

Ethical and Safety Recommendations for Intervention Research on Violence Against Women

**Building on Lessons from WHO's
*Putting Women First: Ethical and Safety Recommendations for
Research on Domestic Violence Against Women***



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Introduction

The Need for Intervention Research Guidelines

In the more than 10 years since the World Health Organization (WHO) released recommendations on *Putting Women First* through ethical and safe research on violence against women (VAW) (1), numerous articles and publications have continued to highlight ethical concerns in VAW research and have suggested recommendations for researchers and practitioners working in this area. Most recently additional guidelines have been released focusing on general recommendations for conducting research on VAW (2), on primary violence prevention initiatives (3), on sexual violence in emergency settings (4), with perpetrators of sexual violence (5), and on violence against children (6). To date, all these guidelines have focused on providing recommendations and guidance within the context of cross-sectional research.

However, as the evidence base on the magnitude, context, and consequences of VAW has grown, research efforts and attention have begun to focus on decreasing the knowledge gap on effective responses through intervention research. Demonstrating this focus, in November 2012, the WHO convened a group of experts, the WHO International Network of VAW Researchers, to meet in person and to deliberate on *Breaking the Cycle of Violence Against Women: Health-based Interventions*. This global network of researchers, scientists, and practitioners was brought together to enhance existing research efforts and to advocate for greater funding for research on interventions to address VAW and policies and programs related to it.

With the increased interest and attention of the global community of researchers, practitioners, and policymakers toward rigorous intervention research for preventing VAW, a discussion of the ethical considerations specific to this type of research is warranted. As was highlighted by the WHO over a decade ago and by many others since then, the sensitive nature of research on VAW requires special ethical and safety considerations (1, 5, 7-10). Although the broad considerations remain the same in intervention research, such as the need to protect the safety of the participant and the researcher, the implementation of intervention research also raises additional ethical and safety questions. For example, how can researchers safely approach selection, recruitment, and follow-up of participants in a study to evaluate the outcomes and impacts of an intervention to prevent violence? How do researchers address randomization of participants into control or intervention arms? How do researchers monitor and manage risk of violence from participation in the intervention? And what additional protections should be put in place when the research involves populations such as pregnant women?

Intention and Content of These Guidelines

The following recommendations have been developed to help answer these and related questions specific to conducting research on health-based interventions to prevent VAW. Research on strategies that use health or health care as an entry point (regardless of the implementation setting, such as a clinic or community) are the focus. However, the discussion may be relevant to other kinds of VAW interventions.

The target audience for these guidelines includes stakeholders engaged in research on health-based interventions to prevent VAW. Such research may be conducted by multidisciplinary and cross-national or regional teams composed of researchers, program implementers, evaluators, activists, advocates, and care providers. Thus, in this document, the terms “research team” and “researcher” represent a range of stakeholders engaged in studying VAW interventions. As such, these recommendations do not address ethical challenges and dilemmas that may arise in the context of collaborations to study VAW interventions. For example, issues related to respect and equity within research teams and across global North-South partnerships (11-13) are not discussed, although we provide a few references on this and related topics wherever possible.

The focus of this document is on ethical and safety considerations for various stages and types of research on health-based interventions to address VAW, from design and development of interventions to evaluation of outcomes and impacts, and finally to obligations upon study completion. We focus specifically on ethical and safety issues associated with conducting longitudinal research (quantitative and/or qualitative) on VAW interventions, including randomized controlled trials, quasi-experimental studies, and prospective program evaluations. The recommendations are intended to support research teams to design ethical and safe studies, discuss these issues with research ethics review boards, and ultimately protect the safety of those implementing and participating in such research.

Importantly, these recommendations are not designed to replace existing research ethics and safety guidelines nor are they designed to replace the WHO’s *Putting Women First: Ethical and Safety Recommendations for Research on Domestic Violence Against Women* (1). Instead, they act as a companion piece. Existing guidelines address a broad range of issues relevant to developing and testing VAW prevention interventions, including informed consent, privacy and confidentiality, and staff recruitment and training. This publication starts by highlighting additional considerations related to the recommendations provided within *Putting Women First*, followed by a presentation of issues specific to research on health-based interventions to address VAW.

There are several related issues that are not discussed in this guidance. We do not address ethical and safety issues involved in working with children or adolescents in the context of VAW intervention research and offer alternative resources on this issue. Furthermore, this document does not address additional protections that may be needed when working with individuals living with HIV infection, and, as noted earlier, does not comprehensively consider issues that may arise in non-health-based VAW interventions.

Finally, given the particular interest and experience of the members of the WHO International Network of VAW Researchers and the evidence suggesting that pregnancy may be an optimal time for intervention, we have included a section on ethical and safety considerations when working within the context of antenatal care. Resources related to other relevant populations, such as children or HIV positive individuals, have been highlighted when possible.

Development of Recommendations and Acknowledgements

These recommendations were developed through a collaborative process that included several in-person discussions with experts, a review of the literature, and peer review of the developed recommendations. The process began with a discussion of ethical issues encountered by researchers during a 2012 in-person meeting in Geneva of the WHO International Network of VAW Researchers on *Breaking the Cycle of Violence Against Women: Health-based Interventions*. Following this meeting, project summaries shared by Network members were reviewed and a literature review was conducted. Using these inputs, the first draft of the recommendation document was developed, circulated to Network members, and discussed in person with members of the WHO Network and their representatives, at the 2013 Sexual Violence Research Initiative (SVRI) conference in Bangkok. Following these discussions, external experts also provided several rounds of peer review.

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Glossary of Relevant Terms

Violence against women (VAW): As defined by the United Nations, violence against women refers to “any act of gender-based violence that results in, or is likely to result in, physical, sexual, or mental harm or suffering to women, including threats of such acts, coercion, or arbitrary deprivation of liberty, whether occurring in public or private life.” This broad definition includes, but is not limited to, violence occurring in the family, violence within the general community, trafficking and forced prostitution, and violence perpetrated or condoned by the state.

Intimate partner violence (IPV): Threatened, attempted, or completed physical, sexual, or psychological harm by a current or former partner or spouse. This includes physical violence, sexual violence, threats of physical or sexual violence, and psychological or emotional violence. IPV can occur among partners of any sexual orientation and does not require sexual intimacy.

Prevention of VAW: Prevention is a sustained process of intervention that seeks to end violence against women by targeting it before it occurs, mitigating harm and responding after the event, and working with survivors and perpetrators over the long term. Possible measures can take the form of education campaigns, safe housing and health services, or support groups.

Longitudinal research: Refers to observational studies that gather data on the same subjects or variables across extended periods of time.

Intervention research: Assesses the impacts of interventions, with the goal of improving existing initiatives and helping design new ones. Research can span different phases of the intervention, from its initial development; to its feasibility, acceptability, and safety upon implementation; and to its overall efficacy and effectiveness.

Informed consent: The communication process by which a potential study or intervention participant receives information relevant to their role and is able to make a voluntary choice to participate. Informed consent often involves discussing the research or intervention itself; stating the potential risks, benefits, and uncertainties of participation; and assessing participant understanding.

Privacy: Participants being able to control the extent, timing, and circumstances under which they share their experiences, thoughts, beliefs, etc. with the researcher.

Confidentiality: An explicit or implicit guarantee by the researcher to the participant that the information disclosed by the participant will only be disseminated in ways consistent with their original understanding. Confidentiality requires researchers to be mindful that only authorized access to information occurs and the privacy of participants is respected.

Therapeutic misconception: An ethical problem in which research participants confuse the procedures and outcomes of clinical research with those of ordinary treatment, inaccurately believing the research process to produce established, and often positive, results.

Undue influence: Factors exert undue influence when they manipulate an individual’s independent judgment and affect their ability to act according to free will. In the context of social science research, this may take the form of incentive systems that induce conflicts of interest within the research participant.

Vicarious trauma: This refers to a negative transformation in researchers’ thoughts, perceptions, and interpretations as a result of empathetic or sustained engagement with traumatic materials and experiences during research. Vicarious trauma can impact perceptions of safety, abilities to trust, self-esteem and esteem of others, feelings of control, and attitudes toward intimacy.

