Trauma research and the Institutional Review Board
Executive Committee, Division 56, June 15, 2013

Social scientists and the IRB

Social scientists in general, and trauma researchers in particular, have historically travelled a difficult road in educating and negotiating with Institutional Review Boards (IRBs). The first IRBs, initiated in 1966 by the Public Health Service, applied solely to those applying to federal grants. IRB oversight spread in the 1970's, especially after passage of the 1974 National Research Act. Social scientists, however, were vociferous in their insistence that the requirements were inappropriate and onerous for social scientists, and compromises were reached in the 1978 recommendations by the National Commission for the Protection of Human Subjects (NCPHS). Opinion columns in influential newspapers and magazines exerted pressure on governmental agencies. In The Nation, an editorial concluded that "in failing to distinguish between medical injections or LSD injections and survey research or interview procedures customary in the social scientists, the proposed guidelines mark a truly terrifying extension of Federal power in American life." In 1980, a President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was formed, a successor to the NCPHS. The commission recommended exemptions for research involving interviews or survey procedures if (a) the participants could not reasonably be identified or (b) the research "did not deal with information which, if confidentiality were breached, could place the subjects at risk of criminal prosecution, civil liability, loss of employment, or other serious adverse consequences, except in settings in which subjects may feel coerced to participate." This understanding exempted most trauma research. The policies of many universities at the time were to allow researchers to make judgments of exempt status, with the understanding that poor application of this standard by the investigator, if discovered, would be seen as an ethics violation. Doctoral committees and candidates, not IRBs, were expected to engage in thorough ethical evaluation of the proposed project. IRBs reviewed research that involved deception, experimentation, vulnerable participant categories, or otherwise potentially risky procedures. The general standard was that competent adults could decide if they wanted to participate in experiments that involved answering questions, even about sensitive topics.

In 1993, the Albuquerque Tribune ran a story about 18 Americans who had been injected with plutonium as part of a government study (in the 1940s) on the effects of radiation. The publicity surrounding this scandal led to new government commissions, the creation of the National Bioethics Advisory Commission, and a re-examination of exempt studies. The scandal reawakened memories of the Tuskegee Syphilis study, in which the U.S. Public Health Service monitored the progress of syphilis in a large group of low income black adults without telling them of their disease status or offering penicillin when it became available during the study's duration (1932-1972; see Reverby, 2009).

Gary Ellis, the recently appointed leader of the Office for Protection from Research Risks (OPRR), later recalled that at this point "it was simply not possible

for OPRR to ignore research that might be ambiguous, whether it was biomedical and behavioral…It was not possible to ignore anything." (Schrag, 2010, p. 131). The Federal Register stated that it would still be true that "the largest portion of social science research will not be subject to IRB review and approval" (Health and Human Services, Final regulations Amending Basic HHS Policy, 8367). In May of 1995, Ellis announced the policy should be instructed to review every proposed study, and that investigators could not use general guidelines to decide that their projects fell under exempt status. Many universities now sign model assurances (in order to receive federal funding) that promise IRB review of all protocols, and some states also require IRB review of all human subjects research.

Recommendations to the trauma researcher: Cost-benefit ratios in trauma research

Trauma research can engender IRBs misunderstanding of the costs and benefits to participants in trauma research protocols. Just as societies and individuals alternately approach and back away from knowledge of trauma (a dynamic that Olafson et al. (1993) refer to as "the cycle of discovery and suppression"), well-intentioned IRBs can be expected at times to protect themselves and their communities from such knowledge. This resistance can be manifested in exaggerations of the risks of trauma research in informed consents or in taking away the right of trauma victims to voice their stories in well-consented studies (through disapproval of specific studies). Experts on IRB regulation bring up many such examples, such as Schrag's (2010) example of a colleague studying the everyday experience of children in the Sri Lankan civil war who was told not to mention violence. Division 56 graduate students have also contributed examples of seemingly extreme regulatory behavior. One IRB asked that the student to forward to the IRB all tapes of fully consented trauma survivors disclosing their trauma (in a study on the nature of trauma narratives) with the rationale that some of the tapes would be deemed too traumatizing to be rated by other adults. In another example, a student was told that even asking a potential participant whether he or she would like to be in a study that contained a trauma questionnaire might be problematic (since trauma survivors might experience the request to be a part of research studies to be coercive) , and proposed that the study be described in a poster on the university billboard and interested participants could volunteer. Several students have noted that their colleagues are shying away from trauma research given the perception that IRB evaluations would be too time-consuming and restrictive. In most cases, the trauma researcher can have faith that the IRB members will be responsible in reviewing the scientific merit and feasibility of research protocols, but they cannot be expected to have detailed knowledge of the relevant research in this area.

