Holland Bloorview
Kids Rehabilitation Hospital

Guidelines for Safety Plans in Research Studies
Where Serious Mental Health Concerns May Arise

Background Researchers who assess or study the mental health of participants must demonstrate preparedness to mitigate imminent risk of harm by submitting safety plans to the Holland Bloorview Research Ethics Board (HBREB) as part of their initial submission. The following provides considerations for the safety plan as it relates to the screening, review, and management of imminent risk associated with serious threats to the welfare of participants and others affected by their participation.

Considerations for Consent and Assent Processes HBREB policies detail both the general consent/ assent processes and elements for informed consent forms and assent disclosures. The HBREB will look for these details and additional steps that researchers will take to disclose potential risks to prospective participants and their parents or substitute decision makers during the consent and assent process. In particular, researchers should address the following additional considerations in their informed consent and assent disclosures and during related discussions:

- The assessments conducted during the research study are separate from any care or treatment received by the participant in a clinical setting.
- The methods and assessments used in the research study may be similar or the same as those used in clinical settings. However, the data collected are used for different purposes. Research data help researchers to generalize to a larger population. Whereas, clinical data help clinicians to assess psychological functioning and inform next steps in a treatment or service for an individual.
- The participant's involvement in the research study and any data collected during the study will not be stored on the participant's health record (unless approved by the HBREB).
- The researcher has an obligation to keep information shared by participant confidential. However, conditions exist where the researcher cannot maintain confidentiality and will take steps to protect the participant or others from harm. In these situations, the researcher will contact the parent or other authorities (including emergency mental health services, general practitioner, or the police) if the participant discloses imminent risk for severe harm to self or others or shares information about suspected or known sexual, physical, or other abuse. (Refer to Holland Bloorview's policies to report suspected or known abuse.)

Considerations for Research Safety Plans Researchers have an ethical duty to assess the imminent risk and take immediate steps to support participants who report serious mental health concerns during the conduct of a study. Research safety plans must include the following three elements: screening for imminent risk, reviewing the screening for imminent risk, and taking immediate steps to mitigate imminent risk of harm. Imminent risk may be defined a strong possibility that participant will engage in life threatening behaviour to oneself or others.

1. **Screening for imminent risk of harm**

- Research staff must have the professional competence, be able to assist in the timely review of research data collected, and follow specific criteria identified in the safety plan to gauge the level of risk.
- Screening for imminent risk must take place immediately if the research assessment is conducted either face-to-face, by phone or by other means (e.g., remote interview via Adobe Connect).
- Information collected during the screening should be collected in a form that can be immediately reviewed by a trained mental health professional.

2. **Reviewing the screening of imminent risk of harm**

- The review of screening for imminent risk must be performed by a trained mental health professional before the participant leaves the research session. The trained mental health professional may be either the research staff member who conducts the initial screening or another team member or consultant who knows when interviews are being conducted.
- If clinical measures indicate any risk, or risk is indicated during a research session, then a trained mental health professional must assess the imminence of that risk immediately.
- If risk is assessed to be imminent by the trained mental health professional, then the researcher is obliged to explain to the participant why confidentiality must be broken and what will happen next.

3. **Taking immediate action to mitigate imminent risk of harm**

- If imminent risk is suspected, the usual initial step would be for the researcher/trained mental health professional to contact the participant's parent/substitute decision maker. If a parent/ substitute decision maker is unavailable or unable to carry through with the recommendations of the trained mental health professional, then the researcher will call 911 and have paramedics/police escort the participant to the nearest emergency department for assessment.
- The researcher/trained mental health professional must wait with the participant and parent/ substitute decision maker (if appropriate) until emergency services respond. If the participant takes part by phone or a related means, then the researcher will keep the participant engaged until emergency services respond.
- Content recommendations when initiating contact with a parent or other third party:
    - Reinforce that the safety of the participant is the most important consideration.
    - Express concern about their participant's response to certain items on assessments. (Note: Copyright laws for specific psychological assessments prohibit sharing measures, in whole or in part, with others.)
    - Assess whether imminent risk of harm is already known to the parent/substitute decision maker and whether the participant is receiving treatment.
    - Recommend immediate clinical assessment if indicated and provide mental health resources. Resources may include providing the location of the nearest hospital for an emergency mental health assessment and a 24-hour mental health crisis line phone number, and recommending follow-up with the family doctor.

    - Confirm the plan to remain with the participant and need to transfer care immediately to a trusted third party.
- The safety plan must have steps to follow if the participant is unwilling to wait before carrying through the recommendations of the trained mental health professional (e.g., immediate phone call to parent).
- The safety plan must include procedures to provide debriefings with research investigators and mental health professionals, as well as mental health support/resources/training for research staff who may have been directly/indirectly involved in the research session.

The research staff/trained mental health professional must record relevant details of the risk assessment and action taken in the research file. The local principal investigator must report to the HBREB unanticipated problems, protocol deviations, and amendment requests if necessary after taking action.

References

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2014.

Lloyd-Richardson EE, Lewis SP, Whitlock JL, Rodham K, Schatten HT. *Research with adolescents who engage in non-suicidal self-injury: ethical considerations and challenges.* Child Adolesc Psychiatry Ment Health 2015;9:37. doi: 10.1186/s13034-015-0071-6.

Related HBREB Standard Operating Procedures

REB-701 Informed Consent Elements
REB-702 Informed Consent Process
REB-704 Informed Assent Elements
REB-705 Informed Assent Process

Refer to other HBREB standard operating procedures for initial and post-approval submissions: http://research.hollandbloorview.ca/ResearchEthicsBoard/StandardOperatingProcedures