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Research Safety Plan

• What is it?
• Why is it needed?
• Who is protected and under what circumstances?
• Who are the responsible parties?
Research Safety Plan: What is it?

• A set of guidelines that specify what your study will do should certain circumstances arise that might represent threats to participant safety

• Example circumstances (will vary based on the study)
  • Suspected child abuse
  • Suicidality (youth; parent)
  • Homicidality
  • Other imminent risks (e.g., life threatening substance use pattern)
  • Medical emergency during a research session
  • Incidental Findings: radiological (MRI), laboratory findings, psychiatric
  • Positive pregnancy test
  • Parent or youth intoxication
Why is a safety plan needed?

I. Legal responsibilities

• Suspected maltreatment must be reported

• Minnesota Statutes Chapter 260E (commonly referred to as the Minnesota Maltreatment of Minors Act) provides definitions of abuse and neglect and what constitutes the endangerment of a child (i.e., abuse).

• Abuse can be physical, emotional, financial, sexual and/or sexual exploitation, or neglect.

• Assessment is not necessary; you can act based on suspicion.
Why is a safety plan needed?

II. Ethical Considerations

The IRB does not currently maintain a standard set of policies.

Researchers are not technically required to intervene in cases of potential self-harm or when incidental findings might be present, but it is considered a best practice to have a study-specific plan.

Why “study-specific”?

Because each study is different in terms of the information elicited and the population

The threshold for intervention is different in a research vs. clinical setting.

Interventions could impact the research!
Who are the responsible parties?

• The study PI is responsible for creating a study-specific safety plan, for assembling staff who will execute the plan, and for adequately training staff so that they know how to respond under various circumstances.
Building a safety plan

• All plans should include provisions for suspected child abuse
• Consider which other scenarios are possible given the nature of your study (examples: ABCD (adolescents); HBCD (infants and mothers)
• Create a written plan to cover those scenarios
• Update as needed
• You are researchers. You are not expected to act as clinicians.
Components of the plan

1. **Contact information**
   - Emergency contacts (PIs, study clinicians)
   - Contact information for all RAs
   - A plan that lists only one person as the contact is likely **not sufficient**.
2. Other contact information

- Police or MN Psychiatric Emergency Response Team: 911
- Fairview University Emergency Room: (612) 273-8383
- Hennepin (HCMC) Acute Psychiatric Services: (612) 873-3161
- Suicide & Crisis Lifeline: 988
- Minnesota Crisis Lines:
  - Hennepin County, Adults 18 and Over: (612) 596-1223
  - Hennepin County, Children 17 and Under: (612) 348-2233
  - From anywhere in Minnesota: Call CRISIS (274747)
  - Front Door (MN Mental Health Resources): (612) 348-4111
- All MN DHS Contact Numbers: https://mn.gov/dhs/general-public/about-dhs/contact-us/contact-numbers/
3. Informed consent and confidentiality limitations

Consider adding to your consent/assent forms

“Everything you say is completely confidential. The few exceptions include the following: someone is being hurt or abused, you have plans to seriously harm yourself, you intend to seriously harm someone else, or you are in immediate danger for another reason. In those cases, I may need to break this confidentiality and inform the right people so that we can make sure everyone is safe.”
4. Abuse of a Child (under 18), Elder (65 and older), or Dependent Adult (18 to 64 and disabled)

“You mentioned [event that happened]. I need to ask a few follow-up questions about that so that I can make sure you are safe.”

1. Can you tell me more about that?

2. When did that happen?
   
a. NOTE: If neglect or abuse has occurred in the last 3 years, then the event must be reported to MN DHS, per Minnesota Statute 260E.06.

3. Who was involved?
   
a. NOTE: If the perpetrator is in a current or recent position of authority or is responsible for the child's care, then it constitutes neglect or abuse, per Minnesota Statute 260E.03

4. Were you or anybody else hurt?
   
a. If yes: How were you/they hurt?

5. Does anyone know that this has happened?
   
a. If no: Would you feel comfortable discussing this with (non-perpetrating parent/guardian, a mental health professional, or another trusted adult)?

