*The following is language related to participant safety that can be used when creating a Data and Safety Monitoring Plan for the Data Safety Monitoring Board (DSMB)*

Data and Safety Monitoring Plan

**Safety Monitoring Plan**

We anticipate that we may encounter situations in the following domains:

(1) Breach of confidentiality associated with reporting suicidality to appropriate authorities or health personnel.

(2) Severe distress as indicated by: (a) an increase of more than one-half standard deviation from their mean score on the PHQ-8 during follow-up assessments, (b) patient verbal report of a significant increase in psychiatric symptoms, (c) patients reporting significant distress due to the content of the self-report measures, or (d) patients reporting significant distress due to the content of the intervention. In each case, the research personnel will consult with the PIs to determine whether the participant’s distress was significant enough to warrant an AE.

(3) Suicidal ideation: Since current suicidal ideation is an inclusion criterion for this study, we anticipate many participants will endorse current suicidal thoughts or recent suicidal behaviors. These symptoms may be indicated by: (a) self-report of significant suicidal ideations and behaviors on the BSS-SR, or (b) endorsement of recent suicidal thoughts, plans, or actions during the C-SSRS, or (c) endorsement of thoughts of suicide or suicidal behaviors during the therapy sessions (including during the pre- and post-session questionnaires) or other assessments. Research staff will review all self-report measures that may indicate an elevated risk for suicide before the participant leaves the assessment or therapy session to ensure participant safety. For those who report suicidal ideation on any of the above scales, determination of high risk suicidality will be based on a combination of the information gathered during the assessments or therapy sessions (both self-report and verbal interview) and the interaction between the research personnel and the participant. All research staff will be trained extensively to respond to emotional distress and to discuss concerns and issues should they arise. All staff will be trained in the study specific risk management protocol, which will resemble a modified version of the VA/DOD Clinical Practice Guideline for Assessment and Management of Patients at Risk for Suicide. More specifically, study staff will be trained to perform attentive and empathic listening as well as exhibit calmness during the interview. The research staff will be trained to identify and address suicidal ideation in participants. If the participant articulates thoughts of death or suicidal ideation, the research team member will ask the participant to elaborate on recent suicidal thoughts/behavior, if the patient has not already provided adequate information to judge risk level. The level of risk will be based on the participant’s responses and whether the research team member perceives that the patient is in immediate danger (e.g., an active plan verbalized). Any determination of risk level must be confirmed by the clinical staff member on call. Study personnel will follow established safety and risk assessment protocols and contact local licensed clinical staff when appropriate. Participants who are determined to be high risk will be referred to their treatment provider, crisis line, proper authority, or emergency psychiatric services, as necessary according to the study protocol.

(4) Homicidal ideation will be indicated by verbal report of thoughts of hurting others. The study does not directly ask about homicidal ideation but this information may be provided by the participant during an interaction with study team members. The protocol for handling homicidal ideation will be similar to that for suicidal ideation. Specifically, the research personnel will be trained to identify and address homicidal ideation in participants. If the participant articulates thoughts of hurting others, the study team member will ask the participant to elaborate on his/her thoughts/behaviors (e.g., is there an identified victim, does the participant have a plan). The situation will be based on the participant’s responses and whether the study team member perceives that the patient or someone else is in immediate danger. Study personnel will follow established safety protocols and contact local licensed clinical staff when appropriate.

(5) Given the study population, it is possible that participants will report other serious psychiatric or medical symptoms. Research staff will be trained to monitor significant abnormal behavior and/or report that the participant perceives him/herself to be in imminent need of medical treatment. If it is determined that the participant requires immediate care, the research staff will contact local licensed clinical staff and coordinate appropriate services.

*Responsibility for patient safety monitoring*

As PI, [insert name] will have the ultimate responsibility for monitoring the overall safety of the participants in the study, determining whether an event is considered an adverse event (AE) or serious adverse event (SAE), and reporting events as needed to the appropriate committees and agencies. The study sites will report to [PI] any serious unanticipated and/or related adverse events immediately as they arise. As a requirement of the Department of Defense (DoD), this study will also include an independent research monitor (RM), [insert name and credentials of RM] The RM will perform oversight functions and report their observations and findings to the IRB or designated official. Functions could include: observing recruitment and enrollment procedures and the consent process for individuals, overseeing study interventions and interactions, reviewing monitoring plans, or overseeing data matching, data collection, and analysis. The RM may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research. The RM will have authority to stop a research protocol in progress, remove individual subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor’s report and will have the responsibility to promptly report their observations and findings to the IRB or other designated official. The RM is required to review all unanticipated problems involving risks to subjects or others, serious adverse events and all subject deaths associated with the protocol and provide an unbiased written report of the event. At a minimum, the research monitor must comment on the outcomes of the event of problem and in the case of a serious adverse event or death, comment on the relationship to participation in the study. The RM must also indicate whether he concurs will the details of the report provided by the principle investigator. Reports for events determined by either the investigator or RM to be possibly or definitely related to participation and report of events resulting in death must be promptly forwarded to the USAMRMC ORP HRPO.

*Time frames for reporting AEs and SAEs*

Given the characteristics of the study population (participants experiencing recent suicidal ideation recruited from an intensive outpatient program), we will create a study specific adverse event reporting plan with our local IRBs. This may include reporting only *unexpected* incidents that are *related* to the study to the appropriate review boards and study monitors on an annual basis. For information regarding study specific reporting requirements, please see the “Study Specific Plan for Reporting Adverse or Other Reportable Events or Information” located at the end of this document. Any SAE related to study intervention or interaction, will be reported to the IRB and DSMB according to their reporting guideline.

