Suicidal Risk Guidance[1]

Both clinical and behavioural research can involve participants who may reveal that they are at risk of suicide, and/or who may be known to be at higher risk of suicide. The purpose of this guidance is to delineate researcher requirements for assuring the safety of participants in cases where suicide risk may prevail among research participants. It also provides researchers with some useful links and resources.

Maintaining safety for human participants is an important part of all research. For those at risk for suicide, there is a higher standard to assure their safety, since they are known to be particularly vulnerable participants. Researchers will need to adapt this guidance to their individual research protocols, providing a plan to protect participants when inclusion of suicidality questions is appropriate and /or when the study population is a high risk population.

A. Considerations when assessing suicidal risk

- Research has confirmed that simply asking a participant about whether they have thoughts of suicide is not a likely trigger of such an event (Gould et. al. 2005). It is usually only when the person reports ideation *as well as an intent, plan, and/or means* to commit suicide that risk for immediate suicide is considered to be more acute.
- University of British Columbia research studies often include measures that screen for depression and/or suicidality risk, such as the Beck Depression Inventory and the PHQ-9. Based on the responses to specific questions on those measures, it may become apparent that the participant is at high risk of committing suicide.
- Risk of suicide may also arise when the study population is a high-risk population, e.g. persons suffering from chronic depression, mental health concerns, etc.
- It is also possible that an unanticipated revelation of suicidal ideation[2] can take place, based on the research procedures.

B. Training and the role of researchers

Clinician researchers dealing with a high risk population are expected to have professional training or to include a mental health professional as an integral member of the study team. Non-clinical researchers conducting research that asks questions that could reveal suicidal ideation should have consulted with a mental health professional in the course of protocol development, and they should have some level of training or professional expertise. This would be the case if, in particular, the study population includes vulnerable participant groups. The Canadian Mental Health Association offers a “safeTALK” course that researchers who intend to work in this area may consider taking.[3]

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[1] Content liberally adapted from Cornell IRB (June 2, 2017), and University of California Berkeley guidelines (August 2017).

[2] Suicidal ideation is defined as “Thinking about, considering, or planning suicide” by the CDC (Centers for Disease Control and Prevention): https://www.cdc.gov/violenceprevention/suicide/definitions.html.

[3] In BC, search for Community Gatekeeper Training, or go to: https://cmha.bc.ca/programs-services/community-gatekeeper-training/.

Some level of expertise in risk of self harm is appropriate, depending on the nature of the study. UBC takes the position elucidated in "Ethical Issues and Practical Challenges in Suicide Research: Collaboration with Institutional Review Boards" (Melanie A. Hom, *et al.* 2016):

> Frequency and type of risk assessment and referral practices will vary depending on study 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.

The ethics application will need to describe relevant expert consultation that has been undertaken in relation to managing suicidal risk; detail researcher expertise where indicated, include the plans for training research team members on the study's suicidal risk management plan; attach, if applicable, the Distress Protocol.

C. Is a comprehensive risk management plan or protocol needed?

Where suicidality appears to be a possible risk, UBC's REBs require researchers to have a comprehensive management plan for handling incidents. The plan will need to include: a means for assessing the risk, procedures for checking responses to suicidal ideation questions, agreement on a measure of timeliness (e.g. within 24-hours of receipt), and procedures for following up with participants where risk of suicidality is revealed. Sample text for a Distress and Suicide protocol is provided in Appendix B.

The following scenarios will need to be considered when developing a risk management plan and for completing the REB application.

1. **Anonymous surveys.** In studies where suicide risk questions are posed in anonymous surveys, individual follow up is clearly not possible. In such instances, the REB requires that:
    a. Resource referral information appropriate to the population and location is provided to participants and attached to the ethics application.
    b. The consent form warns participants that the researchers will be unable to contact them and informs them that a resource referral sheet will be provided.
    c. Consideration be given to adding "check-in" notes at specified points in the instrument or questionnaire (e.g. asking respondents whether they wish to continue or whether they wish to link immediately to the referral information).
2. **Non-anonymous surveys.** In studies where suicide risk questions are posed in surveys and the respondents are identifiable, individual follow up by the researcher is expected. In such instances, the REB requires that:
    a. The REB application explains how the researcher will assess the level and immediacy of risk, including: the timing of response reviews; the criteria for determining that follow up is necessary; method of contact (in person/by phone); the questions that will be asked, and who will conduct the assessment. If the researcher plans to provide a resource referral sheet only, the rationale/justification will need to be provided.

b. A justification must be provided if the researcher proposes to wait longer than two days after receipt to review individual responses.

c. A resource referral sheet that is appropriate to the population and location is provided to participants and attached to the ethics application.

d. The consent form must explain if the researcher plans to intervene or contact individuals and on what basis contact would be made. It should also be mentioned if the researcher plans to provide a resource referral sheet only. The availability of a referral resource sheet will need to be mentioned in either case.