6. Do you feel safe to leave today’s assessment?
1. If the person is in current danger, call 911 immediately.

2. If the person is not in current danger, consider your procedures for deciding whether MN DHS should be contacted.

If you will contact MN DHS, consider whether you will tell the family that you have done so (or will do so). Providing info that MN DHS has been contacted might increase the risk of further abuse.

a. Mandated reporters are not required by Minnesota law to tell the subject of the report (Minnesota Statutes 626.556 Reporting of Maltreatment of Minors & 626.557 Report of Maltreatment of Vulnerable Adults).

b. The “subject” of the report is defined as the person who is being abused or is in danger.

c. The RA should acquire the following details: description and length of the abuse; the subject’s name, current location, age when the abuse occurred, current age, and contact information; the perpetrator’s name, relationship to the subject, current location, and contact information.
Signs of Child Abuse

A child who exhibits the following signs may be victims of:

**SIGNS OF PHYSICAL ABUSE**
- Has unexplained injuries, such as burns, bites, bruises, broken bones, or black eyes.
- Has fading bruises or other noticeable marks after an absence from school.
- Seems scared, anxious, depressed, withdrawn, or aggressive.
- Seems frightened of his or her parents and protests or cries when it is time to go home.
- Shines at the approach of adults.
- Shows changes in eating and sleeping habits.
- Reports injury by a parent or another adult caregiver.
- Abuses animals or pets.

**SIGNS OF NEGLECT**
- Is frequently absent from school.
- Bugs or steals food or money.
- Lacks needed medical care (including immunizations), dental care, or glasses.
- Is consistently dirty and has severe body odor.
- Lacks sufficient clothing for the weather.
- Abuses alcohol or other drugs.
- States that there is no one at home to provide care.

**SIGNS OF SEXUAL ABUSE**
- Has difficulty walking or sitting.
- Experiences bleeding, bruising, or swelling in their private parts.
- Suddenly refuses to go to school, activity or relative’s home.
- Reports nightmares or bedwetting.
- Experiences a sudden change in appetite.
- Demonstrates bizarre, sophisticated, or unusual sexual knowledge or behavior.
- Becomes pregnant or contracts a sexually transmitted disease, particularly if under age 14.
- Runs away.
- Reports sexual abuse by a parent or another adult caregiver.
- Attaches very quickly to strangers or new adults in their environment.

**EMOTIONAL MALTREATMENT**
- Shows extremes in behavior, such as being overly compliant or demanding, extremely passive, or aggressive.
- Is either improperly adult (e.g., parented or parented other children), or improperly infantile (e.g., frequently rocking or head banging).
- delay in physical or emotional development.
- Shows signs of depression or suicidal thoughts.
- Reports an inability to develop emotional bonds with others.

Physical Signs of Elder Abuse

- Dehydration or unusual weight loss
- Missing daily living aids
- Unexplained injuries, bruises, cuts, or sores
- Unsanitary living conditions and poor hygiene
- Unattended medical needs

To learn more, visit ncea.acl.gov
Contacting MN DHS

• MN DHS will advise on whether a report must be filed, how to file the report, and what to do next.
• RAs should remember to write down the staffer’s name, as well as the date and time the report was made for documentation purposes.

MN DHS for children & families:
• 1. Contact information by county and tribe:
   a. Hennepin County Family Services: (612) 348-3552
   b. Ramsey County Human Services: (651) 266-4500
ii. MN DHS for adults:

Report suspected vulnerable adult abuse, neglect, or financial exploitation via MAARC – Adult Abuse Reporting: 1 (844) 880-1574

General inquiries can be made to:

dhs.adultprotection@state.mn.us or (651) 431-2609

3. For addition information, visit: https://mn.gov/dhs/people-we-serve/adults/services/adult-protection/contact-us/

iii. Comprehensive list of MN DHS departments and their contact information: https://mn.gov/dhs/general-public/about-dhs/contact-
Regardless of whether or not MN DHS is contacted, if a follow-up was conducted, the RA should write and file an Incident Report immediately after or as soon as practically possible. The report should describe what the RA was told by the subject, what the MN DHS worker told the RA (if applicable), whether the subject knew the report was being filed (and their response, if applicable), and any follow-up actions dictated by the site clinician. The RA should include in the Incident Report a copy of the report that was submitted to MN DHS, if applicable.

