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Methods for Assessing and Addressing Participant Protection Concerns in Intimate Partner Violence Research

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Abstract

Research on intimate partner violence (IPV) is highly sensitive and may put some participants at increased psychological, emotional, and physical risk. Still, we know little about the risks posed by most social science methods and have minimal guidance regarding appropriate practices for carrying out various forms of research. This study collected data from 59 IPV researchers regarding the most commonly used participant protection methods, the efficacy of those methods, number and nature of adverse events (AE) experienced, and experiences with institutional review boards (IRBs). Participants were invited via e-mail to complete an anonymous online survey. Findings indicate an overall low incidence of AEs as well as a minimal relationship between AEs and IPV inquiry. These findings may provide researchers with preliminary data on the effectiveness of various participant protection methods. Results may also facilitate more innovative and effective participant protections measures, help researchers prevent and cope with AE, and create more mutually beneficial relationships with IRBs.

Keywords

intimate partner violence; research; IRB; human subjects concerns

Intimate partner violence (IPV) is a highly controversial area of research that often carries with it implications for advocacy, policy, and clinical work. Most social scientists in this area typically devote immense effort to ensure that their research participants come to no harm as a result of their participation (Clements & Holtzworth-Munroe, 2009; Delva, 2007; C. M. Sullivan & Cain, 2004). Nevertheless, IPV research falls under the umbrella of “sensitive topics research” (Fontes, 2004; Lee & Renzetti, 1990), and one of the most difficult and controversial elements of conducting IPV research is the potential risk of harming the participants that we are striving to help (Fontes, 2004). In spite of the fact that many participants in this area find their experience rewarding (Shorey, Cornelius, & Bell, 2011), the possibility remains that laboratory and self-report investigations of IPV may put some individuals and couples at increased risk of experiencing emotional distress or violent

episodes. For example, Johnson and Benight (2003) found that although 45% of their sample believed their participation in a study of IPV-related trauma was beneficial, another 25% expressed that they were more upset by participation than they had expected and 6% of the sample reported that they regretted participation.

There exists a substantial literature documenting the complex ethical and safety concerns in this area of study and intervention (Cook & Dickens, 2009; Ellsberg & Heise, 2002; Langford, 2000; C. M. Sullivan & Cain, 2004), but there is insufficient data available to guide researchers in determining how to safely and effectively conduct research with various populations and settings (Bliss, 2002; Btoush & Campbell, 2009; Oakes, 2002; Parrott, 2002). In fact, most researchers operate relatively independently with regard to human subjects protection measures (Oakes, 2002). The lack of evidence-based procedures and appeal to authority pose a further problem inasmuch as the research methodology employed in IPV studies continues to advance tremendously, potentially raising quite different sources of concern. More researchers now include the use of technologies such as Web-based surveys, telephone surveys, daily diary measures, and Palm Pilots to more effectively address their research questions (Moore, Elkins, McNulty, Kivisto, & Handsel, 2011; Rhatigan, Moore, & Street, 2005; T. P. Sullivan, Khondkaryan, Dos Santos, & Peters, 2011). This area of study is also posing new, more controversial research questions. Whereas investigations of IPV and IPV-focused interventions in certain populations (couples, military personnel, immigrants, pregnant women, etc.) were previously vastly understudied, these topics are becoming increasingly popular among researchers and are receiving recognition by national funding agencies as relevant and vital topics (e.g., Monson, Taft, & Fredman, 2009; Rhatigan et al., 2005). These advances have led to improvements in clinical intervention and advocacy services that ultimately help and protect those who are in danger. However, the extent to which the advances may also generate new risk factors for those participating in IPV research remains unknown.

