SOP for Research Involving Suicidal Questions[1]

At Wilfrid Laurier University, the Research Ethics Board (REB) recognizes that in some human participant research studies, it is necessary to collect data pertaining to suicidal thoughts. These protocols raise concerns about potential risk for research participants. After careful consideration, the REB has created the following guidelines to assist investigators who are pursuing this type of research.

Researchers' role in research involving suicidal questions:

This protocol should be used when there is a potential risk that a participant could disclose suicidal ideation (i.e., any thoughts about suicide) in the context of a research study. This disclosure can vary from brief consideration of suicide to detailed plans. Laurier's REB takes the position described in Hom *et al.*, (2016):

> *Frequency and type of risk assessment and referral practices will vary depending on study population, design, and setting; yet, across studies, the roles and responsibilities of the researcher should be limited to that of an informed gatekeeper who routinely (a) takes appropriate actions to assess and categorize a participant's risk, and (b) then connects the participant with appropriate services rather than serving as the de facto provider of those services. It may be necessary for a research clinician to act as the provider during an emergency, until appropriate services are available.*

If populations under study are considered high-risk, researchers must include a safety plan outlining this possibility, how risk will be mitigated, and the qualifications of the research team members who would be responsible in case of an emergency.

The objective of this document is to ensure ethical and safe practices when conducting research that includes questions related to suicide. This standard operating protocol is designed to assist investigators developing research protocols by providing justification for inclusion of suicidality questions and a plan to mitigate risk, when and if inclusion is deemed appropriate. These guidelines will also assist the REB in determining the risk level of the proposed study, and the required level of REB review (*i.e.,* Delegated or Full Board review).

Step 1: Assessing the need to include suicidal questions

Investigators should consider: Are questions about suicidal ideation important/pertinent/necessary for the research? If the study does not focus on suicide, then there are alternative options to including suicidal questions:

1. Questions on suicidality may be deleted from standardized measurements *e.g.*, Beck Depression Inventory (BDI)

[1] Content liberally adapted from University of California Berkeley guidelines (August 2017).

2. Alternative instruments may be used to measure depression/anger

Step 2: Justification of suicidality questions

If investigators deem it necessary to include questions on suicidality, then they must provide the rationale and hypotheses of the research as it pertains to suicidality (section 2.1), discuss risks associated with the suicidality questions (Section 7.2), and steps taken to mitigate these risks specifically (section 7.3), and stopping criteria that may apply in the context of suicidality questions (section 7.4).

Step 3: Mitigating Risk

Will participants be identifiable? If so, please provide the following information:

1. How will level and immediacy of risk be assessed (e.g., in person/by phone, types of questions, persons who will conduct the assessment)
2. The timing of response review. If investigators propose to wait longer than a two-day period to review individually identifiable responses to suicide-related questions, this must be justified within the protocol.
3. A detailed safety plan outlined under Sections 7.3 and 7.4.
4. Qualifications/Experience of the PI/lead investigator, as well as training information for any study team members who may be involved in the assessment of risk and/or implementation of the safety plan. Depending on the scope of the study (*e.g.,* studies with a direct focus on suicidality with direct interaction with participants), the REB may ask researchers to provide documented evidence that they have completed training in a suicide awareness-training program endorsed by a reputable organization such as the Canadian Mental Health Association (*e.g.*, Safe Talk).
5. For participants under the age of majority, the expectation is that parents/guardians will be informed of any disclosure within a reasonable timeline and provided a resource sheet. If parents/guardians will not be informed, researchers must provide the REB with a strong rationale for this decision. It is expected that the following be included:
    a. Disclosure to child participant in the assent form that researchers will inform participant's parents/guardians in the event of suspicion of possible self-harm.
    b. Explicitly disclose in parental consent form that a research instrument includes question(s) regarding thoughts of suicide, how researchers will contact parents in the case of such disclosure, and the inclusion of a resource sheet.

NOTE: If investigators are directly contacting participants, training/experience should include recognizing signs of distress, appropriate language usage, and procedures for responding to participants who express suicidal thoughts.

