



How Concerned Are Institutional Review Boards About Trauma-Related Research? A Survey of Investigators

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Introduction

Research focusing on trauma exposure has been essential in establishing a knowledge base about the nature, prevalence, and consequences of traumatic experiences. Yet, as with all research involving human subjects, the benefits gained from these studies must be weighed against the potential costs. In the case of trauma research it is possible that participants (particularly those who have experienced traumatic events) may experience emotional distress as a result of responding to sensitive questions about their experiences. A number of studies suggest that this type of distress is generally mild and transitory (see Jaffe, DiLillo, Hoffman, Haikalis, & Dykstra, 2015; Legerski & Bunnell, 2010; Newman & Kaloupek, 2004, 2009). Nevertheless, a number of anecdotal reports have surfaced indicating that Institutional Review Boards (IRBs) may be hesitant to approve trauma research due to concerns that participants will become emotionally overwhelmed or even "retraumatized" by reporting past traumas (Ranjbar, 2012; Yeater & Miller, 2014). Despite these isolated reports, the prevalence of IRB concerns about trauma research remains unclear. If these concerns about conducting trauma-related research are prevalent in spite of empirical evidence to the contrary, important research on trauma and its sequelae could be unnecessarily stifled. Further, the mere perception that IRBs hesitate to approve trauma research with human subjects could dissuade some researchers from including trauma-related assessments in their studies. To determine how often IRBs express concerns about trauma-related research, and what the nature of those concerns might be, we conducted a brief survey of trauma researchers and examined the following questions:

1. How many trauma researchers have had IRBs raise concerns about trauma research?
2. How many trauma researchers have had IRBs decline trauma-related protocols?
3. What are common concerns about trauma research raised by IRBs?

Method

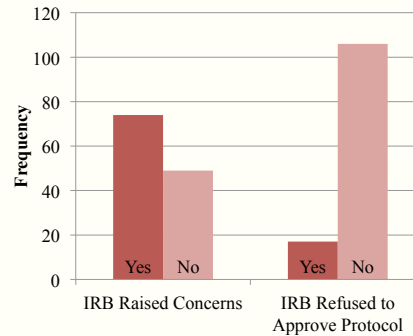
- Individuals aged 19 and older who conduct research with trauma populations were recruited through listservs, websites, and social media outlets, including:
 - Association for Behavioral and Cognitive Therapies (ABCT) member listserv
 - ABCT Child Maltreatment & Interpersonal Violence SIG listserv
 - International Society of Traumatic Stress Studies (ISTSS) website
 - American Psychological Association (APA), Division 37: Society for Child and Family Policy and Practice, Child Maltreatment section listserv
 - APA Division 56: Trauma Psychology listserv and Facebook page
- A total of 123 graduate students and doctoral-level researchers competed the survey
 - 115 participants were from the U.S.
 - 8 participants were from other countries
- No demographics were collected.
- Participants were asked to respond to a three-item survey designed for the current study. Questions included:
 - *Have you had an IRB raise concerns about asking participants questions about their prior trauma experiences? YES or NO*
 - *Have you had an IRB refuse to approve a protocol due to concerns about the effects of asking participants about prior trauma experiences? YES or NO*
 - *Please describe the concerns, if any, raised by your IRB.*

Selected References

- Executive Committee of Division 56. (2013). Trauma research and the Institutional Review Board. Retrieved from http://www.apatraumadivision.org/images/kfinder/files/56_irb_guide.pdf
- Jaffe, A. E., DiLillo, D., Hoffman, L., Haikalis, M., & Dykstra, R. E. (2015). Does it hurt to ask? A meta-analysis of participant reactions to trauma research. *Clinical Psychology Review, 40*, 40-56. doi:10.1016/j.cpr.2015.05.004s
- Yeater, E. A., & Miller, G. F. (2014). "Sensitive" topics research: Is it really harmful to participants? *Observer, 27*(5). Retrieved from <http://www.psychologicalscience.org/index.php/publications/observer/2014/may-august-14/sensitive-topics-research-is-it-really-harmful-to-participants.html>

Results

- 60.2% of trauma researchers ($n = 74$) had an IRB "raise concerns about asking participants questions about their prior trauma experiences."
- 13.9% of researchers ($n = 17$) said an IRB had "refused to approve a protocol due to concerns about the effects of asking participants about prior trauma experiences."



