FORM: IRB Proposal - Exempt Submission	
NUMBER	VERSION DATE
HRP-UT902	9/13/2024

INSTRUCTIONS

- **This form is only for studies that are considered exempt. Exempt research must be minimal risk and fit into at least 1 of 6 exempt categories implemented at UT Austin.**
- **If you are only using secondary data that will not be initially collected solely for this research project, do not complete this form**. Instead, use HRP-UT903 Template IRB Proposal Secondary Use form instead. You can download proposal templates from the Templates tab in UTRMS-IRB Library.
- **If your study does not meet the criteria for exemption, submit HRP-UT901 Standard Submission instead.** You can download proposal templates from the Templates tab in UTRMS-IRB Library.
- To check a box, click on the check box (or double click and type an "X" if using Google Docs). Please note, Word online does not support Word checkboxes. Please download the file and use your desktop version of Microsoft Word.
- To fill in a text box, make sure your cursor is within the grey text box before typing or pasting text.
- **Do not convert this Word document to PDF.** The ability for UTRMS-IRB to implement "tracked changes" is required to facilitate efficient review.

STUDY INFORMATION

Study Title

Include the study title below.

Adapting Stress First Aid (SFA) to the needs of Harm Reduction Workers (HRWs) serving Persons Who Use Drugs (PWUD) – Training and Pilot Testing Phase (Aim 2 and Aim 3)

1 General Exempt Exclusions

Read each statement below and check any statement if true for this study. ***If ANY of the following statements are true, this study does not meet exempt criteria and you should complete HRP-UT901 Standard Submission form instead.***

a ☐ The study is aimed at involving prisoners.

b ☐ The study is FDA-regulated (unless exemption #6 is selected). This includes the use of drugs, medical devices, etc.

c ☐ The research involves deception or **incomplete disclosure** (meaning participants are not provided with or misled about the purpose of the study in the beginning of

the study) AND participants will not be prospectively agreeing to participate in a study that **involves** deception.

d ☐ The study involves more than minimal risk to subjects. Participants are likely to experience more physical, emotional, or mental stress, discomfort than they do in the course of daily life or a routine medical or psychological exam.

STOP – If any of the above are checked, submit HRP-UT901.

2 Exemption Determination Categories

Based on the information below, choose the exempt category(ies) that best applies to your study. If your study does not meet any of the below exempt categories, submit HRP-UT901 Standard Submission form.

a ☐ Category 1: Research conducted in established or commonly accepted educational settings that specifically involve normal educational practices.

The following MUST be true to select category 1: the study will not likely adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction; the research is only conducted in established or commonly accepted educational settings; the study does not involve new, unproven educational practices/activities.
This category can include research on regular and special education instructional strategies, and research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.

i State how the research activity (not the instructional material) is a "normal educational practice."

ii State how the study will not likely adversely impact students' opportunity to learn required educational content or the assessment of eductors who provide instruction.

b ☒ Category 2: Research involving surveys, interviews, observations of public behavior, and/or educational tests (cognitive, diagnostic, aptitude, achievement).

*Note: **only adults** can participate in surveys, interviews, and/or educational tests under this exemption. Observations of public behavior may include children if the investigators do not interact nor participate in the activity being observed. Note: public spaces are open/accessible to the general public (e.g., roads, public squares, parks, beaches), where activities such as filming do not require permission. Private spaces are privately owned with greater limits upon use where activities such as filming requires permission from the owner.*

c ☐ Category 3: Research involving benign behavioral interventions with adults.

Benign Behavioral Intervention (BBI): limited to procedures involving: communication or interpersonal contact with the subject, the performance of a cognitive, intellectual, educational or behavioral tasks, or manipulation of the subject's physical, sensory, social, or emotional environment. BBIs must be brief in duration, painless/harmless, not physically invasive, not likely to have a significant adverse lasting impact on subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Deception is permitted if participants are aware the research involves deception and they prospective agree to participate. ***Only adults can participate in category 3 research.***

d ☐ Category 4: Secondary research with no consent involving identifiable Information and/or biospecimens.

Research must meet one of the following: i) identifiable private information or biospecimens is publicly available; ii) information is recorded by investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; iii) research involves only information collection and analysis involving use of protected health information (PHI) when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, or iv) research is conducted by or on behalf of a federal department or agency using government-generated or government-collected information obtained for non-research activities (see 45 CFR 46.104(d)(4) for additional information).

STOP – if study ONLY meets exempt category 4, complete HRP-UT903 - Template IRB Proposal Secondary Use Submission instead.

e ☐ Category 5: Federally supported/conducted research and demonstration projects of public benefit or service program.

f ☐ Category 6: Taste and quality food evaluation and consumer acceptance study.

