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HIV PREVENTION RESEARCH ETHICS: AN INTRODUCTION TO THE SPECIAL ISSUE

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ABSTRACT: THIS SPECIAL ISSUE OF THE *JOURNAL of Empirical Research on Human Research Ethics* represents a sampling of projects fostered through the NIDA-funded Fordham University HIV Prevention Research Ethics Institute. The first three articles employ processes of co-learning to give voice to the experiences of individuals recovering from substance abuse and engaged in sex work who have participated in HIV prevention studies in the United States, India, and the Philippines. The fourth article describes a unique community-based approach to the development of research ethics training modules designed to increase participation of American Indian and Alaskan Native (AI/AN) tribal members as partners in research on health disparities. The last two articles focus a critical scholarly lens on two underexamined areas confronting IRB review of HIV research: The emerging and continuously changing ethical challenges of using social media sites for recruitment into HIV prevention research, and the handling of research-related complaints from participants involving perceived research harms or research experiences that do not accord with their initial expectations. Together, the articles in this special issue identify key ethical crossroads and provide suggestions for best practices that respect the values and merit the trust of research participants.

KEY WORDS: HIV, research ethics, substance abuse, ethics training, sex workers, international research, community-based research, institutional review boards

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T HIS SPECIAL ISSUE OF THE *JOURNAL OF Empirical Research on Human Research Ethics (JERHRE)* highlights recent innovative research and scholarship on ethical issues critical to the responsible conduct of HIV prevention research. Population statistics on the HIV/AIDS epidemic are daunting. From 2006–2009, the estimated number of people living with HIV in

the United States increased 8.2% from 1,061,100 to 1,148,200 (CDC, 2012). Despite recent improvements in access to antiretroviral treatment and the success of needle exchange and other prevention programs, the rise in HIV infections continues in vulnerable populations in the United States and in developing and transitional countries (UNAIDS, 2012). The continued development and implementation of effective interventions and policies designed to prevent, reduce, and ameliorate health disparities in HIV/AIDS is dependent on the knowledge generated by HIV scientists. Along with the benefits of a global HIV/AIDS research agenda are ethical challenges associated with the multiple vulnerabilities of persons within these populations, the unique nature of communities in which the research is conducted, and the emergence of new technologies to understand and prevent HIV acquisition and transmission. The burdens of HIV/AIDS fall hardest on a nation's poor, people who use illegal drugs, the disempowered (women, prisoners), stigmatized populations (men who have sex with men, female and male sex workers), and marginalized racial/ethnic or tribal groups (CDC, 2013). These vulnerabilities underscore the need for evidence-based ethical decision-making in HIV prevention research.

There is growing concern that in the absence of empirical data, participant protection strategies are often based on untested assumptions about participants and communities, institutional biases, or anecdotal evidence (Deeds et al., 2008). In addition, HIV investigators and other clinical scientists conducting socially sensitive research must often address IRB concerns about population vulnerabilities that are difficult to resolve in the absence of empirical data, and IRBs may lack procedural sophistication to fairly process complaints from vulnerable research participants. In a recent review Anderson and DuBois concluded that the evidentiary basis for addressing ethical concerns such as recruitment incentives, consent comprehension, and treatments involving drug administration is inadequate or hidden within method and results sections of addiction and HIV published studies (Anderson & DuBois, 2007). Although most journals now require authors to confirm that the study had IRB approval and was conducted according to national or international regulations, how these protections were developed,

implemented, and evaluated is rarely reported. For example, in an analysis of articles published in *AIDS* from 2005–2006, Anderson and DuBois found only seven articles in which empirical data relevant to research ethics was provided.

