and stigmatization that prevents adequate access to medical care.

The ever-changing nature of the pandemic, including new variants and the availability of new SARS-CoV-2 vaccines, calls for strategies that can increase access to and uptake of testing among PWID. Rapid tests may offer an advantage over PCR tests for PWID experiencing structural vulnerabilities such as houselessness and lack of access to technology so that they can receive results in real-time and be quickly connected to needed resources. Accessibility of rapid testing for PWID has been previously limited by workforce shortages and the inability to reach PWID who need testing.

We propose a novel community-engaged strategy to improve the accessibility of rapid tests through a supported employment program for PWID, Peer Connect2Test (PeerC2T), to become PHW to distribute SARS-CoV-2 rapid test kits to other PWID. We expect that PeerC2T will improve knowledge, self-efficacy, and health behaviors among PHW (Aim 1). We will use the RE-AIM framework in Aims 2 and 3 to evaluate whether PeerC2T improves SARS-CoV-2 testing uptake among other PWID (RE; Aim 2) and identify intervention considerations (AIM; Aim 3).

The overall goal of this project is to collaborate intentionally with HIV Alliance (HIVA) to develop a transformative community-driven intervention to promote widespread access to rapid testing among PWID. We will also collaborate with the RADx-UP Coordination and Data Collection Center. Findings will clarify the implications of supported employment programs for PWID for SARS-CoV-2 testing uptake among PWID and other public health efforts to improve health outcomes among PWID. Thus, findings from this study may have broad public health implications for leveraging supported employment programs for PWID to prevent the transmission of other infectious diseases.

B. Specific Aims/Study Objectives

Aim 1: Establish the PeerC2T supported employment program for PWID PHW and evaluate the benefits of PeerC2T on PHW. Key benchmarks of Aim 1 are: a) written policies and procedures, and b) completion of a mixed-methods study.

- **Aim 1a:** Using Community Conversation Circles with PWID co-design the Peer Connect2Test (PeerC2T) supported employment intervention, we will develop a supported employment program leveraging equitable implementation practices. The low-barrier employment program will include supportive supervision and ongoing support to PWID to learn workforce skills to become PHW, to deliver COVID-19 rapid tests and related health information.
- **Aim 1b:** Using a mixed-methods approach, we will evaluate the benefits of PeerC2T on PHW, by conducting a pre-post and follow-up assessment of knowledge, self-efficacy, and behaviors related to COVID-19.

Aim 2: Examine the Reach/Effectiveness of PeerC2T

- **Aim 2a:** Assess a) the percentage of PWID who test when approached by PHW.

- **Aim 2b:** Assess b) the individual structural determinants of health (e.g., healthcare access, education, discrimination) as predictors of testing uptake among a subset of PWID who complete a survey containing the RADx-UP common data elements.

Aim 3: Examine Adoption, Implementation, and Maintenance

- **Aim 3a:** Collect data from PHW on the PeerC2T program to understand key considerations for long-term program success.
- **Aim 3b:** Collect data from HIVA staff on the PeerC2T program to understand key considerations for long-term program success.

C. Methods, Materials and Analysis

Aim	Description	Participants	Compensation
Aim 1a	Community Conversation Circles	160	$30/meeting
Aim 1b	Surveys for PHW	100 (3 times points; baseline, post-training, 3 month follow up)	$20 x 3 = $60 +$30 for the Common Data Elements Survey = $90
Aim 1b/ Aim3a	Interviews with PHW (benefits of the program and implementation considerations)	40 (subset)	$50
Aim 2a	PeerC2T Reach	1000	none
Aim 2b	PeerC2T Effectiveness (common data elements survey)	350	$30
Aim 3b	Interviews on Implementation with HIVA Staff	20	$50

Aim 1a: Community Conversation Circles

Methods & Materials

For Aim 1a, we will facilitate Community Conversation Circles (i.e., focus groups with flexible attendance) with PWID to co-design the supported employment program. Community Conversation Circles will be held in Lane, Marion, Josephine, and Douglas counties. Each county will hold meetings up to two times. We expect no more than 20 people to attend each group meeting per county (4 counties x 2 meetings each x 20 participants = N = 160). Participants can attend one or both groups. To facilitate Community Conversation Circles, we will leverage the syringe exchange advisory group meetings HIV Alliance already hosts in Lane, Douglas, Josephine, and Marion counties. Snacks are currently provided at these meetings by HIV Alliance. The meetings occur in a private meeting space in either HIV Alliance office locations or church locations where syringe exchange is held. At the time of consent, participants will also be asked to provide their HIV Alliance ID which includes the first two letters of the city they were born in, the first two letters of their last name, and their date of birth. This will allow us to track attendance in a way that is comfortable to participants. At the second meeting of each group, we will collect HIV Alliance ID on a sign in sheet to track who attends. We intend to track attendance so that we can ensure we have a signed consent form from each individual without asking them to re-consent.

We will also collect a brief survey with demographic information for NIH reporting purposes including race, ethnicity, and gender at the first meeting. Participants will also be invited to share their contact information if they would like to receive a reminder about the next Community Collaboration Circle.

As these are regularly scheduled meetings that staff members from HIV Alliance normally facilitate, the circles will be co-facilitated by a member of the UO study team and a staff member from HIV Alliance. All aspects of the circles related to research will be conducted by the UO research team. Circles will not be audio-recorded and instead will have at least 2 additional research staff on site to take notes and document information provided. Each circle will take up to 2 hours and will include a discussion of the topics/questions described below. Topics may change slightly based on feedback from the Community Conversation Circles planning team which includes the study team and HIV Alliance staff. Data will be analyzed by summarizing the themes

from each listening circles for consideration when developing PeerC2T program materials. As the only data source for the meeting will be meeting notes, there is no identifiable information connected to the participant information other than their attendance at the meeting.

