**Mental Health Safety Plan**

 *Attach to your submission*

I. **Purpose**

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.

**II. This Safety Plan must be included in the protocol if any of the following apply (check all that apply):**

[ ]  Research procedures involve asking participants about the risk of harm to self or others

[ ]  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**)

[ ]  The study involves populations at high risk for self-injury

[ ]  Study medications administered to participants have a side effect of suicidal ideation

[ ]  Other research components that could increase suicidal risks

**III. Confirm the following safety procedures if section II applies to this study** (check all that apply):

1. **Conducting assessments in-person, over the phone, or electronically (if responses are reviewed in real-time)**

1. The study measures will be conducted by:

[ ]  a. The study’s licensed clinician

 The study’s licensed clinician will do **one** of the following:

[ ]  i. Determine which of the measures’ question/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.***

[ ]  ii. Review participant responses to the measures in real time and determine each participant's need for clinical assessment.

[ ]  b. Research staff:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (e.g. RA, graduate student, undergraduate student);

 ***Please do not include names of the individuals***

If a participant is at imminent[[1]](#footnote-1) risk of harm, the research staff conducting the assessment will **immediately** (check all that apply):

[ ]  i. Stop study procedures and contact the study’s licensed clinician

[ ]  ii. Follow the State-designated treatment facility safety procedures if participant is incarcerated.

[ ]  c. An electronic platform (i.e., computer, hand-held device)

If a participant is at imminent[[2]](#footnote-2) risk of harm, the research staff present for the assessment will **immediately** stop study procedures and contact the study’s licensed clinician

 2. Triggering of 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. A resource/referral list will be given to all participants. State when (e.g., at time of consent, after review of the assessments):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Please include the resource/referral with your submission (required document)***

1. **Conducting assessments electronically (if not reviewed in real-time)**

When using an electronic platform, the following information/steps are **required**:

1. The first and last assessment (if multiple assessments) includes 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.”
2. A resource/referral list will begiven to all participants. State when (e.g., at time of consent, after review of the assessments)

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Please include the resource/referral with your submission (required document)***

**IV. Conducting research internationally**

Each country may have its own reporting requirements. Based on the reporting requirements of the country where your research is taking place, please confirm the following (check all that apply):

[ ]  1. The safety plan procedures are culturally sensitive to the population and area where the study is taking place.

[ ]  2. We will follow and defer to all laws in:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(name the country/city). With regard to mental health safety, this country’s law is (state the law): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  3. If the country has no reporting laws regarding mental health:

[ ]  a. We will work with the local clinic or community health providers/assistants and a resource/referral list will be given to all participants. State when (e.g., at time of consent, after review of the assessments):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Please include the resource/referral with your submission (required document)***

[ ]  b. We will follow/choose one option from section III. Please complete section III.

**V. Training** (required)

[ ]  All research staff will be trained on this safety plan and monitored for adherence to the plan.

**VI. Additional Comments**

Below, please describe any safety plan procedures not addressed above (if any).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Imminent is defined as likely to happen soon; giving signs of immediate occurrence. [↑](#footnote-ref-1)
2. Imminent is defined as likely to happen soon; giving signs of immediate occurrence. [↑](#footnote-ref-2)