3. **In-person studies**. In studies that involve in-person interaction between researchers and participants, participants may directly inform a researcher of the possibility of causing harm to self, whether or not such revelations are anticipated by the research team. Researchers should consider whether the possibility of such revelations exists, and develop their plans accordingly, taking the following into consideration:

    a. Do members of the research team who will be interacting directly with participants have sufficient experience/expertise in and training for dealing with situations in which a participant informs about the possibility of causing harm?

    b. When assessing research risk, has the nature of the study, the vulnerability of participants, and the potential risk to researchers, participants, and others been accounted for?

    c. In studies where the researcher is not explicitly seeking to gauge intent to harm self or others, it is still possible that participants may voluntarily disclose such information. Are measures in place to address this eventuality should it arise?

    d. The consent form must explain the potential risks (to an appropriate degree), describe the steps that will be taken in the event of disclosure, and mention that a resource referral sheet will be provided if applicable.

4. **Participants under the age of majority.** In studies where participants are under the age of majority – and where there is potential that participants are vulnerable to suicidal thoughts – researchers will need to address how parents/guardians will be informed about findings of intent to cause self harm. Normally, the REB expects that parents/guardians will have been provided with a resource referral sheet, and will be informed about the disclosure in a timely manner. If they are not going to be informed, the ethics application will need to include a strong justification for not doing so. For children whose parent/guardian will not be providing consent, or for older children who are capable of providing consent on their own behalf, it may be appropriate to provide the resource referral sheet directly to the child. Please note:
    a. The child's assent/consent must disclose that the researchers plan to inform a participant's parents/guardians in the event of suspicion of possible self-harm.
    b. The parental consent form must disclose that a research instrument includes question(s) that measure suicidal intent; describe how the research team will inform the parents; and include reference to the resource referral sheet.

5. **Unanticipated event**. If there is no expectation of a disclosure of intent to harm self or others, but a participant does disclose such information, the researcher will need to take reasonable steps to protect the participant from harm, and then amend the study protocol accordingly. We advise that you contact your REB for guidance.

D. Resources for research participants

A resource referral sheet or equivalent will need to be provided to participants and attached to the ethics application. The document should include emergency contacts, and other resources that will be suitable for the target population, including hospital emergency addresses and phone numbers, crisis centre/mental health hotlines, and community organization help lines. As noted above, the consent forms will need to indicate that resources are being provided.

Appendices

A: Sample informed consent language

B: Sample distress and suicide protocol language

Suicidal Risk Guidance Appendix A: Sample informed consent language[i]

A. Sample consent wording for healthy adult participants, if researchers plan to intervene or contact individuals based on certain findings

> *The researcher may need to tell someone if you talk about harming yourself. If you tell research staff that you are thinking about killing yourself or if you answer "Yes" to questions about having suicidal thoughts, the researcher may ask you more questions about your thoughts. They may give you names and contact information for places you can call for help, or help you to call your doctor, a relative, or therapist. The researcher may also help you to get to a medical facility for your safety.*

B. Sample consent wording for adult participants, if researchers plan to offer resources only (no follow up contact)

***Option 1**: In this research study, we will be asking you questions about sensitive topics. As researchers, we do not provide mental health services. However, we are giving you a list of resources that you can call if you need help.*
[If applicable, include link to resource document.]

***Option 2**: In this research study, we will be asking you questions about your mental state. As researchers, we do not provide mental health services. It is possible that we will not view your responses for several days or weeks after you complete the survey. (OR: This study does not allow us to link your name to your responses.) We want to provide you with contact information should you decide that you need help at any time.*
[If applicable, include link to resource document.]

C. Sample wording for consent and debriefing of parents and children

> ***Consent for parents**: This research study asks questions about sensitive topics. As researchers, we do not provide mental health services. However, we will inform you if your child's responses indicate intent to harm self or others. We also want to provide you with contact information for available resources should you decide you or your child need assistance.*
>
> ***Debriefing for children**: This study asked questions that may have troubled you. If you are feeling sad or anxious and feel like you want to talk to someone, you can tell the researcher or an adult you trust. We are also giving you a list of resources you or your parent may call. We have given this information to your parent also.*

D. Sample debriefing wording for studies where there is no direct contact with participants during the study:

> *In this research study, we asked you questions about sensitive topics/about your mental state. As researchers, we do not provide mental health services. It is possible that we will not view your responses for several days or weeks after you complete the*

surveys. (OR: This study does not allow us to link your name to your responses.) If you would like to talk to someone about how you are feeling, please contact [list names and contact information for appropriate resources].

[i] Adapted from the Cornell University Office of Research Integrity and Assurance HRPPP Guidance Approved by Cornell IRB, June 2, 2017

Appendix B: Sample Distress Protocol for Research Team Members[1]

The following distress protocol content has been adapted from a Protocol provided by Dr. Teresa Liu-Ambrose. The information taken from the original protocol makes certain assumptions about the nature of the research, the participants, and the research team. We have attempted to generalize as much as possible, however, note that not all suggested content will be relevant or needed for all research projects. Please consider this as suggested content only and ensure that your content is appropriate for your research context. Your distress protocol, if one is needed, should be reflective of the level of risk you anticipate, the study personnel who will use it, and other aspects of the research.