Putting Women First Recommendations



Intervention Research Recommendations: Additional Considerations

The following section outlines additional ethical and safety considerations for VAW intervention research. The graphic entitled “*Putting Women First* Recommendations” provides an overview of the original *Putting Women First* recommendations; however, it is highly recommended that researchers closely review the *Putting Women First* document. Only the five recommendations outlined in black in the graphic, with additional considerations for intervention research, are presented below. Their original order and item label (i.e. a, b, c, etc.) have been maintained for easier reference to the original content.

a The safety of respondents and the research team is paramount and should guide all project decisions.

The overall principle underlying this recommendation remains true. However, there are several additional issues—particularly related to confidentiality of the research topic and the consent process—to be considered in the context of intervention research.

Confidentiality of the Research Topic when Involving Couples, Families, or Communities and During Longitudinal Research

Both the focus and length of intervention research may result in or necessitate disclosure of the research topic at the household and/or community level. This may be particularly true for intervention research focused on prevention, which may choose to reach more than one member of a social network or group, and which may involve longer and more frequent presence of the research team in the community. In these instances it may not be possible to completely conceal from household members or the group/community that the research addresses VAW. However, health promotion and/or the promotion of relationship health more broadly can offer a safe entry point for addressing violence. The contextualization of violence as one factor impacting the health of women, children, and the community allows researchers, and participants, to explain the inclusion of violence in the study in a less controversial manner. This approach has been successfully used by numerous researchers (5, 14). See the Appendix for example language.

Considering All Stakeholders

Prior to study implementation, it is recommended that researchers undertake a stakeholder analysis. An analysis of this type allows researchers to not only understand who the various stakeholders are, both formal and informal, but also to identify the most effective messages for each audience. Increased understanding of the level and type of information needed by each stakeholder to support the project, while maintaining confidentiality of the topic, can help researchers to craft culturally appropriate, stakeholder-specific language to be incorporated into study scripts.

Studies that have successfully involved other household or community members in VAW intervention research while maintaining confidentiality of a study's primary focus on violence indicate that the following actions can aid in this effort:

- **Apply careful consideration of the study or intervention title and how it is described** to other team members, the public, participating agencies, and potential participants.
- **Pay attention to the questions each type of participant is asked.** For example, when engaging both victims and perpetrators of violence in interventions where violence is being indirectly assessed (i.e. the focus on violence has not been disclosed to the perpetrator of violence), it is advisable to avoid asking questions about violence perpetration to the perpetrator. Alternatively, questions about perpetration and experience of violence may be posed to both groups.
- **Develop standardized scripts that both staff and participants can comfortably use to answer questions about the study** posed by uninvolved family and community members and avoid disclosing violence as the primary focus.
- **Use standardized scripts during community-based data collection or participant follow-up** when research teams may interact with or be interrupted by uninvolved family and community members.
- **Actively monitor how the research is being discussed within the community**, which may include monitoring rumors by community advisors or interviews with community members to assess awareness of the study's focus on violence (15, 16).

Ongoing Participant Consent

The often longitudinal nature of intervention research requires that participants' consent be monitored to ensure ongoing voluntary informed participation and continued safety. *Putting Women First* underscores the importance of ensuring that women have an opportunity to consider the sensitivity of the research topic and are fully informed about the kinds of questions that will be posed in the interview.¹ This need becomes even more important if a period of time elapses between initial consent and follow-up interviews. Evidence from clinical trials has demonstrated that although participants may be well informed at enrollment, they may not retain critical information regarding the study and remain informed throughout the entire trial period. In particular, understanding risks and benefits of participation, having rights to discontinue study participation, and having opportunities to ask questions have been highlighted as areas requiring more regular follow-up (17). The sensitive nature of VAW intervention research, including the potential for increased physical and social risks if others become aware of participation, further emphasizes the need for ongoing consent in this context.

Relevant to this discussion are recommendations made by Fontes in her article on ethics in research on VAW. In the context of a cross-sectional interview, Fontes suggests using multiple decision points over the course of an interview where women are offered opportunities to either continue or stop participation (8). Applying this principle to longitudinal intervention research, women's willingness to continue their participation can and should be re-assessed on a regular basis. The interval at which this re-assessment occurs, as well as the method of re-assessment, should be determined by the research team and may depend on factors such as the resources available and length and complexity of the study.

¹ The term "interview" is used to refer to either a qualitative and quantitative interview.

ELEMENTS OF ONGOING CONSENT

Timing: Regular intervals, to be determined by the research team, depending on length and complexity of the intervention, at a minimum on an annual basis.

Format: Brief check-in using a comprehension checklist, no form or signature required.

Content: Focus on issues most relevant to making an informed decision to continue or terminate participation, including risks and benefits. Allow opportunity to ask and answer questions. Reassure participants that if they choose to discontinue, there will be no negative consequences, particularly in relation to their access to services.

An informed consent comprehension checklist (see the Appendix for an example), similar to those used in a clinical trial context, is a useful tool to guide and document this discussion. A checklist can also be used to enquire how women feel about continuing in the study as part of a check-in at each study visit. In these instances, researchers should use research staff who are not involved in implementing the intervention so that participants do not feel pressured to continue their participation for the sake of the interventionists. As an added measure of assurance, Principal Investigators (PIs), themselves, may choose to confirm ongoing consent with a subsample of participants.

Consent of Partners, Family, or Other Community Members

Related to the above discussion on confidentiality, research that involves members of a woman's social network as part of the strategy to address violence also brings up unique issues of consent. In these instances, women who are experiencing or are at risk of violence should have the opportunity to make an informed decision about the recruitment of another individual in her network. Recognizing that social networks can often be complex and extensive in many settings, this recommendation specifically pertains to cases when members of a social network (e.g. a mother-in-law or partner) are recruited as part of the strategy to address violence experienced by the primary female participant as opposed to studies that may include members of a social network as primary research participants themselves (e.g. friends, neighbors, cousins).

Ensuring Voluntariness to Consent in the Context of an Intervention Study

Like all researchers, those conducting intervention research on VAW have an ethical obligation to make certain that participants are able to choose to participate in a study, free of coercion or other factors that may impede their ability to accurately weigh the possible risks and benefits. In the context of VAW intervention research, this includes addressing therapeutic misconception and minimizing power hierarchies.

Addressing Therapeutic Misconception

Ensuring that individuals understand that the intervention being studied has not been proven effective and that their circumstances may not improve as a result of participation is a critical responsibility of VAW researchers. The belief that participation will mitigate violence and/or improve their circumstances may be especially likely in contexts where the perpetration of violence is often left unaddressed. Thus, the vulnerability of women in these settings, including added vulnerabilities, such as HIV infection or migrant or disability status, should be considered in relation to what the study offers or is perceived to offer by potential participants. Researchers can minimize the potential for therapeutic misconception by ensuring that the potential benefits and risks of study participation are clearly explained during informed consent and verifying potential participants' comprehension. See the Appendix for sample language.

In a study conducted in Bangalore, India that targeted women experiencing violence, along with their mother-in-laws, the daughter-in-laws were first asked for their consent to recruit the mother-in-law. If and only if she consented was the mother-in-law approached for possible enrollment. If both daughter-in-law and mother-in-law consented, the dyad was enrolled in the study. However, each individual was informed of her right to discontinue participation at any time, independent of the other.



Minimizing Power Hierarchies

In addition to not overstating the therapeutic benefit of the study, researchers should be sensitive to the potential influence of social hierarchies on voluntary informed participation. For example, in many settings, health care workers are treated with respect and deference, and individuals, particularly those who are experiencing violence, may be disinclined to refuse a request made by health care workers. Individuals obtaining informed consent should be trained to minimize these power hierarchies. This may be through standards of behavior or appearances, such as dress, jewelry, or mode of transportation, that can lessen social differences. Another strategy that may mitigate these power hierarchies is to recruit staff who are similar in sociodemographic background to the study population.

In addition to the previously mentioned strategies, those involved in overseeing the research, such as PIs/Research Managers should

- **Monitor enrollment and retention among enrollees, or subgroups of enrollees**, as unusually high enrollment may suggest problems with the informed consent process, including undue inducement.
- **Observe interactions between study staff involved in obtaining informed consent and potential participants** to ensure that interactions are respectful and adhere to approved protocols.

It is important to keep in mind that coercion can take on more nuanced forms than direct pressure or force. Subtleties in the way that staff interact with participants during procedures, such as informed consent, may create a sense of pressure among a population already vulnerable to psychological coercion.