Division 56 makes the following recommendations to facilitate gaining IRB approval for trauma research. If you can, tailor your argument and choice of sources for each of the arguments below to represent your particular sample population (e.g., students, outpatients, inpatients):

Recommendation 1. In your protocol, cite research that illustrates to your IRB that the probability that your trauma questions will unduly upset your participants is quite low. This research appears to apply to most trauma populations that have thus far been studied, but is particularly applicable to nonclinical groups. For inpatient groups, the language used in Carlson et al.'s study of trauma exposure and symptoms might be appropriate ("It is possible that some people will be upset by talking about some of the things that have happened to them in the past. But usually people do not get upset.") Exaggerating the probability of upset or implying that distress is common is not recommended.

Recommendation 2. In your protocol, cite research that illustrates that the probability that your cost-benefit ratio of your research will be positive, both in the view of typical trauma research participants and based on the broader trauma literature.

Recommendation 3. All protocols should include clear statements about methods of assuring participant autonomy. Methods of providing such assurance might include making it clear that participants may stop the process at any time and that questions can be skipped, as well as keeping client self-determination in mind when choosing how and by whom the participant is asked to join the research.

Recommendation 4. In your protocol, consider some instrument that measures the participant reaction to your study such as Newman et al.'s (2001) Reaction to Research Participation Questionnaire (RRPQ) or your own tailored questionnaire covering perceived costs, benefit, and distress together with a dynamic and individually-tailored method of addressing responses to the data collection.

The general finding across research studies in non-psychiatric samples was that distress responses were infrequent, mild, and transitory. Although some studies found that those with more severe trauma histories or those with PTSD symptoms had more distress reactions (Galea et al., 2003; Griffin et al., 2003), emotional reactions to trauma research do not generally predict negative reactions to this research. In fact, emotion or temporary distress is at times reported to correlate *positively* with perceived importance and general positive evaluation of the research in the above studies (Kluemper & Dalenberg, in press), underlining general research findings that disclosure of trauma, although difficult, can be beneficial. Disclosure of trauma has been associated with empirically measured health benefits as well as psychological benefits (Lutgendorf & Antoni, 1999; Pennebaker, Kiecolt-Glaser, & Glaser, 1988). Among psychiatric samples, risks for outpatients appears to be low, but acutely distressed patients (hospitalized inpatients, for example) are more likely to show distress (see Carlson et al. study below).

Sample studies include:

Community samples

- Black and Black (2006, 2007): In a large scale telephone survey conducted by the Center for Disease Control and Prevention, participants were asked

about their history of interpersonal violence. They were told that they could skip any question they wished, and that they could end the interview at any time. Less than 1% of the participants skipped the interpersonal violence questions, while more than 15% skipped questions about their socioeconomic status.

- Galea et al. (2005): In this large study, 5774 adults in New York City were interviewed about the September 11, 2001, terrorist attacks. During the interview, some distress was noted by 12.9% of the interviewees. However, by the time the interview was over, only 1% of those immediately distressed participants were still upset.

Challenge tasks

- Carter-Vischer, Naugle, Bell, and Suvak (2007): In one of the most potentially upsetting experimental studies, Carter-Vischer et al. exposed their participants to highly arousing visuals (e.g. mutilated bodies) and noxious sounds (e.g., sirens), measuring physiological arousal and emotional labeling of faces. One week after the study, 94% of the participants stated that they would participate again in the study if asked at that point in time. Distress was mild and diminished over time. The authors concluded that participants may have experienced some immediate, expected distress from answering trauma-specific questions, but stated that there did not appear to be residual longer lasting effects of the interview.