These issues are further complicated by the often difficult institutional review board (IRB) approval process for investigations that have an IPV focus. As the nature of IPV research continues to evolve, the responsibility of the IRB to protect participants needs to evolve accordingly. Thus, those who serve on IRBs incur an equal impact by the lack of empirical guidance available on the topic of the safety of human subjects protection methods. The pressure on academic and research institutions to uphold stringent participant protection measures is arguably at its height in recent years (Brainard, 2000). In addition to the ethical responsibility of IRB members to keep research participants safe, institutions face legal and financial liability in the wake of an adverse event (AE) or failure to uphold IRB compliance. One result of this responsibility is a recent shift in IRB attention to nonphysical as well as physical risk of research participants (Prentice & Gordon, 2001; Shorey et al., 2011), which is particularly relevant in studies of IPV. Coupled with an extraordinarily demanding workload, lack of compensation, minimal education regarding the objectives of an IRB, and guidelines on how to reach conclusions, these factors may result in a “better safe than sorry” mindset of IRB members (Bell, Whiton, & Connelly, 1998; Candilis, Lidz, & Arnold, 2006; Lederman, 2006; Oakes, 2002). When one considers the intricate and high-stakes nature of human subjects protection and the lack of information available regarding the safety and risks involved with IPV research, it is logical that some IRB members may approach

reviews of IPV research with levels of caution out of proportion to the actual risks of participation (Bledsoe et al., 2007). Several findings have even asserted that avoiding conducting research that inquires about abuse and violence in vulnerable populations may be detrimental to the research process and even some potential research participants (Becker-Blease & Freyd, 2006; Leisey, 2008).

Researchers often express frustrations with the IRB approval process (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978), including IRB overestimates of risk for protocols, inconsistency of IRB decisions between institutions, and feeling a lack of efficacy and contribution to decisions (Becker-Blease & Freyd, 2006; Keith-Spiegel, Koocher, & Tabachnik, 2006; Murray, 1998; Niemonen, 2000; Pattullo, 1984; Sieber, 1982). In fact, Oakes (2002) wrote, “IRBs are under new pressure to scrutinize social scientific research and that frustration emanates from a fundamental rejection of their legitimacy. Remedy lies in educating ourselves and educating IRBs about our methods and risks they pose” (pp. 445–446).

Some researchers are beginning to respond to the growing needs outlined by the literature described earlier by including measures of safety and negative effects resulting from study participation and by urging other researchers to do the same (e.g., Clements & Holtzworth-Munroe, 2009; Owen, Heyman, & Slep, 2006; C. M. Sullivan & Cain, 2004; T. P. Sullivan et al., 2011). These studies were conducted among community couples and IPV-exposed women, and each found that IPV-related inquiry to be nondistressing and safe for participants. Two exceptions within these investigations are that Owen and colleagues (2006) found that although female participants reported that their participation in IPV-focused inquiry provided benefits to them and their intimate relationships, male participants did not note any added benefit from IPV questions. Clements & Holtzworth-Munroe (2009) found that violent couples in their study reported higher levels of fear and jealousy than nonviolent couples following a battery of questionnaires. These authors note that their fear was not necessarily IPV or safety related and could have been related to other factors. T. P. Sullivan and colleagues (2011) reported that in a study using experiencing sampling methodology (ESM), which is new technology being applied to the study of IPV, 100% of participants reported that their physical safety was never put at risk as a result of participating, despite the fact that at least 66% of the sample also reported that their partners knew of their participation. Despite these advances, no studies to date have empirically investigated the effectiveness of various human subjects protection methods (Clements & Holtzworth-Munroe, 2009; Langford, 2000; Parker, Ulrich, & the Nursing Research Consortium on Violence and Abuse, 1990; C. M. Sullivan & Cain, 2004).

This study addressed this gap in the literature by assessing the usage of various human subjects protection measures, determining the prevalence and nature of AEs experienced in IPV research, and assessing researchers' experiences with their IRBs to facilitate a broader discussion of human subjects protection methods and to foster more collaborative relationships between IPV researchers and their IRBs.