A Shared Process of Safe, Informed Consent

Although participants should ultimately be properly informed and empowered enough to make their own determination as to whether it is safe to consent to study participation, this process may be shared with the research team. As an added measure to ensure a participant's ability to voluntarily and safely consent, some research teams have used tools or additional staff to assess the safety of individual participant's circumstances.

For example, a Population Council study involving routine IPV screening and referral protocols used a hospital-based psychologist to assess consenting respondents' psychological readiness to be interviewed. The underlying idea was that as violence is likely to have been experienced at different time periods for respondents identified through a screening process, those who had a more distant IPV encounter will demonstrate a different level of psychological readiness than those who had a more recent IPV encounter.

Alternatively, another University of Melbourne study developed a risk assessment tool that accounted for a participant's individual risk factors and other contextual circumstances (e.g. housing, legal, mental/physical health, support system) to categorize women into high, medium, and low risk. Although not required, tools such as these may be used to further discuss possible risk with potential participants, such that they too can make a more informed decision (18).

C Protecting confidentiality is essential to ensure both women's safety and data quality.

In addition to challenges discussed previously related to maintaining the confidentiality of the research topic, especially in intervention studies involving other members of the woman's social network, studies on health-based interventions to address VAW bring additional challenges and considerations related to protecting the participant's confidentiality.

Protecting Participant Confidentiality when Involving Couples, Families, or Communities in the Intervention and/or Research

Protecting participant confidentiality involves issues similar to those discussed in the section above on maintaining confidentiality of the research topic (recommendation "a" *Putting Women First*). In addition to the recommendations outlined above, partners, family, and/or community members should be asked to respect the confidentiality of all research participants. This may be especially important in group-based interventions or when using focus group discussions as part of data collection. In such cases, intervention research participants may be requested to avoid sharing details regarding other participants. Such confidentiality requests are often made in the context of qualitative research using focus group discussions. The need for confidentiality should be reaffirmed on an ongoing basis and participants should be asked to acknowledge their responsibility to respect the confidentiality of others.

As noted above, researchers should be cognizant of their limitations to protect participants' confidentiality, and should explain these limitations to potential participants during the informed consent process. Researchers may be legally required to report certain types of violence to relevant authorities although this reporting may conflict with the ethical obligation to protect participants' confidentiality and respect their autonomy (see section on *Special Considerations Related to Mandatory Reporting Requirements*). It is essential that researchers understand and appropriately plan for situations in which mandatory reporting requirements may apply recognizing that different standards apply across countries

Protecting Participant Confidentiality During Follow-up and Retention Activities

Intervention studies typically involve following up on individuals and multiple interactions, leading to an increased risk of breaches in confidentiality. As such, researchers should take into account the risks associated with each study-related interaction—keeping such interactions to the necessary minimum—and taking precautions to minimize potential breaches in confidentiality. Recommendations for protecting the safety of participants during follow-up and retention activities are discussed in more detail below, but broadly include

- **establishing safe methods and times** to receive follow-up contact or messages,
- **identifying alternative trusted contact options** in cases when participants are unreachable, and

Researchers in South Africa faced an ethical and legal dilemma when an interviewee voluntarily disclosed incriminating details of child murder. South African law obligated adult citizens, including researchers, to report cases of child maltreatment to authorities, and the interviewee's second surviving child remained at potential risk. In this particular case, it became necessary for researchers to breach participant confidentiality to fulfill their legal duty and minimize harm to greater society (19).



- **using an agreed upon script and code words** (e.g. security question or a phrase that not many people would know) for messages and/or home visits (if acceptable) (15, 16, 20, 21).

All of the above strategies should be discussed with participants upon enrollment and reassessed at regular intervals (in line with ongoing consent). Researchers should also keep in mind that strategies may differ depending on the context in which follow-up (e.g. phone, mail, in person) occurs.

Establishing Safe Methods and Times for Contact

Participant follow-up may occur over the phone, via mail, or in person depending on the circumstances and needs of the research team. Regardless of method, participants should be consulted about the safety of each option and informed about when these points of contact will or can be used safely. For example, although the proliferation of cell phones in low- and middle-income countries has facilitated the follow-up of research participants, it has introduced new risks. When considering follow-up by phone, study staff should confirm a woman's level of cell phone access and use; possible monitoring of her phone by a partner; and whether the phone is shared with anyone else and if so, with whom, to minimize the potential for breaches in confidentiality (22). In addition, staff should discuss whether specific times of day are safer than others for these contacts (e.g. while partner is at work) and should maintain flexibility in their own work schedules to accommodate these needs.

Identifying and Using Safe Contacts

Over the course of an intervention study, research teams may encounter situations in which a participant is unreachable. In VAW intervention research, this may be because of specific constraints faced by women experiencing violence (e.g. such as the need to change residence during the course of the study because of violence) or other reasons. Regardless of the reason, VAW researchers must take special care to identify safe contacts and use these in an ethical and safe manner.

A review of retention among longitudinal survey studies with abused women conducted in the United States recommends obtaining six safe contacts and suggests that close relatives are best, followed by neighbors, friends, and colleagues (23). However, the cultural context and physical environment should be carefully considered when requesting such information, as the number and type of contacts viewed as "trusted" may differ by setting.

Regardless of the level of trust a participant has in a contact, participants should be made aware that external contacts will only be used in rare instances when study staff have made repeated unsuccessful attempts to locate the participant. In these instances, staff should avoid sharing information about the research and the participant with any of the contacts (15, 23). See the Appendix for example language regarding obtaining and using these contacts.

Using Scripts and Code Words

Even in the absence of disclosing research details, in certain settings, contacting neighbors or others in a woman's community may spark rumors that could potentially result in a breach of confidentiality or cause harm. Thus, regardless of the chosen location or method of follow-up (i.e. phone, mail, or in person), researchers must take additional precautions to reduce the risks involved in each contact. Developing and role-playing scripts (as previously described in the section on maintaining confidentiality of the research topic) to be used during interactions with both the participant and other contacts may help increase staff ease with these approaches and avoid mistakes leading to disclosure of participation (15). In addition, when using phones as a point of contact, pre-established codes or security questions should be used to determine whether the correct individual has been identified and is able to safely talk over the phone and in instances where a phone call is interrupted (22).

Additional Strategies when Conducting Follow-up in the Community

Although the need for in-person follow-up is becoming less likely as more and more women have access to cell phones, there may still be instances when it is required. In these instances, researchers should take additional precautions to avoid risks of disclosure. Additional strategies include conducting community meetings in advance of the study to introduce the staff and broader purpose of the study (e.g. to promote women's or families' health) as well as recruiting staff who are from or familiar with the study communities, which may reduce rumors resulting from their activities in the community. However, this decision should be balanced with other confidentiality concerns such as discomfort among participants about sharing their experiences of violence with a known member of their community. In these cases, staff may require additional training and supervision on confidentiality protections because of their relationships and familiarity with the study communities. In addition, requiring staff to take an oath of confidentiality can increase the weight of and adherence to confidentiality protection protocols.

An alternative, and perhaps preferable, solution to hiring staff from the research community is to hire staff from similar nearby communities. This may allow for increased familiarity with the community setting, but without raising ethical concerns associated with staff who live in the same community as participants.



Confidentiality in Health Care Settings

Studies conducted in a health care setting offer several advantages in terms of confidentiality protections. For example, researchers may be able to use health center telephones and/or staff from the health center to follow up with participants under the guise of a routine health care follow-up subsequently reducing the chance that the phone number or individual making the contact is viewed suspiciously by participants' partners or others in their social network (16, 23, 24). Furthermore, women may have the opportunity to visit a health center with little scrutiny from others. However, other risks remain that should be addressed. For one, the health center staff may be known to the woman in her personal life (e.g. friends, family members, neighbors), which can raise issues of confidentiality. Staff should be prepared ahead of time as to how to handle these circumstances (e.g. with use of scripts, code words). Finally, it should not be assumed that women's visits to a health care provider will go unquestioned, especially if women are required to attend at greater frequency than they would otherwise. For example, a recent study assessing the experience of IPV among female participants in an HIV prevention trial, suggested that receiving calls from health centers or visiting the center without approval of their male partner, resulted in threats and actual occurrence of violence (25). As such, women should always be prepared by the study team to respond to questions from family members or others regarding where they are going and why they are going with a certain frequency, and should be consulted regarding safe practices for contact (as described above).

d All research team members should be carefully selected and receive specialized training and ongoing support.

