Cornell University
Office of
Research Integrity and Assurance

Human Research Participant Protection Program

Managing Risk of Harm to Self or Others

Studies that use psychological, epidemiological or clinical tests to determine the psychological state of participants may contain specific markers to indicate intent to harm self or others. The IRB will look to the researchers to provide a scientific justification for any risks to participants from such procedures, and a plan to address/minimize those risks.

Included in this guidance are some examples of the types of studies that could result in the identification of intent to harm self or others, and of acceptable plans for mitigating risk.

1. Possible modes of disclosure of intent to harm self or others

Studies designed to gauge intent to harm self or others: Many[1] standard psychological or epidemiological measures to collect data used for mental health assessment of participants include questions that seek to gauge intent to harm self or others. Many such measures are self-administered by participants either online or in another mode in which there is no direct interaction with the researcher, including during the screening process. It may be generally safe for laypersons (non–clinicians) with the appropriate training and experience or supervision by a trained and experienced researcher to administer such measures. For example, participants may be asked to respond to statements such as "I would like to kill myself" or "I would kill myself if I had the chance". A positive response to such questions from participants who are presumed to be healthy adults normally does not in and of itself require a direct intervention; researchers may only be expected to offer resources that the participant can use to seek help voluntarily.

Note: use of **Clinical Diagnostic Measures** to measure symptoms defined by the DSM-IV for a major depressive disorder are generally suitable for those that have been clinically diagnosed to suffer from major depressive disorder. Researchers proposing to use clinical measures either for clinical diagnosis, as a research instrument or for screening should provide a clear explanation for this choice, and describe the actions that they will take to ensure the safety of those identified as clinically at risk. . If the clinical measure is being used for clinical diagnosis,

[1] Examples of such data collection measures include the WHO Health Index, the UM-CIDI, K-6 negative affect measure, and others. Researchers should consult the resources available with the National Institute of Mental Health (http://www.nimh.nih.gov/index.shtml) for more information about these and other tools.

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the IRB will require evidence of appropriate clinical training for the researcher administering the measures or oversight by a designated, qualified clinician.

Unexpected disclosure of intent to harm self or others: In studies that seek to determine the psychological state of participants, and researchers are not asking explicit questions that seek to gauge intent to harm self or others, it is possible that participants may voluntarily disclose such information, anyway. If researchers believe this possibility might exist, they should include in their IRB application a plan to identify the criteria for taking reasonable steps to protect the participants from harm, and describe those steps.

If there is no anticipation of a disclosure of information that suggests the intent to harm self or others, but a participant does unexpectedly disclose such information, the researcher should taking reasonable steps to protect the participant from harm, and then amend the IRB protocol to include the steps taken in this circumstance.

Direct, in person disclosure of intent to harm self or others: In studies that involve interpersonal interactions between researchers and participants, participants may directly inform the researcher about the possibility of causing harm to self or others (for example, in an interview or focus group setting). Researchers proposing such studies should provide details of the researchers' expertise in dealing with such situations, and plans to mitigate risk, taking into account the nature of the study, the vulnerability of the participant base and the potential risk to participants and others from any revelations.

See Appendix A for a sample protocol for such intervention.

2. Expected level of assistance

For healthy adults: In most cases, researchers only need to suggest voluntary treatment by providing resources that are accessible and appropriate to the population. A list of such resources on paper, a webpage or an email that the participant can take with them, is ideal. An example is provided in Appendix B.

Depending on the study population and the nature of the research interventions, certain types of responses may indicate severe mental distress or active suicidal intent. Researchers should describe in their application if such a possibility exists, the indicators that they will use to identify when a more active intervention is needed and details of the planned interventions. Details of the planned interventions for suicidality findings should include a plan for how imminent risk of harm will be handled for the study's targeted population (Cornell students, community members, or others). These plans should include a timely identification of the specific participants, who will conduct the follow up, and the qualifications of the individuals who will conduct this follow up. When specific interactions or interventions are planned for such individuals, participant contact information should be maintained and linked to responses.

Some examples of consent and debriefing language and resources for each of these situations, are provided in the Appendices.

For children under 18: Researchers should address how parents/guardians will be informed about findings of intent to cause harm to self or others. Ordinarily the IRB will expect that parents or guardians be informed about the disclosure in a timely manner and provided resources where they can seek assistance. If parents/guardians will not be informed, researchers should provide a clear justification for not doing so, in their application. Special requirements for research with children, including waivers of parental consent, are addressed in the IRB document "Informed Consent, Enrollment, and Other Considerations for Research Involving Children". For children in certain institutional settings or older children, it may be appropriate to provide the resources directly to the child rather than, or in addition to, the parents or guardians.

