

PATH R61 Pilot Protocol Document

Official Title:

PATH to reducing burnout among peers who deliver overdose prevention services: Improving workforce and service system outcomes through a combined eLearning and group consultation intervention (R61 Phase Pilot)

NCT Number:

NCT07218562

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12/5/24

**PATH to reducing burnout among peers who deliver overdose prevention services:
Improving workforce and service system outcomes through a combined eLearning and
group consultation intervention**

R61 Pilot Phase Protocol

ClinicalTrials.gov ID: NCT07218562

R61DA061340

Principal Investigator:

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Sponsor: Chestnut Health Systems

Funded by: National Institute on Drug Abuse (NIDA)

V1

12/05/2024

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

STATEMENT OF COMPLIANCE

The study will be conducted in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and the NIDA Conditions of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the Institutional Review Board (IRB). All personnel involved in the conduct of this study have completed Human Subjects Protection and Good Clinical Practice Training.

The protocol, informed consent documents, recruitment materials, and all participant materials are submitted to the IRB for approval. Approval of both the protocol and the consent form must be obtained before any participant is consented. Any amendment to the protocol requires approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:



Date: 12.5.24

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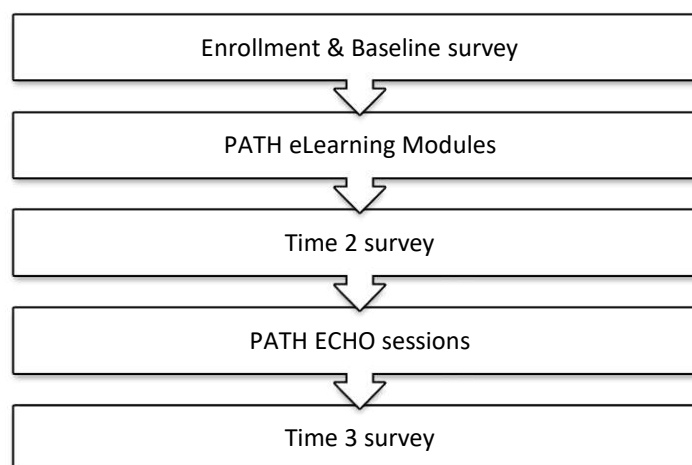
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

- Title:** PATH to reducing burnout among peers who deliver overdose prevention services: Improving workforce and service system outcomes through a combined eLearning and group consultation intervention (R61 Pilot Phase)
- Grant Number:** R61DA061340
- Study Description:** The investigators will test PATH (Peer Advanced Training for total Health) as an educational workforce intervention for improving peer recovery support specialists' (PRSS) overdose prevention (OP) service delivery ability and quality and as a PRSS workforce and service system support. The PATH intervention combines (a) virtual education and (b) case-based consultation.
- During the R61 phase of this grant, the investigators will pilot the PATH intervention with PRSS from two Recovery Community Organizations (RCOs) to understand its acceptability, appropriateness, and feasibility, as well as satisfaction with the training.
- Objectives^{*}:** The primary goal of the R61 phase of this grant is to assess the acceptability, appropriateness, and feasibility of PATH, as well as satisfaction with the PATH training components.
- Endpoints^{*}:**
- Primary Outcome Measures:
1. Acceptability of the intervention
 2. Appropriateness of the intervention
 3. Feasibility of the intervention
 4. Training Satisfaction
 - a. Objectives and content
 - b. Methods and training content
 - c. Usefulness and overall
- Secondary Outcome Measures:
5. Job crafting
 - a. Approach cognitive resources
 - b. Approach cognitive demands
 - c. Avoidance cognitive demands
 6. Moral injury
 7. Boundaries
 8. Professional quality of life
 - a. Burnout
 - b. Compassion satisfaction
 - c. Secondary traumatic stress
 9. Overdose prevention skills, attitudes, and knowledge
 10. Overdose prevention stigma