The provision of an intervention changes the nature of the relationship between researchers and participants and increases researchers' obligations to participants. As a result, new considerations for training and supporting study staff arise in the context of intervention research. These considerations are highlighted below. Researchers are also encouraged to review Chapter Ten: Building Your Research Team from the WHO document *Researching Violence Against Women: A Practical Guide for Researchers and Activists* (2). This document provides detailed guidance regarding staff selection, training, and support that are applicable to intervention research settings.

Division of Counseling and Research Roles

Although the division of counseling and research roles often may be considered a methodological issue, in that separating these roles reduces a potential source of bias, it also poses ethical issues. For one, as *Putting Women First* highlights, researchers are obligated to collect the most valid data possible, which includes an obligation to reduce bias. Furthermore, blinding staff who are providing counseling or other intervention components may be necessary to protect women's confidentiality. In Kotch's longitudinal survey study on maltreatment, social workers who were employed as project staff were

blinded to information on abuse that they would be legally required to report. The key motivation for blinding was respect for participants' confidentiality (other reasons are detailed in the final section of this document in *Special Considerations Related to Mandatory Reporting Requirements*). Blinding was accomplished by placing the most sensitive interview questions at the end of the face-to-face interview questionnaire booklet. At the end of the face-to-face interview, staff were instructed to provide the booklet to the participants who would circle their answers after staff verbally read the questions. The booklet was then sealed with tape and was only opened at the project's central office by staff other than the social workers/interviewers. These data were separated from any identifying information and entered by a different set of staff. Increased confidentiality around the issue of abuse allowed data collectors, despite being social workers, to maintain a greater distinction between their roles as researchers and service providers (26). This approach was feasible because data collection was quantitative, participants were literate (though visuals/symbols could be used for illiterate populations), and the study did not involve testing an intervention in response to maltreatment. As such, social workers were not called upon as part of the research design to provide counseling to participants.

In studies testing or evaluating an intervention, particularly those in which the intervention being tested includes a counseling component, the separation of these roles becomes more challenging. The study size and budget may not allow for hiring additional staff for data collection. In addition, it may not be feasible to separate these roles in studies that test the effectiveness of interventions delivered by health care providers. For example, studies that evaluate different screening or case identification protocols in health care settings typically involve health care providers implementing the protocols, recording information on the outcomes of interest (e.g. numbers of women who disclose experiencing violence), and engaging in appropriate responses. Nevertheless, thoughtful mechanisms that create divisions between counseling and research roles in intervention-based research should be considered, as well as close monitoring throughout the study to ensure that staff adhere to protocols.

Jack's suggested guidelines for nurse-researchers to reflect on this conflict of roles when conducting qualitative research provide several thoughtful considerations that are useful in this context. They include

- **establishing appropriate boundaries with participants** (e.g. around self-disclosure or sharing of personal values, beliefs, or opinions of the researcher);
- **being thoughtful about how the role of researcher is described to the participant**, taking into consideration participants' beliefs about certain clinical roles; and
- **predefining when it is appropriate to intervene within the research context** (27).

As the final point suggests, this need for separation should never prevent researchers from ensuring that participants receive counseling and other support services when needed. Establishing a protocol to respond to participant distress can aid in clearly defining, in advance, when intervention is appropriate, and describing to participants the division of this response from the research.

Distress and Disclosure Protocols

The SARAH study, a study conducted at the University of Melbourne with children of women experiencing domestic violence, includes the following steps to guide researcher responses in cases of distress (18):

1. When distress is detected, inform the participant that the research process has been suspended and that she will use her professional skills as a counsellor to provide brief counselling support to alleviate any distress.
2. Provide and/or refer participant for support.
3. Discuss appropriateness of continuing the research process either then or on another occasion, or to opt out of the project altogether.
4. If continuing with the research, inform the participant that she is resuming her role of researcher and that this process of interrupting the research process can be repeated if the woman or child becomes distressed again or does not want to continue for any reason.

One consideration researchers may want to make is the background training of potential research team members. In Kotch's study, social workers were hired to serve as data collectors. However, there may be instances when hiring individuals with extensive experience in violence-related service provision to fill a research role creates challenges for rigorous intervention study implementation. Similar to therapeutic misconception on the part of participants, staff who are used to providing services and view them as therapeutic may find it difficult to follow a research protocol that limits the extent of intervention in terms of individuals (intervention vs. control group) or services. Special efforts may be needed to ensure that these staff understand and are comfortable with maintaining a distinction between research and service provision roles during the study and implementing all aspects of the research protocol. This is particularly important to avoid falsely conveying to participants that the intervention is intended to be therapeutic rather than under evaluation, but also has implications for data quality and implementation rigor. If the protocol requires aspects such as randomization, which these individuals feel uncomfortable implementing, they should not be considered for a research role. Again, although staff should always be empathetic to women's experiences and be trained to help women access support, maintaining a distinction between research and intervention roles is important to ensure that researchers' ethical obligation to collect rigorous evidence is met.

Additional Areas of Training

Given that research team members may spend a significant period of time with participants dealing with very intimate details of participants' lives, they may require additional skills to cope with and manage their professional roles and relationships. Study training and implementation protocols should address strategies to maintain a professional relationship with participants and handle situations that might arise if a research team member leaves the study. McFarlane and Wiist describe how the termination of the relationship between the research team member and the participant, whether because of staff leaving the study early or the natural end of the study, may be particularly challenging and require special training and support. In the context of their advocacy-focused intervention study that included multiple interactions, including home visits, between participants and their "mentor mothers," they found it necessary to incorporate issues of closure in staff training. In addition, the research coordinator offered each "mentor mother" personal assistance in this process as the study drew to a close (28).

SUMMARY OF TRAINING NEEDS

Timing: At study start-up and according to a well-defined schedule of refresher trainings (some researchers do this as often as every 6-8 weeks).

Topics:

- Maintaining confidentiality through extensive role-playing of scenarios and scripts
- Conducting on-going consent
- Minimizing power dynamics between staff and participants
- Maintaining division of research and intervention roles
- Managing social network relationships
- Managing repeated acts of violence
- Preparing for closure of the research relationship with participants.

Studies involving couples, families, or other members of a participant's social network also require training specific to handling relationship dynamics, including how to handle group dynamics in such a way that confidentiality is promoted and protected (15). Role-playing a variety of scenarios during training that may arise in group settings can also strengthen staff's ability to respond to these dynamics.

Finally, since over the course of a study researchers may encounter new or continued reports of incidents of violence, they should be trained in how to respond and process those repeated acts of violence (29) as laid out in safety protocol procedures (discussed later in this document). Depending on the length of the study, refresher trainings will likely also be important to re-emphasize safety, ethical, and confidentiality procedures, among others.

Assessing and Addressing Need for Staff Support

As *Putting Women First* highlighted, staff involved in research on VAW may not be immune to experiences of violence. This violence may occur or have occurred in their personal lives regardless of their employment with the study and/or may occur as a result of their employment. We emphasize the recommendations highlighted in *Putting Women First* here because of the importance in maintaining continuity of the research team. If left unaddressed, research projects may experience high rates of staff attrition, which given the intense training needs and the need to build trust with participants, can negatively impact the quality and thus the safety of VAW intervention research. Recommendations include offering opportunities for staff to come to terms with and address their experiences of violence. In some cases, staff may need to be reassigned to different job duties; for example, staff who are responsible for intervention implementation may find it emotionally challenging to do so when dealing with their own experiences of violence. PIs may need to assess the scale and source of the conflict to adequately respond and consider the confidentiality of the staff member. For example, if conflict occurs as a result of the staff member's earnings, appropriate solutions may include helping the staff member set up a separate bank account where wages can be provided in a more discrete manner. Ideally, staff should have opportunities to discuss personal issues with the study's PI or Research Manager and have access to external support services. The provision of external services are especially important considering the fact that staff may not always feel comfortable discussing personal issues with their colleagues or supervisor. Moreover, PIs may not always be readily accessible (i.e. in the same location as the staff), and supervisors may not always have the skills or resources to fully address staff needs in this area.

