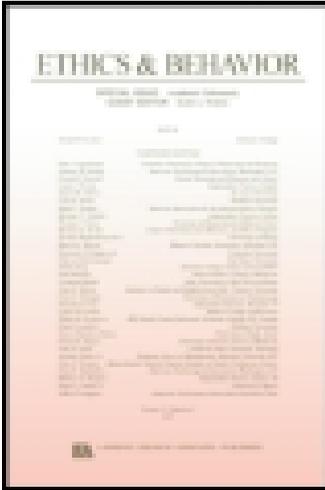


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Enhancing the Responsible Conduct of Sexual Health Prevention Research Across Global and Local Contexts: Training for Evidence-Based Research Ethics

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The HIV/AIDS pandemic has brought global attention to the ethical challenges of conducting research involving socially vulnerable participants. Such challenges require not only ethical deliberation but also an empirical evidentiary basis for research ethics policies and practices. This need has been addressed through the Fordham University HIV and Drug Abuse Prevention Research Ethics Institute, a National Institute on Drug Abuse–funded program that trains and funds early career scientists in conducting research on HIV/drug abuse research ethics. This article describes the ethical framework guiding Institute training and introduces readers to six empirical articles in this special issue that illuminate and help foster the responsible conduct of research.

Keywords: ethics, responsible conduct of research, sexual health, prevention, training, international

The HIV/AIDS epidemic has brought global attention to the critical need for sexual health preventive interventions among socially and economically minoritized populations in the United States and worldwide. Along with the benefits of a global sexual health research agenda are ethical challenges associated with the multiple vulnerabilities of persons within these populations and the unique nature of communities in which the research is conducted. Such challenges require not only ethical deliberation by bioethicists, investigators, and Institutional Review Boards (IRBs) but also empirical data that can provide an evidentiary basis for research ethics policies and practices. This article first describes the research ethics framework of the Fordham University HIV and Drug Abuse Prevention Research Ethics Institute (RETI), which trains and supports early career scientists in conducting empirical research on sexual health research ethics. It then introduces readers to six articles in this special issue that drew on community and participant perspectives to illuminate dimensions critical to the responsible conduct of sexual health research.

The HIV/AIDS global epidemic has brought public attention to the devastating consequences of the disease on individuals, families, and communities, as well as the dire need for sexual health prevention programs to reduce this burden. Despite recent improvements in access to the use of antiretroviral drugs for treatment and prevention and the success of needle exchange and other risk

reduction programs in both the United States and other countries, the rise in HIV infections continues among the poor, the disempowered (women and children), the stigmatized (men who have sex with men, female sex workers), and marginalized racial/ethnic groups (Centers for Disease Control and Prevention [CDC], 2013; UNAIDS, 2013). The World Health Organization (2011) proposed a fundamental shift in health-sector programs in countries over the next 5 years that rests on the generation of new knowledge to confront the rapidly evolving HIV/AIDS epidemic and related health challenges. Along with the benefits of a global sexual health research agenda are ethical challenges associated with the multiple vulnerabilities of persons within these populations and the unique nature of communities in which the research is conducted. Such challenges require not only ethical deliberation by bioethicists, investigators, and IRBs but also empirical data that can provide an evidentiary basis for the responsible conduct of sexual health and drug abuse research.

THE FORDHAM UNIVERSITY HIV AND DRUG ABUSE PREVENTION RESEARCH ETHICS INSTITUTE

The articles compiled for this special issue represent a sampling of research programs fostered and funded through the Fordham University RETI. The Institute, supported with a grant from National Institute on Drug Abuse (NIDA), was initiated in 2011 to train a new generation of sexual health and substance abuse early career investigators with the skills and dedication to conduct empirical research on HIV, drug abuse, and related sexual health research ethics models and practices. The Institute provides early career scientists with education, mentoring, and financial and technical support to generate ethically relevant empirical data designed to inform the decisions of investigators, IRBs, regulators, and community stakeholders in the creation of research ethics policies and practices. Now entering its 4th year, Institute fellows have conducted a wide range of HIV, substance use, and related sexual health research ethics studies across the globe in countries including the United States, India, the Philippines, Peru, Guatemala, Mexico, Thailand, South Africa, Tanzania and Kenya.