Study Population:	All participants will be (a) a PRSS currently employed by a participating RCO pilot site and (b) at least 18 years of age.
Phase[*] or Stage:	N/A; pilot
Description of Sites/Facilities Enrolling	Recovery Community Organizations (RCOs)
Participants:	Peer recovery support specialists (PRSS)
Description of Study Intervention:	PATH is an educational workforce intervention for improving peer recovery support specialists' (PRSS) overdose prevention (OP) service delivery ability and quality and as a PRSS workforce and service system support. PATH includes 4 hours of eLearning modules completed within a 1-month period, as well as 8 weekly ECHO sessions, each lasting 1.5 hours, delivered over a 2-month period. Each ECHO session includes a 30-minute presentation followed by one hour of case-based discussion about a real client or problem. The entire PATH intervention takes 16 hours (4 hours of eLearning and 12 hours of ECHO participation) over 3 months. Participants are expected to complete all 16 hours, completing the eLearning before starting the ECHO activities.
Study Duration[*]:	4 months
Participant Duration:	3 months

1.2 SCHEMA



1.3 SCHEDULE OF ACTIVITIES

Table 1: Schedule of Activities

Procedures:	Time point:		
	Enrollment	Post-eLearning (approximately 1- month post- enrollment)	Post-ECHO (approximately 3- months post enrollment)
Informed Consent	x	x	x
REDCap Survey: -Demographics -Acceptability of the intervention -Appropriateness of the intervention -Feasibility of the intervention -Training satisfaction -Job crafting -Moral injury -Boundaries -Professional quality of life -Overdose prevention skills, attitudes, and knowledge -Overdose prevention stigma	x	x	x
Qualitative focus groups or group interviews			x
Administrative data on eLearning and ECHO engagement			x*
*Data are pulled at a single time point and reflect the full study period.			

2 INTRODUCTION

2.1 STUDY RATIONALE

The overall goal of this study is to improve workforce and service system outcomes within peer recovery support. The investigators aim to test the effectiveness of PATH (Peer Advanced Training for total Health) as a system-level workforce intervention for reducing burnout among peer recovery support specialists (PRSSs) providing overdose prevention (OP) services, as well as assess PATH's ability to improve service quality and service system-level outcomes. PRSSs are individuals in substance use recovery who provide recovery supports. There is a promising and growing evidence base for PRSS interventions [1–3]. PRSSs serve both those who are seeking an abstinence-focused recovery path and those who continue to use drugs and would benefit from OP supports to mitigate negative consequences. Expanding both PRSS and OP services are key national priorities reflected in several US federal agency strategic plans and initiatives [4–7]. While peer and OP services are generally presented as separate and distinct priorities, they are interconnected: OP traces its beginnings to grassroots peer efforts and PRSSs frequently deliver or intersect with OP services today [8–11]. Unfortunately, prior

research demonstrates PRSSs without sufficient personal and professional resources can struggle to deliver OP services [12–17]. Fortunately, in addition to positively impacting client outcomes, evidence also suggests improving PRSSs’ OP capabilities and work environment resources could reduce burnout and improve service quality [6,18–26]. Critically, risk of PRSS burnout is high [27–30], and PATH could be an effective system-level intervention for those who are working in the trenches while maintaining their own recovery.

This study is planned in two phases; before conducting the full clinical trial of PATH, the R61 pilot phase of this study will test the appropriateness, acceptability, and feasibility of PATH, as well as satisfaction with the PATH training, among PRSS from two partner RCOs.

2.2 BACKGROUND

More than 1 million people have died of a drug-related overdose since 1999 [31]. The U.S. National Drug Control Strategy emphasizes that reducing overdoses requires OP service expansion [6], which include pragmatic approaches to reduce the negative effects of substance use without expecting or requiring abstinence. OP is the primary tool for saving lives of people who decline treatment or face access barriers. Unfortunately, OP providers are often underprepared and under-supported [32–35] to deliver these services and work under stressful conditions that place them at high burnout risk [27,36–38]. Prior research supports burnout’s association with poor job performance and service quality [39–42] that, in turn, likely negatively impacts client outcomes at the individual and system levels [43].

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 POTENTIAL RISKS

Possible risks associated with this pilot study are minimal.

Risks related to REDCap survey collection include (a) potential feelings of coercion, (b) potential feelings of discomfort related to sharing thoughts on one’s profession or experiences with the training, and (c) potential loss of confidentiality or privacy related to survey data collection.

Risks related to qualitative data collection include (a) potential feelings of coercion, (b) potential feelings of discomfort sharing one’s opinions, (c) potential loss of confidentiality or privacy related to audio recordings and data collection, (d) potential work-related repercussions should a supervisor learn something negative is shared during data collection.

Risks related to administrative data on ECHO or eLearning engagement include (a) potential loss of confidentiality.

