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Ethics in Drug Abuse and Related HIV Risk Research

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Along with the benefits of a national research agenda on drug abuse and related HIV risk are ethical challenges associated with the multiple vulnerabilities of persons within these populations. Poverty, lack of education, related health conditions, illegal behaviors to obtain illicit drugs, gender, ethnic minority status, and psychological characteristics such as cravings and impulsivity require special research safeguards. However, federal provisions for the protection of vulnerable populations do not include special protections for individuals addicted to drugs. The challenges and value of participant perspectives on research risks and benefits, informed consent, confidentiality, and compensation for research on drug abuse and related HIV risk are discussed in this article.

Approximately 19.5 million Americans are current users of illicit drugs, with 22 million indicating substance abuse dependency (National Survey on Drug Use and Health, 2002). Illicit drug use is characterized by a shifting pattern of crack and cocaine, heroin and morphine, marijuana, methamphetamine, ecstasy (MDMA), and prescription and legally controlled substances such as clonazepam and hydrocodone. The economic burden of substance abuse addicts, their families, and society is at an estimated nationwide cost of $97.7 billion, including the costs of treatment and prevention, reduced job productivity or lost earnings, and crime and social welfare (Lewin Group, 1998). The intertwining effects of drug abuse and HIV/AIDS is becoming a public health crisis, especially in minority communities, where the poorest and most vulnerable are at risk through injection drug use (IDU) and unprotected sex (National Institute on Drug Abuse [NIDA], 2000).

Illicit drug use hits already vulnerable groups the hardest. Racial and ethnic minorities in the United States disproportionately suffer social and health impairments associated with drug abuse including HIV infection and high mortality rates (Buka & Kington, 2001). The primary route of HIV infection among women is IDU, prostitution (in many instances to obtain money for drugs), and sex with an IDU partner (Sanders-Phillips & Schoenbaum, 2001). Due to shifting trends in drugs of abuse, comorbidity, the multiple factors and pathways underlying addiction and treatment resistance, and the chronic relapsing nature of the disorder, few empirically validated treatments have been shown to be broadly effective (Dodgen & Shea, 2000; Gorelick, 1992; Leshner, 1997). The epidemic nature and lack of empirically validated treatments for drug abuse and related HIV behaviors underscores the critical need for understanding psychosocial factors contributing to addiction and related HIV risk behaviors and for tests of new treatments.

Applied developmental scientists have a long-standing and ongoing interest in drug addictions and related HIV risk research involving parent–infant dyads, adolescent health-compromising behaviors, and individual consequences and family sequelae of adult substance abuse. Indication of this focus is the publication over the years of such scholarship in *Applied Developmental Science*. Examples of *Applied Developmental Science* research involving substance abusers published in this journal include special issues on familial and peer influences on adolescent substance use (Windle, 2000) and prevention programs that alter the course of developmental risks (Maggs & Schulenberg, 1998, 2001), and in articles on mother–child interaction in drug-affected dyads (Blackwell, Lockman, & Kaiser, 1999) and family history as predictors of substance abuse and affective disorders (Ohannessian & Hesselbrock, 1999). Given this sample, and the broader scientific activity it represents, it is timely and important to discuss the myriad facets of the ethical issues involved in such research.

Ethical Challenges of Drug Abuse and Related HIV Risk Behaviors Research

Along with the benefits of a national research agenda on substance abuse are ethical challenges associated with clinical science in general, and substance abuse research in particular. The principles of beneficence, respect, and justice formulated by the National Commission (Department of Health, Education, and Welfare,

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1978) and operationalized into federal regulations (Code of Federal Regulations 46, subpart A) (Department of Health and Human Services [DHHS], 2001) require that investigators maximize research benefits and minimize harms; ensure that consent is informed, rational, and voluntary; and ensure that research benefits and burdens are fairly and equally distributed. Factors associated with substance abuse such as poverty, lack of education, related health conditions (e.g., HIV or hepatitis), illegal behaviors to obtain illicit drugs, gender, ethnic minority status, and psychological characteristics such as cravings and impulsivity require special safeguards for research participants and suggest the need for specialized research ethics guidelines. However, current federal provisions for the protection of vulnerable populations such as prisoners and children, do not include special protections for individuals addicted to drugs. Investigators studying illicit drug use and related HIV risk behaviors are thus grappling with ethical questions for which current federal guidelines offer incomplete answers.

