Assessing Trauma and its Effects Without Distress: A Guide to Working with IRBs

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Early in my career, an Institutional Review Board (IRB) I was working with insisted that a proposed study which included questions about sexual abuse was ethically inappropriate to conduct. The IRB members reasoned that since they would not want their family members to answer such personal questions, this study was unethical and should not be conducted. Even information about refusal rates, referral rates, and safety protocols employed in similar studies could not overcome the IRB's reliance on imagined personal substitution with research participants as its chief source of ethical decision-making. Unfortunately, the IRB decided *a priori* that studies of sexual violence were improper. In our final meeting, they suggested ways such future research should be conducted that were clearly harmful to potential participants.

I saw firsthand how personal values, politics, and emotions interfered with reasoned ethical decision-making meant to assure safe research practice. This upsetting but formative professional experience shaped my approach to research ethics and research practice.

In response, I did what a good scientist-practitioner is trained to do — turned my experience into a hypotheses driven research agenda to supplement my other research. How would one assess ethical dimensions of research?What were the base rates of emotional distress in trauma-related studies? How do research participants weigh distress in deciding whether they regret participation? Can they accurately anticipate the degree of distress they might experience during research participation? This brief article will describe my experience and approach since that time, delineating a few general concerns that arise in trauma-related research protocols and lessons learned.

My students and I study the effects of trauma exposure upon mental health, physical health, and social/familial/occupational functioning in both adults and children. Nearly all our studies involve asking participants some information about exposure to a wide range of potentially traumatic life experiences. Our studies typically involve interviews and questionnaires and we are now beginning to add biological samples to our protocols (e.g., DNA). We access many groups including: consumers of domestic violence and sexual assault services, college students, prisoners, substance-users, and journalists.

Finding the balance between the duty to protect against possible harm and becoming extremely protective of research participants is no easy task. In trauma studies overprotection can ultimately discriminate against trauma survivors and impede science on their behalf.And it goes without saying that we do not want to harm anyparticipants. Given this dilemma,my colleagues and I developed a multi-step hypotheses testing model to help gain information and design safe protocols that are scientifically-informed (see Newman, Kaloupek, Keane & Folstein, 1997). First, we identify areas of uncertainty about ethical issues or participant safety in a given protocol. Then we pose any concerns as testable hypotheses. Data gathering begins with a search for existing evidence using both published literature and

consultation with colleagues. This iterative process typically results in the elimination of some concerns, the validation of other concerns, and the emergence of new concerns. The process results in increased clarity, allowing us to articulate the concern and generate options aimed at reducing risk and increasing benefit. As a result of this process, our IRB protocols include a careful analysis of ethical dimensions of research and the cost-benefit ratio. We explain any potential concerns we can anticipate, the available data about the probability of these concerns, and the ways we address those concerns in our protocol.

We also build in ways to assess the efficacy of our protocol at minimizing harm and maximizing benefit. My collaborators and I developed the Reactions to Research Participation Questionnaire (Newman et al., 2001; Kassam-Adams & Newman, 2002) to assess participants' subjective appraisal of the research experience. We use this and other methods to assess areas of uncertainty. Locally, our IRB has been responsive to our approach. We strongly recommend that individual investigators collect their own post-participation data to inform planning and support future submissions to their IRB. In addition to being useful when working with one's local IRB, journals such as the *Journal of Empirical Research on Human Research Ethics* and *Accountability in Research* provide venues to communicate this type of information and provide resources to other IRBs. Many investigators and IRBs have shared with me how useful this information has been in their deliberations.

With respect to trauma-related protocols, many IRBs focus on the potential for "retraumatizing" participants. While the potential for emotional harm is a vital ethical dimension to consider, the research context simply is not equivalent to living through actual life-threatening situations; it is disrespectful to survivors to equate the two. In research, safeguards allow a participant to exhibit control and choice, such as stopping at any time. This is an important distinction that can be helpful to emphasize to IRB members who seek to accurately assess any risk related to recall of potentially upsetting experiences. With respect to unexpected or marked distress, I now provide a summary to my IRB about what we know and don't know in the trauma field about the potential for emotional harm whenever I pursue a new research method or different population that my IRB has not yet reviewed from my lab.

While the potential for emotional distress is not unique to trauma-related studies, traumatic stress investigators have been among the first to systematically assess the experience of research for participants so there is a database upon which to draw. For example, evidence thus far suggests that there is a low probability of significant emotional harm from participating in trauma-focused studies. While unexpected distress may occur for some participants, this distress appears tolerable and appears to be linked with positive outcomes for most (see Newman, Risch & Kassam-Adams, 2007 or Newman & Kaloupek, 2005 for a review of such data). Further, it is unclear if expressed emotional reactivity is an indicator of emotional engagement, a reflection of baseline distress independent of the research experience, or an intensification of existing symptoms or emotional responses that are uncharacteristic of these individuals. Our research base needs to clarify this issue. Nevertheless, there is a small minority who experience unexpected distress and regret participation. Given the small number of participants across studies who experienceboth upset and regret, it is difficult to detect meaningful differences — no distinguishing features have been identified to date that can help us identify in advance whom is likely to experience regret and unexpected upset, and the extent of these reactions is yet unknown. Our practical response has been to tell participants in our informed consent process that most people find the research a positive experience, although a few do not. We let potential participants know that a few individuals find themselves more upset than they anticipated.

Another concern occasionally raised by IRBs is the argument that since traumatic events may render people powerless, issues of choice and voluntariness may warrant special attention. However, available studies suggest that most adult and child participants in trauma-focused studies feel able to refuse participation, to stop or skip questions, and to tell research staff when they do not like aspects of the research protocol. Similarly, it appears that decision-making capacity is not compromised for trauma survivors as a group (Collogan et al, 2004). Supplying this information to IRBs can be helpful.

Finally, I should note that my successful collaborations with an IRB evolved into my participation as an IRB member and now chair. From this vantage point, I have several other suggestions:

Establish a positive working relationship with your IRB staff. For beginning researchers interviewing for their first independent research position, I recommend requesting a meeting with an IRB representative, especially if your specialty area is a sensitive one unfamiliar to this IRB. At minimum, when starting a position, talking with the IRB staff member about potential concerns, areas of emphasis for this particular IRB, and precise procedures for IRB submissions can help begin a productive collaborative relationship.

Complete the IRB application carefully. IRB members can easily detect those protocols that are submitted byresearchers with contempt for IRBs or a tone of “let’s get this over with!” as opposed to those who respect ethical reviews.Despite the IRB members’ efforts to be objective, it is clear that IRB members and staff are far more responsive and willing to take some risk when researchers have clearly communicated a commitment to ethical research practice. Using jargon-free language and explaining scientific procedures can also help the lay members of the board and those from other specialties be more confident in their understanding and aid accurate decision-making.

Join your IRB. For some of you that might sound like a curse, but IRBs need sensible psychology expertise. Psychologists are well trained in critical thinking, ethical scientific behavior, decision-making errors, understanding risk probabilities, and making decisions under conditions of uncertainty.The only way to improve review processes is to actively change them. Recently I read a university’s promotion and tenure criteria that specifically designated IRB service as scientific productivity (designating it as equivalent to a certain number of articles per year). If more departments and institutions encouraged good scientists to contribute to science in this way, IRB local practice could be enhanced.

I have been fortunate that the majority of the IRBs I have worked with are truly interested in ensuring safe practice and promoting research. I am aware that not all IRBs work that way. However, regardless of specific situations, all of us can work proactively with our IRBs to provide scientific methods of assessment and communication to bring greater clarity and accuracy to the field.?

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