2.3.2 POTENTIAL BENEFITS

Possible benefits associated with this pilot include (a) the opportunity to discuss and reflect on recent experiences and (b) the opportunity to inform research that may lead to improved overdose prevention service delivery.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Study procedures aim to minimize risks associated with the collection of data through the following ways: (a) all survey data and PATH engagement data are collected and stored in Research Electronic Data Capture (REDCap) to ensure secure data storage and that only relevant research team members may access these data; (b) all qualitative recording and transcript data are stored in Box folders that only relevant research team members may access; (c) participants are reminded at the start of surveys and during qualitative data collection that participation is voluntary and that they may skip any question or discontinue participation at any time.

3 OBJECTIVES

The objective of the R61 pilot phase of this study is to understand the acceptability, appropriateness, and feasibility of the PATH intervention, as well as satisfaction with the PATH training components.

Surveys and qualitative data collection will be used to assess our primary measure for this pilot, which will be a combined acceptability, appropriateness, and feasibility measure and training satisfaction measure to understand attitudes toward PATH. Data collection will also assess job crafting, boundaries, professional quality of life, moral injury, burnout, compassion satisfaction, secondary traumatic stress, OP knowledge, attitudes, and skills, and OP stigma to assess the impact of PATH on staff outcomes.

4 STUDY DESIGN

The investigators will pilot the PATH intervention with two Recovery Community Organizations (RCOs). All administrator(s)/supervisor(s) and peer recovery support specialist (PRSS) staff employed at the RCOs will be asked to complete the PATH intervention. The study team will specifically partner with RCO administrators who are interested in having their full team complete PATH.

PATH will include 4 hours of eLearning modules completed within a 1-month period, as well as 8 weekly ECHO sessions, each lasting 1.5 hours, delivered over a 2-month period. Each ECHO session includes a 30-minute presentation followed by one hour of case-based discussion about a real client or problem. The full PATH intervention will take 16 hours (4 hours of eLearning and 12 hours of ECHO participation). Participants are expected to complete all 16 hours and to complete the eLearning before starting the ECHO activities.

The investigators will plan and administer the PATH components with the PRSS and administrators/supervisors from the partnering RCOs. All PATH eLearning modules will be completed within the Learning Management Software (LMS) system. Each participant will have a personal login and be given 1 month to complete the modules in their own time. All PATH ECHO sessions will be completed with the assistance of the Indiana University (IU) ECHO Center. Sessions will be scheduled based on the partnering RCOs' availability and will be held as a group meeting.

Voluntary survey data collection will be used to assess the primary and secondary measures for this pilot. Participants will be invited to complete surveys at three timepoints. The baseline survey will be distributed immediately prior to beginning the PATH training activities. Following the completion of the eLearning components of the training (approximately 1-month post-initiation), the second survey will be

distributed to all participants. Following completion of the final ECHO meeting (approximately 3 months post-initiation), the third survey will be distributed to all participants. All surveys will be collected in REDCap. Surveys will include measures on the acceptability, appropriateness, and feasibility of the intervention, as well as training satisfaction. Additionally, survey measures will also include burnout, compassion satisfaction, secondary trauma, job crafting, boundaries, OP knowledge, attitudes, and skills, and OP stigma. Personalized survey links will be sent directly to each participant's email address. Each survey will take approximately 30 minutes to complete.

PATH participants will also be invited to participate in a qualitative focus group or group interview (administrators only) regarding their participation in the PATH training activities. Investigators will conduct 2-3 focus groups or group interviews. Each will last approximately 60-90 minutes and be conducted via Zoom teleconference. Questions will focus on participants' experiences with the PATH training activities, particularly regarding the content, clarity, applicability, relevance, and usefulness of both the eLearning modules and ECHO meetings. Participants will be asked about barriers and facilitators to completing the PATH training activities, as well as suggestions for improvement. Administrators will also be asked regarding their opinions of staff experiences with the PATH training activities, particularly regarding the applicability, relevance, and usefulness of both the eLearning modules and ECHO meetings, as well as the impact of the training on their team. Administrators will also be asked about barriers and facilitators to having their staff complete the PATH training activities, as well as suggestions for improvement.