In addition to staff experiences of violence within their own families, they may be at risk of violence from individuals perpetrating violence against study participants. *Putting Women First* recommends logistical planning to increase interviewer safety such as traveling in pairs, carrying mobile phones, using a designated means of transport, and keeping supervisors abreast of their whereabouts. Researchers should identify an immediate plan of action and sources of support in the event that violence occurs. In addition to using community-based services identified as referral sources for participants (see the following section), developing a community advisory board that can identify potential challenges and mobilize to support staff in cases of danger is one way to proactively address this concern. When considering the composition of the board, researchers should look for women and men who are respected in the local community and individuals who could potentially step in to mediate issues of staff safety. Expectations around board members' role in mediating issues of safety should be discussed in advance.

Finally, research experience suggests that VAW research team members may experience trauma, either physical or emotional, simply as a result of being exposed to participants' experiences of violence. Described as vicarious trauma, the risk of this form of trauma among research team members may be increased by the increased number and level of interactions with participants in intervention research or decreased through the opportunity to offer women an intervention that may mitigate their experience of violence. Regardless, PIs/Research Managers should prepare their staff for the possibility of experiencing this form of trauma and put in place measures to mitigate its occurrence. This should include acknowledging the issue during training, preparing team members to identify early warning signs, developing and using self-care strategies, and engaging with additional support systems and services, such as debriefing opportunities and access to counseling, provided through the study (described above). The Sexual Violence Research Initiative Researcher Handout on vicarious trauma offers additional detailed suggestions on responding to this issue, including forms of self-care and how to structure debriefing opportunities (30, 31).

f Fieldworkers should be trained to refer women requesting assistance to available local services and sources of support. Where few resources exist, it may be necessary for the study to create short-term support mechanisms.

Once again because of the potentially longitudinal nature of intervention research, the responsibility of the research team, as well as the opportunity they have, to refer women to additional services and sources of support may be increased. Depending on the length of the study, this increased responsibility and opportunity may necessitate additional actions to keep up to date the research team's knowledge of resources and relationships with referral service providers. Thus, refresher visits and contacts with service providers by the research team are recommended on a regular basis (e.g. quarterly). If no referral services exist, researchers have an ethical obligation to ensure that the research team has the capacity to handle crisis situations, including crisis counseling and safety planning. In addition, because seeking support can be difficult for women experiencing violence, researchers may find that providing a list of referral services is insufficient and that offering assisted or escorted referrals is beneficial. The need to provide escorted referrals may be compounded in settings where access to transportation is a challenge (15, 28), or where on-site care for violence exists, but may be challenging for women to locate on their own (24). However, researchers will need to weigh their ethical obligations to offer support to women experiencing violence against their ethical obligation to maintain confidentiality and to ensure that they are able to evaluate whether the proposed intervention is efficacious. In the former, being thoughtful and taking precautions to avoid disclosure of a woman's participation in a research study during escorted referrals may be warranted.

g**Researchers and donors have an ethical obligation to help ensure that their findings are properly interpreted and used to advance policy and intervention development.**

Putting Women First emphasizes the ethical obligation of VAW researchers to share results and ensure that they are properly interpreted and used for the advancement of intervention and policy development. As noted in that document, dissemination of results to the participants, researchers, service providers, and the general public should avoid stigmatizing or exacerbating risks faced by participants and the vulnerable populations they represent. Unique to intervention research, is the ethical obligation to advocate for the availability of an intervention, should it be proven effective. In line with ethical guidance in the Helsinki Declaration (32) and the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines (33), VAW intervention researchers need to consider what constitutes reasonable availability of an effective intervention to the study population and/or the broader community or country upon completion of the research.

Because ethical obligations are likely to be context specific and have not been extensively discussed within the research literature on VAW interventions or on social and behavioral interventions more broadly, our specific recommendations focus on the processes for determining post-study obligations, rather than suggesting what should be provided. Based on discussions in the biomedical research context, the following are suggested:

- **Research teams undertake consultations with local stakeholders at the study outset** to discuss the health, social, and economic circumstances that may influence expectations and the future provision of interventions.
- **Discuss sustainability/scale-up of effective interventions with study sponsors prior to study launch.** Issues such as the strength of evidence and what, if any, additional data are needed to determine decisions regarding the availability of effective interventions to the study population or the broader community (e.g. city, state, or country).
- **Clarify actions needed to advance adoption and implementation of efficacious interventions** such as establishing links with advocacy groups, strengthening human resources, or providing training.
- **Maintain transparency with all consultations and resulting decisions,** taking care to minimize any unequal power hierarchies between the research team, community members, and participants (34-36).

Researchers' level of responsibility to undertake these processes will of course be, in part, dependent on the intent of the research. If the intent is to investigate the effectiveness of an intervention, as opposed to earlier phases of intervention research (e.g. feasibility testing), then the obligation to undertake these steps will be increased. Also of note, VAW intervention researchers will have to take care in this process to avoid negating confidentiality protections being used in the community context. Thus, special care regarding who is involved in this process and what is said will be necessary.

DECLARATION OF HELSINKI

Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a nonvulnerable group. In addition, this group should stand to benefit from the knowledge, practices, or interventions that result from the research.

CIOMS INTERNATIONAL ETHICAL GUIDELINES

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that

- the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out; and
- any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

New Recommendations for Intervention Research

1. Intervention studies need to be methodologically sound and build upon the current evidence base of interventions and intervention research experience.

5. Measuring and monitoring harm related to the research should be incorporated into safety protocols.



2. Processes and criteria for participant recruitment should be carefully considered to avoid excluding women who may not initially disclose experience of violence.

4. The provision of services to comparison arm participants should maintain an ethically sound standard of care.

3. Participant randomization should be transparent and described in a way that can be easily understood by those involved in the research.

Along with the considerations discussed previously, conducting intervention research on VAW entails several new ethical considerations.

1 Intervention studies need to be methodologically sound and build upon the current evidence base of interventions and intervention research experience.

Similar to guidance provided in *Putting Women First* recommendation “b,” intervention studies should be methodologically sound and build on the existing evidence base. However, intervention research has the added responsibility of drawing from both research and programmatic experience to avoid repeating ineffective and potentially harmful interventions. In addition to considering whether interventions have previously been tested, intervention research teams must ensure that a particular strategy is tested in a methodologically sound manner. This includes maintaining fidelity to key intervention components (if previously evaluated), with appropriate, well-documented adaptations to the specific context in which it is being tested. A badly implemented intervention study is a lost opportunity to build the evidence base around effective interventions to prevent VAW and a waste of scarce resources. Moreover, it may put participants in direct harm. In particular, this may be a concern when replicating evidence-based strategies to address VAW from high-income countries in lower-income settings without taking into account contextual differences, including in the availability, or lack thereof, of support services (3).

Considering the current lack of evidence around what works to prevent VAW, research teams may need to incrementally build evidence to support larger scale testing of promising approaches. In doing so, researchers should use a phased approach to designing their studies, including when adapting existing interventions to new settings. The Medical Research Council of the United Kingdom and of South Africa have published guidance on these phases of research as they relate to developing and evaluating complex interventions. Phases include (a) thoughtfully developing the intervention; (b) conducting pilot, feasibility, acceptability, and/or safety testing; and finally (c) evaluating the intervention for efficacy and/or effectiveness. Approaching research on innovative interventions in this phased manner allows researchers and interventionists to carefully consider and identify issues of safety and unintended consequences on a smaller scale before exposing large numbers of women to a yet untested approach (37). Once researchers reach the efficacy or effectiveness evaluation stage, a variety of study designs, including randomized controlled trials and alternative randomized design approaches, such as stepped wedge and wait list designs that retain critical elements of methodological rigor (38), may be considered. Research teams should choose a design that is feasible as well as ethically appropriate, keeping in mind their responsibility to generate rigorous evidence. Designs that allow for delayed provision of the intervention to control-arm participants may help overcome resistance among stakeholders and/or research ethics committee review boards to testing an intervention that is widely perceived as beneficial, even if not yet proven beneficial.

FACTORS TO CONSIDER IN RECRUITMENT STRATEGIES

Focus of intervention study: Eligibility criteria for study recruitment will vary depending on whether the intervention that is being tested aims to prevent the first occurrence of VAW or mitigate VAW and its adverse health consequences. For studies that aim to test an intervention’s effectiveness in preventing the initial occurrence of violence, recruiting women who experience violence may not be necessary or appropriate.