3. Consent Procedures

For adult participants if investigators plan to offer only resources: For anonymous studies or those in which the investigator plans to provide only resources for assistance in the event of a disclosure of a mental health condition or suicidal ideation, respondents should not be led to believe that a researcher will read her or his responses and offer immediate assistance. Researchers should describe how they plan to do this in the consenting and debriefing procedures. Sample statements are provided in the Appendices.

For adult participants if researchers plan to intervene or contact individuals based on certain findings: If investigators plan to follow up with participants, following a response that indicates an intent to cause, or imminent risk for, harm to self or others, they should inform participants in the informed consent process or debriefing, that they plan to do so. This information would ordinarily go in the confidentiality section of the consent form or information sheet. See sample consent in Appendices.

For children and other vulnerable populations or for whom parental/guardian consent is sought: Researchers must describe if they plan to inform the participants that their parents/guardians will be informed. The research team must disclose to the parent/guardian in the parental consent that the research instrument includes a question/s to measure suicidal intent and inform them how the research team will inform the parents, should their child indicate such intent.

In rare cases where researchers plan not to communicate to parents/guardians a child's disclosure of intent to cause harm to self or others, they must provide a complete justification for this in their IRB application.

Appendix A: Sample consent language

Sample Consent for adult participants if investigators plan to offer only resources

Sample 1*: This is a research study that involves questions related to sensitive topics. As researchers, we do not provide mental health services. However, we want to provide you with contact information for available resources, should you decide you need assistance at any time.*

Sample 2*: This is a research study that involves questions that ask about your mental state. As researchers, we do not provide mental health services. It is possible that we will not view your responses for several days or weeks after you complete the surveys. (OR: This study does not allow us to associate an individual participant with his or her responses.) We want to provide you with contact information for available resources, should you decide you need assistance at any time.*

Debriefing*: In this study, we asked you questions that asked about your mental state. As researchers, we do not provide mental health services. It is possible that we will not view your responses for several days or weeks after you complete the surveys. (OR: This study does not allow us to associate an individual participant with his or her response.) If you would like to talk to someone about how you are feeling, please seek contact [list names and contact information for researchers qualified to address subjects' concerns] or call [list of local resources with contact information].*

Sample Consent for healthy, adult participants if researchers plan to intervene or contact individuals based on certain findings

The research team may not be able to keep confidential any disclosure or endorsement of thoughts to harm yourself or others. In the event that you tell the research staff that you are thinking about harming yourself or others, or you answer yes to a question about having thoughts about suicide, the research staff may ask you more questions about the thoughts. Depending on how intense your thoughts are or how much you feel like hurting yourself or others, 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 medical facility for safety.

Sample consent for Children and other Vulnerable Populations or for Whom Parental/Guardian Consent is Sought

To parents: *"This is a research study that involves questions related to sensitive topics. As researchers, we do not provide mental health services. However, we will inform you if your child's responses indicate intent to harm self or others. We also want to provide you with contact information for available resources, should you decide you or your child need assistance."*

Debriefing to children: **"***This study asked questions that may have troubled you. If you are feeling sad or anxious and feel like you want to talk to someone, you can tell the researcher, or get help by contacting [list of resources with contact information]. We have given this information to your parent also."*

Appendix B: Suggested protocol for offering assistance for participants who may present a credible risk of causing imminent harm to self or others

If a participant tells a member of the research staff that s/he is thinking about harming another person, killing her-/himself, or answers yes to a question about having thoughts about suicide, the research staff should provide the participant with referrals for treatment, and work with the participant to contact an on call service, their personal physician, trusted family member, or therapist to discuss their thoughts. If those are not reasonable options, please describe a plan to getting the participant to a medical facility for safety.

Appendix C: Mental Health Resources

1. Cornell Health (http://www.health.cornell.edu/) 607-255-5155
   - Available to students, faculty and staff at Cornell University
   - Services include drop-in conversations with a counselor/therapist (Let's Talk), online interactive conversations by appointment with a therapist to determine needs and identify resources (Brief assessment), group therapy and individual therapy
2. Tompkins County Mental Health Department, Mental Health Clinic (http://tompkinscountyny.gov/mh) 607-272-1616
   - The program functions as a Single Entry Point to the Tompkins County Mental Health Services and provides comprehensive, timely, quality mental health assessments, crisis intervention, therapy, consultations and referrals to appropriate programs
3. American Foundation for Suicide Prevention (http://www.afsp.org/) 1-800-273-TALK (8255)
   - Written information on suicide prevention and links to a variety of resources including telephone suicide prevention, telephone crisis support, and text crisis support services