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

Principal Investigator: Beth Stormshak

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 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.

C. Methods, Materials and Analysis

Overall Study Design: This study involves development and implementation of a COVID-19 testing program embedded in HIV Alliance's (HIVA) Syringe Service Programs (SSP) at 10 sites across Oregon (Aim 1). We will evaluate testing utilization rates as our outcome for Aim 1. Across all sites, for Aim 1, we expect to offer testing to 3800 unique individuals in Year One and to administer approximately 150 tests per week. For Aim 1, we will compute the ratio of total persons tested/total persons attending syringe exchange who were offered testing (n=3800) to assess testing program reach. The UO COVI9-19 MAP laboratory will report number of tests collected per site per week and HIV Alliance will share the number of individuals served per site per week. For Aim 1, HIVA SSP clients will also be invited to complete a "Common Data Elements" survey for the funder, National Institutes of Health. No identifying information is collected on the "Common Data Elements" survey. At the time of testing, the HIVA testing facilitator will invite clients to complete the survey and obtain signed informed consent. Consents and surveys will be read by the clients and completed via paper-pencil. Clients who complete the survey will receive a $10 gift card for their participation.

For Aim 2, we will develop a brief motivational enhancement intervention (Connect2Test) to increase testing program utilization and use a randomized control trial (RCT) design to evaluate if this intervention increases COVID-19 testing utilization, in comparison to a control condition. While the testing program will be implemented in 10 HIVA sites for Aim 1 to assess reach of the testing program, the RCT in Aim 2 will be limited to the six syringe exchange sites in Lane County to limit travel. Following 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 and consented participants will be randomized to the intervention or control condition by Qualtrics. At the time of consent, research staff will ask clients to complete a HIPAA Authorization form for the purpose of sharing their testing utilization data with the UO research team. The HIPAA Authorization form will also be programmed in Qualtrics. All participants, regardless of randomization, 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. Clients in the control condition will be invited to participate in testing after completing the survey. Clients in the intervention condition will be invited to participate in testing after the motivational interviewing intervention component. Clients who agree to participate in the RCT will receive a $20 gift card. The target sample size for the RCT in Aim 2 is 250 unique individuals. The RCT will be initiated approximately 2 months after the testing program has been initiated and we anticipate it will take approximately 1 month to reach the target sample size.

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:

Testing Program: Aim 1. The UO COVI9-19 MAP laboratory will report number of tests collected per site per week and HIV Alliance will share the number of individuals served per site per week. HIVA SSP clients will also be invited to complete a "Common Data Elements" survey for the funder, National Institutes of Health. No identifying information is collected on the "Common Data Elements" survey. At the time of testing, the HIVA testing facilitator will invite clients to complete the survey and obtain signed informed consent. Consents and surveys will be read by the clients and completed via paper-pencil. If clients 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. Clients who complete the survey will receive a $10 gift card for their participation.

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

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. Participants who participate in the study will receive a $20 gift card. 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.

Asses implementation experiences from HIVA staff and volunteers: Aim 3. HIVA staff and volunteers will be invited to participate and complete consent via email, which will include a signature. Staff/volunteers who consent to participate will be invited to complete a survey. Data will be collected as anonymous, without asking for participant name or other identifying information. Following survey completion, staff and volunteers

will be invited to participate in a 30-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. All staff and volunteer data will be presented in aggregate so that responses can never be linked to a particular staff or volunteer.

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 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, only participants who speak English will be eligible for the RCT (Aim 2), as Connect2Test materials will only be available in English. We anticipate approximately 3800 unique participants will be included in Aim 1 and approximately 250 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.

Recruitment Procedures:

For 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. No identifying information is collected on the "Common Data Elements" survey. At the time of testing, the HIVA testing facilitator will invite clients to complete the survey and obtain signed informed consent. Consents and surveys will be read by the clients and completed via paper-pencil. In most cases, clients will self-administer the survey but 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. Clients who complete the survey will receive a $10 gift card for their participation.

For Aim 2, 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 utilization data 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 testing utilization 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 every time they visit the exchange. The RCT in Aim 2 will be conducted at the six syringe exchange sites in Lane county; participants will be recruited from these six sites.

For 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 ten staff and up to 20 volunteers will participate in survey and interview data collection. Emails will be sent to staff and volunteer emails by HIVA. Following the survey, participants will be asked to select a time to schedule a 30-minute zoom or phone interview. Staff and volunteers will not be paid for their participation in the survey by will receive $35 each time they participate in an interview (up to two times).

E. Informed Consent Process

Aim 1. To assess the Aim 1 outcome, proportion of HIVA syringe exchange clients being tested, 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 complete the Common Data Elements survey and obtain signed informed consent. No identifying information is collected on the "Common Data Elements" survey. Consents and surveys will be read by the clients and completed via paper-pencil. If clients 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. Clients who complete the survey will receive a $10 gift card for their participation.

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. The research staff will also clarify that the identifying information that the participant includes in the CDE survey will be used by National Institutes of Health (NIH) and Duke Clinical Research Institute (DCRI) to link to other data such as Medicaid data, though once linked the data will be de-identified. The research assistant will also clarify that Medicaid and other data to which NIH/DCRI links will not be used by UO. Participants who participate will receive a $20 gift card. 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 utilization data to the UO research team. 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. Clients will be given a blank paper copy consent and HIPAA form.

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. Data will be collected as anonymous. All staff and volunteers interested in participating will be invited to participate. Staff and volunteers will provide signed informed consent before participating and will be emailed a copy of the consent form when they are emailed the survey link. 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.

F. Provisions for Participant Privacy and Data Confidentiality

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. No identifying information is collected on the "Common Data Elements" for Aim 1. 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 Aim 1, no identifying data will be linked to CDE survey data. Specifically, data will be entered using the HIVA ID only. For Aim 1 outcome, no individual level testing data is being collected by the research team. The CDE survey data is individual level data.

For aim 2, 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. 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
All de-identified 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 stored as de-identified data using their HIVA unique identifier and 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 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 event in order to be tested 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 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 to 3800 persons in year one, after which HIVA will continue to administer testing, adding to the total testing 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

PI: 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.

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: 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: 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.

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

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.

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.