The articles compiled for this special issue represent a sampling of research programs fostered and funded through the Fordham HIV Prevention Research Ethics Institute. Supported with a grant from the National Institute on Drug Abuse (NIDA) and first initiated in 2011, the Institute provides early career professionals with education, mentoring, and financial and technical support to generate ethically relevant empirical data designed to inform future HIV research ethics policies and practices. Through years of experience, seasoned HIV investigators have acquired the knowledge and skills to make significant contributions to HIV ethical practices. However, early career scientists in general have few opportunities for formal research ethics training or ethics consultation with senior colleagues (Anderson et al., 2007; Fisher, Fried, & Feldman, 2009; National Academy of Sciences, 1997). As they become faculty and independent researchers, early career HIV prevention scientists are expected to incorporate the ethical knowledge and values of their field into their relationship with participants, communities, funders, and institutions and to teach this knowledge to others. However, few will have the experience or expertise to identify the myriad ethical challenges that arise in HIV prevention studies or to formulate and evaluate the efficacy of population- and community-sensitive ethical practices. The training program recruits early career investigators who have demonstrated training and experience conducting HIV research. The goal of the program is to increase their capacity to integrate research ethics knowledge and skills into HIV prevention science. The educational objectives of the Fordham HIV Prevention Research Ethics Training Program were formulated around the premise that the ability of scientists to contribute to the empirical database on HIV prevention research ethics requires a multipronged approach that addresses four broad aims: (1) foundational knowledge of and capacity to identify and generate solutions to emerging and contextually linked ethical challenges in HIV prevention research; (2) capacity to ethically engage participants and communities in the construction of participant protections that reflect the values and merit the trust of all stakeholders in HIV prevention research; (3) the methodological expertise to design, implement, and interpret research that will generate data to inform HIV prevention research practices and policies; and (4) ongoing participation in an international information and communication network for enhancing ethical knowledge, ethical

dialogue, and future professional collaborations in HIV prevention research ethics.

The six papers in this special issue take different approaches to exploring various dimensions of HIV prevention research ethics. The topics selected for study drew from the Institute fellows' own experiences confronting ethical challenges in the conduct of HIV risk research involving socially marginalized populations. The first three articles employ processes of co-learning to give voice to the experiences, perspectives, and values of individuals who have participated in the fellows' prior HIV prevention research studies. The co-learning model assumes that experienced or prospective participants have expertise in what they think is important to 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 (Fantuzzo, McWayne, & Childs, 2006; Fisher, 1999, 2002; Fisher & Ragsdale, 2006). 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 (CABs) composed of former research participants, research and professional staff, and community advocates. The CABs helped tailor recruitment, informed consent, and data collection procedures that were respectful, informative, and relevant to the lives of each specific participant population.

The article by Kostick, Weeks, and Mosher explores the ethical intricacies of designing and empirically evaluating a combined drug treatment and HIV prevention program housed within a community clinic setting that included training participants to engage in peer-delivered HIV harm reduction education within their own communities (Weeks et al., 2009). Research participants and research staff were asked to share opinions on existing and preferred channels for mutual communication within the organizational structure of the research program, unanticipated safety risks, and stress resulting from perceived conflicts in responsibilities. Additionally, a small group of not-in-treatment drug users from the study community were asked about their attitudes toward research participants conveying harm reduction messages to peers in their neighborhoods. Applying the critical knowledge generated from this study will contribute to the construction in future studies of procedures that improve the infrastructure of community- and clinic-based prevention studies to enhance support for participant psychosocial needs and provide adequate protections from potential threats to participant safety and psychological well-being from community reactions to their peer education activities.

The next two articles explore research ethics questions from the perspective of female sex workers (FSWs) living

in countries with high rates of poverty and HIV infection. FSWs in these countries face a myriad of life challenges that in turn challenge the adequacy of traditional forms of participant protections. Such challenges include family and community stigma, housing discrimination, as well as violence and harassment from police, clients, and others (Reed et al., 2012). Thus research procedures that do not adequately protect the identity of participating FSWs can lead to life-changing harms. The article by Reed, Khoshnood, Blankenship, and Fisher describes the results of qualitative interviews with FSWs from Andhra Pradesh, India, who had participated in HIV research. The themes that emerged from these interviews highlight the need for human subjects protections fitted to the local context in which these women live and work. For example, for many FSWs street or venue recruitment elicited fears that public exposure would impinge upon their ability to get clients or lead to arrest by law enforcement. Others expressed concerns that interviews would be given to the media. The findings also underscore the importance of training staff to conduct research in respectful ways that avoid exacerbating participants' sense of social stigma and exclusion. Through interviews with FSWs and their managers, Urada and Simmons uncovered unanticipated ethical challenges of HIV survey research conducted in the Philippines. One goal of the study was to explore reasons for missing data on drug and condom use and FSW managers for HIV prevention practices found in previous studies (Urada et al., 2013). Major themes reported in their paper reflect barriers to responding to substance abuse and sexual health survey research based on respondents' overarching distrust and fear of government intrusion in their life and work. For example, participants reported that research prevention efforts to increase condom use inadvertently ran the risk of assisting police who use the presence of condoms as evidence of prostitution. Similarly, some respondents approached the informed consent process for the original survey study with distrust based on the similarity of some survey questions to local government investigations of HIV prevalence. Contrary to stereotypic assumptions regarding FSWs' presumed comfort with discussing their sexual activities, many respondents felt survey questions regarding sexual behaviors were intrusive and inappropriate. The findings support the importance of transparency and involvement of FSWs in the design of research procedures and human subjects protections.

