

Developing Distress Protocols for Research on Sensitive Topics

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Two protocols that were developed to address risks related to emotional distress in an ongoing, qualitative, community-based study of adolescent dating violence are presented. The first protocol is for use in telephone screening to identify individuals at high risk of adverse emotional reactions. The second protocol guides interviewer's responses to emotional distress expressed by participants during in-depth research interviews. The study is briefly described, and the process used to develop the protocols is discussed. The process of developing the protocols caused the authors to reconsider some previously held assumptions about human subject protections in research on sensitive topics.

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CONDUCTING RESEARCH ON sensitive topics raises a number of ethical issues. A sensitive topic is "one that potentially poses for those involved a substantial threat, the emergence of which renders problematic for the researcher and/or the researched the collection, holding, and/or dissemination of research data" (Lee & Renzetti, 1993, p. 5). Topics are considered sensitive if identification of participants would result in stigmatization, dissemination of findings could harm a social group, or the research challenges values that people hold sacred (Lee & Renzetti, 1993). Another characteristic of such research is the risk of inducing or exacerbating emotional distress. Individuals who participate in research on traumatic or aversive events, for example, may experience anxiety, depression, embarrassment, or acute stress reactions as they recall, reexamine, and reveal their experiences (Jorm, Kelly, & Morgan, 2007).

Professional organizations, governmental funding and regulatory bodies, and institutional review boards require that researchers identify and minimize potential risks and ensure that the benefits of the research outweigh these risks (Barnbaum & Byron, 2001). If, therefore, emotional distress is judged to be a risk, researchers must develop strategies to minimize it. Several such strategies are identified in the literature: (a) employing interviewers who are trained to handle psycho-

logical distress, (b) consistent monitoring of participants' emotional reactions, (c) providing frequent breaks during stressful data collection procedures, (d) debriefing, and (e) providing information on available psychological or social services (Griffin, Resick, Waldrop, & Mechanic, 2003; Hawton, Houston, Malmberg, & Simkin, 2003; Stanton & New, 1988).

Researchers conducting studies on emotionally charged issues need to identify potential participants who might be particularly vulnerable to harm and be prepared to respond to negative emotional reactions that occur during the course of the research. Yet, the scientific and research ethics literature offers little practical guidance to assist researchers in developing protocols to ensure these protections. We present two protocols that were developed to address risks related to emotional distress in an ongoing, qualitative, community-

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based study of adolescent dating violence. The first protocol is for telephone screening and can identify individuals at high risk of adverse emotional reactions. The second protocol guides interviewer's responses to emotional distress expressed by participants during the research interviews. The study is briefly described, and the process by which the protocols were developed is discussed.

THE STUDY

The research project is a qualitative study funded by the Centers for Disease Control and Prevention (CDC). The aim of the study was to develop a theoretical framework that describes, explains, and predicts how dating violence unfolds during adolescence. The project is being conducted by a collaborative team of university- and community-based researchers. The research team includes five investigators (three university-based nurse researchers, the executive director of a domestic violence/rape crisis agency, and a hospital-based trauma psychologist), two research associates (master's-level mental health clinicians), and a project manager. Women and men between the ages of 18 and 21 years who are living in northeast Ohio and have experienced dating violence as adolescents are being recruited by fliers placed at public sites in 12 socioeconomically diverse communities. In addition, the researchers are networking with social-service professionals and religious and community leaders, many of whom are promoting the study to young adults with whom they work.

Young adults who are eligible and interested in the study are invited to call a toll-free number. They are connected to a voice mailbox with a message that reviews the requirements, benefits, and risks of participation. Callers are asked to leave their telephone numbers if they wish to participate. A research associate contacts the callers, provides additional study information, and conducts a brief screening interview. If a person meets study criteria, an interview is scheduled in his or her community. During in-depth interviews, participants are asked to reflect back on their adolescence and describe the dating violence they experienced. Qualitative data analytical techniques are being used to develop the theoretical framework.

In the grant application submitted to the funding agency, the researchers indicated an intent to screen out individuals for whom the interviews might be harmful:

The research associates...will conduct a brief telephone screening interview with potential participants prior to scheduling an interview to rule out individuals who are...experiencing acute emotional distress that would make participation risky (e.g., suicidality/homicidality, serious substance abuse, psychosis, or acute post-traumatic distress). If individuals are excluded from the study, they will be offered an appropriate psychological or social service referral. There are no other exclusion criteria.

