Guidance for Research Protocols and Risk of Suicide.

The following are guidelines or suggestions to consider when developing research procedures for protocols that potentially involve identification of suicide risk. The guidelines were developed considering the context of limited clinical resources and intervention capabilities as may be the case in many research projects. Guidelines were not developed with consideration of research conducted in a clinical setting when the Principal Investigator is a psychiatrist, clinical psychologist, or other trained mental health professional.

Researchers are encouraged to develop procedures, using the general guidelines, applicable to their particular research protocols.

1. When is a protocol for suicidality appropriate?

The following aspects of a research indicate the need for a system to identify suicidality and develop an intervention/plan:

Note: Suicidality is defined as suicidal ideation (serious thoughts about taking one's own life), suicide plans/intent and suicide attempts. A research project may touch upon participants' suicidality in terms of personal history, as a current state of things/mind, and/or as future scenarios (e.g., hypothetical situations, imagination).

- Suicidality is assessed directly as part of a test, questionnaire (e.g. Beck Depression Inventory, Patient Health Questionnaire-9), interview, focus group, experiment, or assessment.
- Research procedures involve elements of mental illness or suicide risk, such as, but not limited to, research on moderate to severe mood disorders, self-mutilation, debilitating illnesses, sustained and severe feelings of worthlessness or hopelessness, or use of a biologic agent that is known to be associated with an increase of suicidality.
- Research that does not directly address suicidality, but may during the recruitment and research process potentially generate greater than minimal risk of suicidality.

A suicide identification/intervention protocol **may not be necessary** if the data collection is anonymous and there is no direct participant contact (e.g. anonymous web based questionnaires or questionnaires returned by mail without identifying information). However, although researchers in anonymous research may not be able to identify suicidality of a particular participant, they should develop ways to mitigate risks of suicidality (e.g., provide contact information for suicide hotlines or similar mental health resources; see below, intervention plan).

2. What are the necessary elements in a research protocol involving suicidality?

If a research protocol involves suicidality, the following elements should be clearly developed and indicated in the IRB application:

A. Identification of suicidality

For surveys, interviews, focus groups, or other research procedures in which suicide questions are posed, the suicide questions should be reviewed immediately or as soon as possible, rather than weeks or months after the data collection. This is not applicable in cases of collecting anonymous data when there is no direct subject contact, such as anonymous web-based questionnaires or questionnaires returned by mail without identifying information. In the protocol, researchers should lay out criteria/cutoffs according to which further evaluation or intervention will be implemented.

Unintentional identification of suicidal ideation through disclosure on the part of participants in those research projects that may be associated with mood disorders or debilitating mental or physical illnesses. In these instances, a quick review and further evaluation of the disclosure would be necessary. If deemed appropriate, the research team should follow up with an intervention plan.

In some cases, researchers may not feel equipped to address participants' suicide risk, and as a result, the researchers may refrain from assessing such suicide risks. However, when suicide risks are anticipated to be greater than minimal risk, a lack of expert knowledge on suicidality is not a justification for ignoring the risk during the research process.

B. Intervention plan

- **High/imminent risk.** The research team should be trained on how to assess for suicide risk and the emergency procedures to follow in the event someone is deemed at imminent risk of suicide. In this situation, ordinarily, giving research participants a list of referrals or telling the participants to go to a hospital after disclosure or endorsement of seriously thinking about suicide would not be considered sufficient standards.

  If the person is evaluated as high risk for suicide, the research team should act quickly to protect the safety of the research participant. This may mean staying with the participant until assistance arrives or the person is transported to clinical care. For non-clinicians, the emergency system should outline procedures for contacting other clinicians for guidance, or in the event that clinicians are not available or cannot be contacted, procedures for calling 911 to contact police.

- **Less than imminent risk.** For any results less than imminent risk, the research team should be available to assist in developing a plan for safety with the participant. The

plan for safety will depend on the level of risk and available resources. It may include encouraging the participant to contact their personal physician/mental health provider, making sure the participant has appropriate referrals, encouraging the person to talk to trusted family members or other community support resources, or giving the subject contact information for the suicide hotline or similar crisis management organizations.