3 Study Purpose/Hypotheses

Please briefly describe the study purpose and hypotheses in the box below. To input text, click in the box below and start typing.
Note: Procedures will be explained in a separate section below.

The aim of this study is to pilot and test the feasibility, acceptability, and effectiveness of a Stress First Aid (SFA) intervention adapted for Harm Reduction Workers (HRWs) serving Persons Who Use Drugs (PWUD). SFA materials were adapted for HRWs in Phase 1 (Aim 1) of the study (Study #5156).

Aim 2: Test feasibility and acceptability of adapted SFA/HRW materials and develop cadre of (N = approximately 3) team support champions in an initial SFA/HRW train-the-trainer session.

Aim 3: Conduct Field test of the adapted SFA for HRWs (N = at least 15). The collaborative will be used to reinforce the SFA principles.

As this is a training and pilot testing of implementation of the intervention, there are no hypotheses. The data collected will inform future studies.

4 Procedure Description

Describe all study procedures. Be sure to describe all of the following, as applicable:

- *Description of all research procedures being performed.*
- *Describe/list all research measures/tests that will be used [**NOTE: upload copies of all measures, surveys, scripts, data collection forms, etc., in "Other Attachments" in UTRMS-IRB**].*
- *Where research activities will take place and duration (include expected time commitment of participants).*
- *If the study involves deception, include description of deception below & ensure the consent form includes disclosure to the participant that the study involves deception.*

Research personnel will be responsible for identifying eligible individuals and obtaining consent. Research personnel will respond to interested individuals via email to provide more information about the study and screen individuals for eligibility. Participants will attend the train-the-trainer training (Aim 2). At the beginning of the train-the-trainer training (Aim 2) and the field test training (Aim 3), research personnel will obtain consent from all participants. After each training, research personnel will send a follow up email to participants with information about how to obtain their compensation. All data collection will be self-reported data.

	Aim 2 Training	**Aim 3 Field Test**
Activity	3-day in-person training	2-hour training and up to 4 monthly learning collaborative meetings all held on video-conference software
Participants	Team support champions	Harm reduction workers
Trainers	Richard Westphal and Patricia Watson (consultants)	Willing team support champions/research team if needed
Research Components	Pre- and post-training surveys (10 minutes each)	Baseline and two follow-up assessments at 2-month intervals from baseline (20 minutes each) and optional reaction interview (30 minutes)

Aim 2: We aim to develop a cadre of approximately team support champions in an initial SFA/HRW train-the-trainer session. All champions partaking in the training must participate in the research. Participants will be convened for a 3-day in-person training with members of the research team at The University of Texas at Austin. The first two days of the training will run for 8 hours and the last day will be a shorter 6-hour day. There will be a one-hour break for lunch all three days. The training will include presentations introducing participants to Stress First Aid and the seven core competencies: check, coordinate, cover, calm, connect, competence, confidence. There will be opportunities for teach back to practice and train on each of the SFA competences. Participants will receive an implementation handbook and all materials to provide a training such as slide decks, handouts and workbooks. Primary outcomes are participant familiarity with SFA, measured through changes in SFA knowledge, confidence, and beliefs before the training and ratings of SFA/HRW acceptability, appropriateness and feasibility immediately after the training using REDCap, a secure online survey platform (see Table 1 for measures). Only data for research purposes will be collected in the REDCap surveys. Participants will be given a REDCap survey link to complete the surveys on their phones at the training. Surveys will take approximately 10 minutes each (20 minutes total).

Table 1: Aim 2 and 3 Measures

Concept	Measure	Primary Outcome	Secondary Outcome	Scale
1. Knowledge	SFA-specific knowledge	Aim 2	Aim 3	2 items; 5-point Likert-type
2. Confidence	Confidence in using SFA	Aim 2	Aim 3	6 items; 5-point Likert-type
3. Beliefs	Endorsement of SFA Beliefs	Aim 2	Aim 3	6 items; 5-point Likert-type
4. Acceptability	Acceptability of Intervention Measure (AIM)	Aim 2/3		4 items; 5-point Likert-type
5. Appropriateness	Intervention Appropriateness Measure (IAM)	Aim 2/3		4 items; 5-point Likert-type
6. Feasibility	Feasibility of Intervention Measure (FIM)	Aim 2/3		4 items; 5-point Likert-type
7. Survey Retention	Response rate for each survey administration		Aim 3	Percentage: N respond/N trained
8. Use of SFA	Use of SFA concepts		Aim 3	7 items; 5-point Likert-type; yes/no
9. R33 outcomes	Peer support, self-efficacy, coping strategies		Aim 3	