METHOD

Sample

The sample consisted of 59 doctoral-level researchers. Descriptive statistics of the sample are presented in Table 1. Seventy-one percent of participants worked primarily in the field of psychology and 96.2% of respondents were conducting their research in a university setting, although some survey respondents were also affiliated with hospitals, branches of the military, medical schools, or research firms. In addition, respondents indicated 94 separate samples (e.g., separate data collections) collected from 33 different types of populations (e.g., women in shelter, men in batterer intervention; community samples, high school students). Response choices included 22 possible different populations, and at least 2 respondents marked each one. Ten respondents offered at least one additional population they have sampled from, resulting in 33 different populations. Some examples include parolees, female refugees, police response recipients, and HIV-positive individuals. Responses reflected experience with 144,600 male, 138,094 female, and 9,297 couple research participants assessed over the course of these investigators' careers.

Measures

The online survey consisted of 51 questions, which were a combination of Likert scale, multiple answer, and open-ended questions. Each question also afforded survey respondents the option of choosing "other" and providing their own answer. The final two questions were entirely open-ended, offering survey respondents the opportunity to comment on human subjects protection issues of their choosing and the study or survey overall. For example, one survey item read "Please mark any of the populations that you have included in your IPV samples during the past 5 years AND, additionally, please mark those populations in which you experienced adverse events." Another survey item read, "How would you characterize your relationship with your IRB?" Answer choices for this item were listed on a 5-point Likert scale ranging from "very collaborative" to "very adversarial."

Procedure

All study procedures were IRB approved. Survey respondents were recruited via e-mail for an anonymous, Web-based survey. In an attempt to reach the broadest range of participants possible with minimal overlap and participant burden, the pool of professionals invited to complete the survey ($N = 252$) was compiled from a list of attendees to an interdisciplinary conference with a focus on interpersonal violence and special interest groups therein. These attendees were e-mailed invitations to participate and follow-up invitations were mailed on two separate occasions following the initial contact. No compensation was offered for participation. Survey respondents were asked to report on various aspects of the participant protection methods used in their research, how effective those methods were, the number and nature of any AE experienced over time, and their experiences with the IRB of their current research setting. According to the Department of Health and Human Services (DHHS; 2011), an AE as it pertains to human subjects research does not have a single standard definition, but is defined broadly as:

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, [*sic*] abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice). Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research. (<http://www.hhs.gov/ohrp/policy/advevtguid.html#Q2>)

Because research institutions' offices of research and compliance tend to adopt an abbreviated but equally broad version of this definition, we did not provide this definition for participants in this study.

RESULTS

The Relationship Between AEs and IPV Inquiry

To begin addressing the question of how much risk participants encounter over and above their everyday lives, respondents to our survey were asked to report the extent to which the AEs they reported were related to inquiry about IPV. Eighty percent of respondents who had ever experienced an AE during the course of their career reported that it was “not at all” related to IPV inquiry. Three respondents (12%) reported that their AEs were “slightly related to IPV inquiry and two respondents (8%) reported that the AE they had experienced was “significantly” or “entirely” related to IPV inquiry. Altogether, across the duration of all of our participants' careers, only five AEs were related to IPV inquiry and only one of those had occurred in the last 5 years.

History of Adverse Events

In spite of the extensive experience of this sample, most researchers (39; 66%) had never experienced an AE during the course of their career. Among the 20 participants who had reported at least one AE, one researcher reported 50 AEs, whereas a second reported 19. The remaining 18 researchers in our sample who had reported experiencing at least one AE reported 21 AEs among them: Just 13 of which had occurred in the past 5 years.

Characteristics of Outlying AE Experiences

The respondents who had reported 50 and 19 AEs were in the fields of public health and medicine, respectively, and both reported that all of those AEs were not at all related to IPV inquiry. In fact, all but 1 of the 50 AEs reported by the first researcher were side effects from medication. The one identified outlying instance was deemed coincidental and unrelated to the investigation in which the participant was involved. Each of the 19 AEs reported by the second researcher were unrelated to the studies being conducted and involved unfortunate life events, such as illness and car accidents. It is also worth noting that both participants' research focused entirely on ethnic minority, immigrant, and non-English speaking populations.