Location of study: In certain settings, physicians routinely screen women for experience of domestic violence. In these cases, researchers can contact physicians to ask for their help in recruitment. Although it would be unethical for the researchers themselves to approach the women with such information, initial contact could be made by the physician or nurse who has access to the information about violence.

2

Processes and criteria for participant recruitment should be carefully considered to avoid excluding women who may not initially disclose experience of violence.

As research experience has indicated, given the sensitive nature of the topic of violence, many individuals may not immediately disclose their experiences of violence. Depending on the nature of the intervention and the context in which it is to be tested, this has implications for how researchers recruit women. Research teams have an obligation to ensure that intervention research reaches those most in need. However, in settings where there may be under-reporting of VAW, it may be difficult to identify these individuals. This challenge may be especially acute when recruitment activities occur outside of settings where women seek support for or are routinely asked about violence (e.g. health care settings in the United States). Thus, researchers must consider how, when, and what measures should be used to determine risk or exposure, if required to recruit only women who report having experienced violence. Drawing from lessons outlined in recommendation “b” of WHO *Putting Women First*, researchers should avoid loaded terms when asking about violence; carefully consider the context of recruitment, including who is present; and consider the gender, skills, and attitudes of those hired to recruit participants.

Researchers conducting intervention studies may have the opportunity to develop a multistep screening process, such that violence is not mentioned or used as an eligibility criterion at initial screening, but rather at a later point in time. This may offer staff and potential participants an opportunity to establish rapport and increase women’s willingness to disclose. In contexts where disclosure of violence is more common, or if a multistep screening process is not feasible, researchers should, at a minimum, ask questions about violence further into the screening questionnaire. Other strategies to increase disclosure include

- **asking questions in multiple ways** (e.g. both directly and indirectly)
- **asking questions multiple times** during the screening questionnaire.

For standard examples of how to ask about violence in a way that maximizes disclosure, researchers are encouraged to consult the *WHO Multi-country Study on Women’s Health and Domestic Violence Against Women: Initial Results on Prevalence, Health Outcomes, and Women’s Responses* (39).

Alternatively, if evidence exists demonstrating a sufficiently high incidence of VAW in a given population or setting, researchers may consider not using disclosure of violence as a criterion for eligibility (15, 40).



WEAVE, an Australian study designed to enhance general practitioners ability to respond to domestic violence, used a two-stage screening process to recruit participants. The first stage involved a questionnaire mailed to participants. Numerous questions were asked regarding health topics, from alcohol use to smoking to depression, with questions on violence buried among these other topics. The second stage involved a call from a research team member who again emphasized the contextualization of the issue of violence within broader emotional health (41).

3 Participant randomization should be transparent and described in a way that can be easily understood by those involved in the research.

The strongest research designs invariably include a comparison (control) group to clearly understand and measure changes that occur as a result of an intervention. Although deemed necessary to more conclusively understand intervention efficacy, randomizing participants to a control group may raise ethical concerns, particularly when all participants are identified as needing intervention of some sort. This dilemma, however, is not exclusive to the case of VAW intervention research, although many of the issues described above, including the particular vulnerability of this population and the possible expectations of participants in these circumstances, make this issue worthy of extra consideration. Attending to this issue may include considering alternative randomized study designs, such as the stepped wedge or wait list designs that incorporate provision of the intervention to control participants at a later point (as described above) (42, 43). Regardless of study design, when randomization is employed, research teams should inform potential participants about what level of access to the intervention may be expected after the duration of the study (as discussed in the section on post-study obligations). The randomization rationale and process should also be transparent and described in such a way that can be easily understood by everyone involved in the research, from the study staff to the participants. A common approach is to describe randomization as a lottery where the opportunity to receive the study intervention is decided by chance (44-46).

4 The provision of services to comparison arm participants should maintain an ethically sound standard of care.

If deemed feasible and ethically sound and appropriate to randomize participants to a control group, researchers must ensure that an ethical standard of care is provided to these individuals. As recently outlined in ethical guidance on the conduct of cluster randomized trials, the delayed provision of an intervention being tested to control arm participants does not justify the lack of provision of services known to be effective to all participants (47). Following recommendations above related to providing support, researchers conducting intervention research have an ethical obligation to offer support to women experiencing violence. At a minimum, research teams should be prepared to address crisis settings, including by offering crisis counseling, safety planning, and/or contact information for referral services (48). In settings where referral services are unavailable, local capacity to provide crisis counseling and safety planning should be developed and these services should be made available to all participants.

5 Measuring and monitoring harm related to the research should be incorporated into safety protocols.

Researchers have an ethical obligation to monitor and measure harms or threats of harm that may occur during the conduct of a study and determine what, if any, experiences result from research participation. Drawing on clinical research experience and guidelines on tracking adverse events and social harms, VAW intervention research teams need to determine up front what and how they will measure, report, and respond to these issues. Although any potential harm that comes to the researchers' attention should be documented, a case-by-case approach will be necessary to determine whether the incident is study related and what, if any, follow-up actions are needed. Complicating researchers' ability to determine which events are study-related is the fact that the study population is likely to be at risk of violence even in the absence of the research. Thus, it becomes particularly important that researchers anticipate and define a process for documenting, investigating, and responding to safety issues and incidents (See the Appendix for an example of a documentation form). Level of severity should also be taken into consideration. For example, while general mental distress may not warrant further investigation because of the baseline levels of distress experienced by the study population, serious threats of suicidal intention or attempts are situations to which research teams should be prepared to respond. Asking women periodically whether they feel more, less, or the same level of threat in terms of their personal safety may be another way to assess the safety of the intervention. Finally, researchers should build in regular, formal reviews of data through the use of a Data Safety and Monitoring Board (DSMB) that can help assess differences in severity and frequency of violence between control and intervention arm participants or over time, if no control group is used.

Special Considerations for Research in Antenatal Care Settings

Research on interventions to address VAW has focused and is likely to continue to focus on antenatal care for several reasons. First, there is considerable evidence from around the world indicating that violence is common during pregnancy (49), and that violence has severe consequences for the health of women and children (50-55). Second, concerted efforts to improve maternal and child health globally have resulted in high utilization of antenatal care services; these services offer a window of opportunity to prevent, identify, and respond to violence. Health care settings can provide a safe and confidential environment for violence interventions under the guise of health promotion. As such, interventions in this setting also bring unique ethical considerations because of the pregnant status of women. In this setting, researchers must be prepared to address the potential increased risk of preterm birth and pregnancy loss and have mechanisms in place to determine if the event is study related (see section on monitoring adverse outcomes). For those studies where recruitment of pregnant women occurs outside of the antenatal care setting, researchers should ensure that women are aware of antenatal care recommendations and where and how to access these services and other services of relevance. For example, the research team should be prepared to provide referrals to services such as HIV testing, voluntary counseling and testing (VCT), and other related referrals, given the high overlap between these issues (56, 57).

Finally, although it is not within the scope of this document to review detailed considerations in terms of the ethics and safety of child participants, these may also be of importance when VAW intervention research conducted with pregnant women extends beyond the perinatal period and/or includes data collection on the infant/child. As such, it is recommended that researchers consult additional resources, such as the report published by the global Child Protection Monitoring and Evaluation Reference Group (CP MERG), *Ethical Principles, Dilemmas, and Risks in Collecting Data on Violence Against Children* (6).

Recruiting during Antenatal Care

Although antenatal care offers a unique window of opportunity to recruit women who may be experiencing violence, researchers should also be aware of potential safety challenges. Male partners, sometimes potential perpetrators, may accompany their female partners to the clinic. In South Africa, this is especially the case for migrants who may have language barriers. In these cases the male partner may attend specifically to serve as an interpreter. Being cognizant of the presence of any potential perpetrators, researchers should avoid conducting any activities related to recruitment, screening, or other study activities within the waiting rooms or in any areas that may be obvious to others. Furthermore, external translators should always be used.