Aim 3: We will conduct a 4-month field test of the feasibility, acceptability and appropriateness of the adapted SFA/HRW (see Tables 1 and 2 for measures). The training format is a virtual 2-hour SFA training and monthly virtual learning collaborative meetings over Zoom. The 2-hour training will introduce SFA concepts and how to use SFA on a day-to-day basis in your work life and with coworkers. The 2-hour training and monthly collaboratives will be led by any Aim 2 participants who chose to be a champion in the Aim 3 field test, they are not required as stated in the Aim 2 RIS. The research team may lead the training and/or monthly collaboratives, on an as needed basis. We anticipate one group of 7-8 participants from each of the organizations for the Aim 3 Field Test. We anticipate a sample size of about 15 and between 1-3 separate trainings to accommodate participant schedules. The trainings and monthly learning collaborative meetings will not be recorded. There will be a presentation made available for harm reduction organization leaders on SFA implementation, at some point between recruitment and enrollment. Participants in the field test will provide informed consent and will complete a baseline assessment prior to SFA training, a brief post-training reaction interview, and two follow-ups at 2 and 4 months after baseline. The same survey will be used for the baseline and two follow-up assessments. Assessments and interviews will be completed via REDCap, a secure online survey platform, and Zoom video platform. Only data for research purposes will be collected in the REDCap surveys and interviews. Participants will receive the surveys via a REDCap link to their email. The surveys will take approximately 20 minutes each. A random selection of participants will participate in brief post-training reaction interviews. Interviews will take approximately 30 minutes each and will be audio recorded via Zoom.

Table 2: Aim 3 Measures (breakdown of Item 9 (R33 outcomes) in Table 1)

Variable	Outcome	Subscales	Scale
Social Support scale (NIH Promis emotional and instrumental support scales)[54]	Primary	Emotional support, informational support	1, 8 item and 1, 10 item subscales; 5-point Likert-type scales

Burnout (Copenhagen Burnout Inventory)[58]	Secondary	Personal, work-related, client-related	19-item 5-point Likert-type scale.
Use of SFA practices	Primary	none	4 items; 5-point Likert-type; yes/no
Job-related Affective Well-being scale[57]	Secondary	None for the short version	20-item 5-point Likert-type scale.
Secondary traumatic stress scale [59]	Secondary	Intrusion, avoidance, arousal	17-item 5-point Likert-type scale.
Use of coping strategies (COPE)[56]	Primary	5 problem-focused items, 5 emotion-focused items, 3 disengagement items + SUD item	4, 5-item subscales; 4-point Likert-type scales.
Self-efficacy (NIH Promis Self-efficacy)[55]	Primary	none	10-items; 7-point Likert type items.
Work Engagement(Utrecht)[60] (shortened version)	Secondary	Vigor, dedication, absorption	9-item 7-point Likert-type scale.
Turnover[61]	Secondary	Peer support champion turnover & HRW turnover	3-item 6-point Likert-type scale.

If post-intervention data suggest low levels of acceptability, appropriateness, and feasibility (e.g. mean scores < 4). We will elicit feedback during the post-intervention reaction interviews to understand participants' ratings and identify additional changes to the curriculum and training. In the event of post-intervention data that suggests a failed training, with consultation with our program officer we would review the problems and revise the study methods, focusing on findings from the post-intervention reaction interviews and the open-ended questions of the Use of SFA Concepts measure to inform necessary changes: (What has made using Stress First Aid practices difficult over the past 2 months? What Stress First Aid practice has been the most useful for you? Is there anything else that you would like to tell us about your work stress or team support experience?).

5 Target Population(s)

Describe the general characteristics of the subject populations or groups, including gender, health status, and any other relevant characteristics. ***If you have multiple research populations (e.g., teachers and students), clearly outline characteristics for each group.***

Harm Reduction, Community Health and Peer support Workers (HRWs) in Texas who do harm reduction work with persons who use drugs: individuals responsible for various tasks including but not limited to distributing harm reduction supplies, supervising drug use, responding to overdoses, and advocacy. This can include trained and licensed mental health professionals such as social workers as well as people with lived or living experiences of substance use, sometimes referred to as "peer workers." This can include paid employees and unpaid volunteers. They can work in large mental health/social service organizations and small harm reduction organizations that are typically dependent on external grant funding.

a Age range (minimum & maximum)

Include age range below. ***If you have multiple research populations (e.g., teachers and students), clearly outline age range for each group.***

HRWs: 18-100 years old

b Inclusion and Exclusion Criteria

Describe the specific criteria that will be used to decide who will be included in or excluded from the research from interested or potential subjects. Define technical terms in lay language, as applicable.

