Mental health and research

- Crises in participants
  - Planning
  - Monitoring
  - Ending participation
- Caring for the researcher(s)

Planning

- What is considered an “unexpected” or “serious adverse event”?
- Office for Human Research Protections guidelines
  - https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q2
  - Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

Planning

- Identify potential issues, create a plan ahead of time, and detail in study protocol
- Include:
  - Clinical backup for nonclinical staff conducting assessments
  - Warm transfers to crisis lines
  - Setting up contractual links ahead of time for transfers
  - Training study staff
  - Setting up privacy protections for transfer of information
  - Informing parents/guardians if working with youth

Monitoring

- Clinical/safety monitoring of participants
- Monitoring of safety data across sites/arms
- Monitoring documents and data for standards of good clinical practice, fidelity with approved protocol
- Review of data for accuracy and consistency

Monitoring

- Who oversees good clinical practice? Are they independent from the research team?
- Study procedures for assessing and addressing worsening/development of symptoms
  - May be part of research/intervention design
  - Timeframe for assessing? Depends on level of risk

End of participation

- Assess safety of individuals
- Provide information that will help them stay safe (i.e., crisis line numbers, community or other resources)
- Assure they are not being abandoned without care – link to care when needed
- Invite those who end early to continue with follow up assessments

Caring for the researcher(s)

- Recognizing the emotional challenges
- Blurry line between “at home” and “at work”
- Degrees of separation from the topic
- Compassion fatigue
- Provide space and coaching/supervision (horizontal and vertical, group and one-on-one)
- Creating a culture of care – lead from the top

NIMH Conducting Research with Participants at Elevated Risk for Suicide: Considerations for Researchers

https://www.nimh.nih.gov/funding/clinical-research/conducting-research-with-participants-at-elevated-risk-for-suicide-considerations-for-researchers.shtml#crises

NIMH Clinical Research Toolbox

https://www.nimh.nih.gov/funding/clinical-research/clinical-research-toolbox/nimh-clinical-research-toolbox.shtml

OUR SCIENCE **TRANSFORMS THE HUMAN EXPERIENCE**
AND INSPIRES LEADERS