Semi-structured Community Collaboration Circle Topics for Meeting 1	**Semi-structured Community Collaboration Circle Topics for Meeting 2**
1. Introduction/ice breaker/study background (who is the funder, who is conducting the research, what are we hoping to do) (10 min) 2. Establishing group norms (10 min, e.g., what do you need from each other and the research team to feel safe? What do you need to feel like the process has been rewarding?) 3. What kind of support would you like from an employer? What are the things that have made you feel successful in previous work? 4. The goal of the funding is to make sure we can get COVID-19 rapid tests to people who need it. We are currently thinking this would happen during street outreach, meaning you would go out with a peer street outreach worker to hand out rapid tests. How would you envision doing that or how have you done that already in your community? 5. Is this something you would be interested in applying for? What training would you need to feel successful? 6. Part of the goals of this program is to help people who need employment gain marketable skills while also earning income. What are some ways HIV Alliance could support you in addition to paying you for your time?	1. Recap of group norms 2. Brief overview of the study 3. Overview of what has been created based on feedback since the last meeting and reactions (e.g., training manual highlights/training plan, policy highlights, shifts available, what does the work look like in practice) 4. How will we know that this program has made a difference in the lives of people who are employed by HIV Alliance? 5. How will we know this program has made a difference in the lives of the people receiving the services (e.g., COVID-19 rapid tests)?

Aim 1b: Surveys for PHW
Methods & Materials:
PHW hired as part of the HIVA Supported Employment program will be invited to participate in three surveys related to their experiences as PHWs.

All three surveys will be conducted via Qualtrics. A member of the research team will reach out to each PHW via phone, text, email, social media, or in person to schedule a time to complete each survey. Participants will be offered the option to complete the surveys in person (at an HIVA location or a private community location easy for them to access), on their own online, or over the phone with a member of the research team. We will also collect information from HIV Alliance on the trainings the PHW receives and the number and type of shifts the PHW works.

	Purpose	**Timepoint**	**Constructs/Measures**	**Survey Length**
PHW Baseline Survey	PWID current knowledge, self-efficacy, and behaviors related to COVID-19 self and	After onboarding, prior to beginning training	- Knowledge - Self-efficacy - Behavior - Overall well-being	20 minutes

	community prevention, characteristics of the individuals who become PHW		(flourishing scale) - CDE Survey (intervention moderators)	
PHW Post-Training Survey	Understand immediate gains in knowledge, self-efficacy, and behavioral intentions related to COVID-19 self and community prevention	Two weeks after onboarding or immediately upon completion of the first two steps of PHW training (whichever is completed last)	- Knowledge - Self-efficacy - Behavioral intentions - System Usability Scale (SUS)	20 minutes
PHW Follow-Up Survey	Understand sustainment in knowledge, self-efficacy, behavior, and chance in overall well-being and other contextual factors	Three months after completing onboarding	- Knowledge - Self-efficacy - Behavior - Overall well-being (flourishing scale) - System Usability Scale (SUS)	20 minutes

- The "Knowledge", and "Self-efficacy" measures have been developed specifically for this study based on skills taught in the supported employment training.
- The "Behavior" measure was adapted from questions from the Preventative Medicine Attitudes and Activities Questionnaire.
- The "Behavior Intentions" measure was adapted from the same questions from the Preventative Medicine Attitudes and Activities Questionnaire with response options reframed based on how often they intend to engage in the behavior.
- The "System Usability Scale" in an existing measure that will be adapted used to measure training satisfaction and intervention satisfaction.
- The "Overall well-being" measure from the "Flourishing scale" is an existing measure that will be used to measure the respondent's self-perceived success in important areas such as relationships, self-esteem, purpose, and optimism.
- The "Common Data Elements (CDE) Survey" is a measure required by our funder, the National Institutes of Health for all Rapid Acceleration of Diagnostics for Underserved Populations (RADx-UP) projects.

As part of Aim 2b (detailed in the Aim 2b section), PHWs who engage in community outreach of PWID to offer rapid COVID-19 tests will also hand out flyers to any person who has been offered testing, regardless of whether the individual decides to take a test. The flyers will include a space for the PHW to put a code word that links the Aim 2b participant to the PHW that they received information from. Adding this study code will allow us to identify if there are differences based on the PHW that impact whether people choose to complete testing or not. The code word used on flyers will be different than the unique study ID provided to the participant. The consent form will acknowledge this process and note the unique way the project will identify them through flyers that they distribute to PWID so that we can track who is calling after their outreach. To minimize the risk of coercion, we will clarify that there are no incentives for handing out flyers or for getting people to take a test.