The educational objectives of the Institute are formulated around the premise that training scientists to conduct studies designed to inform the responsible conduct of research requires a multipronged approach that provides training fellows with (a) foundational knowledge of and capacity to identify and generate solutions to emerging and contextually linked ethical challenges in HIV, substance use, and related sexual health prevention research; (b) the capacity to ethically engage participants and communities in the construction of participant protections that reflect the values and merit the trust of all stakeholders; (c) the methodological expertise to design, implement, interpret, and disseminate research that will generate data to inform research ethics practices, regulations, and policies; and (d) ongoing participation in an international information and communication network for enhancing ethical knowledge, ethical dialogue, and future professional collaborations in producing evidence-based research ethics guidelines (Fisher, 2014; www.fordham.edu/ethicsinstitute).

Goodness-of-Fit Ethics

Institute trainees are encouraged to approach empirical examination of research ethics within a goodness-of-fit ethical framework (GFE) that conceptualizes participant respect and protections

in terms of the goodness-of-fit between the specific research context and the unique characteristics of the participant population (Fisher, 2003b; Fisher & Goodman, 2009; Masty & Fisher, 2008). In the design of their mentored research projects, Institute fellows apply a GFE conceptualization of research risks and benefits that shifts judgments regarding ethical procedures away from an exclusive focus on assumed participant vulnerabilities to (a) an examination of those aspects of the research setting that are creating or exacerbating research vulnerability and (b) consideration of how the design and ethical procedures can be modified to best advance science and participant and social welfare (Fisher & Goodman, 2009; Fisher & Ragsdale, 2006). This framework is especially important in addressing institutional and scientific biases that often single out female sex workers, persons who inject drugs, men who have sex with men, and other populations at high risk for HIV and related sexual health diseases as posing “unique” and “difficult” ethical challenges that can be resolved only through exclusion of those with the greatest need for evidence-based sexual health prevention programs (e.g., restricting participation in sexual health research to young men who have sex with men to 18 years or older) or paternalistic practices (e.g., avoiding monetary payments for street drug users; see Oransky, Fisher, Mahadevan, & Singer, 2009).

Colearning and the Importance of Participant Perspectives

GFE assumes that engaging participants in dialogue about the responsible conduct of research presents an opportunity to correct biases and misperceptions that arise when research ethics decision making is restricted to the perspectives of investigators, IRB members, and regulators. To correct an institutionally biased imbalance in moral perspectives, Institute fellows incorporate a colearning model of community–participant dialogue (Fisher, 1999, 2002) in which they share with participants their expertise about the scientific method, extant empirical knowledge, and standards for the responsible conduct of research and participants share their insider expertise on the social validity of the study, how they have or will react to planned procedures, the subjective risk–benefit balance of the research, and the moral and cultural frameworks informing their perspectives (DuBois et al., 2011; Fantuzzo, McWayne, & Childs, 2006; Fisher, 1999, 2002; Fisher & Ragsdale, 2006). This sharing of expertise leads to (a) the construction of recruitment and data collection procedures that can avoid exacerbating stigmatizing community attitudes toward participants or accidentally creating public awareness of illegal behaviors, (b) design of respectful informed consent procedures that fit the content and format to participants cultural traditions and their understanding and familiarity with research and their research rights, (c) identifying unforeseen participant research risks and where possible fitting potential research benefits to participant needs, and (d) creating fair incentives or compensation for research participation. The articles in this special issue exemplify the value of goodness-of-fit colearning by providing a window into how socially marginalized individuals from the United States and resource poor nations around the globe view ethical challenges and solutions for sexual health research.

AN OVERVIEW OF THE SPECIAL ISSUE CONTRIBUTIONS

The six articles in this special issue take different approaches to exploring various dimensions of sexual health prevention research ethics. The topics selected for study drew from the Institute fellows’ own experiences confronting ethical challenges in the conduct of HIV, HPV, and drug

use risk research involving socially marginalized populations globally and locally. All articles describe how they employed processes of colearning to give voice to the experiences, perspectives, and values of individuals who have or will participate in the fellows' prevention research studies. In beginning the difficult work of matching an interview format and questions to population needs, each author drew on the wisdom of community advisory boards comprised of former research participants, research and professional staff, and community advocates. The community advisory boards helped tailor recruitment, informed consent, and data collection procedures that were respectful, informative, and relevant to the lives of each specific participant population.