The telephone screening guide included a brief script advising individuals experiencing "significant stress or severe emotional distress" not to participate because the topic of dating violence was sensitive and might bring up "tough" feelings. We then asked four loosely structured questions to determine whether individuals were experiencing significant stress, severe emotional problems, abuse in a current relationship, or thoughts of harming themselves. In addition, we inquired about prescribed psychiatric medications and recent psychiatric hospitalizations. We also included a general question: "Are there any reasons you can think of that might make participating in interviews about your adolescent partner violence/mistreatment too stressful for you?" We assumed that these questions would provide enough information for the telephone screeners to determine whether participants "were experiencing acute emotional distress that would make participation risky."

We indicated in the grant application that master's-level clinicians would conduct the interviews and have a list community referrals available in the event that a participant became distressed or indicated a desire to pursue counseling. In addition, one of the coinvestigators, who is a licensed psychologist at a hospital-based trauma program, was designated to assist participants who needed emergency treatment or requested ongoing counseling. We did not have a detailed protocol to guide the interviewers in assessing and responding to emotional distress that became apparent during the interviews.

Because it was possible that the research would produce data related to illegal activities, such as perpetration of violence, the research application also included a plan to secure a Certificate of Confidentiality from the CDC. A Certificate of Confidentiality is a legal document issued by federal agencies that exempts researchers from releasing identifiable and sensitive information about participants of a research (Barnbaum & Byron, 2001). To obtain the certificate, we were required to provide

detailed protocols that outlined specific procedures to be used to manage emotional distress.

Because we could not find suitable models or templates of such protocols in the literature, we constructed them by explicating and expanding on the procedures outlined in the grant application. In our beginning discussions about the content and the format of the protocols, the research team raised issues related to inclusion and exclusion of vulnerable persons, how best to ascertain whether a person was to be enrolled or excluded, and appropriate strategies to manage participant distress. We also examined the literature on emotional distress and research participation, considered ethical issues related to protecting participants from emotional harm, and used team meetings to construct and refine the protocols.

Review of Research on the Risk of Emotional Distress in Research on Sensitive Topics

Before constructing the protocols, we reviewed research on emotional distress and participation in studies on sensitive topics. A number of studies have been conducted to determine the incidence of emotional distress reported by participants in research on emotionally charged topics, such as psychiatric illness, suicide, and trauma (e.g., [Boothroyd, 2000](#); [Boothroyd & Best, 2003](#); [Dean, Stein, Jaycox, Kataoka, & Wong, 2004](#); [Griffin et al., 2003](#); [Hawton et al., 2003](#); [Newman, Walker, & Gefland, 1999](#)). Most studies queried individuals about their reactions to the research at the conclusion of their involvement. Several comprehensive reviews of these studies have been conducted to guide researchers and regulatory bodies in decision making about risk protection.

A review of 46 studies that examined distress after participation in psychiatric research was published recently ([Jorm et al., 2007](#)). The review revealed that only a small minority of participants (<10%) in community and clinical samples reported distress immediately after participation, and positive reactions were more common than were negative ones. Individuals most likely to report distress were those who had mental disorders or were experiencing psychiatric symptoms before their participation in the research. Although few long-term follow-up studies had been conducted, available evidence indicated that there is little risk of lasting emotional harm from participation in psychiatric research. A wide range

of perceived positive benefits were reported. These benefits included catharsis, an increase in self-awareness, a feeling of empowerment, a sense of purpose, and an opportunity to help others ([Jorm et al., 2007](#)).

A review of 12 studies of participants' appraisals of their experiences in trauma-related research also revealed that most participants perceived benefits from their involvement, and only a small subset indicated some degree of marked or unexpected upset ([Newman & Kaloupek, 2004](#)). Some participant characteristics associated with upset included distress before participation, younger and older age, multiple trauma exposure, social vulnerability (e.g., minority status), and greater physical injury. Only a small subset of those who experienced distress regretted their participation or rated the overall experience as negative ([Newman & Kaloupek, 2004](#)).

