RESEARCH INVOLVING RISK OF SUICIDE

Description

Some studies may involve research with participants at heightened risk of suicide, while other studies may only include a standard survey asking about a participant's mental health (questions about depression or suicide) as part of a larger project. Because of the unique challenges surrounding this type of research, this guidance is intended to help study teams prepare plans to minimize risks that may be present. For the purposes of this guidance, recommendations are grouped into different topics, although they may overlap. It is important for the researcher to evaluate the proposed study procedures and the study population to plan for mitigation of risk.

Research Involving Surveys Asking About Suicidal Thoughts and Behaviors

There are varying degrees of involvement by the researcher when including measures of depression or suicide risk. Investigators can minimize risks by incorporating the following elements in their research plan and/or consent procedure.

1. **Anonymous survey asking about suicidal thoughts and behaviors**
   Asking participants about suicidal thoughts and behaviors may not increase the risk of suicide, but there are two important ways researchers may provide additional safety precautions if the survey asks explicitly about suicide or self-harm.

POINTS TO ADDRESS	
ERICA Application	• **Resources and Responsibilities page**, question 4, *"Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research":* ○ Researchers should describe any resources which will be provided to respondents.
Informed Consent	• Research participants should be informed of the limitations of an anonymous survey, i.e., if a participant discloses significant distress in the survey, the researcher would be unable to send help or provide support because they would be unable to link the responses to the respondent. ○ *See Appendix A: Sample Consent Language for sample consent language for anonymous surveys* • If the survey asks explicitly about suicide or self-harm, specific local support resources should be provided in the informed consent. ○ *See Appendix A: Sample Consent Language for sample consent language for anonymous surveys*

2. **Non-anonymous survey, interview, or focus groups asking about suicidal thoughts and behaviors**
   A researcher may administer surveys or measures that explicitly ask about depression or suicide. Because there is a possibility that a participant may indicate suicidal ideation, researchers should be prepared to provide the IRB with a plan of what resources will be offered to participants. In most cases involving the general population of adults, researchers only need to suggest voluntary contact of resources that are accessible and appropriate to the population.

During a focus group or interview that includes questions about suicidal thoughts and behaviors, participants may directly inform the researcher about the possibility of causing harm to self or others. Researchers should be prepared to provide any details of expertise in dealing with such situations and actions that will be taken to safely assist the participant in obtaining any necessary services.

POINTS TO ADDRESS	
ERICA Application	• **Resources and Responsibilities page**, question 4, *"Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research":* ○ If a survey is administered, how will researchers determine if a participant is in immediate or imminent danger of suicide? For example, what indicators will the researcher use to assess survey responses to determine risk of immediate or imminent danger of suicide? ○ If questions are asked about suicidal thoughts and behaviors during an interview or focus group, how will researchers respond if a participant directly discloses the possibility of causing harm to themselves or others? Describe any actions that will be taken to safely assist the participant. ○ How will researchers respond to participants identified as at-risk of suicide or self-harm? For example, will the researcher suggest voluntary treatment, provide a list of resources, make a referral to additional services, etc.?
Informed Consent	• The informed consent should state that confidentiality may not be kept if the participant discloses thoughts of suicide or self-harm. ○ *See Appendix A: Sample Consent Language, Confidentiality* • If the survey or measure asks about depression or suicide, a statement should be included regarding any resources that will be provided or any intervention that will be initiated. ○ *See Appendix A: Sample Consent Language, sample consent language for offering resources or sample consent language for intervention*

Research Involving Participants at Elevated Risk for Suicide

Researchers should consider the targeted research population and be aware of the potential for the elevated risk for suicide when preparing research plans. Many factors may contribute to whether a group is at an increased risk for suicide and whether the proposed research may impact that group of participants.