Goodness-of-Fit Ethics for Research Involving Female Sex Workers

The first article in this issue by Goldenberg, Rivera-Mindt, Rocha Jimenez, Brouwer, Miranda, and Fisher (2015/*this issue*) explored perceived benefits and risks of participation in HIV research among female sex workers (FSWs) in Tecun Uman, Guatemala. FSWs remain disproportionately impacted by HIV and sexually transmitted infections (STIs; Baral et al., 2012) and continue to face substantial structural barriers to HIV prevention, treatment, and care based on stigmatization and criminalization of sex work activities (Shannon, Goldenberg, Deering, & Strathdee, 2014). As in all the studies in this special issue, ethics-relevant questions regarding sexual health research were preceded by an explanation of research in general and HIV epidemiological, ethnographic, and clinical trial research in particular. Except in instances in which participant understanding of research methodology or distinctions between research and treatment are the ethical questions under examination, ensuring that participants are fully aware of the nature and purpose of research is critical to ensuring that our methods promote respectful colearning and ensure the scientific validity of data gathered (Fisher & Wallace, 2000). This is especially important when exploring the views of participants with limited education or exposure to research. Women who participated in the focus groups and individual interviews conducted by Goldenberg and her colleagues had an average of only 2 years of education and represented a range of research participation experiences (e.g., research-exposed/research naïve), work venues (e.g., indoor/outdoor), and ages. The authors found that fears concerning confidentiality associated with both internalized and community stigma associated with sex work and HIV represented a critical barrier to research participation. Key benefits of participation included health education and access to HIV/STI prevention and testing, as well as positive and trusting relationships between sex workers and research teams. Control exerted by managers at entertainment venues at which the women worked had mixed influences on perceived research risks and benefits. In some cases, managers encouraged participation as a means of providing sexual health information or treatment; in other cases, managers as gatekeepers refused to allow FSW participation. Results underscore the critical need for sexual health investigators working with FSWs to develop population-tailored procedures to reduce stigma; engage managers; and reinforce trusting, reciprocal relationships between sex work communities and researchers.

Like Goldenberg and her colleagues, Brown, Davtyan, and Fisher (2015/*this issue*) focused on ethical challenges in conducting research involving FSWs. The authors engaged former research participants in retrospective discussion on their ethically relevant experiences in the Sunflower Study, a Phase 4 trial that successfully administered an HPV vaccine intervention for FSWs working in Lima, Peru (Brown et al., 2012). HPV infection favors HIV acquisition in women,

and both infections contribute to a vicious circle contributing to the pandemics of both in some regions of the world (Konopnicki, DeWit, & Clumeck, 2013). The availability of the HPV vaccine has significantly reduced the risk of cervical cancer, but to date public awareness and understanding of HPV in general and the vaccine specifically present significant barriers to its use (Brown, Carcamo, Blas, Valderrama, & Halsey, 2010). The Sunflower Study was unique in providing all participants with HPV testing, treatment for those testing positive, and access to the vaccine for all testing negative. Despite differences in locale, a research focus on HIV versus HPV prevention, and experience participating in sexual health studies, participants' ethically relevant concerns in many cases paralleled those reported in the Goldenberg et al. study and in previous research conducted by RETI fellows (Reed, Khoshnood, Blankenship, & Fisher; 2014; Urada & Simmons, 2014). In relating their experiences, Brown and his colleagues found that FSWs reflected on both the perceived health benefits of participating in the study as well as fears about learning they might test positive for HPV, HIV, or other sexual health diseases. They also described approaching the research setting with trepidation that research staff would stigmatize them further and relief when they were treated with respect. Similar reactions were described for concerns regarding the ability of staff to maintain confidentiality. Although the research experience overall was positive, some participants voiced a sense of abandonment when the research study was concluded.

Fitting Sexual Health Prevention Strategies to Underserved Groups in the United States

The next two articles explored ethical challenges in conducting research aimed at increasing access of socially and economically vulnerable populations to preventive strategies known to be effective in reducing sexual health risk among vulnerable populations. Basta, Stambaugh, and Fisher (2015/[this issue](#)) sought to assess barriers to and the effectiveness of a brief intervention for enhancing informed consent to a study teaching rural Appalachians recruited from an outpatient mental health and drug treatment clinic on the use of HIV home testing kits. NIDA has promoted the Seek, Test, Treat, and Retain model of care to reduce HIV infections among high-risk populations. The new FDA approved Oraquick rapid HIV home testing kits, available without prescription, provides an opportunity for overcoming barriers to HIV testing. Prior to the intervention, survey items illuminated barriers to HIV testing including misconceptions regarding the relationship of HIV to AIDS, fear of getting recognized at the HIV testing sites, concerns about the confidentiality of results, and as also reported by Brown et al. (2015/[this issue](#)) trepidation about learning they were HIV positive accompanied by fear of losing a partner or spouse if they tested positive. The educational intervention led to a reduction in HIV misconceptions as well as a reduction in endorsement of items reflecting stigmatization of individuals with HIV. In addition 95% of the participants agreed to take the home kit test onsite and reported a positive experience and motivation to use the home kits in the future. This study demonstrates that providing a brief educative intervention in settings in which rural participants feel respected and safe can increase their comfort with HIV home testing.