In constructing the distress protocols, therefore, we were guided by findings that (a) most participants tolerate research on sensitive topics well; (b) most participants find benefit in participating in research on sensitive topics; (c) a small group of participants will experience marked or unexpected distress; (d) responses that indicate distress do not necessarily imply harm; and (e) although it is rare, there are some participants, especially those who are distressed before participation, who report negative effects from participation.

RELEVANT ETHICAL ISSUES

The research team deliberated on several ethical issues that were raised during the development of the protocol. The three broad principles of ethical research identified in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ([Department of Health, Education, & Welfare, 1979](#)) served as a basis for these deliberations. The three principles are autonomy, beneficence (and nonmaleficence), and justice ([Barnbaum & Byron, 2001](#)). Autonomy is the right to determine one's own life course. Researchers honor the principle of autonomy by providing sufficient information regarding the risks and benefits of the research so that individuals may freely accept or decline participation. Beneficence is the promotion of the welfare of individuals; this principle also includes nonmaleficence, the mandate to do no harm. To ensure beneficence and nonmaleficence,

researchers are called upon to seek the greatest benefit for research participants while minimizing harm. The ethical principle of justice requires researchers to equitably allocate the benefits and the burdens of research.

Because the aim of the protocols is to protect participants from the harm, nonmaleficence was the primary ethical principle involved in their development. To minimize the risk of negative emotional effects, the protocols needed to guide researchers in (a) identifying those who were particularly vulnerable to harm, (b) screening out those at high risk based on exclusion criteria, and (c) intervening if research participants became distressed during the course of the research.

As several researchers have pointed out, however, efforts to protect participants from harm may violate the principles of autonomy and justice (Becker-Blease & Freyd, 2006; Newman & Kaloupek, 2004; Newman et al., 1999; Stanton & New, 1988). Exclusion criteria that are overly rigid or conservative or procedures that call for cessation of a participant's participation at the first sign of distress, for example, may violate the principle of autonomy (Newman & Kaloupek, 2004). By ensuring that vulnerable persons are not exposed to harm, a researcher runs the risk of denying them the right to participate in a research study. Procedures that impose interventions on participants who are experiencing distress, such as a "follow-up" call by a mental health professional made without the participants' request or consent, would also violate the principle of autonomy (Stanton & New, 1988).

Procedures that decrease the risk of emotional harm may also breach the principle of justice (Becker-Blease & Freyd, 2006). For example, if all individuals who have a psychiatric disorder are screened out because they are deemed vulnerable, they would not enjoy the rewards of the research either as individuals or as a group. As individuals, they would be denied the personal benefits of research participation, which, according to the empirical findings discussed earlier, may be considerable. As a group, they would be denied the benefits of scientific knowledge gleaned from their experiences. If no trauma studies are conducted with those who are mentally ill, for example, little knowledge would be gained about the effects of trauma on mental health, thereby impeding the development of treatments that might improve the quality of their lives.

In constructing the protocols, therefore, we sought to balance autonomy, beneficence (nonmaleficence), and justice. We specified exclusion criteria that promoted inclusiveness and excluded only those at highest risk, designed screening questions that involved participants in risk assessment whenever possible, and identified minimally intrusive strategies to reduce the risk of harm.

THE PROTOCOLS

Screening Interview and Distress Protocol

The screening interview and distress protocol is presented in [Figure 1](#). This protocol is being used by research associates who conduct telephone screening interviews.

The aim of the telephone screening is to screen out individuals for whom participation in the research interview would be too risky. Because the funding agency asked for a detailed protocol for this screening, we sought to clarify our original exclusion criteria and provide a clearer plan for assessing these criteria. We rejected the use of published instruments, such as standardized psychiatric screening tools, as they did not offer the flexibility we needed to conduct the screening.

We deliberated about which indices would suggest that participation in the study would be ill advised for an individual. We knew that a small portion of individuals who participate in research on sensitive topics would experience negative emotional effects. Guided by the ethical principle of nonmaleficence, we aimed to develop criteria to identify those callers at high risk of adverse reactions. We also knew that most participants in such research will not experience adverse reactions. Mindful of the ethical principles of autonomy and justice, therefore, we aimed to develop criteria that would not exclude those who could safely participate. On the basis of empirical evidence that those most likely to experience adverse reactions are those in distress before participation, we determined that individuals who were experiencing acute distress (regardless of past history) and/or a high level of stress at the time of the telephone interview would be screened out because their distress would likely be exacerbated if they found the interview upsetting. Individuals who had recently experienced a life crisis and were distraught would be excluded, for example, whereas individuals who had a history of emotional

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SCREENING INTERVIEW AND DISTRESS PROTOCOL

All screening will be conducted by an experienced mental health clinician (MHC).