Results

- 85 researchers also responded to an open-ended prompt to describe the concerns raised by their IRB. Survey respondents indicated the following common IRB concerns.
- Many researchers ($n = 40$) noted IRB concerns that asking about trauma might trigger intense negative emotions that "re-traumatize" or cause harm to participants (e.g., requiring treatment or leading to suicidal ideation).
 - Many researchers reported that IRBs required additional measures be taken to address participant distress. Specifically, some IRBs requested or required clinical personnel to be on site ($n = 6$), some IRBs indicated a preference for administering particularly sensitive questions only through clinical interview (eliminating the possibility of phone or online surveys; $n = 6$), others required extensive "emergency" protocols ($n = 12$), and still others required removal of specific measures from the study protocol ($n = 2$).
 - Another concern reported by respondents pertained to the importance of preserving participant confidentiality ($n = 8$). Many also cited related concerns about complying with requirements for mandated reporting of abuse ($n = 10$).
 - Several respondents indicated full informed consent procedures detailing the nature of the trauma assessment (at times supplemented with a quiz assessing comprehension) were helpful in obtaining IRB approval ($n = 7$).
 - Numerous respondents indicated the importance of providing mental health referral resources ($n = 12$).
 - Researchers ($n = 16$) often reported "educating" IRBs by providing a great deal of empirical research and data from previous studies showing lack of participant distress. Though a few ($n = 3$) reported this procedure as extremely onerous, others ($n = 13$) indicated that after educating their IRB and conducting a number of trauma-related studies, IRB concerns have been more minimal.

Conclusions

These findings suggest widespread unease among IRBs about approving trauma-related research, with 60.2% of respondents reporting IRBs have raised concerns about trauma studies. Some IRBs seem to require various "extra" precautions, based on the unfounded assumption that participation will re-traumatize individuals. This represents a misperception of the cost-benefit ratio and indicates IRBs may hold trauma research to a higher standard than other studies focusing on sensitive topics (e.g., drug use, sexual behaviors). Though protecting participants is of utmost importance, this unease is at odds with data showing that trauma research leads to minimal distress and even has some benefits for individuals who have experienced trauma (e.g., feeling understood, helping other victims; Jaffe et al., 2015; Legerski & Bunnell, 2010). Moreover, there are costs of not asking about trauma, including potentially conveying to victims that trauma is not worthy of study, makes researchers uncomfortable, or should not be disclosed (Becker-Blease & Freyd, 2006). There may also be costs to modifying important aspects of the research protocol, including the mode of administration. Although survey respondents indicated some IRBs prefer in-person interviews for sensitive topics to monitor and reduce participant distress, empirical findings suggest interviews may be associated with somewhat more distress than self-report assessments (Jaffe et al., 2015). Further, participants may also be more willing to disclose sensitive information via computer-based surveys than to an interviewer (Turner, Ku, Rogers, Lindberg, & Pleck, 1998). In this way, the costs and benefits to various research approaches should be weighed when designing protocols for submission to the IRB.

Limitations and Future Directions

The current survey provides initial estimates of the prevalence of IRB concerns about trauma-related research. However, there are a number of limitations inherent to a brief, anonymous questionnaire. For example, it is unclear whether the current results are representative of IRBs nationwide. It is possible, for instance, that trauma researchers with a history of negative IRB experiences were more likely than other trauma researchers to respond to this survey. Further, each survey respondent may have had numerous interactions with IRBs on various projects. Though a single negative experience could have been reflected in the current survey, this could be outweighed by many positive (unrepresented) experiences with IRBs. Lastly, open-ended responses indicated that IRB concerns for trauma research with adults could be different from IRB concerns for trauma research with children, including issues related to mandatory reporting. This possibility should be explored further in future studies.

Recommendations

Future trauma-related research may be facilitated by increased communication between researchers and IRBs. Specifically, we recommend jointly developing protocols that minimize participant risk, educating IRBs about empirical data on the actual degree of distress associated with participation, and conveying to IRBs the potential costs of not asking about trauma (for further recommendations, see Executive Committee of Division 56, 2013). This education might best be undertaken outside the context of a specific protocol being reviewed so that IRB personnel will have this information on hand when evaluating proposals involving trauma. A number of survey respondents indicated that education has helped improve the IRB approval process over the years, with the process becoming simplified and less onerous over time. Researchers are therefore encouraged to persist in efforts to obtain IRB approval, particularly given the importance of research on the occurrence and consequences of trauma.