For example, the research team decides that although the subject has endorsed suicide ideation, there is no intent or plan, nor history of suicide attempts, but the subject does have bouts of depression. The research team may provide the participants with referrals for treatment and the Suicide Prevention Hotline number, or discuss contacting the subject's primary physician or trusted family member to garner support or assistance. Documentation of the assessment and procedures ultimately followed is important.

- **Anonymous & Not-in-Person Studies.** For those projects where the research team does not have direct contact with participants and data is gathered anonymously, a list of referrals, such as the number for the Suicide Hotline (800-273-8255), should be provided to all potential participants. The referral sheet should also contain a statement about using the referral information if the participant endorsed suicidal thoughts or was experiencing depression.

  For example, the referral information can be included in a packet mailed to subjects who will complete questionnaires and return them without any identifying information.

  As another example, the referral information could be included at the end of an anonymous questionnaire completed on the internet.

C. Qualifications of the research team

The IRB application should clearly describe how the research team is qualified to assess and intervene. If non-clinical research staff (e.g., student research assistants) are involved in data collection, then a qualified research member should be readily available, either in person or by phone, within an hour. Availability of a qualified research member may not be applicable for non-in-person anonymous studies.

All research personnel/staff should be trained on how to assess for suicide risk and the emergency procedures to follow in the event someone is deemed at imminent risk of suicide.

D. Informed consent:

During the informed consent process, specify to the participants about what will happen if they exhibit (in connection to the research process) serious thought of taking one's life (suicidal ideation) and, in particular, if they are deemed to be an imminent danger to

self. This information would ordinarily go in the confidentiality section of the consent form or information sheet. This may include, but not limited to, issues about limits of confidentiality, as well as the potential for involuntary referrals to clinical actions.

The informed consent process may also collect emergency contact information and obtain permission to communicate with the contact in the event when the participant is determined to be at imminent suicide risk.

EXAMPLE OF CONSENT FORM LANGUAGE: The research team may not be able to keep confidential any disclosure or endorsement of thoughts to harm yourself. In the event that you tell the research staff that you are thinking about killing yourself or you answer yes to a question about having current serious thoughts about suicide, the research staff will ask you more questions about the thoughts. Depending on how intense your thoughts are or how much you feel like hurting yourself, the research staff may provide you with referrals for treatment, work with you to contact your personal physician, trusted family member, or therapist to discuss your thoughts of harming yourself; or work with you on a plan that may include getting you to a hospital for safety.

3. What measures commonly assess suicidality and are there alternatives?

Examples of questionnaires/measures that assess suicidality (organized by construct). NOTE: Researchers should lay out criteria/cutoffs according to which further evaluation or intervention will be implemented.

Depression

- Beck Depression Inventory (BDI)
- Center of Epidemiological Studies Depression Scale Revised (CES-DR)
- Patient Health Questionnaire-9 (PHQ-9)
- Hamilton Depression Rating Scale (HAM-D)
- Montgomery-Åsberg Depression Rating Scale (MADRS)
- Quick Inventory of Depressive Symptomatology-Self-Report (QIDS-SR)

Examples of questionnaires that may not assess suicidality.

Depression

- Center of Epidemiological Studies Depression Scale (CES-D; Note: the CES-DR does assess suicidality)
- Center of Epidemiological Studies Depression Scale for Children (CES-DC)
- Geriatric Depression Scale (GDS)
- Hospital Anxiety and Depression Scale (HADS)

Trauma/PTSD

- Life Events Checklist for DSM-5 (LEC-5)
- PTSD Checklist for DSM-5 (PCL-5)

4. Additional resources: See other evidence-based frameworks for assessment of suicide risk:

- Bryan, C. J., & Rudd, M. D. (2006). Advances in the assessment of suicide risk. *Journal of clinical psychology*, *62*(2), 185-200.
- Chu, C., Klein, K. M., Buchman-Schmitt, J. M., Hom, M. A., Hagan, C. R., & Joiner, T. E. (2015). Routinized assessment of suicide risk in clinical practice: An empirically informed update. *Journal of clinical psychology*, *71*(12), 1186-1200.