Analysis:

We will use repeated measures approaches (e.g., repeated measures analysis of variance, paired t-tests) to evaluate change in knowledge, self-efficacy, behavior, and overall well-being by comparing baseline scores to scores obtained during the post-training and 3-month follow-up assessments. Change in baseline to post-training scores will inform on immediate gains realized from the training. Change in study outcomes at baseline to the 3-month follow-up assessment will test for maintenance of gains observed at post-training or identify changes that take longer to manifest (e.g., overall well-being). Using paired t-tests to estimate power and the parameters outlined above, we have sufficient power (>.80) to detect medium effects (d = .46) for pre- to post-training and 3-month follow-up change. We will conduct ancillary analyses to bolster our confidence in the internal validity of the quasi-experimental design. First, we will analyze dose-response based on time spent engaged in the training to determine whether the amount of training is significantly

associated with change in the outcome measures. Second, we will examine if those who report greater satisfaction with the PeerC2T employment program will have greater improvement in baseline- to post-training and 3-month follow-up test scores using residual gain score analysis. Finally, treating PHW post-training satisfaction as a process variable, we will assess correlations between the satisfaction ratings. To the extent that there is sufficient variability in training satisfaction, positive associations between these measures and change in baseline to post-training and 3-month follow-up scores will provide support for the acceptability and effectiveness of the training. We have sufficient power to detect correlations between medium to large effects (r = .42). Program feasibility benchmarks are: (a) meaningful pre- to post-training and 3-month follow-up differences (Cohen's d > .46) in PHW knowledge, self-efficacy, behaviors, and well-being; (b) high ratings for PHW satisfaction and program acceptability (mean ratings of > 5 on 7-point scale) and at the 75th percentile or greater on the SUS. Benchmarks are based recommended effect sizes of at least d >.25 to demonstrate meaningful change; and SUS score normative distributions associated with "high" acceptability.

Aim 1b/3a: Interviews for PHW
Methods & Materials:
Of the PHWs who complete a baseline survey in Aim 1b, 40 participants will be chosen to complete a one-time semi-structured interview with a member of the research team. We will use purposeful sampling to recruit PHWs with diverse experiences, based on their reported demographics, to complete interviews about their experiences with the HIVA Supported Employment program.

The interviews will take place over the phone, zoom or in person at a private location, depending on the preference of the PHW. Interviews will be audio recorded for subsequent transcription.

	Purpose	**Timepoint**	**Constructs/Measures**	**Interview Length**
PHW Interviews	Overall impact of the PeerC2T on PHW from the PHW perspective including how the program has impacted them	3 months post-training	- Perceptions of program benefits (Aim 1b) - Information about implementation (Aim 3a)	30-45 minutes

- Interviews will include questions developed for this project that can be triangulated with quantitative data on the way PeerC2T changed their understanding of COVID-19 and SARS-CoV-2 rapid testing and flourishing. In relation to Aim 1b, questions will include the extent to which PeerC2T (a) provided PWID with purpose and meaning; (b) helped them create more meaningful social relationships; (c) provided opportunities for engaging with society in a positive way; (d) helped PWH feel competent and capable; and (e) facilitated optimism about the future. In relation to Aim 3a, interviews will include questions to understand (a) how PHW viewed their role; (b) any adaptations PHWs made when delivering the PeerC2t intervention; and (c) reasons for adaptations.

Analysis:
Content analysis techniques will be used to analyze the transcript text. Coding of text will proceed in two stages. First, a topical indexing coding dictionary will be developed to identify the text pertaining to topics generated. Following the procedures our team has previously successfully used in formative research, data management and data reduction will be accomplished using the NVivo text-analysis software that supports coding, organization, searching, and retrieval of qualitative data. A detailed coding scheme will be developed to capture the content, themes, or sentiment of responses within topics. Specific themes (i.e., content codes) within central concepts will be identified by the evaluation team, and all text pertaining to a specific topic will be coded individually by trained coders. Coder reliability for content will be determined through interrater comparisons of at least 20% of the randomly chosen text in major topical categories.

Aim 2a: PeerC2T Reach
Methods & Materials:

In Aim 2a, we will assess the percentage of PWID who accept a test kit when approached by PHW. HIVA will oversee the distribution of rapid tests through the Supported Employment program and will report aggregate program data back to the research team.

HIVA routinely collects demographic information from people requesting services. For each person PHWs approach and offer testing, the PHW will tally that a person was offered testing and document whether they agreed to testing or not. These programmatic administrative data will be provided back to the research team in aggregate for reporting purposes to NIH. Because this information is program data and we will not be collecting any identifiers, these participants would not be considered engaged in research and will not complete a consent form.

All people approached about testing will receive a flyer that invites them to participate in a survey (described under Aim 2b).

Using the processes outlined above, we anticipate that PHW will reach out to 1,000 PWID to offer testing.

Analysis:

PHW will reach out to at least 1,000 PWID, track the number of individuals who agree and do not agree to rapid testing, and we will compute the percentage who accept the kit and agree to self-test. We based the proposed non-probability target of PWID on a sample frame of 4,804 unique syringe exchange clients HIV Alliance reported in 2021. With the proposed sample of 1,000, we will be 95% confident that the true population percentage of HIV syringe exchange clients who agree to self-test will be within a ± 3% margin of error of the sample estimate. If we are not successful in obtaining the full target sample, we would still be within a ± 4% margin of error in our sample estimate with approximately half the proposed target sample (n = 534).

Aim 2b: PeerC2T Effectiveness

Methods & Materials:

As stated above, PHWs will provide a flyer to all people approached about testing that invites them to participate in a research survey. Potential participants can reach out via the study phone number or come to an HIVA event or the HIVA office to take the survey. Potential participants will receive information about times from the study team either on the flyer or via text, call, email, or social media. If a participant prefers an alternative meeting location and time, they will be able to contact the study team and the team will make alternate arrangements. The flyer will be provided to the study team and each flyer will have a unique identifier printed to ensure only people who have been engaged by the PWID PHW can participate. We will also only allow individuals to take the CDE survey one time and will create a secure searchable database for research assistants to verify whether an individual has completed a survey in the past to verify eligibility. PHW will not be eligible to complete the survey. People who have taken the survey will not be prohibited from becoming a PHW in the future.