Project staff will notify the Site PIs of SAEs and AEs immediately. These will then be communicated immediately to Dr. Ilgen. Upon notification of the event, [PI] will take the appropriate action. If [PI] is unavailable, [insert names of backup] will be responsible for responding to a SAE, and will notify [PI] as soon as possible.

*Triggers that will dictate when action is required*

Given the characteristics of the study population, we anticipate that there will be several triggers that will dictate when action is required. These may include the participant’s expression of severe distress, suicidal or homicidal ideation, and/or other serious psychiatric or medical symptoms. All research staff will be extensively trained and adequately prepared for situations in which a participant may express severe distress and/or suicidal ideation. This project will have a detailed risk assessment protocol in place to handle potential crises that all research staff will be trained on. In addition to the study specific protocol, all project staff will be trained on VA’s suicide risk assessment and response guidelines, including the capability of directly connecting suicidal participants to the 24-hour VA suicide hotline, as well as arranging with local psychiatry crisis management staff to assess and potentially hospitalize the patient. Subsequent to any participant’s expression of severe distress, ideation, or other serious symptoms, project staff will make all reasonable attempts to re-contact the participant to monitor his or her well-being until the acute situation is resolved.

All research staff will also be trained and prepared for situations in which a participant not currently in treatment reports severe substance misuse, for example if the participant has recently experienced increased substance use plus an emergency substance-related situation requiring immediate health care. Our protocol in this regard is based on previous research that developed and implemented human subjects protections termed “rescue treatment” or “protective transfer” in studies of people with substance use disorders receiving less than standard treatment or having a poor response to standard or experimental treatments. In our study, participants who report at follow-up (on the TLFB) that they experienced an increased (compared to baseline) number of days out of the past 30 in substance-related problems, and were hospitalized or made an emergency room or acute care outpatient visit due to those problems within the past 30 days, will be protected by having project staff provide them with a resource brochure with local substance abuse resources and/or a referral to substance abuse treatment. Participants who require rescue treatment will be referred to the VA closest to where they are residing. If the VA is rejected by the participant for any reason, project staff will utilize SAMHSA’s online substance abuse treatment facility locator to provide a referral.

*Other factors in place to ensure participant safety*

The research staff will be trained to contact the PI, Co-Investigators, or Project Coordinator immediately if emotional distress or any potential emergency (suicidality, expression of intent to harm others, evidence of child, dependent adult, or elder abuse) is identified. The participant will be evaluated, and as all study participants are Veterans, connected with the appropriate level of treatment services at the VA.

Senior clinicians are always on call for consultation if a patient seems distressed or needs special attention. All patients are instructed on how to obtain emergency care, should that be required.

**Study Specific Plan for Reporting Adverse or Other Reportable Events or Information**

We will report all AEs that are **unexpected and directly related** to the study (except as noted in first row of the table below). “Unexpected” means that the event has not been addressed or described in the informed consent document, protocol, data and safety monitoring plan, and/or is not a characteristic of the study population. “Related” means events that are caused by the research itself, not the disease or population under study. Unexpected events that are not directly related to the study will not be reported (see examples in table), with the exception of participant death.

|  |  |  |
| --- | --- | --- |
| **Type of Event** | **Examples** | **Reporting Timeframe** |
| **Expected** and **Study-Related** *Serious* Adverse Events | * Hospitalization as a direct result of study interaction resulting from report of suicidal thoughts or behaviors. * Hospitalizations as a direct result of study interaction resulting from report of substance use (i.e. overdose, acute intoxication). | Reported in accordance with IRB and DSMB guidelines |
| **Expected** and **Study-Related** Adverse Events | * Participants reporting suicidal thoughts or behaviors. * Breach of confidentiality associated with reporting suicidality to agency staff, appropriate authorities, and/or mental health personnel. * Discomfort associated with answering survey questions/discussing intervention topics. * Intervention resulting from suicidal thoughts or substance use (i.e. Emergency Room visit). | Not reported to IRB |
| **Unexpected** and **Not Study-Related** Adverse Events | * Medical hospitalizations * Accidents/Injury | Not reported to IRB |
| **Unexpected** and **Not Study-Related** *Serious* Adverse Events | * Deaths | Reported in accordance with IRB and DSMB guidelines |
| **Unexpected** and **Study-Related** Adverse Events – Serious and Non-Serious |  | Reported in accordance with IRB and DSMB guidelines |
| **Unexpected** and **Study-Related** *Serious* Adverse Events |  | Reported in accordance with IRB and DSMB guidelines |
| Expected protocol deviations/exceptions | * Missed appointments and/or sessions. * Breach of confidentiality associated with reporting suspected abuse to Child Protective Services. | Not reported to IRB |
| **Unanticipated Problem Involving Risks to subjects or Others (UAP) – Serious and Non-Serious** |  | Reported in accordance with IRB and DSMB guidelines |

**Data Safety and Monitoring Board (DSMB)**

A DSMB will be established for this study with a charter modeled after the VA Health Services Research & Development DSMB Charter. The DSMB will be responsible for assessing study participant safety, and monitoring overall conduct and integrity of the study. The DSMB provides ongoing evaluation of study progress including patient accrual and retention, monitoring of adverse events, and the adequacy and efficiency of the analysis plan to discern outcomes that might require study modifications, or result in early cessation of the study due its benefits or harms. DSMB annual reports/findings will be reported to the local IRBs.