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Effectiveness of Participant Protection Methods

None of the AEs reported by respondents resulted in a change to their research protocol to prevent reoccurrence. When asked what, if any, procedure might have prevented their AEs from occurring, 19 of the 21 participants who responded listed "none." Both of the other two respondents agreed that more adequate research assistant training might have improved their methods and subsequently prevented the AE from occurring. This respondent also stated that concealing the purpose of the investigation would have been beneficial. However, the other respondent stated that complete clarity of the purpose of the investigation might have prevented participant distress, which was the nature of the AE reported.

Experiences With IRBs

Consistent with Oakes's (2002) recommendations regarding communication with IRBs, participants were asked if they had ever served on an IRB during the course of their career. Most respondents (68.5%) had not, indicating that most members of this sample had contact with their IRB only from the standpoint of being evaluated. This finding implies an important point of intervention that may prove to aid researchers in developing better relationships with their IRBs.

When asked about the extent to which IRBs were useful in aiding the safety of the protocols being proposed, 16 of the 36 respondents who replied indicated that the recommendations made by their IRB did not at all enhance the safety of their participants. In fact, 8 participants reported that their IRB's recommendations "slightly" and "somewhat" enhanced their participants' safety and just four participants reported that those recommendations were "considerably" helpful. Those who provided examples of ways in which their IRBs have been helpful noted that they have developed methods to train and monitor research staff more closely, to treat research participants with respect, and to increase the privacy that research participants are afforded in the interview process. No respondents reported that IRB suggestions enhanced their participants' safety "a great deal." To better understand the content of these evaluations, respondents were asked to report on their IRBs most common concerns. Upholding participant confidentiality was the most commonly reported primary concern voiced by IRBs during the review process, followed by risk of future violence and emotional distress.

Few researchers in this sample reported difficulties with the protocol approval process. Just 7.8% of respondents had been completely prevented from conducting a study by their IRB and, when asked about the extent to which IRB changes hindered the scientific quality of their investigations, 15 participants responded not at all, 9 responded slightly or somewhat, and just 2 responded considerably or a great deal. To gauge the amount of time spent attempting to obtain IRB approval, respondents were asked to report how many rounds of revision their protocols typically required prior to granting approval. Most respondents (53%) indicated that their IRBs required one revision; 23% report that they usually participated in 2–3 rounds of revision; and 13% reported typically receiving approval on their first submission.

When asked about the nature of their relationship with their IRB, 30.6% of the sample responded “very collaborative,” 34.7% responded “somewhat collaborative,” 20.4% responded “neutral,” and 14.3% responded “somewhat adversarial.” No respondents reported that their relationship with their IRB was “very adversarial.” The underlying reasons for these responses and the division between researchers' experiences of their IRBs requires further investigation.

DISCUSSION

The primary purpose of this study was to examine and report the current methods of human subjects protection in IPV research and the positive and negative aspects of IPV researchers' experiences with their IRBs. The results of this exploratory and descriptive investigation provide documentation of commonly used participant protection methods and the apparent efficacy of those methods in minimizing AE. Results regarding the usage of human subjects protection measures indicate that most researchers who conduct IPV research use several integral elements consistently in their protocols (see Figure 1). Findings suggest that IPV researchers experience a very low incidence of AE. It is not clear whether our methods of protection are highly effective or the actual risk of AEs because the IPV focus is very low, or both. It should be acknowledged that the sample in this study was a group that was very experienced, which may contribute to a conscientious method of conducting research in this sensitive area. Given the presumed but unknown risks of conducting IPV research, the IRBs may have required a very high degree of protection. Regardless, these findings indicate that IPV research, as it is currently practiced, is unlikely to generate AE directly related to the research and may result in a positive experience for participants (e.g., Shorey et al., 2011).

Although the present sample demonstrated similarity regarding their general approach to protecting subjects, our findings indicate that researchers' IRB-related experiences range in character from efficient and collegial to long-drawn-out and hostile, when attempting to obtain IRB approval. However, the broad consensus was that adversarial IRBs that impede the appropriate study of IPV are uncommon. In fact, the IRBs are viewed as generally collegial, even if their recommendations are not uniformly perceived as reducing the risk to participants in IPV research.