Drug abuse disproportionately affects poor urban neighborhoods and ethnic minority persons living in these neighborhoods. The social, economic, and health risks associated with substance abuse are exacerbated in these populations because of disparities in education, housing, and health services rooted in historical racial and ethnic oppression and current forms of ethnic prejudice and institutional racism (Fisher, Jackson, & Villarruel, 1997). Members of historically oppressed racial and ethnic populations may be additionally vulnerable to research risks because of social prejudices and increased HIV risk associated with men who have sex with men status, persons who exchange sex for drugs, and those who have infected sexual partners (Sterk, 1999). Thus the ethical conduct of drug abuse research requires sensitivity to the effects of sexism, racism, heterosexism, and classicism on perceptions of and reactions to research procedures (Farmers, Connors, & Simmons, 1996; Singer, 1994).

The Importance of Participant Perspectives

Federal regulations for human experimentation are purposely broad to ensure their applicability across diverse and shifting research activities, settings, and populations. Thus ethical decisions for drug abuse research require contextually sensitive interpretations of these regulations. Engaging in this system of interpretation, investigators draw upon organizational policies, their Institutional Review Boards (IRBs), and their own moral compass. However, participants with the psychological, medical, social, and economic vulnerabilities tied to drug abuse and related HIV risk behaviors may not concur with these interpretations.

The importance of involving prospective participants in research planning was first recognized in the 1980s when the outcry of AIDS activists against placebo-controlled AZT trials drew attention to how differences in investigator and community perspectives jeopardized recruitment and the validity of HIV/AIDS-related research (C. Levine, Neveloff, Dubler, & Levine, 1991). In response, investigators began to include prospective participants and community advocates in HIV/AIDS research planning (Melton, Levine, Koocher, Rosenthal, & Thompson, 1988).

The views of illicit drug users can help investigators identify research practices that cause participant distress, violate participant privacy, or threaten participant autonomy not readily discerned through professional logic or scientific inference (Fisher, 1997, 1999; Marshall, 1999). Participant perspectives can also help investigators and their IRBs avoid rejecting study procedures as harmful, when in fact prospective participants see them posing little if any such risks, and evaluate the benefits as clearly outweighing such risks. For example, contrary to concerns raised by policymakers, recent studies found teenagers and parents from diverse ethnic and economic groups did not believe that exposure to survey questions about adolescent drug use would encourage adolescents to use drugs (Fisher, in press; Fisher & Wallace, 2000). Researchers have also found that distrust and fear of privacy invasion for drug abuse and related HIV behavioral research can be minimized when efforts are made to respect participant preferences for front line workers familiar with the neighborhood and for studies designed to inform social policies that strengthen community resources (Fullilove & Fullilove, 1993; Stevenson, DeMoya, & Boruch, 1993).

In this article I discuss the challenges and value of participant perspectives within four domains of research ethics for drug abuse and related HIV risk behaviors: research risks and benefits, informed consent, confidentiality and disclosure, and compensation and incentives for research participation.

Research Risks and Benefits

Ethical justification for research requires a favorable benefit-to-risk balance (DHHS, 2001). In this section I first discuss the benefits and risks of substance abuse and related HIV research designs that include tests of HIV serostatus, collateral data sources, psychosocial assessments, and randomized clinical trials. I then turn to the unique ethical vulnerabilities of ethnic minority participants. In the final section I discuss

how participant and community perspectives contribute to a favorable research risk–benefit balance.

Testing HIV Serostatus

Injection drug users are second to homosexual/bisexual men in developing AIDS in the United States and are a primary source of HIV transmission to sex partners and children who do not themselves inject drugs (Metzger, Navaline, & Woody, 2000). In addition to the spread of HIV/AIDS through needle sharing, intoxication and prostitution to obtain money for drugs place drug abusers at high risk for engaging in sexual practices that spread the HIV/AIDS virus (Des Jarlais, Gyudish, Friedman, & Hagen, 2000). For this reason, many studies designed to determine the interpersonal correlates of drug use and the effectiveness of drug abuse treatment programs use HIV serostatus or seroconversion as a predictor or outcome measure (Brettle, 1991; Jewell & Shiboski, 1993; Needle, Brown, Cyle, & Weissman, 1994; Swan, 1995). Participating in a study that provides HIV testing can be perceived as a benefit by participants who test positive for HIV if participation includes HIV counseling and referrals to affordable treatment centers. It can also bring relief to participants who test negative for the virus. However, testing may also present risks.

