

**Brown University**

**Appendix F. Mental Health Safety Plan**

**Protocol Title:**

**Principal Investigator (PI):**

**IRB Protocol # (if amendment):**

**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](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#appendices) (**complete and attach the linked document**)[ ]  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 PROCEDURES** |
| **Confirm the following safety procedures that will be used if conducting assessments in-person, over the phone, or electronically (if responses are reviewed in real-time). If responses are not reviewed in real-time, please skip to** [**Conducting Assessments Electronically (Not in Real Time)**](#electronicassessment)**.**1. The study measures will be administered by (check all that apply): [ ]  a. The study’s licensed clinician [ ]  b. Research staff[ ]  c. An electronic platform (i.e., computer, hand-held device)------------------------------------------------------------------------------------------------------------------------------ 2. The study’s licensed clinician 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 clinician.*** ---------------------------------------------------------------------------------------------------------------------------------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](#imminent) risk of harm(check all that apply):[ ]  a. Stop study procedures and contact the study’s licensed clinician; OR[ ]  b. Follow the State-designated treatment facility safety procedures if participant is incarcerated. [ ]  c. N/A – the licensed clinician 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](#imminent) risk of harm, the research staff present for the assessment will **immediately** stop study procedures and contact the study’s licensed clinician |
| **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 clinician determines there is no imminent risk of harm, then (choose one):[ ]  a. The study clinician will determine which procedures may continue; OR [ ]  b. The participant will be withdrawn from the study. Describe why: |
| **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):  |
| **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): |
| **INTERNATIONAL RESEARCH** |
| [ ]  Yes [ ]  No  | This study involves research activities outside of the United States. If “no,” please skip to [Training](#training).If “yes,” please list the countries:  |
| 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:[ ]  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. |
| **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. |
| **ADDITIONAL INFORMATION (OPTIONAL)** |
| Please describe any Safety Plan procedures not addressed above: |

Imminent: is defined as likely to happen soon; giving signs of immediate occurrence.