This is (name) from the Kent State University College of Nursing. Thank you for your interest in our study. Do you have any questions about the study? [If yes, answer questions. If no, proceed.]

Could you please verify your name, address, and phone number?

Because the topic of dating violence/mistreatment can be sensitive and might bring up tough feelings, we are advising individuals who are experiencing a high level of stress or emotional distress or whose participation might put them in danger not participate at this time. Is it all right if we ask you some questions to determine if there is any reason you should not participate? [If no, thank for time and interest. If yes, conduct screening interview]

Screening Questions	NO	YES	Follow-up Questions	Caller's Responses	Acute Emotional Distress or Safety Concern? (Y or N)	Imminent Danger? (Y or N)
1. Are you experiencing a high level of stress or any emotional distress?			If YES, ask questions 1. Tell me what you are experiencing. 2. Is it getting in the way of you doing things you need to do (school, work, family obligations)? 3. Is it getting in the way of you taking care of yourself? 4. Have you been in the hospital recently for this problem?			
2. Are you currently having thoughts of harming yourself?			1. Tell me what thoughts you are having. 2. Do you intend to harm yourself? 3. How do you intend to harm yourself? 4. When do you intend to harm yourself? 5. Do you have the means to harm yourself?			
3. Are you currently having thoughts of harming someone else?			1. Tell me what thoughts you are having. 2. Do you intend to harm someone else? Who? 3. How do you intend to harm him/her/them? 4. When do you intend to harm him/her/them? 5. Do you have the means to harm him/her/them?			
4. If you participated in the study, would you be in any danger if anyone else found out?			1. How might you be in danger? 2. How might the other person find out you were participating? 3. What do you think the other person would do if they found out you were participating in the study?			

Actions for screener:

- If answers to screening questions are all NO, read the confidentiality statement below and schedule an interview.

CONFIDENTIALITY STATEMENT

All answers that you give will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under law, we must report to the state suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

- If a participant's responses reflect **acute distress or safety concerns but NOT imminent danger**, take the following actions:

- Do not schedule an interview.
- Recommend that the caller contact his/her mental health care provider OR Dr. X (study psychologist, 555-555-5555) for follow-up.
- Indicate that, with the caller's permission, Dr. X (study psychologist) will call him/her the next day to see if he/she is okay.
- Notify Dr. X and Dr. Y (Principal Investigator, 555-555-5550) of the results of the screening.

- If a participant's responses to additional screening questions reflect **imminent danger**:

- Contact local law authorities.
- Indicate that, with the caller's permission, Dr. X will contact him/her the next day to see if he/she is okay.
- Notify Dr. X and Dr. Y the results of the screening immediately.

Fig 1. The screening interview and distress protocol.

problems or who endured ongoing life stresses that they managed on a day-to-day basis would be included. Thus, Screening Question 1 prompts the screener to ask individuals if they are experiencing a high level of stress or emotional distress. If an individual answers "yes," a series of follow-up questions are used to determine whether the distress is currently interfering with the person's life in a significant way. The participants' responses are recorded on the protocol.

The second and third screening questions concern thoughts about suicidality or homicidality, which are important indices of acute emotional distress and could signal imminent danger. If an individual answers "yes" to either of these questions, follow-up questions are included to assess the acuity and severity of these thoughts. Because the study concerns dating violence, the protocol includes a fourth screening question to determine whether an individual would be in danger if another person

(e.g., the perpetrator) were to find out that he or she was participating in the study. Follow-up questions are provided for this issue as well.

The protocol requires the screener to make determinations about each potential participant's levels of emotional distress and intervene accordingly. Interventions are based on the ethical principles of nonmaleficence and autonomy; except in the event of imminent danger, potential participants in distress determine which, if any, follow-up recommendations they wish to pursue.