Special Considerations Related to Mandatory Reporting Requirements

In the course of VAW intervention research, staff may become aware of certain types of safety risks or violence that they may be legally mandated to report to relevant authorities. For example, a participant may disclose an intention to engage in self-harm or harm to others or an experience of sexual assault. Alternatively, given the co-occurrence of domestic violence and child maltreatment (58), information pertaining to the safety and well-being of participants' children (e.g. the incidence of child physical or sexual abuse) may come to light during the course of the research. Researchers' legal obligations to report this information may conflict with their ethical obligations to protect participants' confidentiality, respect their decision-making autonomy, and ensure additional protections for vulnerable groups such as children.

Researchers should anticipate and be prepared to address these situations. They should:

- **Ensure an appropriate and timely response**, such as referrals to or the provision of crisis counseling, safety planning, or child care services.
- **Be aware of relevant local reporting laws and procedures** as well as the likely implications and outcomes of reporting.
- **Develop a plan to handle issues related to mandatory reporting requirements**, including strategies to minimize the possibility of collecting certain kinds of information.

- **Explain to potential participants during the informed consent process of the researchers' obligation to report certain incidents** (See the Appendix for example language).

In some cases, researchers may feel that reporting may lead to increased risks to the woman and/or child. For example, reporting may increase a woman's risk of violence or lead to a child being placed in an institution where she/he is even more vulnerable to abuse or neglect. In such situations, researchers should ensure that their actions are in the best interest of the individual concerned and that they base their actions on the principle of nonmaleficence.

The decisions made by researchers conducting a longitudinal survey study of maltreatment of women and children in the United States are illustrative of this issue. The study team realized that 1) the majority of reported cases of maltreatment are ultimately not substantiated by the legal system, 2) that reporting may put the child at risk by angering the accused family members, and 3) that even if successfully proven, interventions themselves may have negative long-term consequences. Thus, they limited data collectors' chances of identifying cases that would require mandatory reporting by minimizing their access to sensitive data and training interviewers to strictly adhere to structured questions (26).

Conclusion

In light of the global statistics on the prevalence of VAW and the large body of evidence that demonstrates the myriad adverse impacts of violence on the health and well-being of women and children (39, 49, 59, 60), it is imperative that attention and resources be focused on the identification of effective approaches to prevent and mitigate violence. Investments in generating evidence on what works to prevent violence are in fact increasing (61–63), and health-based interventions comprise an important and growing category of work in this area. As noted in the WHO’s *Putting Women First* guidance, ensuring that research on VAW is conducted in an ethical and safe manner is of the utmost importance. *Putting Women First* also provides a comprehensive description of issues that VAW research teams should consider in designing and implementing their studies. However, additional ethical and safety challenges arise in the context of research on interventions to address VAW because it is often longitudinal, raises specific kinds of expectations among participants and communities, and may not only involve women but also engage members of their family, social network, and community. Moreover, since the focus of intervention research is likely to be on women who are at higher risk of experiencing violence, monitoring safety can be especially difficult because of the need to untangle baseline and study-related risks of violence. Existing ethical and safety guidelines do not address these particular challenges associated with conducting research on interventions to prevent and mitigate VAW.

Using the existing literature and consultations with experts in the field, we have summarized additional ethical and safety challenges associated with research on health-based interventions to prevent and mitigate VAW and offer recommendations to research teams on how to address these challenges. The recommendations offered in this document fall into two broad categories: additional considerations related to recommendations provided within *Putting Women First* and new recommendations associated with challenges that can arise specifically in the context of VAW intervention research (see Table 1). As with all recommendations, research teams will need to interpret the information contained herein within the context of their research questions and setting. Finally, given the relatively new focus of the field on intervention research, we recognize that these recommendations will need to be updated as additional experience is gained. As such, we hope this will be a growing resource for future research teams. If you would like to contribute your own experiences to future editions of this document, please send your suggested contributions to the authors: Suneeta Krishnan (skrishnan@rti.org) and Miriam Hartmann (mhartmann@rti.org).

Table 1. Summary of Recommendations for VAW Intervention Research

Additional Considerations to Recommendations from <i>Putting Women First</i>
a. The safety of respondents and the research team is paramount and should guide all project decisions.
<p>Confidentiality of research topic</p> <ul style="list-style-type: none"> • Consider research/intervention title and description so that it avoids a focus on violence. • Pay attention to questions each type of participant is asked to avoid disclosure of topic. • Develop standardized scripts for staff and participants to respond to questions. • Monitor community responses to research, particularly awareness of violence as research focus. <p>Participant consent</p> <ul style="list-style-type: none"> • Institute regular process of ongoing consent. • Use staff not conducting the intervention to confirm consent. • Have PI confirm ongoing consent with subsample (optional). • When research involves members of a woman’s social network as part of the strategy to address violence, offer women experiencing violence an opportunity to make informed decision about their recruitment. • Ensure risks/benefits are fully explained and verify participant comprehension to minimize therapeutic misconception. • Minimize power hierarchies by setting standards of dress, behavior, and/or by hiring staff of similar socioeconomic background. • Monitor enrollment rates among enrollees, or subgroups of enrollees. • Observe interactions between staff obtaining informed consent and participants.
c. Protecting confidentiality is essential to ensure both women’s safety and data quality.
<p>Confidentiality of participants</p> <ul style="list-style-type: none"> • Reaffirm need for confidentiality continually. • Ask participants to acknowledge their responsibility to respect confidentiality of others. • Communicate limits of researchers’ ability to respect confidentiality of participants (e.g. mandatory reporting requirements). • Identify safe methods and times for participant follow up and assess on an ongoing basis <ul style="list-style-type: none"> » Confirm privacy levels of cell phones » Identify trusted contacts » Pre-arranged script and code words to ensure safety/in case of interruption.

Table 1. Summary of Recommendations for VAW Intervention Research (continued)

d. All research team members should be carefully selected and receive specialized training and ongoing support.

Division of roles

- Establish appropriate boundaries and explain staff roles to participants.
- Predefine when and what type of intervention is necessary and acceptable through a protocol for responding to participant distress
 - » Delineate to participant when acting as researcher vs. counsellor
 - » Emphasize distinction of research and service roles to staff.
- Consider background training of staff hired into research roles.

Additional staff training

- Offer strategies for maintaining professional relationships with participants.
- Train staff on handling relationship/group dynamics.
- Train to respond and process repeated acts of violence.
- Conduct refresher trainings on safety, ethics, and confidentiality procedures, among others.

Support services for staff

- Offer opportunities for staff to come to terms with and address their experiences of violence.
- Offer opportunities for staff to discuss personal issues with PI/Research Manager.
- Offer access to external support services.
- Make logistical plans to ensure interviewer safety (e.g. travel in pairs, carry mobile phones, designate means of travel).
- Develop community advisory board to mediate potential issues of staff safety.
- Normalize potential for vicarious trauma and offer strategies to mitigate its experience.

f. Fieldworkers should be trained to refer women requesting assistance to available local services and sources of support. Where few resources exist, it may be necessary for the study to create short-term support mechanisms.

Support services for participants

- Maintain staff knowledge of referral service providers through regular (e.g. quarterly) visits and contacts.
- Build capacity to handle crises as needed while maintaining confidentiality (e.g. train local providers, offer escorted referrals if transportation is difficult).

g. Researchers and donors have an ethical obligation to help ensure that their findings are properly interpreted and used to advance policy and intervention development.

Determine what constitutes reasonable availability of intervention, if proven effective

- Consult local stakeholders to assess context that may affect intervention provision.
- Agree with study sponsors and other decision-makers evidence needed to make effective interventions more widely available.
- Clarify actions needed for intervention adoption.

