THE UNIVERSITY OF ARIZONA Research & Partnerships

Research Involving Mental Health Topics

Background

Many human research studies include questionnaires or assessments related to mental health, behavior, or quality of life. These instruments may also include questions about a participant's thoughts of self-harm or harm to others. While such questions can be scientifically important, they may also introduce psychological or safety risks. In fulfilling its responsibility to protect research participants, the University of Arizona IRB evaluates whether adequate protections are in place for studies involving sensitive mental health topics.

This guidance document is intended to assist investigators in identifying risk of harm in their research and in developing appropriate safety protocols to mitigate any associated risks.

Identifying Risk of Harm

In some studies, information obtained from participants may be anticipated based on the characteristics of the study population or study design. For example, a study may use standard psychological or epidemiological measures to assess participants' mental health, including questions designed to evaluate thoughts of self-harm or harm to others. In other cases, voluntary disclosure of such information may arise unexpectedly during the research.

Studies may require additional information in the IRB protocol, when they include:

- Questions about suicidal ideation, self-harm, or intent to harm others
- Assessment of psychological distress (e.g., depression, trauma, stress, anxiety)
- Collection of real-time or identifiable data that could indicate participant risk
- Vulnerable populations (e.g., minors, individuals with known mental health conditions)

Even when risk is expected to be minimal, researchers must consider how they will respond if a participant indicates distress or risk of harm.

Procedures for Responding to Participant Risk

When a participant may be at risk of immediate harm to themselves or others, clearly defined procedures must be in place. These procedures should be appropriate to the level of risk and study design and must be fully described in the IRB protocol, including the following:

1. What types of concerning responses may arise and how these responses will be identified (e.g., specific survey items, score thresholds, open-ended responses).
2. How the risk of mental or psychological harm to participants will be evaluated, including the likelihood and severity of any emotional distress that may result from participation.
3. When will investigators review a participant's response to questionnaires and assessments (e.g., in real time or after data collection), and the frequency at which this review will occur.
4. If participants' responses will not be individually assessed, the IRB protocol should explain why the investigators believe an individually identifiable assessment will not be included.
5. Who will be responsible for assessing the level and immediacy of risk.
6. Qualifications of researchers and/or clinicians involved in participant interactions, assessments, and safety interventions.
7. Confirmation that research staff directly interacting with participants will be adequately trained on the study's protocol.
8. For higher-risk studies, consider including licensed clinician involvement or on-call procedures for urgent situations.

Participant Support and Resources

Outline in the IRB protocol step-by-step procedures for responding to participant risk, which may include:

- Providing mental health resources. A copy of the resource document should be uploaded to eIRB as a "Participant material". Explain how and when the resource will be available to participants.
- Referring participants to appropriate support services (e.g., counseling services or crisis lines), including a description of how this information will be provided or communicated to participants.
- Transferring the participant to appropriate crisis intervention or de-escalation procedures if imminent risk is identified. "Imminent risk" is defined as a situation in which a participant's responses or behavior indicate a credible and immediate threat of serious harm to themselves or others, requiring prompt action without delay.
- In anonymous studies, follow-up with participants may not be possible; therefore, researchers should ensure that comprehensive support resources are provided at the outset. Similarly, in online studies, researchers should consider incorporating automated triggers that deliver relevant resources when certain responses are selected.

Mandated Reporting

Investigators must comply with all applicable mandated reporting requirements when information obtained during the course of research meets the legal threshold for reporting. This includes notifying appropriate authorities or agencies in accordance with state and federal law.

Mandated reporting obligations typically apply to individuals in roles involving responsibility for the care, supervision, or treatment of vulnerable populations, including minors and certain adults. Depending on professional licensure, some members of the research team may be considered mandated reporters under Arizona law.

In the context of mental health research, situations that may trigger mandated reporting obligations include, but are not limited to:

- Imminent risk of harm to self or others, such as credible threats of suicide or violence
- Suspected child abuse or neglect, including physical, emotional, or sexual abuse
- Abuse, neglect, or exploitation of vulnerable adults
- Disclosure of ongoing domestic violence when it involves a protected population (e.g., minors present in the home)
- Situations involving inability to care for oneself that rise to the level of reportable neglect (depending on legal definitions)

<u>Discretionary Reporters</u>

Discretionary reporters are individuals who are not legally required to report but may choose to do so based on ethical considerations. Even when not legally mandated, researchers should consider whether a situation presents a serious risk of harm that may warrant reporting or intervention.

Arizona law provides protections for individuals who report suspected abuse or neglect in good faith, including protection from civil and criminal liability.

Best Practices for Research Teams:

1. Clearly define roles within the research team and determine who may be a mandated reporter.
2. Establish a participant safety or response plan outlining steps to take if reportable information is disclosed.
3. Train research staff on recognizing reportable situations and appropriate response procedures.

See HSPP guidance on *Mandatory Reporting* for more information.

Informed Consent

When mental health related content is involved, the informed consent process should clearly communicate:

- The nature of sensitive questions (e.g., topics related to mental health or self-harm)
- Participants may skip questions or withdraw at any time without penalty
- What will happen if concerning responses are identified
- If investigators plan to follow up with participants when a response indicates intent to harm oneself or others
- Any limits to confidentiality (e.g., if there is a plan to intervene in cases of imminent risk, or if information must be disclosed under mandated reporting requirements)
- Available support resources

Sample Informed Consent Language

If investigators plan to only offer resources:

> *This study includes questions about your mental health and emotional well-being. Some questions may be sensitive, including questions about thoughts of self-harm or distress. Your responses will not be individually identified, so the research team cannot provide you with personal feedback or intervention based on any of your answers. If you feel that you need support at any time, please contact one of the resources listed below.*

If investigators plan to intervene or contact participants based on findings:

> *Information you share about thoughts of harming yourself or others may not be kept confidential. If you indicate to the research team that you are experiencing such thoughts, research staff may ask additional questions to better understand your situation. Based on the level of risk, the research team may provide referrals for support services, assist you in contacting your physician, therapist, or a trusted individual, or help facilitate a plan to ensure your safety, which may include seeking care at a medical facility.*

Additional Guidance for Researchers

- National Institute of Mental Health (NIMH): Conducting Research with Participants at Elevated Risk for Suicide: Considerations for Researchers
- NIMH Guidance on Risk-Based Monitoring
- FDA Guidance for Industry, Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials

Mental Health Resources

- University of Arizona Counseling & Psych Services (CAPS)
- Crisis Resources and Hotlines

- Suicide Prevention & Support Resources
- International Help Lines, Crisis Lines, and Mental Health Directories