Undergraduates

- Cromer et al. (2006) compared distress experienced while completing self report trauma surveys to distress experienced in everyday life. The majority of the sample (63%) reported that distress related to trauma surveys rated experience was no more distressing than other experiences in everyday life. Of those who rated trauma questioning as more distressing that the experiences of everyday life, 99% rated importance and other positive aspects of the research as outweighing the relative distress.
- DePrince and Chu (2008): Undergraduates (n = 129) and community sample (n = 385) completed questionnaires about PTSD, dissocation, and trauma history. Undergraduates' average distress scores were lower than neutral, and means from the community sample were not significantly different than neutral.
- Yeater et al. (2012): This research group gathered data from 504 young adults, explicitly asking participants to compare the distress of completing a trauma survey to the stress of everyday life, the comparison defining minimal risk in the typical IRB analysis. The surveys chosen were "the most provocative (and potentially distressing) questionnaires that we could find." The conclusion was that "despite the number, variety, and extremity of questions in the trauma-sex condition, the overwhelming majority of participants – even women who reported a history of sexual victimization – were not distressed" (p. 784). The experience of filling out questionnaires

was less distressing than "normal life stressors." Filling out trauma surveys was determined to be a minimal risk activity.

Refugees

- Dyregov, Dyregov, and Raundalen, 2000: Bosnian refugees (twelve adults and 14 children) were interviewed regarding traumatic life events and their experiences of the Bosnian War. Eighty-seven percent rated the experience as positive (4-5 on a 5 point scale).

Outpatients

- Edwards, Dube, Felitti, & Anda (2007): Over 30,000 members of a large HMO were asked about a wide range of health behaviors and childhood abuse experiences. Participants were given a hotline number to call if they experienced distress or upset due to filling out the questionnaires. Over a 24 month period, the hotline received no calls.
- Newman, Walker, & Gefland (1999): The authors studied 1174 women in an HMO who completed a trauma-focused health survey and a subset of 252 women who later completed a trauma-focused research interview. The majority found the interview and the questionnaire study to be a positive experience and did not regret participating. A large proportion reported immediate perceptions of personal gain. After 48 hours, no participants reported regret and nearly three-quarters of the sample endorsed benefit. The mean level of upset was low.

Inpatients

- Carlson et al. (2003): In a study of psychiatric inpatients, structured interviews for PTSD and childhood physical and sexual assault were administered. Interviews were stopped if the patient showed strong indications of distress regardless of the individual's willingness to continue. Interviewers discontinued 16 of the 223 evaluations. An additional 23% of those who completed the interviewed scored their distress at 4 or 5 on a 5 point scale. Degree of "upset" was correlated with severity of current symptoms and with severity of prior trauma.

Specific Trauma Groups

Bereaved

- Runeson and Beskow (1991): In a 2-week follow up of their study on trauma survivors who had lost someone to suicide, the authors found that 83% of the participants reported increased sense of benefit compared to immediately after the interview, and 57% reported feeling better than they had felt prior to research participation. Importantly, none of the study participants reported feeling worse at follow-up than they had prior to research participation.

- Brabin & Berah (1995): Intensive interviews were conducted with 257 mothers and 160 fathers who had a stillborn baby some years earlier. Asked if the interviews were distressing and helpful/unhelpful, a small proportion found the interview distressing. Nearly all reported that it had also been helpful.

Motor vehicle accidents

- Ruzek and Zatzick, 2000: The authors interviewed 117 motor vehicle accident victims regarding traumatic life events, PTSD, dissociation and depression. Thirteen percent reported being unexpectedly upset, but 95% of participants reported that the benefits of the interview outweighed the costs of the distress and they would participate again

Empirical evaluation of the cost/benefit ratio associated with your line of research will give the clearest evidence for the participant reaction to your individualized protocols. This can be monitored during the course of the study to assure that your study is not putting participants at risk, and allow researchers to change procedures to reduce risk if ever needed.

In case of distress, researchers should show empathy to any distress that is expressed by the respondent and provide a mechanism for follow-up. Given (a) the likelihood that distress will be transitory, (b) the dangers associated with pathologizing normative transitory distress, and (c) the increase in positive reactions to research over time, a graduated response to immediate mild to moderate distress is recommended. An example would be to normalize immediate distress in a supportive manner, and to provide numbers for low-cost counseling for those who find that their distress does not dissipate quickly. For those reporting high distress, direct follow-up by the experimenter is recommended.