The protocol outlines three sets of interventions for the screener. If individuals do not answer any of the screening questions affirmatively, they are considered not to be in acute emotional distress or imminent danger. In this case, the protocol directs

the screener to read a confidentiality statement and schedule an interview. If individuals answer any of the screening questions affirmatively and their answers to the follow-up questions indicate acute distress or a safety concern but no imminent danger, the screener is directed to (a) not schedule an interview, (b) recommend that the individual contact his or her mental health care provider or the study psychologist for follow-up, (c) offer a follow-up call from the study psychologist the next day, and (d) inform the study psychologist and principal investigator. In the rare event that individuals respond to the screening questions affirmatively and provide information in the follow-up questions that suggests imminent danger, the protocol dictates that the screener (a) contact local law authorities, (b) offer a

ADOLESCENT DATING VIOLENCE STUDY RESEARCH INTERVIEW AND DISTRESS PROTOCOL

The following protocol outlines the actions of the MHC (mental health clinician) if, during the course of the interview, a participant exhibits acute distress or safety concerns - or imminent danger to self or others.

Indications of Distress During Interview	Follow-up Questions	Participant Behaviors/Responses	Acute Emotional Distress/ Safety Concern? (Y or N)	Imminent Danger (Y or N)
Indicate they are experiencing a high level of stress or emotional distress. OR exhibit behaviors suggestive that the interview is too stressful such as uncontrolled crying, incoherent speech, indications of flashbacks, etc.	1. Stop the interview. 2. Offer support and allow the participant time to regroup. 3. Assess mental status: a. Tell me what thoughts you are having. b. Tell me what you are feeling right now. c. Do you feel you are able to go on about your day? d. Do you feel safe? (if NO, ask questions below) 4. Determine if the person is experiencing acute emotional distress beyond what would be normally expected in an interview about a sensitive topic.			
Indicate they are thinking of hurting themselves	1. Stop the interview. 2. Express concern and conduct a safety assessment: a. Tell me what thoughts you are having. b. Do you intend to harm yourself? c. How do you intend to harm yourself? d. When do you intend to harm yourself? e. Do you have the means to harm yourself? 3. Determine if the person is an imminent danger to self.			
Indicate they are thinking of hurting others	1. Stop the interview. 2. Express concern and conduct a safety assessment: a. Tell me what thoughts you are having. b. Do you intend to harm someone else? Who? c. How do you intend to harm him/her/them? d. When do you intend to harm him/her/them? e. Do you have the means to harm him/her/them? 3. Determine if the person is an imminent danger to others.			
Indicate they would be in any danger if anyone else found out about their participation in the study	1. Stop the interview. 2. Assess danger from other person: a. How might you be in danger? b. How might the other person find out you were participating? c. What do you think the other person would do if they found out you were participating in the study? 3. Determine if the person is experiencing a safety concern.			

Actions for MHC:

- If a participant's distress reflects an emotional response reflective of what would be expected in an interview about a sensitive topic, offer support and extend the opportunity to: (a) stop the interview; (b) regroup; (c) continue.
- If a participant's distress reflects **acute emotional distress or a safety concern beyond what would be expected in an interview about a sensitive topic, but NOT imminent danger**, take the following actions:
 - Encourage the participant to contact his/her mental health provider OR Dr. X (study psychologist) for follow-up.
 - Provide the participant with Dr. X's (study psychologist) number (555-555-5555) and the number of the emergency room at hospital (555-555-5550) and encourage the participant to call either if he/she experiences increased distress in the hours/days following the interview.
 - Indicate that, with the participant's permission, Dr. X (study psychologist) will contact him/her the next day to see if he/she is okay.
 - Notify Dr. X (study psychologist) and Dr. Y (Principal Investigator) of the recommendations given to participant.
- If a participant's distress reflects **imminent danger**, take the following actions:
 - Contact local law authorities unless arrangements can be made for the participant to be transported to the emergency room by a family member.
 - Indicate that, with the participant's permission, Dr. X will contact him/her the next day to see if he/she is okay.
 - Immediately notify Dr. X and Dr. Y of actions taken.

Fig 2. The research interview distress protocol.

follow-up call from the study psychologist the next day, and (c) notify the study psychologist and the principal investigator.