Will participants be anonymous? If so, please provide the following information:

1. Context/rationale based on current findings for why they believe individual assessment and feedback are unnecessary - *e.g.,* a paragraph providing such context might read as follows:

    Studies indicate that merely reporting past or recent suicidal thoughts does not necessarily indicate an imminent risk of acting on those thoughts. The risk of suicide is more acute when the

individual reports not just ideation, but also expresses intent, has a plan, and/or access to means to carry out the act.

2. If participants are not considered to be at high risk for suicidal behavior and will not be asked about their intentions, plans, or access to means for suicide, this must be clearly stated in the explanation regarding the absence of individual identification and subsequent safety planning for participant responses.
3. Consider adding "check-in" points over the course of the instrument or questionnaire (*e.g.*, asking respondents whether they wish to continue or whether they wish to link immediately to the referral information).

Regardless of the study method, the following must be considered:

- At the very least, the measures to minimize risk should include a resource document to be given to subjects (*e.g*., listings/contact information for local mental health resources, crisis intervention services, suicide hotline, etc.).
- Questions related to suicide should be clear, non-suggestive, and avoid leading language.

Step 4: The Consent Process

Participants must be fully informed about the nature of the study during the consent process, including the inclusion of questions related to suicide. During the consent process, investigators must provide clear information on the voluntary nature of participation, confidentiality measures, and procedures for withdrawing from the study. Incentives should not be withheld as a result of withdrawing from the study as per TCPS2 Article 3.1.

Here are some considerations for consent:

1. In the case of anonymous/anonymized studies (*e.g.,* online studies), the consent form should clearly state that individuals will not be individually assessed in the Risks/Discomforts section and provide resource referral information, *e.g.*:

   Due to the anonymous [anonymized] nature of this study, your responses will not be individually identified or assessed. As such, we will not be able to provide you with feedback or referrals based on any of your personal answers. If negative feelings persist following this study, please refer to the resources provided.

2. If responses are identifiable and individually assessed (*e.g.,* in-person/in-lab study), investigators should explain in the Risks section of the consent form what will happen if a participant becomes uncomfortable or upset during a study session, including information about resources that will be made available. The consent form should clarify whether the researcher intends to intervene or contact participants, specifying the criteria for such contact. Additionally, it should indicate whether the researcher plans solely to provide a resource referral sheet. The availability of the referral resource sheet must be clearly stated in either scenario.

3. Limitations to Confidentiality: If applicable, investigators should state any limitations to confidentiality, *e.g.*:

   There are situations where we cannot guarantee confidentiality and/or anonymity. If you reveal information that you may harm yourself or someone else or if a child needs protection, the research team is required to contact the relevant legal authorities.

Step 5: Reporting a Suicide Risk

Typically, the urgency of suicide risk is assessed when a participant possesses both a plan and the means to enact it, with a credible indication that they may act imminently. However, the absence of a concrete plan and means does not automatically dismiss the urgency determination. For instance, individuals experiencing current suicidal thoughts, expressing hopelessness, and disclosing a history of suicide attempts might still be categorized as urgent. Ultimately, such decisions rely on trained judgment and consultation with a supervisor or equivalent authority.

If you feel that a student or others could be in immediate danger, contact Laurier Special Constable Service or call 911.

Using the online Care Report form, researchers can easily refer Laurier students when they may require elevated levels of coordinated support, or share reports of disruptive, problematic, threatening, or concerning behaviour.

In the event that the safety plan was initiated due to a perceived risk, researchers must complete an adverse event report as soon as possible and document the occurrence with the REB.

Appendix:

If researchers are seeking sample language for informed consent or sample distress protocol, please refer to Appendices of The University of British Columbia Suicidal Risk Guidance document.

If researchers are seeking sample debriefing language, please refer to Appendix A of the Carleton University Suicidal Thoughts Protocol for use in Research Settings protocol.

References:

Melanie A. Hom, et al., 2016. “Ethical Issues and Practical Challenges in Suicide Research: Collaboration with Institutional Review Boards” http://econtent.hogrefe.com/doi/abs/10.1027/0227-5910/a000415