# Northwestern University IRB Guidance on Suicidality in Human Research Protocols

## I. Overview

Research initiated by investigators from multiple disciplines often includes questionnaires focused on mental health, psychological functioning, and mood. Some of those questionnaires focus directly on suicidal thoughts and behaviors or include one or more individual questions about suicidality. Research protocols that involve the identification of suicidal ideation in participants raise concerns about potential risks for those participants. Even though empirical research has shown that asking about suicidality does not increase suicidal risk, research studies that include assessments of suicidality require additional monitoring of participants' responses, as further detailed below.

This guidance document focuses on measures or individual questions that assess thoughts or behaviors of suicide to clarify decisions about whether to measure this construct (e.g., the PHQ-9, or BDI); what researcher responsibilities are when suicidal ideation/behaviors are identified and under what study settings; and what information needs to be included in the protocol and what consent language is required. The guidance will also help study teams to determine if a plan for following up with participants whose responses raise concerns about intent to harm themselves is necessary, and how to describe the plan in the IRB application.

It is important to note that some measures of mood, depression, and other constructs include individual items that directly ask about suicidal ideation or behavior. This document is intended to provide guidance on managing those items as well, even if the overall content of the questionnaire (e.g., mood, depressive symptoms) does not reflect an increased risk to participants.

## II. Decisions about including Suicidality Questionnaires/Items

The decision as to whether to include a measure of suicidality depends on the research questions and aims of the research study. The primary question for the research team is to determine if such questions are necessary to the study. If the questions are central to the aims of the research, the questionnaires should be included, and the sections below guide the research team in managing various scenarios. The decision to retain a questionnaire or items on a questionnaire should be justified and addressed in multiple relevant sections of the protocol. If suicidality (or the specific items) is peripheral to the research questions, researchers have several options:

a. If the questionnaire itself concerns suicidality, the researcher may choose not to administer the questionnaire at all.
b. If there is an individual item(s) on a questionnaire focused on a different construct (e.g., depression), the researcher may choose to delete the specific suicidality item and justify this exclusion in the protocol (e.g., based on research questions, aims, etc.). However, the researcher needs to keep in mind considerations such as the

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copyright status of the measure (i.e., can it be modified), and the fact that the elimination of individual items may alter the validity of the questionnaire.

c. In cases where there is an individual item reflecting suicidality, the researcher can choose to administer a different questionnaire assessing that construct (e.g., depression) that does not contain such an item.

### III. Requirements for Identification and Follow-up Plan

Studies that include questionnaires or questionnaire items that focus on suicidal ideation or behaviors must include a plan in the research protocol for monitoring participants' responses and following up with them based on several study considerations, with relevant language included in participant-facing study-related documents (e.g., consent). The nature of the monitoring and follow-up will vary depending on the sample and study procedures (e.g., online or remote assessment vs. in-person assessment; anonymous participants vs. identified participants).

A. Anonymous survey

As noted above, simply asking participants about suicidal thoughts and behaviors does not increase their risk of suicide, but there is a possibility of increased distress, especially if participants are disclosing the distress as a "call for help." If participants' responses will not be individually identified, the investigators should include in the protocol an explanation for why such identifiable assessment is not necessary (based on risk) or feasible. However, if the survey asks explicitly about suicide, then specific local support services and/or *resources should be provided on the survey and in the informed consent. In addition, the consent form should (a) inform participants explicitly about the specific topics on the survey (e.g., suicide, self-harm) and clarify that the researcher cannot connect a participant's answer to the person and refer to the *resource referral document that will be offered.

B. Non-anonymous online survey

If participants' responses to an online survey will be linked to the identifiable individual, the protocol must provide information about how the research team will conduct further assessment for those who endorse suicidality through responses to suicide-relevant items (and what level of response constitutes risk). The researcher must respond to the participant on the same day (<24 hours) the survey was submitted. The protocol must explain how the research team will assess the level and immediacy of risk (e.g., by phone, in-person, type of questions, who will conduct assessment) and steps that will be taken both if the participant does and does not meet the criteria for imminent risk. Qualifications of the primary investigator and training information for any study team members involved in the assessment and/or implementation of the plan should be described. This detailed follow-up plan must be provided within the IRB protocol document. At minimum, if the assessment determines there is no imminent risk, a *resource referral document should be provided to such participants. (e.g., National Suicide Prevention Lifeline, local

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student counseling resources, referral to a local emergency department, etc.). The informed consent must explicitly state an assessment will be conducted if there is a risk of self-harm, and that confidentiality will be breached in these circumstances.

C. In-person assessment (non-anonymous)
When measures of suicidality are administered in-person, the scores or responses must be examined before the participant leaves the research setting, and this needs to be made explicit in the research protocol and consent form. The protocol should include specific score/response cut-off points and describe the follow-up plan if the participant meets or exceeds this threshold. The protocol must explain how the research team will assess the level and immediacy of risk (e.g., type of questions, who will conduct assessment), and steps that will be taken both if the participant does and does not meet the criteria for imminent risk. Qualifications of the primary investigator and training information for any study team members involved in the assessment and/or implementation of the plan should be described. This detailed follow-up plan must be provided within the IRB protocol document. If the risk assessment indicates that no imminent risk is present, an appropriate response includes the sharing of *resources. If an imminent risk is present, a qualified member of the research team must remain with the participant until support services have been received. The response may include staying with the participant and calling 988, or calling campus resources (if in an educational setting), or following policies established by the institution or clinical setting. Providing a resource referral document or telling the participant to go to the emergency room is <u>not</u> sufficient in cases of imminent risk. The informed consent form must explicitly state that an assessment will be conducted if there is a risk of self-harm and that confidentiality will be breached in these circumstances.

