Considering Trauma: A Descriptive Report on Building Safety into an Intimate Partner Violence-related Study Protocol

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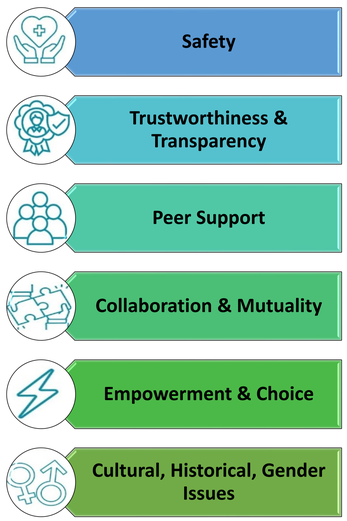
Building Interdisciplinary Research Careers in Women's Health

BACKGROUND

- In the United States, one in three women and one in four men report experiencing intimate partner violence (IPV) at some point in their lives.
- Thus, it is critically important for any human subjects' researcher to thoughtfully consider and incorporate methods for safe, trauma-informed protection and empowerment into their protocol procedures.

OBJECTIVE AND METHODS

- Describe intentional efforts to incorporate safe, trauma-informed practices into a research protocol examining IPV-related brain injuries in a sample of adult women presenting to an emergency department for care.
- Our study protocol was informed by SAMHSA's Principles of Trauma-Informed Care framework, along with examples gleaned from the IPV research literature.



SAMHSA Principles of Trauma-Informed Care[1]

RESULTS

Trauma-Informed Principle (SAMHSA, 2024)	IPV Research Literature Examples	Examples of Use in Current BIRCWH Study Protocol
Safety: includes physical and emotional safety during interpersonal interactions, as well as safe physical settings	• All study team involved in recruitment, retention, and data collection must receive IPV-related training including safety issues.[2,3] • Ensure recruitment activities do not interfere with or delay emergency care.[3] • Obtain a safe contact method from participants (e.g., phone number, whether to call or text, good times to contact).[3] In any phone contacts, the study team must first ask the participant if she is safe to talk.[3] To protect safety and privacy, the study team can use a vague title like "a women's health study."[2,3] • Ensure strict confidentiality strategies are implemented to safeguard sensitive study data.[3] Conduct recruitment and data collection interviews in private.[2,3]	• Study PI delivered a 2-hour synchronous training (in-person and online) for all research coordinators that included participant and staff safety protocols. PI also regularly attends team meetings to review study progress and reinforce training. • Study team members will rely on the patients' clinical providers to determine if a patient is consentable and whether/when they can be approached for recruitment. • An IRB-approved, detailed phone script guides study team members on how to address various situations (e.g., if someone other than participant answers, how to ask/respond to concerns about participant's safety, referring to research as a "women's health study"). • A detailed study visit manual guides study team members in: approaching potential participants, including strategies to ensure privacy and confidentiality.

Trustworthiness & Transparency: build and maintain trust, follow through on commitments, create a culture of honesty	• Informed consent procedures must describe how the data will be used, any risks to data exposure outside of the study team, and steps taken to protect the participant's privacy and confidentiality.[3]
	• Inform potential participants of limits to confidentiality, including any mandatory reporting requirements.[3,4]
	• Explain NIH Certificate of Confidentiality to potential participants during informed consent procedures and that it can protect from compelled identifiable research data disclosures for legal proceedings.[3,5,6]
		• To support potential participants' decisions on whether or not to join the study, Informed consent documents and procedures explicitly describe:
		  ○ How participant data may be used
		  ○ Steps taken to protect privacy/confidentiality of data
		  ○ Mandatory reporting requirements
		  ○ Certificate of Confidentiality

Collaboration & Mutuality: level power differences, promote sense of agency and control
 	
Empowerment & Choice: recognize strengths in others, encourage shared decision-making, identify and offer choices
	• Allow participants to stop at any time and to withdraw from the study if they wish.[3,7] Communicate that their care or access to services will not be affected regardless of whether or not they choose to participate in the study.[3]
	• Provide resource options for participants.[3]
		• Informed consent documents and procedures explicitly describe:
		  ○ Participant's ability to stop or withdraw at any time, including how to do so after a study visit is complete, and
		  ○ That their care will not be affected regardless of choice to participate or not, or choice to withdraw once enrolled.
		
		• Detailed resource sheet developed, including local and national hotline numbers, along with descriptions of local clinic resources. Partnered with study site social workers to inform about study and establish pathway for "warm hand-offs" of participants requesting resources.

Cultural, Historical, Gender Issues: acknowledge these issues, offer culturally competent/gender responsive services, move past biases and stereotypes	• Provide training for study team members that includes IPV research concepts and discusses potential biases or stereotypes in working with this population.[3,7]	• Study PI delivered 2-hour synchronous training (in-person and online) for all research coordinators: included IPV and brain injury concepts, female-specific BI concerns, in-depth protocol procedures discussion, potential myths/concerns regarding IPV.

CONCLUSIONS

- We identified multiple specific strategies for implementing trauma-informed care into research with survivors of IPV.
- These practices fall into the broad categories of supporting participant autonomy (consistent with the ethical and trauma-informed care principle of empowerment and choice) and safety (consistent with ethical principles of beneficence and nonmaleficence and the trauma-informed care principle of safety).
- Given the prevalence of IPV and other trauma in the United States today, recognizing the importance of trauma-informed research is an important step in building trust among communities.
- This work may support other researchers in developing protocols studying populations who have been exposed to violence and trauma.

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This work is supported by K12 BIRCWH grant K12AR084229