Throughout the PATH intervention, duration and dose of a participant's engagement will be tracked (i.e., time spent completing eLearning modules and time spent on ECHO sessions). To track PATH engagement, we will obtain ECHO meeting participation from the ECHO administrators and will also track time spent completing eLearning modules, which will be identified in the learning management software.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

Inclusion criteria include:

1. be a PRSS currently employed by participating RCO pilot sites
2. be at least 18 years of age

5.2 EXCLUSION CRITERIA

Not applicable.

5.3 STRATEGIES FOR RECRUITMENT AND RETENTION

PRSS from the pilot RCOs will be initially informed of the PATH intervention and its purpose, frequency, and duration by their RCO administrator or direct supervisor. At least two weeks before the staff are scheduled to begin PATH, the RCO administrator will introduce the PRSS to PATH and to the study opportunity, providing an overview of the data collection and voluntary nature of the data collection components. The RCO administrator will provide staff emails, names, and roles to the research team so

they may distribute invitations to the LMS system and for surveys. The research team will also send an email to staff providing a study overview, including: the purpose of the data collection, voluntary nature of the data collection, confidentiality of data, and data collection incentives. The research team will include details on the timeline of the data collection. PRSS will be instructed that they will be invited to participate at each timepoint, but they may choose not to participate in any data collection component.

At the three designated survey points, the survey management system (i.e., REDCap) will send survey links directly to the PRSS, as well as up to 5 survey reminders. The beginning of the survey will include the full consent information, including details of the study and its purpose, the voluntary nature of the survey, expected survey duration, survey incentive, and risks and benefits of participation. The study team will also reiterate to the PRSS that administrators will not be informed which staff decline participation. At the beginning of each survey, a notification will appear stating that continuing with the survey provides consent to participate.

After completing all components of PATH, the study team will also send staff an invitation to participate in the qualitative focus group or group interview (administrators only). Like the survey invitations, the study team will detail the purpose of the data collection, its voluntary nature, incentive, and risks and benefits in the invitation, as well as remind staff that administrators are not made aware of which staff participate. Qualitative data collection will occur via Zoom. All participants will be provided with an electronic copy of the consent form. At the start of the focus group, prior to any data collection, the researcher will verbally review the full form, answer any questions, and solicit the participants' verbal voluntary consent. It will be noted that participation in the focus group requires consent to audio record, as it would be too challenging to take notes and achieve a high level of detail with multiple participants. Each consent will be noted on the form by the researcher, and the researcher will sign off as the witness obtaining consent.

PATH participants will receive a \$50 gift card for each survey completed (up to \$150). PATH participants will also receive \$50 gift card for participating in qualitative data collection. All gift cards will be distributed to the participant electronically.

6 STUDY INTERVENTION

PATH is an educational workforce intervention for improving peer recovery support specialists' (PRSS) overdose prevention (OP) service delivery ability and quality and as a PRSS workforce and service system support. PATH will include 4 hours of eLearning modules completed within a 1-month period, as well as 8 weekly ECHO sessions lasting 1.5 hours each delivered over 2 months. Each ECHO session includes a 30-minute presentation followed by one hour of case-based discussion about a real client or problem. The entire PATH intervention will take 16 hours (4 hours of eLearning and 12 hours of ECHO participation). Participants are expected to complete all 16 hours and to complete the eLearning before starting ECHO activities.

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

Participants are free to opt out of data collection components or to entirely withdraw from the study at any time.

If a participant wishes to discontinue their involvement with the study or forgo additional data collection activities, they may notify any study team member or not respond to data collection requests. Discontinuation from the study will not adversely affect the participant.

If a participant wishes to withdraw from the study, they can notify any team member and no further data collection requests will be made; existing data will be deleted. Withdrawal from the study will not adversely affect the participant.

The reason for participant discontinuation or withdrawal from the study will be tracked.

7.1 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if they fail to complete the data collection component within two weeks of receiving the invitation.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.1.1 DEFINITION OF ADVERSE EVENTS

This protocol uses the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, ***whether or not considered intervention related***.

8.1.2 DEFINITION OF SERIOUS ADVERSE EVENTS

An adverse event (AE) or suspected adverse reaction is considered "serious" if it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

8.1.3 CLASSIFICATION OF AN ADVERSE EVENT

8.1.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant’s daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious”.

8.1.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Related** – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.
- **Not Related** – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

OR

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.
- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.
- **Potentially Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant’s clinical condition, other concomitant events). Although an AE may rate only as “possibly related” soon after discovery, it can be flagged as requiring more information and later be upgraded to “probably related” or “definitely related”, as appropriate.
- **Unlikely to be related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant’s clinical condition, other concomitant treatments).