Aim 2: Willingness and ability to devote about 22.5 hours to receiving the training and completing pre- and post-training assessments.

Aim 3: Willingness and ability to devote up to 5.5 hours over the course of a 4 month period of time to attend a 2-hour training and complete baseline and two follow-up assessments (20 minutes each), as well as up to 4, 30-minute learning collaborative meetings, and an optional 30 minute reaction interview.

1) Inclusion Criteria: legal age of majority (18 +), ability to read and speak conversational English, and work as an HRW in substance misuse.
2) Exclusion Criteria: Inability to provide consent.

6 Total Sample Size

Enter the total target sample size below.

Aim 2: Total N = approximately 3 team support champions

Aim 3: Total N = at least 15 HRWs

7 Recruitment and Screening Procedures

Describe the recruitment and/or screening procedures below. If your study includes identifying potential participants using PHI (e.g., a partial HIPAA waiver for recruitment is needed), note this below and complete HRP-UT907 - Template IRB Supplemental Form PHI. Download HRP-UT907 from UTRMS-IRB Library Templates.
NOTE: Upload copies of all recruitment materials to UTRMS-IRB in the "Recruitment Materials" section.

Aim 2: We will seek to enroll approximately 3 team support champions (Aim 2). Participants will be recruited through the research team's existing Harm Reduction Community Advisory Board (CAB) members, a network established through a prior study (TXCOPE CAB). Recruitment will be done via email with introduction from CAB members. Participants will be recruited from San Antonio Nexus Connection (SANC) and Addiction Research Institute (ARI).

Aim 3: We will seek to enroll at least 15 HRWs for the Aim 3 field test. Participants will be recruited from SANC and Communities for Recovery (C4R) and other qualified organizations as needed. Participants will be recruited through email. Emails will be obtained through direct outreach to local partners who will forward information on to their workers. The research team will provide the flyer to

the organizations, who can then share it among their organizations. The flyer has a QR code to the consent and baseline REDCap survey, to make enrollment easier and more efficient for participants. The research team would send the study emails to the partners and they may forward it on. The research team will send study emails if/when organizations share contact information for interested participants with the research team.

For both Aims 2 and 3, CAB members and organizations will forward all study questions to the study team.

8 Consent/Research Information Process

Consent/providing research information is required when there is interaction (in person or not) with participants. Provide a description of consent/assent procedures in the box below. If the study involves deception, include the debriefing process and upload debriefing form to UTRMS-IRB in "Consent Forms" section. ***NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section. This is required for UTRMS-IRB to appropriately stamp consent forms for approval.***

Aim 2: Participants in the train-the-trainer training will be provided a Research Information Sheet (RIS) before the training session starts and provide verbal consent. Participants will receive the RIS via email prior to the training and a physical copy before the training starts. Consent will be obtained via a question on REDCap prior to the start of the survey. The REDCap survey will have a check box that states "By checking this box and moving on to the survey, you consent to participating in this study." If the box is not checked, participants will not be able to continue with the survey/assessment. The consent process will only occur at the time of the Pre-Training survey.

Aim 3: Participants in the field test will be provided a RIS before the training session starts and provide verbal consent. Participants will receive the RIS via email prior to the training and a physical copy before the training starts. Consent will be obtained via a question on REDCap prior to the start of the baseline assessment. The consent process will occur at the beginning of each assessment, since there will be a 2-month time lapse between surveys.

9 Privacy & Confidentiality

Describe how you will protect the identity and privacy of study participants during their participation.
Provide general information below regarding confidentiality and data security plan.
Include the following:

- *If data will be recorded in a way that a participant's identity can be readily ascertained, directly or indirectly through identifiers linked to participants.*
- *If identifiers will be coded to protect confidentiality describe how and where identifiers are stored.*
- *Describe where and how data is stored and maintained.*
- *Include details regarding storage of consent forms, if applicable.*

To input text, click in the light grey area below.

Aim 2: Participants will complete pre- and post-training assessments that will be completed via REDCap, a secure online survey and data management platform (see Table 1 for measures).

Aim 3: Participants will complete a baseline assessment prior to SFA training, a brief post-intervention reaction interview (if selected) and two follow-ups at 2 and 4 months after baseline (see Tables 1 and 2 for measures). All assessments will be completed via REDCap, a secure online survey and data management platform. The post-intervention interview will occur using the secure Zoom platform. Post-intervention reaction interviews will be recorded and transcribed verbatim.

