

## Guidance: Research Protocols and Risk of Suicide

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### General Introduction

Following is a set of 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. These are not necessary in many clinical studies when research is conducted in a clinical setting when the Principal Investigator is a psychiatrist, clinical psychologist, or other trained health professional.

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

### Applicable Elements of a Protocol

The following elements of a study that indicate the need for a viable system for management of subjects identified as having current suicidal ideation (thoughts about suicide, which may be as detailed as a formulated plan, without the suicidal act itself):

- Questions regarding suicide are part of the testing, interview, or assessment protocol.
- Subject sample or research procedures involve elements of depression or suicide risk, such as research on mood disorders, severe mental disorders, self-mutilation, debilitating illnesses, or use of a chemotherapy agent that is known to be associated with an increase of depression.

### Identification of Suicidal Ideation

- ***Intentional identification of suicidal ideation*** through questions posed during an interview, assessment, or administration of a measurement instrument, such as the Beck Depression Inventory, due to the nature of the research. If the question is posed, either by

interview or questionnaire item, be prepared to quickly review and further evaluate a positive response. The suicide question or positive response 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.

- **Unintentional identification of suicidal ideation** through disclosure on the part of subjects in those research projects involving subject populations or procedures 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.

## Elements of Assessment

- Have clinicians or trained interview/data collection staff gather additional information<sup>1</sup> to evaluate lethality or imminent danger to self and guide intervention.
  - **If the person collecting the data or conducting the interview is a trained clinician**, that is, a psychologist, nurse practitioner, psychiatrist, clinical social worker, or the like, then the clinician gathers his or her own information and can act on the information as clinically indicated. That is assuming the clinician has experience with managing suicide risk.
  - **If the person is not a clinician or is not familiar with suicide risk management**, then a system should be in place to gather the necessary information about lethality and/or contact the appropriate clinician or make an appropriate referral for further evaluation and treatment. For example, procedures for non-clinicians may include a list of questions to ask in the event of a subject endorsing current suicidal ideation, and the direct contact information for a research clinician or other agreed upon clinician to review the responses to those questions. The clinician can then direct or advise the non-clinician regarding the safety procedure to follow. The procedures would have to include a clinician being readily available in person, or by phone or pager, ordinarily within an hour, for direct consult.
- An adequate assessment of lethality or imminent danger to self should, at minimum, include gathering information about the specific thoughts of suicide, whether or not the person has a plan, determine if the person has the means to carry out the plan, history of suicide attempts, family history of suicide; the person's mental health history, history of use of medication, alcohol or illicit substances that may lead to lowering of inhibitions, and the person's family or community support system.<sup>234</sup>

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<sup>1</sup> Information collected to evaluate lethality or imminent danger should not be included in research records.

<sup>2</sup> Bongar, Bruce (2002). *The Suicidal Patient: Clinical and Legal Standards of Care*. Washington D.C.: American Psychological Association.

<sup>3</sup> Jacobs, Douglas G., M.D., Editor (1999). *The Harvard Medical School Guide to Suicide Assessment and Intervention*. San Francisco, California: Jossey-Bass Publishers.

<sup>4</sup> Simpson, Skip, J.D. and Stacey, Michael, J.D. (May 2004). *Avoiding the malpractice snare: documenting suicide risk assessment*. *Journal of Psychiatric Practice*, 10(3), 1-5.

## Intervention

- **All 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.** Ordinarily, giving research subjects a list of referrals or telling the subject to go to a hospital after disclosure or endorsement of seriously thinking about suicide would not be considered sufficient standards.
- **Clinical research staff should be readily available** if the interview or data collection is conducted by non-clinicians or research assistants, either in person, by phone, or pager response, ordinarily within an hour.
- If the person is evaluated as high risk for suicide, **the research staff should act quickly to protect the safety of the subject.** This may mean staying with the subject until assistance arrives or the person is transported to a hospital.
  - For non-clinicians, the emergency system should outline procedures for contacting research clinicians for guidance, or in the event that clinicians are not available or cannot be contacted, procedures for calling 911 to contact police and the Systematic Mental Assessment Response Team (SMART) to evaluate the situation and transport the person to the nearest hospital.
  - For example, the clinician may have a plan outlined that includes a direct contact with a treating clinician at the clinic where the research is being conducted;
    - or emergency referral to a local psychiatric emergency room established;
    - or has outlined a procedure to maintain direct observation and for calling 911 for an evaluation of the situation and transport of the person to the nearest hospital.
- **For any results less than imminent risk**, research clinicians should be available to assist in developing a plan for safety with the subject. The plan for safety will depend on the level of risk and available resources.

It may include contacting the person's personal physician, making sure the subject has appropriate referrals with a plan to contact subjects as a means to evaluate the subject following through with the referrals, encouraging the person to talk to trusted family members or other community support resources, or giving the subject suicide hotline information.

- For example, the clinician 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 clinician or clinician representative may provide the subject 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.

- **For those projects that gather anonymous data regarding severe depression or thoughts of suicide**, a list of referrals, including 211 information and the number for the Suicide Hotline should be provided to all potential subjects.
  - The referral sheet should also contain a statement about using the referral information if the subject 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.

## Informed Consent

Inform the subjects about what will happen if they endorse suicidal ideation and, in particular, if they are deemed to be an imminent danger to self by way of the research informed consent process. This information would ordinarily go in the confidentiality section of the consent form or information sheet. Below is sample wording regarding the issue.

### 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 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.

## Additional References

Baerger, Dana Royce (2001). Risk management with the suicidal patient: lessons from case law. *Professional Psychology: Research and Practice*, Vol. 32, No. 4, 359-366.

Kleespies, Phillip M., Vielhauer, Melanie J., and Knight, Jeffrey A. (Fall/Winter 2004-5). Ethical issues in research on behavioral emergencies and crises. *Behavioral Emergencies Update*. American Psychological Association.

Pearson, Jane L., Stanley, Barbara, King, Cheryl, and Fisher, Celia (January 2001). Issues to consider in intervention research with persons at high risk for suicidality. National Institute of Mental Health.

Stanton, A. L., Burke, E., & Kershaw, D. (1991). Effects of researcher follow up of distressed subjects: trade off between ethical responsibility and validity? *Ethics and Behavior*, 1, 105-112.