- **Not Related** – The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

8.1.3.3 EXPECTEDNESS

Unanticipated AEs are events that are not consistent with the foreseeable risk associated with research procedures or are not expected in the natural progression of any underlying condition of the sample.

Per Chestnut Health IRB policies, all deaths are considered unanticipated events.

8.1.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) would only be brought to our attention by notification from an administrator.

Subject withdrawals or complaints will be monitored by the PIs with assistance from the Project Manager to ensure study procedures designed to protect the privacy and confidentiality of participants are adequate and no unanticipated distress or unintended outcomes have resulted from any of the study procedures.

8.1.5 ADVERSE EVENT REPORTING

Unanticipated adverse events will be reported to the IRB within 2 business days. Adverse events related to the study will be reported in annual reporting to the IRB. All adverse events, whether related or unrelated and anticipated or unanticipated, will be reported at the study conclusion on Clinical Trials.gov.

8.1.6 SERIOUS ADVERSE EVENT REPORTING

Unanticipated serious adverse events will be reported to the IRB within 2 business days. All deaths will be considered unexpected. Serious adverse events related to the study will be reported in annual reporting to the IRB. All adverse events, whether related or unrelated and anticipated or unanticipated, will be reported at the study conclusion on Clinical Trials.gov.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

The primary outcomes for this pilot include (1) Acceptability, Appropriateness, and Feasibility of the PATH intervention and (2) Training Satisfaction with the PATH components. The investigators hypothesize that scores will be high and stable over time, indicating positive perceptions of PATH.

9.2 SAMPLE SIZE DETERMINATION

Not applicable.

9.3 POPULATIONS FOR ANALYSES

All participants will be included in analyses.

9.4 STATISTICAL ANALYSES

Descriptive statistics (e.g., frequency, mean, median, range, and standard deviation as appropriate) will be used to summarize all survey and administrative training data collected.

Qualitative data will be analyzed thematically using the questions as an a priori coding structure; relevant and repetitive themes will be identified and used to establish logical and theoretical links across complex data. We will use qualitative data as a complement to quantitative data to help understand quantitative outcomes and to help tell a more complete story.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study procedures and risks will be given to the participant at the start of each data collection component, and documentation will be obtained each time.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

At the three designated survey points, the survey management system (i.e., REDCap) will send survey links directly to PATH participants. The beginning of the survey will include the full consent information, including details of the study and its purpose, the voluntary nature of the survey, expected survey duration, survey incentive, and risks and benefits of participation. The study team will also reiterate that administrators will not be informed which staff decline participation. At the beginning of each survey, a notification will appear stating that continuing with the survey (i.e., selecting 'yes, I consent') provides consent to participate.

Regarding qualitative data collection, the study team will send PATH participants an invitation to participate in the qualitative data collection. Like the survey invitations, the study team will detail the

purpose of the focus group, its voluntary nature, incentive, and risks and benefits in the invitation, as well as remind staff that administrators are not made aware of which staff participate. The focus groups will occur via Zoom. All participants will be provided with an electronic copy of the consent form. At the start of the focus group, prior to any data collection, the researcher will verbally review the full form, answer any questions, and solicit the participants' voluntary consent. It will be noted that participation in the focus group requires consent to audio record, as it would be too challenging to take notes and achieve a high level of detail with multiple participants. Each participant will provide their verbal consent to participate and record prior. Each consent will be noted on the form, and the researcher will sign off as the witness/person obtaining consent.

10.1.2 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

We will collect the survey data in REDCap and keep it stored there through the duration of the study. REDCap is password protected and HIPAA compliant; user access to this database will be restricted to those who collect, manage, or clean this data. The participant IDs will be connected to the participant's name within REDCap. Administrative data on PATH engagement will also be stored in REDCap. Any data downloaded for analyses will have names removed and be stored in a secure Box Health folder accessible only by research team members designated to work with the data.

Focus groups and interviews will only be conducted on a secure Zoom. Qualitative data will be stored in a separate Box Health folder. The audio recordings for each will be uploaded, and a member of the research team will then transcribe the audio files. Following analysis, the audio files will be deleted. A separate qualitative data collection tracking form will be used to record the completion date, RCO name, and participant name(s) of each focus group or interview. The tracking form will be stored separately from any data.