Harms associated with experimental procedures and postexperimental debriefing and counseling. Clair, Singer, Huertes, and Weeks (2003) raised the possibility that saliva tests to establish HIV status for research purposes may reinforce participant misconceptions that HIV/AIDS is spread through saliva. In addition, some members of historically oppressed groups fear that blood draws are not to *test* for HIV but to *infect* minorities with HIV as a form of racial genocide (Fisher & Wallace, 2000). Others fear that knowledge of their HIV status gained through research participation will result in social stigmatization, distress associated with recognition that to date the disease has no cure, or fears that the illness will leave them in a weakened state and vulnerable to community predators (Fairchild & Bayer, 1999).

Unlike participant options regarding research on other diseases, individuals tested for HIV/AIDS must be informed of and cannot be given the option "not to know" the results of testing (Office for Human Research Protections [OHRP], 1993) except if such knowledge would (a) increase suicidality or (b) preclude persons from whom valuable knowledge is needed from study participation. Participants must also receive risk-reduction counseling that includes (a) safer sex guidelines; (b) information on why drug users should not share needles, breast-feed, or donate or sell blood plasma, organs, or sperm; and (c) the necessity of receiving appropriate medical care early in any pregnancy. Provision of these counseling services may itself pose threats to confidentiality if it includes participation in group therapy or psychoeducational groups where the group leader cannot ensure that comembers of the group will safeguard knowledge regarding the participants' HIV serostatus (Perry, 1987). Des Jarlais and Friedman (1988) questioned whether DHHS-required counseling efforts directed at the use of clean needles and safer sex practices may inadvertently increase drug use and sexual activities in addicts who believe that such practices make them "AIDS safe."

Use of collateral data sources. A social network approach has been found to be useful in studying and predicting HIV transmission (Sterk, 1999; Trotter & Schensul, 1998). However, the advantage of this methodology can have negative social repercussions or legal liability if family members or fellow addicts are recruited as research informants. Given the interpersonal nature of HIV transmission, Des Jarlais and Friedman (1988) raised concerns about harms done to long-standing personal relationships if partners are included in the research while also noting that failure to recruit sexual partners in research may expose them to risks of HIV infection that could otherwise be avoided.

Surveys, Ethnographic Interviews, and Participant Observation

Surveys, ethnographic interviews, and participant observations examining the psychosocial and behavioral correlates of drug addiction can inform interventions to reduce needle sharing, unsafe sexual practices, and other risk behaviors. At the same time, such procedures have the potential to activate underlying anxieties, invade privacy, or lead to the disclosure of confidential information that could result in social or legal harms.

Potential iatrogenic effects. Surveys and interviews are often designed to have participants (a) share private information about drug use, history of physical or sexual abuse, and high-risk sexual behaviors or (b) participate in testing for psychological disorders that may cause personal distress, trigger drug cravings, or leave the impression that addictive behaviors are condoned or untreatable (Des Jarlais & Friedman, 1988; Herek & Glunt, 1988; Perry, 1987). However, there is a paucity of data on the potential iatrogenic effects of participation in research on street use of illicit drugs, the influence of interviewer characteristics, and the value of debriefing procedures for preventing or ameliorating negative postexperimental

reactions. Investigators conducting participant observation may also find that the methods needed to verify patterns of drug use and other high-risk behaviors inadvertently produce their own risks. Buchanan et al. (2002) eloquently described the ethical quandaries faced by researchers who had to determine whether they should replace syringes taken from known drug use sites with clean needles to conduct bioassays assessing HIV and hepatitis contamination. Buchanan et al. also described concerns arising from public contact among investigators and drug users that may place study participants at greater risk for arrest or alienation from their drug suppliers (see also Marshall, 1992).

Multiple relationships. The intimacy between researchers and study participants inherent in ethnographic and participant observation research can benefit participants by creating a social support network and access to information about health care and social services not otherwise available. It may also help raise participant self-esteem in their role as "expert" and through a sense of altruism in sharing their knowledge and experience to help others. Such intimacy can also create ambiguous or blurred personal and professional boundaries that can threaten the validity of data collected and result in bidirectional participant–investigator coercion, exploitation, or harm. Study participants may feel bound by a personal relationship with an investigator to continue in a research project they find discomforting or investigators may feel pressured to yield to participant demands for involvement in illegal behaviors (e.g., holding or transporting drugs) or for money or other resources above those allocated for participation in the research (Singer et al., 1999).