For participants who engage in testing, we will include a HIPAA authorization to confirm the test results with HIVA. The HIPAA authorization will be bi-directional so that we can share that the participant was engaged in the research and HIVA can confirm whether a test result is in their records.

The Aim 2b survey will be conducted via Qualtrics. Participants will be offered the option to complete the surveys in person (at an HIVA location or a private community location easy for them to access), on their own online, or over the phone with a member of the research team.

	Purpose	**Timepoint**	**Constructs/Measures**	**Survey Length**
HIV Alliance ID	To request information about rapid testing uptake	After being offered COVID-19 testing from a PHW and connecting with the research team to complete the survey.	First Name Last Name Date of Birth City of Birth	1 minute
PHW Follow-Up	To assess structural determinants of health as		- CDE Survey (including healthcare	20 minutes

Survey (Common Data Elements Survey)	predictors of testing uptake among PWID.		access, educational attainment, social relationships, discrimination, income, food security and housing stability)	

- The "Common Data Elements (CDE) Survey" is a measure required by our funder, the National Institutes of Health for all Rapid Acceleration of Diagnostics for Underserved Populations (RADx-UP) projects.

Analysis:

To test whether social determinates of health (e.g., healthcare access, education, and discrimination) predict the uptake of PWID who agree to rapid testing, we will use logistic regression models estimated with a logit link. We will report odds ratios and 95% confidence intervals. We will first estimate univariate models to evaluate the unique effects of each SDOH. Next, to evaluate the unique contribution of SDOH in the context of multiple SDOH, we will estimate a multivariable model and include any univariable predictor associated with uptake of rapid testing at $p < .30$. Although we have no specific hypotheses regarding the interactive effects of SDOH, we will explore how the intersection of SDOH may contribute to the likelihood of rapid testing. We will add pairs of SDOH variables, informed on from the univariable and multivariable logistic regression models, and the multiplicative interaction term between the SDOH variables will address whether the level of one SDOH affected the magnitude of another SDOH on testing uptake. We will probe all significant interactions by computing sample-estimated intercepts and slopes of the log odds of the outcomes at conditional levels of one of the SDOH. Power estimates based on logistic regression models demonstrated there is sufficient power to detect odds ratios as small as 1.88 or greater, small to medium effects for Aim 2b.

Aim 3b: Implementation HIVA Staff

Methods & Materials:

In Aim 3b, we will examine the adoption, implementation, and maintenance of the supported employment program through examining administrative program data routinely collected by HIVA (e.g., number of clients served by each program total and number of clients reached by PHW) and semi-structured interviews with HIVA staff (n=20) following program implementation.

HIVA staff who are involved in the supported employment program will be invited to participate in a one-time semi-structured interview with a member of the research team. Interviews will take place over the phone, zoom or in person in a private space, depending on the preference of the HIVA staff member. Interviews will be audio recorded for subsequent transcription.

	Constructs/Measures	**Interview Length**
HIVA Staff Interviews	- Satisfaction with supported employment program - Willingness to integrate program into practice if funding was available - Ways the development of the supported employment program changed policies and practices within HIVA	30 minutes

- Interviews will include questions developed for this project that will be coded to look for themes that are congruent and incongruent with program adoption, implementation and maintenance.

Analysis:

Content analysis techniques will be used to analyze the transcript text. Coding of text will proceed in two stages. First, a topical indexing coding dictionary will be developed to identify the text pertaining to topics generated. Following the procedures our team has previously successfully used in formative research, data management and data reduction will be accomplished using the NVivo text-analysis software that supports coding, organization, searching, and retrieval of qualitative data. A detailed coding scheme will be developed to capture the content, themes, or sentiment of responses within topics. Specific themes (i.e., content codes) within central concepts will be identified by the evaluation team, and all text pertaining to a specific topic will

be coded individually by trained coders. Coder reliability for content will be determined through interrater comparisons of at least 20% of the randomly chosen text in major topical categories.

D. Research Population & Recruitment Methods

Aim 1a: Community Conversation Circles

Research Population. People who are 18 years or older and are utilizing HIV Alliance's syringe exchange services in Lane, Marion, Josephine, or Douglas counties will be recruited to participate in this phase of the research.

We will not include prisoners in our research population. Given our recruitment methods, incarcerated individuals will not be recruited for the initial community circles (people must be present in person at the initial meeting to be involved in the project). Given our contact methods for future circles require people to have access to a phone or internet, it's unlikely that we would be able to contact participants who become incarcerated after the initial meeting. If a participant becomes incarcerated during the study, we will not continue to assess them.

Inclusion Criteria. Participants must be: 1) 18 years or older, 2) Utilizing HIV Alliance's syringe exchange program, 3) Able to speak and understand English.

Recruitment Methods. The initial Community Conversation Circle for each cohort will be pre-scheduled by the study team. Within a week prior to the first scheduled circle, members of the research staff will be present in person at HIV Alliance syringe exchange sites in the targeted counties to hand out flyers to people utilizing syringe exchange services, invite them to participate in the upcoming circle and answer questions they have about participation. Participants will be notified that we will enroll the first 20 people to show up to the initial meeting and will begin enrolling people 30 minutes prior to the scheduled meeting time. Recruitment materials (Phase 1 Flyer) will include details about the initially scheduled Community Conversation Circle.

Within a week prior to each scheduled cohort meeting, members of the study team will be present at HIV Alliance syringe exchange sites in the targeted counties handing out flyers (**Phase 1 Flyer**) about the upcoming meeting and inviting people to participate.