Additionally, we have a Certificate of Confidentiality (COC) from NIH to provide an additional layer of protection for participants. This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceedings, whether at the federal, state, or local level.

10.1.3 FUTURE USE OF DATA

Data collected for this study will be analyzed and stored by Chestnut Health Systems researchers. Data will be archived with ICPSR and made accessible through the appropriate data sharing requests.

10.1.4 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator
<i>Dennis Watson, PhD</i>
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312-274-5316
<i>dpwatson@chestnut.org</i>

10.1.5 QUALITY ASSURANCE AND QUALITY CONTROL

The project manager and principal investigators will perform internal quality management of study conduct to ensure data collection tools and storage remain as intended.

Quality control (QC) procedures will be implemented as follows:

Informed consent --- The project manager will review the documentation of the consenting process for completion and accuracy.

Electronic data --- Data will be entered directly into the study database. To ensure accuracy completeness, records will be reviewed by the project manager. Data checks will also be conducted by the principal investigator.

10.1.6 DATA HANDLING AND RECORD KEEPING

10.1.6.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Coordination of data collection will be the responsibility of the project manager and principal investigator. Survey data will be directly collected in the REDCap data collection system, which is accessible by team members only and can be immediately reviewed by the project manager.

Qualitative transcripts will be completed by a member of the research team. All transcripts will be reviewed by the principal investigator for accuracy and completeness.

10.1.6.2 STUDY RECORDS RETENTION

Study documents will be retained for 3 years after the final participant is enrolled.

10.1.7 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the protocol document. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

It will be the responsibility of the principal investigator to use continuous vigilance to identify and report deviations. All major deviations will be reported to the IRB promptly, within 5 business days. Minor protocol deviations will be reported at the time of the subsequent IRB renewal or closure.

10.1.8 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. A limited data set with all identifiers removed may be requested from researchers. Considerations for ensuring confidentiality of these shared data are described in Section 0.

10.1.9 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

10.2 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
CFR	Code of Federal Regulations
COC	Certificate of Confidentiality
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
OP	Overdose prevention
ICH	International Council on Harmonisation
IRB	Institutional Review Board
NIH	National Institutes of Health
PATH	Peer Advanced Training for total Health
PRSS	Peer Recovery Support Specialist
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SOA	Schedule of Activities
SUD	Substance Use Disorder
UP	Unanticipated Problem

11 REFERENCES

1. Bassuk EL, Hanson J, Greene RN, Richard M, Laudet A. Peer-delivered recovery support services for addictions in the United States: a systematic review. *J Subst Abuse Treat.* 2016;63:1-9. doi:10.1016/j.jsat.2016.01.003
2. Gagne C, White W, Anthony WA. Recovery: A common vision for the fields of mental health and addictions. *Psychiatr Rehabil J.* 2007;31(1):32-37. doi:10.2975/31.1.2007.32.37
3. Reif S, Braude L, Lyman DR, et al. Peer recovery support for individuals with substance use disorders: assessing the evidence. *Psychiatr Serv Wash DC.* ^{1,2}2014;65(7):853-861. doi:10.1176/appi.ps.201400047
4. SAMHSA harm reduction framework. U.S. Substance Abuse and Mental Health Services Administration. Published February 22, 2023. Accessed September 9, 2023. <https://www.samhsa.gov/find-help/harm-reduction/framework>
5. Core competencies for peer workers in behavioral health services. U.S. Substance Abuse and Mental Health Services Administration. Published December 2015. Accessed September 9, 2023. <https://www.samhsa.gov/brss-tacs/recovery-support-tools/peers/core-competencies-peer-workers>
6. U.S. White House. 2022 National drug control strategy. Office of National Drug Control Strategy. National Drug Control Strategy. Published online April 18, 2022. Accessed September 1, 2023. <https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf>
7. National Institute on Drug Abuse. 2022-2016 NIDA strategic plan. National Institutes of Health. Published September 2022. Accessed September 1, 2023. <https://nida.nih.gov/^{1,2}about-nida/2022-2026-strategic-plan/introduction>
8. Mercer F, Miler JA, Pauly B, et al. Peer support and overdose prevention responses: a systematic 'state-of-the-art' review. *Int J Environ Res Public Health.* 2021;18(22):12073. doi:10.3390/ijerph182212073
9. Hagaman A, Foster KN, Kidd M, Pack RP. An examination of peer recovery support specialist work roles and activities within the recovery ecosystems of Central Appalachia. *Addiction Research & Theory.* 2023;31(5):328-334.¹ doi:10.1080/16066359.2022.2163387
10. McGuire AB, Powell KG, Treitler P, et al. Emergency department-based peer support for opioid use disorder: emergent functions and forms. *J Subst Abuse Treat.* 2020;108:82-87. doi:10.1016/j.jsat.2019.06.013
11. Szalavitz M. *Undoing drugs: The Untold Story of Harm reduction and the Future of Addiction.* Hachette Book Group; 2021.
12. Davis D, Hawk M. Incongruence between trauma center social workers' beliefs about substance use interventions and intentions to intervene. *Soc Work Health Care.* 2015;54(4):320-344. doi:10.1080/00981389.2014.990129
13. Rosenberg H, Phillips KT. Acceptability and availability of harm-reduction interventions for drug abuse in American substance abuse treatment agencies. *Psychol Addict Behav.* 2003;17(3):203-210. doi:10.1037/0893-164X.17.3.203