The University of Utah IRB has not designated specific groups that are at an elevated risk for suicide. However, the IRB may ask researchers to include safety precautions for certain research when considering the research procedures and the study population. Such groups include but are not limited to[1]: American Indians/Alaska Natives; members of the Armed Forces and veterans; LGBTQ+ populations, loss survivors, disaster survivors,

[1] See https://www.samhsa.gov/suicide/at-risk; https://www.ncbi.nlm.nih.gov/books/NBK109909/
Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

individuals with mental and/or substance use disorders; men in midlife; and older men.

Although research procedures may not include explicitly asking about suicidal thoughts and behaviors, a response plan should still be in place if sensitive topics will be discussed with participants at an elevated risk for suicide.

POINTS TO ADDRESS	
ERICA Application	• **Resources and Responsibilities page, question 4**, *"Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research":* ○ How will researchers assess participants throughout the project for the risk of suicide? ○ How will researchers respond to participants identified as at-risk of suicide or self-harm? The researcher may want to provide mental health resources regardless of any scores or measures. • **Safety Monitoring Plan page** (if applicable): ○ The University of Utah IRB generally only requires investigators to outline a safety monitoring plan when studies are determined by the IRB to be greater than minimal risk. However, depending on the research topic, it may be appropriate for investigators to consider a safety monitoring plan if the study involves **participants at an elevated risk for suicide**, regardless of the IRB's determination of the overall risk level of the study. ▪ *See Appendix C to view the Safety Monitoring Plan page in ERICA.* ○ If a Safety Monitoring Plan will be included, please answer "yes" to the question "Is there a safety monitoring plan for this study?" on the **Study Information page (4), question 8**. The **Safety Monitoring Plan page** will automatically populate for the investigator to complete.
Informed Consent	• The informed consent should state that confidentiality may not be kept if the participant discloses thoughts of suicide, self-harm or harm to others. • Additional resources may be specific to the population (e.g., websites or hotlines for Veterans when studies involve veterans, etc.). ○ *See Appendix A: Sample Consent language, sample consent language for participants at elevated risk for suicide or sample consent language for intervention*

Unexpected Disclosure of Intent to Harm Self or Others

In some studies, there may not be any explicit questions regarding the intent to harm self or others. However, it may be possible that a voluntary disclosure of suicidal ideation may still occur. If there is no anticipation of the disclosure of information suggesting risk of harm to self or others, and a participant unexpectedly does disclose such information, the researcher may refer to the resources in this guidance (see Appendix B: Mental Health

Resources) to help protect the participant from harm. The IRB protocol should then be amended to include steps taken to protect participants from harm.

Children

When research involving the risk of suicide involves children, the investigator must address how the parents/guardians will be informed about disclosures of the intent to harm self or others. If researchers do not intend to inform parents/guardians, a justification must be provided to the IRB.

References & Links

Conducting Research with Participants at Elevated Risk for Suicide: Considerations for Researchers	*https://nimh.nih.gov/funding/clinical-research/conducting-research-with-participants-at-elevated-risk-for-suicide-considerations-for-researchers#regulatory*

Appendix A: Consent Language Samples

Note: The sample text may include a referral. Researchers should verify that the phone numbers or websites are operational before sharing with participants.

Confidentiality: There are some cases in which a researcher is obligated or authorized by law to report issues, such as serious threats to public health or safety. For example, if you indicate that you or someone else is at imminent risk of harm (for example suicide or serious threats toward the wellbeing of others) we will need to contact the appropriate authorities to protect you or the public.

Sample consent language for anonymous surveys: We don't keep your name with your survey. So, if you tell us that you are thinking about hurting yourself or someone else in your survey answers, we won't be able to contact you. Please tell someone who can help right away. You can call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) to talk to a counselor near you.

If you do not need help right away but would like to talk to someone about the problems you might be having, you can find help here: <<insert phone number or website>>

Sample consent language for offering resources only: As part of the research, we may ask questions about how you feel mentally and emotionally. As researchers, we do not provide mental health services. Also, it is possible that we will not view your answers for several days or weeks after you complete the surveys. If you are thinking about hurting yourself or someone else, please tell someone who can help immediately. Call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) to talk to a counselor near you.