Participant Enrollment. We aim to enroll up to 160 participants into Community Conversation Circle cohorts. We will have an opportunity for up to 20 participants to participate in each cohort but anticipate groups may be smaller than that.

Compensation. Participants will receive $30 in the form of a gift card or cash for each meeting they attend. The availability of cash will be informed by the Prevention Science Institute business manager. Participants will be able to choose between Fred Meyer or Grocery Outlet gift cards. Gift cards will be provided immediately following the group meeting.

Aim 1b: Surveys for PHW

Research Population. People who are 18 years of age or older and are hired to work as Peer Health Workers (PHWs) for the Supported Employment program at HIVA will be recruited to participate in this phase of research.

Inclusion Criteria. Participants must be: 1) 18 years or older, 2) Hired as a PHW for HIVA's Supported Employment program, 3) Able to speak and understand English.

Recruitment Methods. At the time of onboarding, participants will be notified that the Supported Employment program is being offered as part of a research study in conjunction with the University of Oregon. The onboarding manager at HIVA will ask the PHW to sign a release of information that allows them to notify the UO team of the new PHWs onboarding including their contact information. Once contact information is received by the research team, a member of the team will reach out to the PHW via phone, text, email, social media, or in person to schedule a time to meet (virtually or in person) and discuss the research opportunity.

Participant Enrollment. We aim to enroll up to 100 PHWs in this phase of our research.

Compensation. Participants will receive $20 for each survey they complete for a total possible compensation of $60 for program survey completion. They will also be able to complete the common data elements survey for an additional $30 (the same survey Aim 2b participants complete). Compensation will be provided in the form of gift cards or cash and will be provided to the participant following the completion of each survey. Compensation will be provided in person, via mail, or electronically via email, social media, or phone.

Aim 1b/3a: Interviews for PHW
Research Population. A subset of people who are 18 years of age or older and are hired to work as PHWs for the Supported Employment program at HIVA will be invited to participate in qualitative interviews.
Inclusion Criteria. Participants must: 1) Be 18 years or older, 2) Be hired as a PHW for HIVA's Supported Employment program, 3) Have worked as a PHW for at least 1 month, 4) Have completed at least 3 shifts, 5) Be able to speak and understand English.
Recruitment Methods. We will use purposeful sampling to recruit PHWs with diverse experiences early on and later in program establishment to complete interviews about their experiences with the HIVA Supported Employment program. Selected participants will be invited via email, text, phone, social media, or in person to schedule and complete a semi-structured interview at the time of their 3-month follow- up survey.
Participant Enrollment. We aim to enroll up to 40 PHWs in this phase of our research.
Compensation. Participants will receive $50 for completing the semi structed interview. Compensation will be provided in the form of gift cards or cash and will be provided to the participant following the completion of the interview. Compensation will be provided in person, via mail, or electronically via email, social media, or phone.

Aim 2a: PeerC2T Reach
Because the data collected for this aim are aggregate program data from HIVA and identifiers will not be included, these participants are not considered engaged in the research.

Aim 2b: PeerC2T Effectiveness
Research Population. People who are 18 years or older and were offered COVID testing from a PHW in Lane, Marion, Josephine, or Douglas counties will be recruited to participate in this phase of the research.
Inclusion Criteria. Participants must be: 1) 18 years or older, 2) Have been previously offered COVID testing from a project PHW, 3) Able to speak and understand English.
Recruitment Methods. All people approached by PHWs in Aim 2a will be given a flyer that invites them to participate in a survey. The flyer will include specified times that the participant can come to HIVA to complete their survey or will provide the option to contact the study team to set up alternative arrangements or identify other potential times when research teams may be on site.
Participant Enrollment. We aim to enroll 350 participants in Aim 2b with 175 participants being people who agreed to complete COVID testing and 175 participants being people who declined COVID testing.
Compensation. Participants will receive a $30 gift card or cash upon completion of the survey. Compensation will be provided in person, via mail, or electronically via email, social media, or phone.

Aim 3b: Implementation HIVA Staff
Research Population. HIVA staff members who are involved in the supported employment program will be invited to participate in this phase of the research.
Inclusion Criteria. Participants must be: 1) A staff member at HIVA, 2) Have participated in the development and/or implementation of the supported employment program.
Recruitment Methods. Research staff will reach to staff members at HIVA via email, phone, social media, or in person to invite them to participate. The first 20 eligible staff who express interest in participating will be invited to participate.
Participant Enrollment. We expect to complete interviews with up to 20 HIVA staff members.
Compensation. Participants will receive $50 in gift card, cash, or check upon completion of the interview. Compensation will be provided in person, via mail, or electronically via email, social media, or phone.

E. Informed Consent Process

Consent Practices Across All Aims:

All consented participants 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. To ensure understanding, participants will be encouraged to ask any questions they have about the consent form and/or their participation in the study. They will be informed about potential benefits and harms. For participants who complete study activities at multiple time points, ongoing consent will be ensured through reminding participants that their participation is voluntary and giving them space to ask any questions about study activities or to re-review the consent at any time. Members of the research team providing consent will complete training with the Project Coordinator prior to consenting participants.