14. Watson DP, Orwat J, Wagner DE, Shuman V, Tolliv^{1,2}er R. The housing first model (HFM) fidelity index: designing and testing a tool for measuring integrity of housing programs that serve active substance users. *Subst Abuse Treat Prev Policy*. 2013;8:16. doi:10.1186/1747-597X-8-16
15. Mancini MA, Linhorst DM, Broderick F, Bayliff S. Challenges to implementing the harm reduction approach. *J Soc Work Pract Addict*. 2008;8(3):380-408. doi:10.1080/15332560802224576
16. O'Campo P, Zerger S, Gozdzik A, Jeyaratnam J, Stergiopoulos V. Strategies to balance fidelity to housing first principles with local realities: lessons from a large urban center. *J Health Care Poor Underserved*. 2015;26(2):536-553. doi:10.1353/hpu.2015.0031
17. Ramsey AT, van den Berk-C^{2,32,3}ark C, David A Patterson Silver Wolf (Adelv unegv Waya). Provider-agency fit in substance abuse treatment organizations: implications for learning climate, morale, and evidence-based practice implementation. *BMC Res Notes*. 2015;8(1):194. doi:10.1186/s13104-015-1110-3
18. Khan GK, Harvey L, Johnson S, et al. Integration of a community-based harm reduction program into a safety net hospital: a qualitative study. *Harm Reduct J*. 2022;19(1):35. doi:10.1186/s12954-022-00622-8
19. Stack E, Hildebran C, Leichtling G, et al. Peer recovery support services across the continuum: in community, hospital, corrections, and treatment and recovery agency settings - a narrative review. *J Addict Med*. 2022;16(1):93-100. doi:10.1097/ADM.0000000000000810
20. Small W, Wood E, Tobin D, Rikley J, Lapushinsky D, Kerr T. The injection support team: A peer-driven program to address unsafe injecting in a canadian setting. *Subst Use Misuse*. 2012;47(5):491-501. doi:10.3109/10826084.2012.644107
21. Wood E, Kerr T, Spittal PM, et al. An external evaluation of a peer-run "unsanctioned" syringe exchange program. *J Urban Health*. 2003;80(3):455-464. doi:10.1093/jurban/jtg052
22. Callon C, Charles G, Alexander R, Small W, Kerr T. 'On the same level': facilitators' experiences running a drug user-led safer injecting education campaign. *Harm Reduct J*. 2013;10(1):4. doi:10.1186/1477-7517-10-4
23. Serovich JM, Brucker PS, Kimberly JA. Barriers to social support for persons living with HIV/AIDS. *AIDS Care*. 2000;12(5):651-662. doi:10.1080/095401200750003824
24. Carter R, Cust F, Boath E. Peer support workers' experiences of supporting women with postnatal depression: a constant comparative exploration. *J Reprod Infant Psychol*. 2018;36(2):168-176. doi:10.1080/02646838.2017.1416336
25. Fernandes RM, Cary M, Duarte G, et al. Effectiveness of needle and syringe programmes in people who inject drugs – an overview of systematic reviews. *BMC Public Health*. 2017;17(1):1-15. doi:10.1186/s12889-017-4210-2
26. Clark AK, Wilder CM, Winstanley EL. A systematic review of community opioid overdose prevention and naloxone distribution programs. *J Addict Med*. 2014;8(3):153-163. doi:10.1097/ADM.0000000000000034