Greater levels of unexpected upset can be expected (according to Newman and Kaloupek's 2004 review) in instances of more severe preexisting distress, complex trauma, in cases of social vulnerability, and after more serious physical injury.

Recommendations to the trauma researcher: Confidentiality

Recommendation 5: Although risk of trauma disclosure is generally low, this statement presumes that the researcher has put into place a clear and workable method of protecting client confidentiality. Educate your IRB in your protocol about mandated reporting rules as well as professional ethical responsibilities for reporting in your area and reveal your plan to address this. If your research protocol includes questions on groups where there is mandated reported in your jurisdication (e.g, child or elder abuse, etc.), and your participants are identifiable, information should be provided to participants about whether specific or general reporting requirements apply to your protocol. If your trauma questions are more general, or not related to child/elder abuse, it is still reasonable to state that confidentiality will be protected "except as required by law."

Recommendation 6: With respect to confidentiality, it may be useful to consider the degree to which your proposed study may become identified (whether true or not) as a study of a specific group of trauma survivors. This may lead to a social risk for participants to experience stigma. This may raise two related concerns. First, a clear plan of de-identification should be presented with your protocol. Second, it may be useful to present to the IRB ways the study will protect the confidentiality of survivors during the process of the study. For example, data collection processes should ensure that others will not be privy to information leading them to make assumptions about the participants that may be stigmatizing (e.g., identifying a specific room that will be used for individuals in Trauma Study X).

Summary:

The general body of research above is consistent with a minimal risk description of most trauma-related research. Minimal risk is defined as levels of harm or discomfort that is not greater than those "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations and tests (National Commission for the Protection of Human Subjects of Behavioral Research, 1978). Thus, minimal risk does not require an absence of transitory distress. The trauma researcher is often at an advantage to those serving on Institutional Review Boards in that he or she knows the trauma literature well, and can maximize benefits and minimize risk through this knowledge. Abdicating this responsibility can lead to changes in the protocol that are well-meant, but actually increase harm. Avoiding such harm is a duty of all psychologists (APA Code of Ethics, Standard 3.04).

Finally, trauma researchers are often those who are facilitating the telling of a story to a supportive audience for the first time. As Becker-Blease and Freyd (2006) discuss, there is a danger in NOT telling, in facilitating silence, or in sending the message to students (and particularly to trauma victims themselves) that trauma disclosure presents a greater risk than does inhibiting disclosure. As Herman (1992) wrote:

> It is very tempting to take the side of the perpetrator. All the perpetrator asks is that the bystander do nothing. He appeals to the universal desire to see, hear, and speak no evil. The victim, on the contrary, asks the bystander to share the burden of pain. The victim demands action, engagement, and remembering (pp. 7-8).

Finding a way to tell these stories well, to examine their meaning, and to promote the understanding necessary to prevent the further occurrence of trauma, is one purpose of trauma research. Implicit in this goal is the duty to perform the research with integrity and respect.

The following descriptions have been used by Division 56 researchers in IRB approved research.

Sample confidentiality plan:

All participants will be assigned a participant number that will be used to identify their data collected during the course of participation in the research. Consent forms will be stored separately from other study materials. Participants' names will not be kept with video recorded data, however, there is a possibility that participants could be identified based upon their video. Participants in the study will sign a separate consent form stating their consent for their video recorded narratives to be viewed by research participants in future studies. Video data, questionnaire data, and informed consents will be kept in separate secure locations .

The following limits to confidentiality will be given: Your data will be kept confidential and will not be released except as required by law. California law mandates the filing and reporting of reasonable suspicion of child, dependent adult, or elder abuse. Participation in this research could result in the investigator being required to report child, dependent adult, or elder abuse. If you express intentions or plans to hurt yourself or someone else, the researcher will ask you additional questions about these thoughts, and depending on the intensity, may work with you to contact a your physician, family member, friend, or may work with you on a plan that includes getting you to a hospital for safety.

