**Brown University**

**Appendix F. Mental Health Safety Plan**

**Protocol Title:** Click or tap here to enter text.

**Principal Investigator (PI):** Click or tap here to enter text.

**IRB Protocol # (if amendment):** Click or tap here to enter text.

**Date of submission:** Click here to enter a date.

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| **This research study participant Mental Health Safety Plan (“Safety Plan”) is a set of procedures developed to ensure the well-being of research participants who may experience significant emotional distress (e.g., depression), or be at risk of harming themselves or others during the course of a research study.**  |
| **SAFETY PLAN SCREENER** |
| **This Safety Plan must be included in the protocol if any of the following apply (check all that apply):**[ ]  a. Research procedures involve asking participants about the risk of harm to self or others[ ]  b. Assessments about emotional distress/depression/suicide are used (**complete** [**Assessments Checklist**](#Checklist)**)**[ ]  c. The study involves populations at high risk for self-injury [ ]  d. Study medications administered to participants have a side effect of suicidal ideation[ ]  e. Other research components that could increase suicidal risks[ ]  f. None of the above. **STOP HERE**. You do not need to complete this Appendix. |
| **SAFETY PLAN REQUIREMENTS AND TRAINING** |
| **All research staff are required to be trained on this Safety Plan and monitored for compliance with the Plan.** [ ]  I affirm that all research staff will be trained and monitored for compliance with this Plan.---------------------------------------------------------------------------------------------------------------------------------**If conducting assessments in-person, over the phone, or electronically (if responses are reviewed in real-time),** a [licensed medical provider](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#L) must be retained to serve as a consultant and resource for this study. [ ]  I affirm that the safety procedures outlined below have been approved by the licensed medical provider and will be used by all research staff.**If responses are not reviewed in real-time,** please skip to [Conducting Assessments Electronically (Not in Real Time)](#electronicassessment). |
| **SAFETY PLAN PROCEDURES** |
| 1. The study measures will be administered by (check all that apply): [ ]  a. The study’s licensed medical provider [ ]  b. Research staff[ ]  c. An electronic platform (i.e., computer, hand-held device)---------------------------------------------------------------------------------------------------------------------------------2. The study’s licensed medical provider will do **one** of the following: [ ]  a. Personally review participant responses to the measures in real time and determine each participant's need for clinical assessment; OR[ ]  b. Determine which of the measures’ questions/response combinations will trigger the safety plan and participant evaluation **before** **the research staff** use it with any participants***The IRB does not need details regarding which questions from the measures would trigger the safety plan if this is done by a licensed medical provider.*** ---------------------------------------------------------------------------------------------------------------------------------3. The research staff ([ ]  RA, [ ]  graduate student, [ ]  undergraduate student) conducting the assessment will **immediately** do one of the following if a participant is at imminent risk of harm(check all that apply):[ ]  a. Stop study procedures and contact the study’s licensed medical provider[ ]  b. Follow the State-designated treatment facility safety procedures if participant is incarcerated[ ]  c. N/A – the licensed medical provider will be the only party administering measures in-person---------------------------------------------------------------------------------------------------------------------------------4. If an electronic platform (i.e., computer, hand-held device) will be used to administer the measures and someone will be present at the time of administration, you must affirm the following by checking the box below:[ ]  If a participant is at imminent risk of harm, the research staff present for the assessment will **immediately** stop study procedures and contact the study’s licensed medical provider.*Note: Imminent is defined as likely to happen soon; giving signs of immediate occurrence.* |
| **CONTINUED STUDY INVOLVEMENT** |
| Triggering the Safety Plan may impact a participant’s continued involvement in the study. If the Safety Plan is triggered and the licensed medical provider determines there is no imminent risk of harm, then (choose one):[ ]  a. The study’s licensed medical provider will determine which procedures may continue [ ]  b. The participant will be withdrawn from the study. Describe why: Click or tap here to enter text.  |
| **RESOURCE/REFERRAL LIST** |
| [ ]  A resource/referral list will be given to all participants and is attached.State when the list will be given (e.g., at time of consent, after review of the assessments): Click or tap here to enter text.  |
| **CONDUCTING ASSESSMENTS ELECTRONICALLY – NOT REVIEWED IN REAL TIME** |
| When using an electronic platform where participants’ responses will not be monitored/reviewed in real time, the following information/steps are **required**. Please check the boxes below to affirm the following: [ ]  The first and last assessment (if multiple assessments) include this statement: “**These assessments will not be reviewed immediately**. Everyone participating in this research study will receive a list of contacts if they want to speak to someone about any health concerns or abuse.” [ ]  A resource/referral list will begiven to all participants [attach list]. State when the list will be given (e.g., at time of consent, after review of the assessments): Click or tap here to enter text. |
| **INTERNATIONAL RESEARCH** |
| [ ]  Yes [ ]  No  | This study involves research activities outside of the United States. If “no,” please skip to next section.If “yes,” please list the countries: Click or tap here to enter text. |
| Each country may have its own reporting requirements. Based on the laws of the country or countries in which your research is taking place, please confirm the following (check all that apply):[ ]  a. The Safety Plan procedures are culturally sensitive to the population and the area in which the  procedures are taking place;[ ]  b. We will follow/defer to the laws in the country/countries listed above. With regard to mental health safety, the country’s law(s) is as follows:Click or tap here to enter text.[ ]  c. The country/countries has no reporting law regarding mental health. We will:[ ]  (i) work with a local health clinic / local community health providers and a resource/referral list will be given to all participants [attach list]. State when the list will be given (e.g., at time of consent, after review of the assessments):OR[ ] (ii) Follow the procedures listed in the [Safety Plan Procedures](#safetyplanprocedures) or [Conducting Assessments Electronically](#electronicassessment) section. |
| **ADDITIONAL INFORMATION (OPTIONAL)** |
| Please describe any Safety Plan procedures not addressed above:Click or tap here to enter text. |
| **ASSESSMENTS CHECKLIST** |
| **This is not an all-inclusive list. Please add any assessments that are not listed.****Check all that apply:**[ ]  Beck Family of Assessment (e.g. BDI, BDI-II, BAI, BSS, BYI-II)[ ]  CDI Family of Assessments (e.g. CDI-2)[ ]  CES-D Family of Assessments (e.g CES-D, CESD-R)[ ]  Depression Anxiety Stress Scales (DASS)[ ]  ICD Family of Assessments (e.g. ICD-10)[ ]  Structured Diagnostic Interviews (e.g. DSM-5)[ ]  Kessler Family Screening Scales (e.g. K6, K10)[ ]  Assess for suicide and/or homicide risk[ ]  Illinois Snapshot of Early Literacy (ISEL)[ ]  Other: Click or tap here to enter text. |