A. Describe when the protocol should be followed.

Sample text
The distress and suicidal protocol will be followed in cases where an individual scores 10 or greater on the PHQ-9 (indicative of major depression) ***and*** who reports "Several days," "More than half the days," or "Nearly every day" for Question 9: "During the past two weeks, how often have you been bothered by thinking that you would be better off dead or that you want to hurt yourself in some way?" Some scenarios in which a participant may indicate experiencing significant distress include, but are not limited to: ▪ the participant's mood is deteriorating (without thoughts of harming self) ▪ the participant has extremely low mood and thoughts of ending their life (these thoughts may be fleeting or be regular) ▪ the participant, in addition to having thoughts of ending their life, may also have plans in place for suicide The highest risk is for those individuals who have **thoughts** of killing themselves, **plans** in place as to how they would do so, and the **means** (e.g. knives, a rope, drugs) by which to end their life.

B. Describe the overall purpose and importance of the protocol.

Sample text
The aim of this guide is to assist research staff in dealing with these scenarios, to provide procedures that ensure staff are supported by researchers/clinicians, and to ensure the safety of participants. These discussions can be distressing and unsettling; if you experience feelings you want to talk about, reach out to a trusted colleague to debrief. The principal investigator or study physician must be notified so they can follow up with the participant, to be assessed for their risk of suicide. Even if the participant is made ineligible for the study based on their scores, individuals must receive follow up.

[1] Adapted and used with the permission of Teresa Liu-Ambrose, member of the UBC Clinical Research Ethics Board

C. Provide general guidance to users of the protocol, as appropriate.

Sample text
▪ Address the participant in a calm and respectful manner and let the participant know that you take their concerns seriously and give them high importance. ▪ Avoid responding too quickly or with anxiety. Speak in a compassionate tone and allow for silences from the participant. Rather than saying, "So you've got plans?" or "So you've got things at home with you?" validate what the person has told you and reflect back to them what they have said. E.g. "So you think about killing yourself every day and these kinds of thoughts are happening constantly? And when you have these thoughts, they scare you? ▪ Let the person know that you are employed as a researcher, or are a research student etc. and that as such you are not in a position to provide a clinical/ therapeutic service. However, explain that it is your role to contact a person who will be able to help. ▪ Try to anticipate any likely obstacle to help-seeking (e.g., clinician is engaged) and discuss how the person can manage those (e.g., give at least 3 referrals to mental health services).

D. Describe the steps to be followed. *Include and adapt these sections as appropriate for your context. These are examples of content from Dr. Liu-Ambrose's Distress Protocol and may not apply in all situations.*

Sample text
1. Acknowledge the person's distress and offer information, e.g.: ▪ *All the information gathered as part of this study is confidential, but any time when we are really concerned for somebody's mood or their safety, we have a duty to tell a clinician/health care worker so that they can be in contact with you.* ▪ *I'm concerned about you, so I want to give you information on resources that are available to receive support and help and so you can have them for future reference.* ▪ *I'm going to contact one of our clinicians/researchers on the project to call you. Someone will contact you as soon as possible. If you feel you want to talk to someone in the meantime it might be helpful to make an appointment with your doctor or contact a telephone service such as Crisis Centre 24/7 at 1-800-784-2433* ▪ *Provide referrals that are appropriate to the participant's location and/or situation, e.g. Veteran's Affairs contact.* 2. Be prepared for a variety of responses. Some participants will say nothing, others will express relief, and others will express further hopelessness: e.g.: ▪ *"I've tried calling x before and it didn't help." or "Well, if I call Lifeline they'll just tell me to have a rest or something."* 3. There are always good reasons for their so-called resistance. Say to them: ▪ *I know everything feels helpless now. I'm just really glad you told me about this and I'm happy I can hopefully get you some support.* 4. Explain that they will receive a call from the study physician. Be transparent. Say that you will explain the conversation to the physician. Explain what the participant can expect, e.g.: ▪ *The doctor will call you to get a better idea about how to keep you safe.* 5. If you feel that the person is at risk of harming themselves, has just harmed themselves, or plans to harm themselves within a short time frame (e.g., within the next few hours or even days):

- If you are able and it seems appropriate, inform the participant that you are seeking immediate medical attention on their behalf. Call 911 and provide details of the emergency.
- Explain that in this situation you also have to call the Principal Investigator and/or the study physician.

6. Fill in a Suicide/Distress Checklist Report and notify the Principal Investigator and/or the Study Physician
   - The report should be completed for each participant who matches the criteria.
   - Note the time, date, context (in-person or phone interview, etc.) and the information you have provided to the respondent and what other actions you have taken.
   - Contact the Principal Investigator as soon as possible and provide the relevant details so follow-up can be undertaken.
7. Describe under what circumstances an incident report needs to be attached to the ethics application (by whom, appropriate time frame, details to include).