Sample risk/benefit statement to a university IRB:

Sample 1: While the majority of participants are expected to have neutral or positive experiences participating in this study, we are aware that there is the risk someone may respond negatively to being asked personal questions about traumatic events and emotional distress. A recent study (Cromer, Freyd, Binder, DePrince, & Becker-Blease, 2006) reported averages of low levels of distress (rated below "neutral" using a scale) for questions that assessed childhood abuse using a very similar form of the BBTS. Furthermore, there were no differences in distress levels between questions about GPA, body image or traumatic experiences. However, participants rated questions about trauma as more important to include in psychological research than questions about body image or grades, and their mean ratings placed trauma research in the "important" to "very important" range.

Additional published research indicates that asking these types of questions is not significantly distressing to participants, even to those who have experienced traumatic events (e.g., Carlson, Newman, Daniels, Armstrong, Roth, & Loewenstein, 2003; Kassam-Adams & Newman, 2002; Newman, Walker, & Gefland, 1999; Walker, Newman, Koss, & Bernstein, 1997). The questions asked are similar to frequently-encountered descriptions on the news and in other media.

Because of the minimal risk of this study, we do not foresee emergencies. However, participants will be given information about where they can seek help if they become distressed (they can ask questions of the PI, go to the counseling center, etc.). We are not retaining personally identifying information, so we will not be able

to follow up with participants during or after the study

Sample 2: As compensation for participation in the research study, after completing all study procedures, participants will receive a $15 or extra credit. Because participants are freely describing their trauma history, they will have the opportunity to determine the intensity of their description or to withhold any information they do not wish to share with the interviewers. Participants will also be clearly warned that the investigators are mandated reporters and must report ongoing abuse to children/elders/dependent adults or information which suggests that children/elders/dependent adults are currently at risk. There are no directly questions on this issue on the THQ. In over 6,000 participants that have been tested to date, there have been no disclosures of unreported abuse when the warnings were given.

Participants may potentially become upset or distressed by speaking about a traumatic experience. However, previous research supports a conclusion of minimal risk in trauma survey research (Legerski & Bonnell, 2010; Ruzek & Zatzick, 2000). Additionally, research has shown that research participants report minimal distress when asked about their trauma history, and may perceive trauma questions as having greater importance and more positive cost-benefit ratings compared to other types of psychological research (Cromer, Freyd, Binder, DePrince, & Becker-Blease, 2006).

In the event that the participant shows distress, it will be reiterated that the individual has the right to discontinue the research at any time. The assessment of distress will be made again that the end of the study, through use of the RRPQ. If any participant reports negative attitudes toward the study as manifested by interview responses or scores on the RRPQ Drawbacks questions, then the participant will be further interviewed and offered a list of low cost therapy resources.

The following are summary articles that go into more detail than can be covered here. Researchers are urged to spend time thinking about and discussing this important area.

Becker-Blease, K. & Freyd, J. (2006). Research participants telling the truth about their lives: The ethics of asking and not asking about abuse. American Psychologist, 61, 218-226.

Collogan, L., Tuma, F., & Fleischman, A. (2004). Research with victims of disaster: Institutional review board considerations. IRB: Ethics and Human Research, 26, 9-11.

Legerski, J. & Bonnell, S. (2010). The risks, benefits, and ethics of trauma-focused research participation. Ethics & Behavior, 20, 429-442.

Newman, E. & Kaloupek, D. (2004). The risks and benefits of participating in trauma-focused research studies. Journal of Traumatic Stress, 17, 383-394.

Newman, E. (2008). Assessing trauma and its effects without distress: A guide to working with IRBs. APS Observer, 21, 1-3.

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Kassam-Adams, N., & Newman, E. (2005). Child and parent reactions to participation in research following pediatric traumatic injury. *General Hospital Psychiatry, 27*, 29-35.

Kluemper, N., & Dalenberg, C. (in press). Is the dissociative adult suggestible: A test of the trauma and fantasy models of dissociation.

Lutgendorf, S. K., & Antoni, M. H. (1999). Emotional and cognitive processing in a trauma disclosure paradigm. Cognitive Therapy and Research, 23(4), 423–440.

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