The article by Pearson, Parker, Fisher, and Moreno describes a unique cultural adaptation of the community engagement research (CEnR) model (Anderson et al., 2012; DuBois et al., 2011; Friedman Ross et al., 2010) to the development of research ethics training modules to

increase participation of American Indian and Alaskan Native (AI/AN) tribal members as partners in HIV and other research on health disparities. Based on their extensive research experience in Indian country the first two authors were concerned about the failure of existing human subjects protection training modules to resonate with AI/AN community members resulting in fewer members meeting eligibility requirements to become research team members. With the permission of the Collaborative Institutional Training Initiative (CITI; citiprogram.org) partners, the authors used a CEnR approach to adapt and evaluate the cultural appropriateness for Pacific Northwest tribes of the risk-benefit behavioral science CITI human subjects training module. The novel iterative process of module development included three expert panels composed of: (1) tribal members who had obtained human subject protection certification and conducted research in their tribal communities; (2) AI/AN investigators; and (3) AI/AN research ethics experts. Piloting a parallel randomized-controlled trial involving forty AI/AN community members demonstrated the advantages of the cultural adaptation over the traditional CITI module in improving quiz scores, overall reported relevance, and respondent satisfaction and research self-efficacy.

The last two papers in this special issue focus a critical scholarly lens on two underexamined areas of research ethics. Curtis draws on her extensive experience in using search engines and social networking sites in the conduct of research, to provide critical insight into the emerging and continuously changing ethical challenges of using these sites for recruitment into HIV prevention research. Her article draws attention to how the ability of researchers to target many more segments of HIV vulnerable populations through online advertising and recruitment has and will continue to challenge the adequacy of current and established human subjects protections. She carefully documents the information trajectories and related privacy risks incurred through the use of online behavioral advertising for research recruitment including the Google search engine, website banners, and Facebook ads. This is followed by best practices recommendations for investigators and IRBs to develop adequate protections against informational risk as they strive to stay current with continuously changing Internet technology. The paper by Underhill draws on her social policy and legal training to illuminate a poorly examined aspect of research ethics obligations: How IRBs handle research-related complaints from participants involving perceived research harms or research experiences that do not accord with their initial expectations. The issue is of particular import for IRBs unversed in addressing the complexity of potential adverse events

associated with current HIV prevention research on the efficacy of antiretroviral pre-exposure prophylaxis, microbicides, HIV vaccines, and other prevention technologies. The paper provides readers with an overview of the type and frequency of participant complaints to IRBs, the complaint options available to participants, the roles and responsibilities of IRBs and factors that may influence the effectiveness of IRB-led systems for resolving these disputes, and the application of research-related dispute resolution processes to the emerging generation of biomedical HIV prevention research.

Ethical planning for HIV prevention research requires flexibility and sensitivity to the contextual challenges and concerns of diverse research populations. The knowledge required to meet these obligations includes understanding the cultural lens through which individuals view their research experiences as well as familiarity with strategies for reducing informational risk raised by emerging technologies and with legal venues for fairly addressing participant complaints when they arise. Together, the articles in this special issue identify key ethical crossroads and provide suggestions for best practices that can provide encouragement and support for the continuing efforts of investigators and IRBs to respect the values and merit the trust of research populations.

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