If you do not need help right away but would like to talk to someone about the problems you might be having, you can find help here: <<insert phone number or website>>

Sample consent language for potential intervention: If you tell us that you are thinking about hurting yourself or others, the research staff may ask you more questions. Depending on how intense your thoughts are or how much you feel like hurting yourself or others, the research staff may give you referrals for treatment, work with you to contact your personal doctor, trusted family member, or therapist to discuss your thoughts of harming yourself. We may need to work with you on a plan that might include getting you to a medical facility for safety.

Sample consent language for participants at elevated risk for suicide: This research study involves questions about sensitive topics. As researchers, we do not provide mental health services. However, we would like to provide you with contact information for available resources, should you decide you need assistance at any time <<insert phone number or website>>

Appendix B: Mental Health Resources

Note: The following resources are provided as a courtesy. Researchers should verify that the phone numbers or websites are operational before sharing with participants.

National Suicide Prevention Lifeline 1-800-273-8255 https://suicidepreventionlifeline.org/

- Provides 24/7, free and confidential support for people in distress, prevention and crisis resources individuals, and best practices for professionals.

Safe UT Crisis Chat and Tip Line 1-833-372-3388 https://healthcare.utah.edu/hmhi/safe-ut/

- Statewide service that provides real-time crisis intervention to **youth** through live chat and a confidential tip program.
- Licensed clinicians in our 24/7 CrisisLine call center respond to all incoming chats and calls by providing supportive or crisis counseling, suicide prevention, and referral services.
- Safe UT is intended to help anyone with emotional crises, bullying, relationship problems, mental health, or suicide-related issues.

Live On https://liveonutah.org/

- Utah's campaign to prevent suicide by promoting education, providing resources, and changing the culture around suicide and mental health.
- Contact list for support groups for suicide loss survivors

University of Utah Counseling Center 801-581-6826 https://counselingcenter.utah.edu/

- The University Counseling Center (UCC) offers crisis services Monday through Friday 8 AM - 5 PM. UCC staff members are available to assist U of U students, staff or faculty members.

Utah Warm Line: 833-SPEAKUT (833-773-2588 toll free) / 801-587-1055 (local)

- Open seven days a week, from 8 a.m. to 11 p.m. Call to speak with a certified peer support specialist.
- This service is for people who are not in crisis, but seeking emotional support, engagement, or encouragement. Certified peer specialists offer support and empower callers to resolve problems by fostering a sense of hope, dignity, and self-respect.
- Resource for people who are feeling stressed, overwhelmed, isolated, or like they just need someone to talk to.

Appendix C: Safety Monitoring Plan in ERICA

Safety Monitoring Plan

A safety monitoring plan must be designed for greater than minimal risk studies in order to minimize threats to the safety and welfare of the research participants. Please review the following policies and procedures to ensure safety monitoring compliance for the study:

- *Investigator Guidance Series: Data and Safety Monitoring*
- *VHA Handbook 1200.05, page 28*

1. **Describe the safety monitoring entity for this study:**
   a. **Select all that apply:**

      There are no items to display

      Please specify:

   b. **Describe the expertise and affiliation of the individual(s) selected above who will monitor the study:**
2. **Describe the data and events that will be monitored and reviewed (e.g., vital signs, safety blood labs, depression scales, neurological exams, types of adverse events, etc.):**
3. **Describe the types of reports that will be produced by the monitoring entity (e.g., safety, study progress, interim analysis, etc.):**
4. **Describe the specific triggers or stopping rules for the study:**
   a. **Under what conditions will a participant be withdrawn from the study?**
   b. **Under what conditions will the study be modified or stopped?**
5. **How often will the data and events be reviewed by the monitoring entity (e.g., after every 5 submits, monthly, quarterly, twice a year, etc.)?**
   The monitoring frequency should be commensurate with the level of risk to the participants.