Note about Clinical Trials Compliance:
For aims that meet the definition of a clinical trial, the consent forms include language indicating that a description of the clinical trial will be available on clinicaltrials.gov as required by US law. In concordance with Health and Human Services (HHS) and National Institutes of Health (NIH) requirements, we will:

- Register the study in clinicaltrials.gov no later than 21 calendar days after the enrollment of the first participant (this has been completed)
- Make all consent forms will be made publicly available on clinicaltrials.gov within 60 days after the last study visit by any participant
- Provide our study results within 1 year of study completion on the clinicaltrials.gov website

Aim 1a: Community Conversation Circles
Upon arriving for the initial Community Conversation Circle, participants will be provided with the consent form on paper and will be asked if they would prefer to read the form themselves or to have a member of the research team review the form with them. If a participant chooses to review the form independently, a member of the research team will be available to answer questions while the participant reviews the consent. A member of the UO research team will also review the consent form, prior to facilitating the group discussion. Participants will be given a copy of the consent form to keep.

Aim 1b: Surveys for PHW:
Prior to beginning the baseline survey, participants will be provided with a consent form to complete via Qualtrics. Participants will be asked whether they would prefer to read the forms themselves or have a member of the research team review the form with them. If the participant chooses to review the form independently, a member of the research team will be available to answer questions. Participants will be offered a paper copy of the consent form or an emailed copy of the consent form to keep. If the participant prefers to complete the consent process over the phone, the research team member will send the link to sign the consent via email, social media, or text message. Participants will also be asked to complete an information sharing agreement that allows the study team to receive employment records and services records from HIV Alliance. This agreement will be signed on Qualtrics using the signature function on Qualtrics.

Aim 1b/3a: Interviews for PHW
Prior to completing the interview, participants will be provided with a consent form to complete via Qualtrics. Participants will be asked whether they would prefer to read the forms themselves or have a member of the research team review the form with them. If the participant chooses to review the form independently, a member of the research team will be available to answer questions. Participants will be offered a paper copy of the consent form or an emailed copy of the consent form to keep. If the participant prefers to complete the consent process over the phone, the research team member will send the link to sign the consent via email, social media, or text message. This agreement will be signed on Qualtrics using the signature function on Qualtrics.

Aim 2a: PeerC2T Reach
Because data collected for this aim are aggregate program data from HIVA and identifiers will not be included, these participants are not considered engaged in the research. We will not consent people who peer health workers are interacting with/inviting to take a rapid test in this aim of the project.

Aim 2b: PeerC2T Effectiveness

Prior to beginning the survey, participants will be provided a consent form to complete via Qualtrics. Participants will be asked whether they would prefer to read the forms themselves or to have a member of the research team review the form with them. If a participant chooses to review the form independently, a member of the research team will be available to answer questions while the participant reviews the ROI and consent. Participants will be offered a paper copy of the consent form or an emailed copy of the consent form to keep. If the participant prefers to complete the consent process over the phone, the research team member will send the link to sign the consent via email, social media, or text message. Participants will also be asked to complete an information sharing agreement that allows the study team to receive information about the participant's COVID-19 rapid testing from HIV Alliance. This agreement will be signed on Qualtrics using the signature function on Qualtrics.

Aim 3b: Implementation HIVA Staff

Prior to completing the interview, participants will be provided with a consent form to complete via Qualtrics. Participants will be asked whether they would prefer to read the forms themselves or have a member of the research team review the form with them. If the participant chooses to review the form independently, a member of the research team will be available to answer questions. Participants will be offered a paper copy of the consent form or an emailed copy of the consent form to keep. If the participant prefers to complete the consent process over the phone, the research team member will send the link to sign the consent via email, social media, or text message using the signature function on Qualtrics.

F. Provisions for Participant Privacy and Data Confidentiality

1. Privacy (all aims)

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. The research team will not have access to HIVA client protected health information.

2. Data Disposition (all aims)

For all identifiable data, consents, and HIPAA Authorization are programmed with the survey questions but identifying information (names on consent/HIPAA) will be 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 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.

Contact information will be stored for the duration of the project. In the consent form, we have included a statement allowing for re-contact of participants to invite them to participate in other research studies for which they may be eligible. No contact information or identifiable data will be shared with other research projects but a member of this research team may contact participants about other studies.

3. Confidentiality (all aims)

All research data 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 collected through Qualtrics is protected by Qualtrics' high-end firewall systems. Their servers are scanned regularly to ensure that any vulnerabilities are quickly found, and patched, and complete penetration tests are performed yearly. Their confidential system component design uses multiple checks to certify that packets from one subsystem can only be received by a designated subsystem. Access to systems to severely restricted to specific individuals, whose access is monitored and audited for compliance. Qualtrics uses TLS encryption for all transmitted data, and they protect surveys with passwords and HTTP referrer checking. Qualtrics' services are hosted by trusted data centers that are independently audited using the industry standard SSAE-16 method. When the results of this project are published, participant names will not be

used. Data will remain in Qualtrics during the data collection process. When the data collection process has concluded and all data have been downloaded from Qualtrics, we will delete all study records linking identifying information to data in Qualtrics. Access to this data through Qualtrics will be restricted to staff members who require access for data or participant management.

After data are entered, they 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.

Note about Paper Forms (relevant to Aim 1a only):
Data collected on paper forms will be collected by researchers upon completion before the beginning of the initial circle discussion for each cohort. Research staff will store the completed forms in a bag that they will keep on their person for the duration of the circle and will transport them back to PSI for locked storage after the circle ends.
Paper files will be stored in locked cabinets at PSI. Entrances to staff and data storage areas are locked and accessible only to authorized staff.