Table 1. Summary of Recommendations for VAW Intervention Research (continued)

New Recommendations for Intervention Research
1. Intervention studies need to be methodologically sound and build upon the current evidence base of interventions and intervention research experience.
<ul style="list-style-type: none"> • Draw from research and programmatic experience. • Maintain fidelity to key components and methodology of original study when replicating. • Use a phased approach to build evidence <ul style="list-style-type: none"> » Initial development/concept » Pilot, feasibility, acceptability, and/or safety testing » Evaluation of efficacy/effectiveness.
2. Processes and criteria for participant recruitment should be carefully considered to avoid excluding women who may not initially disclose experience of violence.
<ul style="list-style-type: none"> • Be mindful of recruitment context, people present, and gender, skill, and attitude of recruiters. • Leverage existing networks (e.g. physician-patient relationships). • Use multistep screening process. • Ask questions multiple times and in multiple ways during screening. • In areas of high incidences of VAW, consider foregoing disclosure of violence criterion.
3. Participant randomization should be transparent and described in a way that can be easily understood by those involved in the research.
<ul style="list-style-type: none"> • Consider alternative randomized study designs (e.g. “stepped wedge”). • Describe methodology in accessible terms (e.g. analogy of lottery).
4. The provision of services to control participants should maintain an ethically sound standard of care.
<ul style="list-style-type: none"> • Be prepared to address crisis settings through counseling, safety planning, and/or contact information for referral services. • Build local capacity of services if none are available.
5. Measuring and monitoring harm related to the research should be incorporated into safety protocol procedures.
<ul style="list-style-type: none"> • Define process for documenting, investigating, and responding to safety issues and incidents. • Conduct regular, formal reviews of data to assess fluctuations in severity and frequency of violence.

Appendix: Sample Language

The following examples are included to provide research teams with a general idea of how to operationalize some of the guidance provided within the recommendations. They are not meant to be used verbatim and should be modified to fit the specific context and population of the research.

a) To describe the project as part of larger health study

“[Project name] is a project which is interested in understanding women’s experiences of the health care they receive from their primary provider, particularly in relation to relationship issues and emotional health (such as being afraid of your partner, domestic violence and so on).”

“[Project name] is a family health research project that is going to be conducted by a group of researchers, doctors, and counselors working in the field of health research for more than 5 years. Our research is a collaboration between [name of collaborators]. We have been working to understand and improve women’s health issues such as menstruation, uterus problems, sexually transmitted infections, and relationships between women and men. The research we undertake is to help improve health services for women, families, and the community. We are now planning to conduct programs and research to help improve family health based on health challenges experienced by older women, younger women, and infants.”

b) Standardized phone script for follow-up

Staff instructions: Contact with participants will be made by the designated staff member, by phone, after obtaining agreement from the woman that she may be called at the initial interview. If possible, try to establish with the woman when it is a good time to call her (e.g. when she will be alone). If necessary, a code may be established with the woman to indicate that she is not alone when the research assistant calls.

If the participant is there:

“Hi [Insert Her First Name], my name is [Insert Your First Name]. I am calling you to [mention purpose of the call, such follow-up]. Is this a good time to talk? It will take [indicate an estimate of the time for the call].”

If not a good time to talk:

“When would be a good time for me to call back?”
[Participant offers another time] “Great, I’ll call you back at [Repeat the time back to her]. If by chance I miss you when I call back, may I leave a message with whoever answers the phone or on an answering machine? [Write answer on index card] Very good. I’m looking forward to talking with you, [Insert Participant’s First Name].”

If OK to talk now:

“I would like to [insert purpose of call, such as follow-up on the study].”

On completion of the follow-up call:

“Would it be OK if I call you on [either participant or staff offers a date and time] for the next call? If you are not at home, can I leave a message? [Make notes on index card] I would like to give you a phone number that you can call if you need to leave me a message. You can call our hotline number at any time at [provide number].”

If participant is not home and someone else has answered the phone:

“Hi. May I speak to [Insert Potential Participant’s Name]? [She’s Not There] Okay. My name is [Insert Your Name]. Do you know when would be a better time to call her back? [Wait For Reply]. Thank you. I would also like to leave a phone number for her to call. She can call [provide number] and leave a message of a good time to call her back and I will get back to her as soon as possible or I will just try calling her back later. I appreciate your time. Thank you.” [If the person wants to know more about what you are calling about, use a culturally specific pre-prepared explanation that was determined to be safe (e.g. calling from a health center about a service).]

c) Informed consent comprehension checklist for ongoing consent

Please see Table 2 for the informed consent comprehension checklist for ongoing consent.

Table 2. Informed Consent Comprehension Checklist for Ongoing Consent

	Open-Ended Question/ Statement	Required Points of Comprehension	<input type="checkbox"/>	Comments
1	Please tell me your understanding of the purpose of the study.	[insert key purpose of study; should demonstrate understanding that intervention is not known to produce therapeutic benefits.]		
5	What are the possible risks for continuing in the study?	[insert key risks, e.g. participating in the study may increase conflict in the home]		
6	What will happen if a woman decides to leave the study?	Free to make her own decision about leaving the study		
		No change to her access to health care whether she stays in the study or not		
		Only people working on the study have access to her information		
8	What are the possible benefits for participants in the study?	[insert benefits; e.g. opportunity to discuss experiences]		
9	What should participants do if they have questions or concerns about their health or about what is happening in the study?	Must state how to contact study staff		
<p>Outcome</p> <p><input type="checkbox"/> Demonstrated comprehension of all required points, decided to continue to participate.</p> <p><input type="checkbox"/> Demonstrated comprehension of all required points, decided NOT to continue participation in study.</p> <p><input type="checkbox"/> Did not demonstrate comprehension of all required points (yet), needs more time/discussion.</p> <p><input type="checkbox"/> Other (specify): _____</p> <p>Staff Signature: _____</p>				

d) For addressing therapeutic misconception

“First let me tell you a little bit about the study. We are trying to find the best ways to help women who have been abused by their partners. We are looking at what can be done to help abused women to better manage their health. So this study may or may not help to stop the abuse, but what we find out from doing this study will help other women to manage their health better in the future.”

e) For obtaining safe contacts

“Sometimes we can find it difficult to make contact with people again at later dates for a variety of reasons, such as [insert local relevant reasons (e.g. moving, visiting relatives)]. Would you mind providing the contact details, just first name and best phone number, of [insert appropriate #] people who will always know how to contact you (e.g., a parent, close friend, etc.)? We wouldn’t call them unless we had tried to contact you unsuccessfully on four occasions, and we would state we were calling about [insert contextually safe reason (e.g. health care)]. We would not state anything about the study topic.”

f) Documenting adverse events/social harms

Table 3 provides the form used to document adverse events/social harms.

g) Explaining mandatory reporting requirements around child abuse to participants

[Prior to disclosure, if the participant seems to be moving toward a disclosure of current abuse]: “It sounds like you might want to talk about current issues of violence that are occurring. Before you tell me more about these issues, I want to remind you that if you disclose current child abuse, I may have to inform someone outside of the research process.”

[If following this, the participant does disclose current abuse or imminent risk of harm]: “Thank you for sharing that with me. Like I said, I may need to inform [insert relevant people/groups that need to be informed]. Is the first time you’ve told someone about this? Your safety is my greatest concern, which is why I need to report this.”

Table 3. Form to Document Adverse Events/Social Harms

Adverse Events (AE)/Social Harms Report (SH)	
Instructions: This form is to be completed for any participant who reports an adverse event or social harm. Staff member completes form based on investigation.	
1	Describe the adverse event/social harm: <input type="checkbox"/> Participant declined to describe
2	Date of event onset <div style="display: flex; justify-content: space-around; align-items: center;"> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div> <div style="display: flex; justify-content: space-around; align-items: center; font-size: small;"> dd MMM yy </div>
3	What type of harm is this event? (<i>mark all that apply</i>) <input type="checkbox"/> Physical <input type="checkbox"/> Emotional <input type="checkbox"/> Financial <input type="checkbox"/> Other, specify: _____
4	Did this event include unwanted disclosure of study participation? <input type="checkbox"/> Yes, specify to who: _____ <input type="checkbox"/> No <input type="checkbox"/> Unknown/information not provided
5	What impact did this situation have on the participant's quality of life? <input type="checkbox"/> No disturbance <input type="checkbox"/> A minimal disturbance that had no significant impact <input type="checkbox"/> A moderately upsetting disturbance, but did not have a significant impact <input type="checkbox"/> Other, specify: _____ <input type="checkbox"/> Unknown/information not provided
6	Based on your discussion with the participant and other relevant individuals, was this situation related to study participation? <input type="checkbox"/> Yes <input type="checkbox"/> No
7	Based on your discussion with the participant and other relevant individuals, do you think this situation is resolved? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other, specify: _____
8	What action, recommendation, or suggestion was provided to the participant to help resolve this situation? Describe:
9	Referrals made (<i>mark all that apply</i>) <input type="checkbox"/> Counselor on site <input type="checkbox"/> Other, specify: _____ <input type="checkbox"/> No referrals needed
Additional Comments:	

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