One notable finding was that few members of this experienced sample had ever served on an IRB. From the perspective of improving communications and education between IPV

researchers and IRB members, having a stronger presence in the review of proposed research may be beneficial for both groups. We believe that such involvement may lead researchers to provide data concerning the actual risks when available. It should also lead IRBs to request this information, thereby facilitating a mutually informative relationship.

Limitations

This is the first empirical study of its kind within the interpersonal violence community and, therefore, has several limitations. First, there was minimal literature to draw upon when designing this investigation and, as a result, this study was not able to investigate the questions under consideration in more nuanced ways. We hope that future studies investigating this topic will expand upon the questions investigated here and that this study may inform that work. Second, the existing sample is small and our response rate was limited. Unfortunately, our recruitment methods made it impossible to describe the population of researchers who opted not to participate. Considering that less than 25% of the invited researchers chose to participate, the extent to which our sample is representative of the larger population of IPV researchers cannot be derived. Future studies may benefit from choosing a study design that allows for this information to be collected. The generalizability of this study's findings may also be limited because of the fact that this sample was comprised primarily of experienced researchers who reported few AEs and minimal difficulty with IRBs.

Perhaps this sample represents researchers who reflect the best practices in this field of study, which results in safe and effective research methodology, whereas those who have more difficult research experience may have been less inclined to participate. Future studies may benefit from including a wider range of experience in their samples. Input from more researchers, and more information about those who decline participation, would enhance the applicability of these findings and inform future investigations. Future studies may also benefit from using more involved recruitment methods such as in person invitations to participate. Third, the factors that underlie researchers' vast differences in evaluations of their IRBs remain unknown, and more information regarding those responses would be beneficial. Finally, this study did not include a component in which researchers might provide information about the methods by which they communicate with their IRBs, and this information may provide additional insights into how we might improve those relationships.

CONCLUSIONS

One purpose of this investigation was to provide empirical evidence to empower IPV researchers to communicate more effectively with their IRBs. More frequent contact between ourselves and IRBs, both formal and informal, may be an integral first step to achieving the goal of greater efficacy in protecting our research participants and the scientific integrity of our investigations. The field of IPV study is continuing to evolve. It is expected that as interpersonal violence and its precipitants and correlates will become an even greater funding and investigative priority, available methodologies will also improve, which may present greater demand for innovative participant protection methods. Therefore,

it is imperative that our community remains mindful of how varying methodologies might inform more innovative and safe protocols for protecting participants. The most relevant question remains: What are the risks, for whom and under what circumstances, that participants in IPV research incur as a result of participating in IPV research? Further research may help us understand in more explicit terms the aspects of IPV research that participants find helpful, distressing, or both.

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Figure 1.

Usage of human subjects protection methods. A = complete anonymity; B = interviewing/assessing participants in person; C = interviewing/assessing participants by phone; D = prevent participants' partners from being aware of their participation; E = prevent participants' partners from being aware of their answers; F = certificates of confidentiality; G = using same-sex interviewers or research assistants; H = training research staff in safety planning; I = providing referral lists of community resources; J = require women's consent to invite male partner to participate; K = require men's consent to invite female partner to participate; L = report to police or other authority violence that is occurring; M = report to university officials violence that is occurring with college students; N = report to parents regarding violence between college students.

Table 1

Means and Standard Deviations of Sample Descriptors

	Observed Range	Mean	Standard Deviation	% Female/% Male
Age	29–67	45.86	11.27	—
Years since PhD	1–58	15.16	10.43	—
Years IPV experience	2–35	14.75	8.02	—
Number IPV studies	1–45	10.77	10.95	—
Publications	1–265	27.91	45.56	—
Gender	—	—	—	25.0/73.3

Note. IPV = intimate partner violence. $n = 59$.