27. Olding M, Boyd J, Kerr T, McNeil R. "And we just have to keep going": Task shifting and the production of burnout among overdose response workers with lived experience. *Soc Sci Med*. 2021;270:113631. doi:10.1016/j.socscimed.2020.113631
28. Abraham KM, Erickson PS, Sata MJ, Lewis SB. Job satisfaction and burnout among peer support specialists: the contributions of supervisory mentorship, recovery-oriented workplaces, and role clarity. *Adv Ment Health*. 2022;20(1):38-50. doi:10.1080/18387357.2021.1977667
29. Mamdani Z, McKenzie S, Pauly B, et al. "Running myself ragged": stressors faced by peer workers in overdose response settings. *Harm Reduct J*. 2021;18(1):18. doi:10.1186/s12954-020-00449-1
30. Tate MC, Roy A, Pinchinat M, et al. Impact of being a peer recovery specialist on work and personal life: implications for training and supervision. *Community Ment Health J*. 2022;58(1):193-204. doi:10.1007/s10597-021-00811-y
31. National Center for Health Statistics. Wide-ranging online data for epidemiologic research (WONDER). Centers for Disease Control and Prevention. Published 2022. Accessed September 1, 2023. <http://wonder.cdc.gov>
32. Watson DP, Young J, Ahonen E, et al. Development and testing of an implementation strategy for a complex housing intervention: protocol for a mixed methods study. *Implement Sci*. 2014;9:138. doi:10.1186/s13012-014-0138-4
33. Marshall Z, Dechman MK, Minichiello A, Alcock L, Harris GE. Peering into the literature: a systematic review of the roles of people who inject drugs in harm reduction initiatives. *Drug Alcohol Depend*. 2015;151:1-14. doi:10.1016/j.drugalcdep.2015.03.002
34. Chang J, Shelly S, Busz M, et al. Peer driven or driven peers? A rapid review of peer involvement of people who use drugs in HIV and harm reduction services in low- and middle-income countries. *Harm Reduct J*. 2021;18(1):15. doi:10.1186/s12954-021-00461-z
35. Gugala E, Briggs O, Moczygemba LR, Brown CM, Hill LG. Opioid harm reduction: a scoping review of physician and system-level gaps in knowledge, education, and practice. *Subst Abuse*. 2022;43(1):972-987. doi:10.1080/08897077.2022.2060423
36. Frankeberger J, Gagnon K, Withers J, Hawk M. Harm reduction principles in a street medicine program: a qualitative study. *Cult Med Psychiatry*. Published online October 13, 2022. doi:10.1007/s11013-022-09807-z
37. Unach⁵⁻⁷⁵⁻⁷ukwu IC, Abrams MP, Dolan A, et al. "The new normal has become a nonstop crisis": a qualitative study of burnout among Philadelphia's harm reduction and substance use disorder treatment workers during the COVID-19 pandemic. *Harm Reduct J*. 2023;20(1):32. doi:10.1186/s12954-023-00752-7
38. Jawa R, Laks J, Saravanan N, Demers L, Wishik-Miller G. Physician trainees' compassion satisfaction, burnout, and self-efficacy when caring for people who inject drugs. *Subst Abuse*. 2022;43(1):675-681. doi:10.1080/08897077.2021.1986881
39. Taris TW. Is there a relationship between burnout and objective performance? A critical review of 16 studies. *Work Stress*. 2006;20(4):316-334. doi:10.1080/02678370601065893

40. Nahrgang JD, Morgeson FP, Hofmann DA. Safety at work: a meta-analytic investigation of the link between job demands, job resources, burnout, engagement, and safety outcomes. *J Appl Psychol*. 2011;96(1):71-94. doi:10.1037/a0021484
41. Crawford ER, LePine JA, Rich BL. Linking job demands and resources to employee engagement and burnout: a theoretical extension and meta-analytic test. *J Appl Psychol*. 2010;95(5):834-848. doi:10.1037/a0019364
42. Abd El Ghafar Mansour R, Mohamed Elmorsey R. Occupational stress: measuring its impact on employee performance and turnover. *Eur J Bus Manag*. 2016;8(21):12-21.
43. Proctor EK, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. 2011;38(2):65-76. doi:10.1007/s10488-010-0319-7