G. Potential Research Risks of Discomforts to Participants (all aims)

The overall risk involved in the project is minor, given the goals of the research.
Potential risks and discomforts involved in participation include (1) possible violation of confidentiality. This risk is unlikely but possible. To minimize this risk, all records obtained from participants will be kept strictly confidential. To ensure strict confidentiality, data will not include identifiers. Additionally, for Community Conversation Circles, the consent form will detail that while our group norms will include a conversation about confidentiality, we cannot guarantee that others in the group will not share what they share.

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 included in our RAP submission.

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

H. Potential Benefits of the Research (all aims)

This study has the potential to identify a strategy that could positively improve the lives of PWID who are trained as peer health workers for the supported employment program. It also has the potential to reach people in need of testing 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.

I. Investigator Qualification, Roles and Training (all aims)

1. Investigator Qualification

PI: Camille Cioffi, Ph.D., Cioffi is a Research Assistant Professor 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 P50 Center of Excellence and several RADx-UP grants through the National Institutes of Health. On the P50 Center of Excellence, 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 Dr. Leve engaging in weekly meetings in her various roles. 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.

2. Roles and Research Duties

The Investigators will provide oversight of all project activities and data analysis, as well as training and supervision of research staff.

The Research Coordinator (RC) will lead day-to-day research activities, communications with PI and Co-PI, training and supervising research assistants, ensuring high quality data collection and data entry, and secure data transfer and storage.

The Data Managers will clean data to prepare for analysis and maintain the participant database.

The Research Assistants (RAs) will facilitate recruitment and consent procedures, facilitate paper data collection, complete data entry of paper data, take notes on community conversation circles and communicate with participants about follow up activities.

3. Training and Oversight

All research staff who will have contact with participants and/ or data will complete the CITI Human Subjects and GCP training courses, to ensure proper understanding of ethics involved in human subject's research. Prior to engaging with participants, research assistants will be trained by the Research Coordinator in the following:

1. obtaining consent and appropriately answering consent related questions
2. maintaining participant confidentiality including appropriate handling of data collection, data management and reporting procedures

UNABLE TO DELETE THE FOLLOWING – DOCUMENT IS LOCKED

F. Provisions for Participant Privacy and Data Confidentiality

G. Potential Research Risks or Discomforts to Participants

H. Potential Benefits of the Research

I. Investigator Experience

UNIVERSITY OF OREGON

Consent for Research Participation

Title: Peer Connect 2 Test: Participant Peer Surveys

Sponsor: National Institute on Drug Abuse (NIDA)

Researcher(s): Camille Cioffi, University of Oregon

Leslie Leve, University of Oregon

Researcher Contact Info: Coordinator: Ashley Nash

Phone: 541-346-0440**;** Email: anash@uoregon.edu

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

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation. • **Purpose**. The purpose of this research is to evaluate the supported employment program for community rapid COVID-19 testing provided by people who inject drugs. • **Duration.** It is expected that your participation will last about 20 minutes per survey and you will be asked to complete three surveys over about 3 months. You will also be asked to complete a common data elements survey, required by our funder, at the same time as when you take the first survey. You receive $20 for each of the three regular surveys and $30 for taking the common data elements survey for a total of $90. • **Procedures and Activities.** You will be asked to complete three surveys with questions about your knowledge, behaviors, thoughts and feelings related to the supported employment program and trainings. • **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 people may appreciate having the opportunity to share their lived experiences and provide program feedback. We also hope that information gained from this study will help develop a meaningful supported employment program for people who might face barriers to employment such as current drug use or criminal legal system involvement. You might not personally benefit from this research. • **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 foryour 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.

Why is this research being done?

The goal of this project is to collaborate with HIV Alliance to develop and evaluate a transformative community-driven supported employment program for community rapid COVID-19 testing provided by people who inject drugs. Findings will clarify the implications of supported employment programs for people who inject drugs for COVID-19 testing uptake and other public health efforts to improve outcomes for people who inject drugs. You are being asked to participate because you were hired as a peer health worker for HIV Alliance's supported employment program. About 100 people will take part in this research.

What happens if I agree to participate in this research?

Surveys: If you agree to participate in this research, you will complete three brief surveys. Each survey will take about 20 minutes to complete and will include questions about your knowledge, behaviors, thoughts and feelings related to the supported employment program and training and understanding of COVID-19 prevention.

You will have the option to complete each survey in person at HIV Alliance or a private community location, on your own online, or over the phone with a member of the research team. You can skip any question that you don't want to answer, and you can stop participating at any time.

Survey Timeline:

- Survey 1: Prior to beginning training for the HIV Alliance supported employment program
- Survey 2: Either two weeks after you complete onboarding for the HIV Alliance supported employment program or upon completion of the COVID-19 rapid test training of the supported employment training (whichever is completed last)
- Survey 3: Three months after completing your onboarding to the HIV Alliance supported employment program, you will be asked to complete a third survey.

Common data elements survey: You will also be invited to participate in the common data elements survey that is required by our funding agency for which you would receive an additional $30 gift card.

Program Information: In addition to completing three surveys, the research team will collect information from HIV Alliance about your engagement in the supported employment program including the trainings that you have completed and the number, types of shifts you have worked, the peer support services you have received, and any other services you have received from HIV Alliance.

Outreach Tracking: As part of the supported employment program, you may engage in community outreach to offer community members rapid COVID-19 testing. During this process, you may hand out flyers with information inviting people to participate in a different portion of this study, The flyers you hand out will include a space for a code word that is specific to you. We will use this code word to track the outreach you complete and aid in understanding how differences in outreach impact testing. The code word on your flyers will be different from the unique ID that we will use to track any other data about you in this study. There are no incentives to you for handing out flyers or getting people to take a test.

