CUNY HRPP Guidance: Studies Obtaining Information on Suicidal Ideation or Suicide Attempts

1. Purpose

The purpose of this document is to assist the CUNY research community in designing studies that obtain information related to suicide. Such information, obtained from questions about substance use, trauma, mental health, etc., can indicate that a subject is at risk for suicide or is actively planning suicide. This document provides guidance for carrying out such research in a way that is consistent with the Belmont Report principles of Beneficence, Justice, and Respect for Persons, and meets the criteria for approval in the Common Rule. Important considerations include the plans for response to subjects who provide information suggesting a risk of suicide and communicating to subjects during the informed consent process. Obtaining information related to suicide should always be justified by and relevant to the research aims. Studies that obtain information related to suicide will be reviewed on an expedited basis or by the convened UI-IRB, as appropriate; studies requesting an exception to the requirements described in this guidance will generally require review by the convened UI-IRB.

2. Types of studies (Note that here, "anonymous" means no collection of identifiers or contact information)

2.1. Anonymous Surveys of Adults Not Known to be at Risk for Suicide

The use of anonymous surveys that ask individual questions about suicidal ideation or suicide attempts in order to assess mood, depression, etc., is generally appropriate if justified by the research aims and if the study will:

- Provide suicide prevention resources to all subjects (regardless of their answers to the suicidal ideation or suicide attempt questions) in both the consent form and the survey, with a statement that that the subject is encouraged to use the resources if they are having thoughts of suicide or self-harm; and

- Include language in the consent form that informs subjects explicitly about: (1) the specific topics in the survey (including suicide, self-harm, etc.) and (2) the lack of follow-up, with language similar to: "Some of the questions ask about self-harm. The survey does not ask your name, so we will not be able to follow up with you if the questions upset you or you need help. Please call 988 or visit https://988lifeline.org/ if you are having thoughts of suicide or self-harm."

The use of anonymous surveys that include questions about suicidal ideation or suicide attempts is generally not appropriate in studies that: (1) target persons with known suicide risk, (2) administer a questionnaire specifically to assess suicidal ideation or suicide attempts, or (3) include children. However, an investigator may request an exception to this general rule by providing a justification for the use of anonymous surveys in such studies where the justification is specifically related to the anticipated risks and benefits of the study.

2.2. Non-Anonymous Self-Administered Surveys

The use of surveys that ask questions about suicidal ideation or suicide attempts and that are self-administered and retain identifiers and contact information are generally appropriate if justified by the research aims and if the study will:

- Provide suicide prevention resources to all subjects (regardless of their answers to the questions about suicidal ideation or suicide attempts) in both the consent form and the survey, with a statement that that the subject is encouraged to use the resources if they are having thoughts of suicide or self-harm; and

- Include either:

    - A plan to follow up with subjects (and parents/guardians of child subjects) who reveal a risk for suicide or self-harm; or

    - A justification of why no follow up will be done specifically relating to the risks and benefits of the study; and

- Include language in the consent form that: (1) informs subjects explicitly about the specific topics in the survey (including suicide, self-harm, etc.) and (2) informs subjects about follow-up plans or lack thereof, including explicit information about how and the extent to which the survey responses provided will be kept confidential.

2.3. In-person Non-Anonymous Survey, Interview, Focus Group, Interaction, or Intervention

Asking questions about suicidal ideation or suicide attempts in a study that involves direct interaction with subjects (which may include in-person or remote surveys, interviews, or focus groups) are generally appropriate if justified by the research aims and if the study will:

- Provide suicide prevention resources to all subjects (regardless of their answers to the questions on suicidal ideation or suicide attempts) in both the consent form and during the interaction, with a statement that that the subject is encouraged to use the resources if they are having thoughts of suicide or self-harm; and

- Include a plan to follow up with subjects (and parents/guardians of child subjects) who reveal a risk for suicide or self-harm; and

- Include language in the consent form that: (1) informs subjects explicitly about the specific topics in the survey (including suicide, self-harm, etc.) and (2) informs subjects of follow-up plans, including explicit information about how and the extent to which the subjects' participation and responses will be kept confidential.

Note that in contrast to self-administered surveys, the general rule is that studies that involve direct interaction with subjects shall include follow-up. However, in some

cases, the investigator may request an exception to this general rule by providing a strong justification that subjects in such studies are adequately protected without follow-up. Such a request must be based on a determination of a mental health professional or clinician (which could be a member of the research team with such a credential).

3. Follow-up plans

Plans for follow-up with subjects showing a risk of suicide or self-harm must be described in the IRB application and shall include the following:

- The criteria used to determine the level of response;
- The timeframe for response;
- Description of how and to what extent information about the subject and their thoughts/risk of suicide or self-harm will be kept confidential;
- The personnel who will be involved in the response and their qualifications. In general, a mental health professional or clinician should be included, either as a member of the research team or on an ad hoc basis; and
- A detailed description of the response protocols, including for subjects at imminent risk. Simply providing the name of the subject to a counseling or other center is not considered sufficient follow up.