The fourth article in this issue also examined attitudes of individuals to the use of new evidence-based methods to reduce sexual health risk among high-risk populations. Using a mixed-methods approach, Broaddus Marsch, and Fisher (2015/[this issue](#)) explored the ethical intricacies of using sexual safety negotiation text message versus traditional small-group interventions to decrease HIV acquisition and transmission among uninsured and underinsured African

American women living in the U.S. Midwest. Data from the CDC (2014) indicate the incidence of HIV infection among African American women to be higher than other racial/ethnic populations in the United States despite some success of culturally tailored small-group intervention programs (Jemmott, Jemmott, & O'Leary, 2007). A promising new medium for HIV prevention within urban and minority populations is the use of mobile phone text messaging to disseminate knowledge about sexual health risk, also known as mHealth (Duggan & Rainie, 2012). To date, however, there is little information on how prospective participants perceive the risks and potential benefits of participating in mHealth versus small-group HIV interventions. Both modalities raise distinctly different confidentiality concerns. Text messaging provides a written record of an individual's participation, requires technical expertise to ensure data are protected, and educating participants in ways they can protect confidentiality of their text messaging. Confidentiality of information discussed within small-group interventions depends not only on investigator implemented protections but also on participant self-monitoring of information shared, and the perceived obligation of group members to refrain from discussing shared information outside of the group. Participants in Broaddus and Marsch's focus groups and surveys expressed these concerns. Additional risks associated with small groups included fear of stigmatization and anxiety produced by discussion of sexual topics or sexual violence experienced by themselves or others. By contrast, the mHealth methods was perceived as giving women greater control on what they wished to communicate or be exposed to. Participants also saw benefits in the convenience and ubiquity of text messaging and the opportunity to learn from others in small-group activities. Although there was no clear preference for either modality, questionnaire data suggested that concerns about costs of childcare and transportation among some women and concerns about social stigma favored the mHealth modality. Although IRBs may be wary of new forms of HIV intervention modalities, in addition to formal requirements for human subjects protections, participant perspectives on the risks and benefits of mHealth compared to small-group interventions may assist IRBs in understanding population based benefits of new technologies as they continue to develop.

Fitting Human Subjects Protections to the Needs of Vulnerable Youth in Resource Poor Countries

The final two articles in this special issue focus on the challenges of conducting sexual health prevention programs and research involving adolescents. Researchers often confront barriers to sexual health prevention programs for adolescents based on cultural mores regarding sexual behavior among youth, IRB/ethics review committee overestimations of risks associated with engaging youth in discussions regarding sexual risk, and disagreements over the extent to which waiver of guardian permission protects or violates the rights of adolescents to participate in health research (Fisher et al., 2013; Fisher & Mustanski, 2014). The article by Thokoane describes barriers and opportunities for implementing an innovative community-based sexual and reproductive health rights program for adolescents in Hammanskraal, South Africa. Young people represent the majority of the population in South Africa, and they are also the most affected by the HIV epidemic (Shisana et al., 2014).

In South Africa, peer education is considered an effective tool for effectively tailoring sexual health messages to youth and other at-risk populations. The aim of the intervention program was to increase awareness and knowledge of sexual and reproductive health rights and services among