D. In-person interview
When participants are asked explicitly about suicidal thoughts and behaviors in an interview, a clear follow-up plan to the disclosure of suicidal thoughts and behaviors needs to be detailed in the protocol, including how the research team will assess the level and immediacy of risk (e.g., type of questions, who will conduct assessment), and steps that will be taken both if the participant does and does not meet criteria for imminent risk. Qualifications of the primary investigator and training information for any study team members involved in the assessment and/or implementation of the plan should be described. The research team member conducting this assessment must be trained in assessing potential self-harm. If the risk assessment indicates that no imminent risk is present, an appropriate response includes the sharing of *resources. If an imminent risk is present, a qualified member of the research team must remain with the participant until support services have been received. The response may include staying with the participant and calling 988 or campus resources (if in an educational setting). Providing a resource referral document or telling the participant to go to the emergency room is <u>not</u> sufficient in

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cases of imminent risk. The informed consent form must explicitly state that an assessment will be conducted if there is a risk of self-harm and that confidentiality will be breached in these circumstances.

E. Incidental disclosure of suicidal ideation/behaviors in populations known to be at higher risk for suicide (e.g., major depressive disorder, trauma survivors, veterans, etc.)
There are situations where interviews do not include questionnaires or individual items that ask explicitly about suicidal thoughts and behaviors, but participants' responses may indicate that they are at risk for self-harm. In these cases, the risk needs to be identified and described in the protocol, and a plan for assessing and following up with at-risk participants presented. If the risk assessment indicates that no imminent risk is present, an appropriate response includes the sharing of resources. If an imminent risk is present, a qualified member of the research team must remain with the participant until support services have been received. The response may include staying with the participant and calling 988, or calling campus resources (if in an educational setting), or following policies established by the institution or clinical setting. Providing a resource referral document or telling the participant to go to the emergency room is <u>not</u> sufficient in cases of imminent risk. The informed consent form must explicitly state that an assessment will be conducted if there is a risk of self-harm and that confidentiality will be breached in these circumstances.

## IV. Language to include in Follow-Up Plan

Any study that uses diagnostic or symptom severity measures that identify suicidal thoughts or uses instruments that include individual questions about self-harm, suicidal thoughts, or suicidal behaviors is required to monitor scores or responses and submit a plan for following up with participants. The plan should include how the study team will assess the level and immediacy of risk (e.g., in-person/phone, the questions and scores/responses that will lead to the implementation of the follow-up plan, persons who will conduct the assessment), and the timing of the review of responses. The detailed safety plan must be provided within the IRB protocol document. Qualifications of the PI/study team and training for any other study team members who may be involved in the assessment must be described.

The resource referral information provided to participants should be submitted as part of the IRB application.

All assessments and actions taken with each participant should be documented in a study form created for such documentation, including the assessment conducted and responses, action taken, referrals made, etc.

There are situations in which a follow-up plan for handling suicidality responses may not be required: (1) The data are collected anonymously; (2) the study team can't reasonably assess

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the responses in time to provide adequate follow-up (e.g., large numbers of participants completing surveys at the same time); (3) the data are sent directly to an external coordinating center that does not have a plan for review and follow-up of suicidality findings. If the study team believes that such a plan is not feasible or required, such as for the reasons outlined above, an explanation needs to be provided as to why no review and follow-up should be required for the study.

### V. Language to include in consent

If responses will not be individually identified and assessed, the consent form should clearly describe this in the Risks/Discomfort section, along with a note of the resource referral document. For example, "We will not be able to link your responses to you, so we will not be providing you with personal feedback or referrals based on your responses to questions. If you are concerned about your mood, please refer to the attached resource referral information sheet." Or, where suicidality is considered more likely, "If you have been thinking about death or suicide, we encourage you to visit *[website]* or call *[lifeline number]*. The study team needs to take into consideration the location of the participants (internationally, domestically) to ensure access to the *resources are available to them and in the appropriate language.

If responses will be individually identified (e.g., in-person study), the consent form should explain in the Risks/Discomforts section what the participants' options are in the event they become uncomfortable or upset during study procedures, including reference to the resource referral information document. The consent should also include language describing whether participants will be informed if their responses to questionnaires/items suggest suicidality, and what follow-up will occur. When responses can be individually identified, and a follow-up plan is in place, the Confidentiality section should explain limitations related to the assessment of suicidal intent, e.g., "We will keep your information as confidential as possible, except for certain information that we must report for legal or ethical reasons, such as child abuse, elder abuse or intent to hurt yourself or others."

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## **Appendix**: Suggested Resources to include when creating a protocol-specific Resource Referral Document

**Northwestern Specific Resources:**

Counseling and Psychological Services (CAPS)
CAPS provides clinical services, educational workshops, and consultation with NU faculty, staff and parents.
Crisis Support for non-life-threatening crises offered Monday- Friday 8:30am-5:00pm
Call 847-491-2151 to request a same-day virtual appointment.

Northwestern Medicine (NM) Healthy Tips
Online emotional health resources for NU patients and family members, including suicide awareness and prevention.

**Online and Text Resources:**

**988** Suicide and Crisis Lifeline, a three-digit dialing code that routes callers to the National Suicide Prevention Lifeline
Twenty-four hours a day, seven days a week
www.suicidepreventionlifeline.org

Crisis Text Line
Text HOME to 741 741 from anywhere in the US to reach a volunteer Crisis Counselor.
Twenty-four hours a day, seven days a week
www.crisistextline.org.

The Trevor Lifeline (U.S. only)
1-866-4-U-TREVOR (488-7386)
Twenty-four hours a day, seven days a week
The Trevor Project primarily serves young people, ages 13-24.
www.thetrevorproject.org

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