Disclosures. The nature of SFA includes focusing on stress, burnout, and trauma and sensitive information may be shared by participants during the training. Therefore, we provide two required disclosures in the Aim 2 and 3 RIS: 1) breaking confidentiality under certain situations, and 2) the research being covered by a Certificate of Confidentiality from the National Institutes of Health to protect participants privacy.

To help ensure confidentiality, participants' names will be minimized. Only audio recordings of the conversation will be saved (not video). These audio recordings will be identified with participant numbers only and stored in a secure folder on a secured server, with access restricted to staff for this specific research study. As soon as the audio recordings are transcribed, they will be deleted. Transcripts will be reviewed and de-identified prior to analyses. Transcription will occur using an encrypted platform.

Access to Individually Identifiable Information. All participants will be assigned a unique ID. These IDs will be used to identify all participants on all research materials, surveys, transcripts, tracking forms, as well as in the database. The sheet containing the links between participant names and identifiers will be kept in a separate password protected folder on Box. Consent will be linked to participants REDCap surveys. All electronic data will be maintained on the university's secure servers. Participant information will not be released to any party outside the research team at any time Participants' names will never appear in any report resulting from the project. An identifier key will be created that will link the participant ID to subject names and contact information, to facilitate follow-up with participants; contact information will have participant ID numbers but will not have any data.

This is follow-up for the Aim 3 Field Test. Due to the extensive follow-up process for the Aim 3 Field Test, an email field will be linked to survey responses on REDCap, a secure, HIPAA-compliant online survey platform, to facilitate follow-ups and pairing participant Baseline, 2-month, and 4-month Follow-up surveys. REDCap will be the only platform through which emails are stored with participant data during the Aim 3 Field Test. All participant data will be maintained on the university's secure servers behind dual authentication processes. Participant information will not be released to any party outside the research team at any time. At the conclusion of the Aim 3 Field test and follow-up surveys are completed, email records will be removed from REDCap and stored only with unique IDs in a separate password protected folder on Box.

10 Research Data/Records Destruction Details

Confirm general data destruction timeline. ***One of the following must be checked.***

☒ Research Data/Records will be retained for at least 3 years after study completion per UT record retention policy.

☐ Research Data/Records will be retained for longer than 3 years and retention information is provided below.

Describe data retention timeline below. To input text, click in the light grey area below.

All records will be stored in a folder on UT Box. We will follow all UT Austin and federal policies for data retention. Identifiable data will be destroyed 3 years after the study's completion.

11 Compensation (monetary, class credit, etc.)

Click on the check box (or double click and type an "X" if using Google Docs). Consent forms should include consistent information regarding compensation. ***A or B must be checked****.*

A ☒ Subjects receive compensation.

i ☒ Confirm: Amount of compensation and its form is reasonable for this population for the activities requested of them.

ii Total Amount of Compensation & Method

Include the total amount of compensation below and include the method of payment (e.g., course credit, gift card, cash).

Aim 2: Study participants will receive $50 per hour of participation, for a total of $1,125 for the 3-day in person training (a total of 22.5 hours).

Aim 3: Participants will be compensated for the time spent completing assessments at $50 for each full assessment and $25 for the post-intervention reaction interview, for a total of $175.

After each training assessment or post-intervention reaction interview is complete, they will receive an email with instructions for obtaining their gift card through the Tango system.

B ☐ Subjects will not receive compensation.

CONFLICTS OF INTEREST

This section is ***required*** *for all studies.*

12 Financial Conflicts of Interest

Financial interest includes utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project. Additional guidance on financial conflicts of interest is available on the COI website

A or B must be checked.

A ☐ The PI has a financial interest related to this study

i If A is checked above, please briefly describe the interest:

To input text, click in the light grey area below.

B ☒ To the best of your knowledge, the PI does NOT have a financial interest related to this study

13 Non-financial Conflicts of Interest

Non-financial Interests could include such things as:
- utilizing your unlicensed intellectual property in the study,
- serving as an unpaid advisory board member or officer/director with a related entity,
- equity or business ownership in a company that has yet to make a profit and is related to this project,
- conflict of time/effort,
- personal and professional relationships/affiliations,
- intellectual passions or personal beliefs
- other factors that could create bias in the study

A or B must be checked.

A ☐ The PI has a non-financial interest related to this study

i If A is checked above, please briefly describe the interest:

To input text, click in the light grey area below.

B ☒ To the best of your knowledge, the PI does NOT have a non-financial interest related to this study