the young people through a culturally based “study circle” format and to facilitate access and age-appropriate services through local providers. The community-based intervention sought to maximize the benefits of recommendations from the 2011 Pretoria Department of Health report and subsequent government policies that opened opportunities for minors in South Africa to “be able to protect, promote, enjoy and express their sexual and reproductive health and rights” (Thokoane, 2015/*this issue*). Data from the study circles workshop were intended to be used as platform for the young people to discuss sensitive sexual health topics, inform youth about the health rights in a safe environment, and share ideas that would identify challenges they face in obtaining sexual health services and solutions to overcome such challenges. Thokoane reports on the multiple challenges she faced in implementing the program. For example, problems encountered during IRB approval of youth consent procedures reflected confusion in South African legal standards that (a) considered youth younger than age 18 legal minors with limited capacity to act independent of adults; (b) permit under the South African Children’s Act (38 of 2005) children 12 years and older to independently consent to medical treatment; (c) make it a criminal offense under the Sexual Offences Act (32 of 2007) to have sexual intercourse at an age younger than 16, even if it is consensual; and (d) grant minors the right to consent independently to certain types of research (Parliament of South Africa, 2005, 2007; Strobe, Slack, & Essack, 2010). (Adolescent health researchers in the United States face similar legal challenges when requesting that IRBs extend the sexual health treatment rights of adolescents under state mature minor laws to sexual health research; Fisher et al., 2013; Fisher & Mustanski, 2014; Institute of Medicine of the National Academy, 2006.) Once the project was initiated (with guardian consent required), members of Thokoane’s research team quickly became aware that adolescents were not responsive to oral and written materials and that self-esteem, especially of young women, was a major barrier to open discussion and learning. The team thus adopted role-playing and sessions on self-awareness, identity, and confidence into the study circle format. In analyzing the study circle outcomes, Thokoane discusses how school-based education regarding “human rights” does not necessarily translate into youth understanding of their sexual health rights, nor do laws permitting adolescent access to sexual health testing and treatment translate into provider competence in ensuring these rights.

The final article in this issue by Guadamuz, Goldsamt, and Boonmongkon (2015/*this issue*) continues to explore the global challenge of involving minors, in this case young men who have sex with men (YMSM), in sexual health research conducted in Bangkok, Thailand. Gay, bisexual, and transgender youth living in Thailand exhibit higher prevalence of mental health disorders, childhood sexual abuse, drug and alcohol abuse, intimate partner violence, peer victimization and bullying, and sexually transmitted infections, including HIV (CDC, 2013). Reasons for this have been postulated to include deep-rooted societal and internalized homophobia, gender and sexual orientation-based discrimination and stigma, and minority stress (Guadamuz et al., 2013). As in the United States (Fisher, 2002, 2003a; Fisher et al., 2013; Fisher & Mustanski, 2014) and South Africa (Thokoane, *this issue*), laws and cultural mores create reluctance on the part of ethics review committees to waive the requirement for guardian permission for adolescent participation in sexual health research. Although this presents barriers for all youth, it is particularly problematic for sexual minority youth who in many instances may not have informed their parents about their sexual orientation or have suffered physical or social abuse when they have disclosed (D’Augelli, Grossman, & Starks, 2008). YMSM reluctance to participate in research when guardian permission is required thus threatens scientific validity or sampling and deprives

these youth of fair opportunity to participate in research that can improve sexual health services for themselves and other YMSM (Fisher et al., 2013; Fisher & Mustanski, 2014; Mustanski, 2011). To gain further insight into these issues, Guadamuz and his colleagues conducted focus groups with YMSM youth and parents of males of unknown sexual orientation using methods tailored to Thai cultural practices. Although gender (mothers and fathers) and economic differences emerged, generally parents were accepting of research to reduce HIV risk but were not in favor of guardian waiver with one exception: Fathers in particular thought a study conducted within their child's schools would provide the necessary protection if guardian permission was waived. Similar to research conducted with ethnic minority and pediatric cancer patients in the United States (Fisher, 2002, 2003a; Masty & Fisher, 2008), youth held generally positive attitudes toward guardian permission as a form of respect and protection. However, these attitudes were tempered by concerns about harms posed by disclosing same-sex attraction to parents through permission forms. Data derived from the colearning method applied by Guadamuz and his colleagues provide ethics review committees with an understanding of participant and parent perspectives that can encourage creative collaboration with investigators to develop age-, cultural-, and population-appropriate guardian permission and waiver practices that reflect the values and merit the trust of sexual minority youth and their families.

CONCLUSION

The articles in this special issue allow us to view the responsible conduct of sexual health research through the critical lens of research participants. They draw on participant perspectives to provide suggestions for best practices to support the efforts of investigators and IRBs to conduct scientifically valid and morally responsible research. Ethical planning for sexual health research involving socially vulnerable adult and adolescent populations requires flexibility and sensitivity to the cultural challenges and concerns of diverse research populations. As illuminated in these articles, the knowledge required to meet these obligations includes understanding the cultural lens through which participants view their research experiences and the ability and willingness to construct research methods and ethical practices fitted to their research needs and the social and legal context in which they live.

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