The purpose of this documentation is to have information in our files to affirm that appropriate steps were taken, so that we have a response if the IRB becomes involved, and so that we can track these situations retrospectively as the family is followed over time.
5. Suicidality/Non-suicidal self-injury

Consider immediacy of threat

Consider level of intent, whether there is a plan, lethality of the plan, and whether there is the means to carry it out

“I noticed that you said yes to some questions that asked about whether you ever think about harming yourself. I do have some follow-up questions that I need to ask so that we can make sure you are safe.”
1. Can you tell me more about that?
2. When was that? How long did that last?
3. Have you ever done anything to hurt yourself?
   If yes: Can you tell me more about what you have done to hurt yourself?
4. Do you have a plan for what you might do (to harm/kill yourself?)
5. Do you have the means to carry out that plan?
6. Does anyone know that you have thought about these things?
   If no: How would you feel about discussing this with (a parent/guardian, mental health professional, or another trusted adult)?
7. Is it possible that you might do anything to act on these feelings/thoughts after you leave today’s assessment?
Consider **immediacy** of danger

- If there is an immediate suicide threat, call 911. This is very rare.
- If the participant indicates that they have a plan, are likely to carry it out, cannot guarantee that they will be safe after leaving the assessment, and if they are a minor, **consider** whether confidentiality will need to be broken, and their parent/guardian will need to be informed.
- If the situation occurs during a remote assessment, do not hang up the phone or end the video call. For remote assessments, it is a best practice to make sure you know of the person’s exact location before the assessment begins.
Options if danger is not immediate

This will be the case most of the time

• Do nothing
• Break confidentiality and recommend that treatment be pursued
• Break confidentiality in a less explicit manner
• Encourage the youth to take advantage of social supports
• Provide resources to the youth and family re: crisis hotlines, etc.
• It is a best practice to internally document the study’s response to reports of suicidal ideation/self-harm.
6. Homicidality

- If there is an immediate homicidal threat, call 911.
- Consider whether to break confidentiality (as with suicidal behavior).
Homicidality

“I noticed that you said yes to some questions that asked about whether you ever think about harming another person. I need to better understand your answers so that we can make sure everyone is safe.”

1. Can you tell me more about that?
2. Have you ever done anything to harm another person?
   If yes: Can you tell me more about what you have done to harm another person?
3. Do you have a plan for what you might do?
4. Do you have the means to carry out that plan?
5. Does anyone know that you have thought about these things?
   If no: How would you feel about discussing this with (a parent/guardian, mental health professional, or another trusted adult)?
6. Is it possible that you might do anything to act on these feelings after you leave the assessment today?
7. Medical Emergencies

• Call 911.
• Make sure your staff know where to find first aid kits.
• Locations of defibrillators.
• Take emergency action steps first then inform parents, others.
• Staff who respond to a medical emergency should be prepared to provide to emergency responders: their name, phone number, and location; the participant’s name, age, and location; and the nature of the emergency.
• Don’t leave the affected person alone.
• Might be a good idea to always work in pairs.
• Will need to file an incident report with the IRB.
8. Incidental findings

- Anticipate how these will be handled within your consent forms
- Why? Not everyone wants to be informed
- Radiological
- Lab-based
- Pregnancy status
  - Minnesota law **does not require** parents to be notified if a youth participant is pregnant.
9. Other situations (hard to anticipate)

• The youth appears intoxicated or tests positive on a drug screen.
• The youth appears to be ill.
• The family reveals a positive COVID test within their household.
• Parents are belligerent or difficult to deal with in some way.
• The parent appears to be intoxicated and has driven to the assessment.
• The parent appears to be severely ill.
• The parent is carrying a weapon.
• The parent arrives by car with an infant but does not have a car seat.
10. Study-specific opportunities for consultation

- A consultation strategy should be part of your plan
- With PI(s)
- With designated clinicians (who should be named on your IRB forms)
- Among study staff members/lead RA/study coordinator
- In the absence of truly imminent danger (rare), there is nearly always time to engage in consultation even after an assessment has ended. You do not need to panic or feel rushed.
MIDB Policies and Resources

• We are now asking researchers to acknowledge that they have devised research safety plans for their MIDB studies.
• We want to be helpful to you as you develop your safety plans.
• We will share examples of well-developed plans.
• If your study experiences an **immediate emergency** where you need clinical consultation AND your named study clinicians are unresponsive, an MIDB clinic social worker can help. Details to come.
Questions?