SUIDICAL IDEATION IN PROTOCOLS

This guidance document, with the Suicidal Ideation Decision Tree, is intended for investigators planning to conduct research that may involve asking subjects questions regarding suicidal ideation. Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

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A. Introduction

In recent years, UC Berkeley's Institutional Review Board (IRB), the Committee for Protection of Human Subjects (CPHS), has seen an increasing number of human research protocol submissions which involve identification of suicidal ideation in subjects. Such protocols raise particular concerns about potential risks for research participants. They can present ethical and practical challenges in evaluating and minimizing these risks – for investigators and IRB members alike. After careful consideration, the CPHS has developed the general guidelines offered below for investigators who wish to undertake such research.

Investigators are encouraged to adapt this guidance as it applies to their individual research protocols, providing justification for inclusion of suicidality questions and a plan to protect subjects when inclusion is appropriate. At baseline, when such protocols are submitted, assessed risk level and complexity will determine whether they can be expedited or need Full Committee review. The CPHS will evaluate whether adequate rationale, safety plans, and qualifications of the research team members to implement these plans have been shown.

B. Deciding Whether to Include Suicidality Questions

Suitable provisions for assessing and handling risks of suicidality will depend on the nature of the research. Protocols may range from a clinical study which focuses on individuals with major depressive disorders and history of suicide attempts to a study where questions about suicidal ideation are somewhat peripheral, e.g., they are included in one of a number of instruments being used to screen or gather information about a low-risk/non-vulnerable subject population. Type of setting, such as in-lab versus online procedures, is also important to consider (see part D below).

The first step in considering inclusion of such questions is to determine whether obtaining this information is necessary to the study. Appropriate next steps will follow accordingly. *Please see **Decision Tree**, which illustrates the basic path.*

Step 1: Investigators should consider: Is asking about suicidal ideation important/necessary for the research? If the study focuses on suicide, these questions (and related assessment and safety plans per below) need to be included. However, if this is not the case, there are several alternate options, including:

1. Questions on suicidality may be deleted before use of a standard instrument such as the Beck Depression Inventory (BDI); or
2. Another instrument to measure depression/anger may be used.

C. Justifying Inclusion of Suicidality Questions

If investigators decide that obtaining information on suicidal ideation is necessary for their particular study, they need to proceed to the next step in the process.

Step 2: The protocol must present the hypothesis of the research and rationale for why inclusion is necessary. This should be explained under Study Purpose, Subject Population, Risks/Discomforts, and/or other sections as appropriate.

D. Identification, Assessment, and Safety Plan

Step 3: In addition to presenting justification for including suicidal ideation questions, the protocol must explain if the research team will conduct further individual assessment for subjects who endorse suicidality through positive responses to suicide-relevant items. Of course, assessment and intervention possibilities will vary depending on whether study procedures will be conducted in-person (e.g., in the PI's lab), by phone, online, or other methods.

1. <u>If subjects' responses will be assessed and can be tied to the individual</u>:
   - The protocol must explain how the investigators will assess level and immediacy of risk (e.g., in person/by phone, types of questions, persons who will conduct the assessment). Timing of response review must also be discussed. 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.
   - A detailed safety plan must be provided in the protocol (Risks and Discomforts section).
   - Qualifications of the PI/lead investigator, as well as training information for any study team members who may be involved in such assessment and/or implementation of the safety plan, must be described.

   NOTE: At the least, the measures to minimize risk should include a ***resource referral*** document to be given to subjects (e.g., listings/contact information for local mental health resources, crisis intervention services, suicide hotline, etc.).

2. <u>If subjects' responses will not be individually identified</u>, the explanation should include why the investigators believe such individually identifiable assessment is not necessary (risk-wise) or feasible. For example, studies conducted anonymously online normally would not allow for "real-time" assessment of participants' answers or individual follow-up if concerns were to be identified.

   For studies where there will not be individually identified assessment or feedback to subjects regarding their answers to suicidality questions, investigators should provide 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:

> Research has found that a person reporting past (or even recent) suicidal ideation does not, by itself, indicate imminent risk that s/he will act on this impulse. Rather, it is usually only when the person reports ideation *as well as intent, plan, and/or means* to commit suicide that risk for immediate suicide is considered to be more acute.

If subjects are not at high risk for suicidality and will not be asked questions about intent, plan, and/or means to commit suicide, this should be specified in the explanation regarding no individual identification of/safety plan for subject responses.

Nevertheless, as above, provisions should be made to offer ***resource referral information*** in **all** studies involving questions about suicidal ideation. The consent form should warn subjects that there will be no individual feedback, and should refer to the resource referral sheet that will be offered. Also, "check-in" notes to the subjects (e.g., asking whether they wish to continue, whether they wish to link immediately to the referral information) may be required at several points throughout the instrument/questionnaire.

E. The Role of Researchers

In general, the CPHS holds the following viewpoint regarding research involving suicidality, 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 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." For high-risk subject populations, the safety plan should include this possibility and the qualifications of the PI/ study team members who would be responsible in such an emergency.

F. Consent Form Language

1. If responses will not be individually assessed (such as for an online study), the consent form should clearly convey this in the Risks/Discomforts section, along with note of resource referral information, e.g.:

   > "Your responses will not be individually identified, so we will not be providing you with personal feedback or referrals based on any of your answers. If you are worried about your mood, please refer to the attached resource referral information sheet." [Or, where suicidality is more likely, "If you have been thinking about death or suicide, we encourage you to visit the website of the International Association for Suicide Prevention (https://www.iasp.info), which can provide resources for finding help around the world."]

2. If responses will be individually assessed (such as for an in-person/in-lab study), the consent form should explain under Risks/Discomforts what the options are should the person become uncomfortable or upset during the study procedures, including reference to resource referral information and/or in-person referral.

3. Confidentiality limitations: If applicable (i.e., if the participant can be individually identified and there is a safety plan in place), the Confidentiality discussion should explain limitations related to assessment of suicidal intent, e.g.:

   > "We will keep your information as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as child abuse, elder abuse, or intent to hurt yourself or others."

   (Note: If the PI and/or other study personnel are mandated reporters, the above wording may need to be revised accordingly.)

G. Suicidal Ideation Questions in Screening Forms

The CPHS has determined that questions regarding suicidal ideation may not be added to *RPP, SONA, or other UCB subject pool* screening forms. When such questions are used, they must be included in the main protocol, with appropriate justification and other related elements as described above.