Interview: Some people involved in this research will be invited to participate in an additional interview at the same time as Survey 3. If you are invited to complete this interview, we will ask you to complete a separate consent form with details about this additional study activity.

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 understand impact of the supported employment program on people who participate in the program and the broader community. We may publish/present the results of this research, however, we will keep your name and other identifying information confidential.

Identifiers will be removed from identifiable private information collected in this research. After the removal of identifiers, the information may be used for future research or distributed to another investigator for future research without obtaining additional consent. Any results of this research that are made public will be in aggregate form only and never include information that can be linked back to you.

As described in more detail below, if you chose to participate, we will share your data with the National Institutes of Health (NIH) and 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.

We will keep your contact information for the duration of the project and may contact you to invite you to participate in other studies that you may be eligible for during and after your participation in this study. We will not share your contact information with anyone outside of our research team and do not have to participate in any other research studies that you are not interested in. You may request we stop contacting you about other research studies at any time by responding to outreach in writing.

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.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy and the security of your personal information including:

- Conducting research in a private setting
- Storing consent forms, and surveys on our secure server
- Strictly limiting access to our secure server to authorized research staff involved in the project
- Assigning a unique identifier instead of including identifying information on surveys

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). Despite these precautions to protect the confidentiality of your privacy and information, we can never fully guarantee your privacy or the confidentiality of all study information.

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.

The research team includes individuals who are mandatory reporters. If the research team has reasonable cause to suspect abuse or neglect of a child or adult, a report may be required under Oregon State Law. In such a case, the research team may be obligated to breach confidentiality and may be required to disclose personal information.

This research is covered by a Certificate of Confidentiality from NIH. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if

there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see above); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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, the University of Oregon or HIV Alliance.

If you decide to leave this research, please contact the research team so that the investigator can remove your information from the contact list so you will not be asked to continue completing surveys and you will not be invited to participate in other future studies.

Will I be paid for participating in this research?

You will receive $20 after completing each of the three surveys for a total of $60 if you complete all three program surveys. You will also receive an additional $30 for completing the common data elements survey. Altogether, you could receive up to $90 if you participate in all of the study surveys. You will receive each payment in person, or we will arrange with you the best way to send or give you the payment if you complete the surveys remotely.

Who can answer my questions about this research?

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

Ashley Nash
541-346-0440
anash@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
ResearchCompliance@uoregon.edu

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.

UNIVERSITY OF OREGON

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 on QUALTRICS.)

Name of Adult Participant	Signature of Adult Participant	Date

UNIVERSITY OF OREGON

Consent for Research Participation

Title:	Peer Connect2Test: Survey with Community Members
Sponsor:	National Institute on Drug Abuse (NIDA)
Researcher(s):	Camille Cioffi, University of Oregon
	Leslie Leve, University of Oregon
Researcher Contact Info:	Coordinator: Ashley Nash
	Phone: 541-346-0440**;** Email: anash@uoregon.edu

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

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research is to understand factors that increase the choice to get tested for COVID-19.
- **Duration.** It is expected that your participation will last about 20 minutes.
- **Procedures and Activities.** You will be asked to complete one survey with 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 receive $30 after completing this survey.
- **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 benefits that may be expected include contributing to understanding factors that motivate people to get tested for COVID-19. You might not personally benefit from this research.
- **Alternatives.** The alternative to participation is to get tested for free and not share your intake information and test results 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 foryour 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.

Why is this research being done?

The goal of this project is to collaborate with HIV Alliance to understand factors that increase the choice to get tested for COVID-19. Findings will clarify the implications of supported employment programs for COVID-19 testing uptake and other public health efforts to improve outcomes. You are being asked to participate because you were offered COVID testing from a peer health worker for HIV Alliance's supported employment program. About 350 people will take part in this research.

What happens if I agree to participate in this research?

If you agree to be in this research, you will complete one brief survey. The survey will take about 20 minutes to complete and will include 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 have the option to complete each survey in person (at HIV Alliance or a private community location), on your own online, or over the phone with a member of the research team. You can skip any question that you don't want to answer, and you can stop participating at any time.

In addition to completing this survey, the research team will share with HIV Alliance that you are involved in this research and if you shared COVID-19 test results with them, we will collect that information from HIV Alliance. Your participation in this research will not affect your relationship with HIV Alliance.

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 understand factors that increase the choice to get tested for COVID-19. We may publish/present the results of this research, however, we will keep your name and other identifying information confidential.
Identifiers will be removed from identifiable private information collected in this research. After the removal of identifiers, the information may be used for future research or distributed to another investigator for future research without obtaining additional consent. Any results of this research that are made public will be in aggregate form only and never include information that can be linked back to you.

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.

We will keep your contact information for the duration of the project and may contact you to invite you to participate in other studies that you may be eligible for during and after your participation in this study. We will not share your contact information with anyone outside of our research team and do not have to participate in any other research studies that you are not interested in. You may request we stop contacting you about other research studies at any time by responding to outreach in writing.

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.

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This research is covered by a Certificate of Confidentiality from NIH. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see above); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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, the University of Oregon or HIV Alliance.

Will I be paid for participating in this research?

You will receive $30 after completing this survey. You will receive each payment in person, or we will arrange with you the best way to send or give you the payment if you complete the survey remotely.

Who can answer my questions about this research?

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

Ashley Nash
541-346-0440
anash@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
ResearchCompliance@uoregon.edu

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 on QUALTRICS.)

Name of Adult Participant	Signature of Adult Participant	Date