Research Interview Distress Protocol

The research interview distress protocol is presented in [Figure 2](#). This protocol is being used by the research associates who conduct research interviews.

In specifying procedures to be used if a participant experienced an adverse reaction during the interviews, we were guided by research findings that suggested that such reactions were rare but possible and by the ethical principle of nonmaleficence. We anticipated that discussing experiences of dating violence could be distressing for many participants. Thus, we sought to design a protocol that would help interviewers determine when such distress exceeded what would be normally expected during the course of an interview on a sensitive topic and might signal an adverse reaction. Research findings suggested that participants who experience distress rarely regret participation or report lasting harm. On the basis of that finding and the ethical principles of autonomy and justice, we aimed to develop a protocol that would not hinder the participation of individuals who are distressed but unlikely to experience adverse reactions.

The research interview distress protocol requires interviewers to be aware of four indications of acute emotional distress beyond what would be expected in an interview on a sensitive topic: (a) statements or behaviors that suggest that the interview is too stressful, (b) statements that reveal a participant is considering hurting himself or herself, (c) statements that reveal that a participant is considering hurting someone else, or (d) statements that reveal a participant might be in danger if another person found out about the interview. The protocol contains follow-up questions that promote dialogue to reveal acute emotional distress or imminent danger.

As with the screening interview and distress protocol, three determinations can be made. If the interviewer determines that a participant's distress reflects what would be expected in an interview on a sensitive topic, support is offered and the participant is provided an opportunity to stop, regroup, or continue. If a participant is in acute emotional distress or imminent danger, the procedures are similar to those outlined in the screening

protocol, with two variations. For those participants who are experiencing acute distress but are not at risk of imminent danger, a call to the study psychologist or mental health provider is suggested if they feel that their distress worsens after the interview. Because interviews are conducted in person, the interviewer can have a participant who is in imminent danger contact a family member to take him or her to the emergency room, thereby avoiding having to contact the police.

DISCUSSION

We found the task of developing detailed distress protocols time consuming and, at times, trying. We discovered, as did [Newman and Kaloupek \(2004\)](#), that "all researchers must accommodate individual differences in risk-benefit perspectives when constructing study procedures...but they often lack a reliable point of reference for decisions about how to do so" (p. 383). We had to operationalize some decisions that had been previously based on the research associate's unarticulated clinical judgments. The challenge was to develop protocols that had enough specificity and detail for our funding agencies and regulatory bodies but did not prevent our clinically trained research associates from making sound judgments based on each unique situation.

The two protocols presented here, therefore, might serve as templates for those who research sensitive topics and seek to outline procedures for managing emotional distress. The delineation of the process by which we constructed the protocols, including a review of the empirical literature and a determination of relevant ethical principles, may also inform researchers. We recognize that the protocols will need to be empirically examined. In the course of the 3-year study, we will gather data on their feasibility and utility.

In the process of designing the protocol, we revisited some of our assumptions about the risk of emotional harm in research. As trauma researchers and clinicians, we had been particularly concerned about the "Pandora's box phenomenon"—that is, that in-depth interviews about abuse may "unleash painful emotions and memories" ([Draucker, 1999](#), p. 162). Although this remains a legitimate concern, our literature search revealed that research on sensitive topics, including that on trauma, is well tolerated by most participants and that adverse reactions are rare. [Becker-Blease and Freyd \(2006\)](#),

for example, challenged the common assumption that research questions about abuse trigger traumatic memories. They argued that it is more likely that such memories are triggered by violence portrayed in the media or sensory or sexual experiences that mimic abuse experiences. They also suggested that distressing questions are not necessarily overwhelming or undesired and challenged the notion that negative feelings are dangers from which participants need protection. They argued the following:

Even when the negative feelings evoked by research are more closely associated with the experience of trauma or abuse (e.g., feelings of betrayal or grief), this is not necessarily an indication of psychological harm. Feelings like grief, anger, and fear in response to remembering a trauma may be a transitory negative state that is understandable and not harmful. (p. 222)

The process of developing the protocols forced us to balance consideration of the benefits of research on sensitive topics against the risks; the ethical principles of autonomy, justice, and non-maleficence; and the strengths, resiliency, and vulnerability of participants.

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