Risks and Benefits of Randomized Clinical Trials

Random assignment to one or more experimental treatments and one or more control groups, known as the randomized clinical trial (RCT), is widely used in drug-addictions research to identify effective treatments, block the euphoric effects of drugs, or reduce cravings or withdrawal symptoms.

Benefits of randomized clinical trials. When evaluating the balance of risks to benefits, investigators need to consider whether research participation will delay or prevent participants' entry into a treatment that he or she would otherwise have sought (Annas, 1989; Gorelick, Pickens, & Bonkovsky, 1999). Some direct benefits may be possible, however. By enrolling in treatment protocols, participants may be able to gain access to new medications that have not yet been made available for general use. The incentive to enroll in trials of experimental medications may be strong for individuals who have failed at conventional forms of drug treatment. If the experimental medications for drug addiction prove efficacious, in these cases, participation can be lifesaving.

Medication side effects, drug–drug interactions, and population vulnerability. When participants in clinical trials are active addicts, new medications may interact with street drugs or with other medications they are taking for comorbid disorders. In addition, drug-addicted individuals whose immune systems are compromised because of infection with HIV may be more vulnerable to the harmful effects of new medications (Jatlow, 1999; McCance-Katz, 1999; Morse & Pharm, 1999). Screening for such vulnerabilities and exclusion from clinical trials is one practice aimed at reducing risk and enhancing scientific control. These precautions pose their own ethical challenges because they deny persons with comorbid psychiatric and medical disorders the opportunity to benefit from research on potentially efficacious new medications.

Randomization to treatment, placebo, and alternative treatment control groups. In RCT designs, experimental treatment groups may consist of patients receiving different dosage levels of the investigational medication, different medications, or medication combinations. Control groups typically receive a placebo or a medication of known efficacy, to which the investigational medication is contrasted. There has been much written about placebo-controlled trials; with ethical scrutiny reaching its highest level in response to research directed at the HIV epidemic (Angell, 1997; Bayer, 1990; C. Levine, 1988).

The risks of randomization to a placebo or the experimental medication will vary with the stage of research (Shore, 2000). In early testing of a new medication, randomization to the placebo might pose lower risk. Ethical justification for an RCT design requires (a) there are no empirically established differences in expected outcome between the experimental and control conditions, or (b) there is a current or likely dispute among experts in the clinical community as to which condition is superior in all known respects (Freedman, 1987; Rothman & Michaels, 1994). Arguments for placebo use include the need to determine if (a) a population would have improved without the experimental treatment; (b) a new intervention tested against a standard treatment, might work less well, but still be efficacious; (c) a standard treatment might have side effects that the treatment avoids; and (d) patients who do not respond to standard interventions might be helped by the experimental treatment (Imber et al., 1986; Lieberman, 1996; Shore, 2000).

Ethical evaluation of RCT (C. Levine et al., 1991; Lieberman, 1996) must also consider whether risks involved are temporary and reversible (as it might be with some negative side effects of medications aimed at reducing drug cravings) or enduring and irreversible (as might occur in drug–drug interactions that might compromise already vulnerable immune systems in HIV seropostive participants). Other considerations include whether a study should be discontinued in the presence of data sufficient to indicate the superiority or inferiority of one arm of the trial and whether participants assigned to the placebo group are eligible to receive the investigational medication once the study is complete, assuming that it proves to be effective (Meinert, 1998).

RCTs involving medical provision of addictive drugs. Recent experiments in Switzerland demonstrate the potential value of heroin prescription as a treatment for opiate addiction. Study participants given heroin under supervised conditions when compared to a control group given standard treatment showed a decrease in illicit drug use and criminal and HIV risk behaviors and improved health status (Perneger, Giner, del Rio, & Mino, 1998). Irrespective of the outcome, it might be argued that all IDU individuals benefit from participation in such a study because assignment to either arm of the trial entails high-quality medical care. On the other hand, when the outcome of prescribing an addictive drug is unknown, research involvement may exacerbate addiction, result in cravings compounding compulsive high-risk behaviors, or lead participants to believe that drug use is condoned by science or society (Gorelick et al., 1999; Nahas, 1990).

Treatment termination, follow-up, and aftercare of participants. The duration of treatment protocols can vary from weeks to months posing additional ethical challenges. After a clinical trial has ended, access to investigational medications may be limited or participants may not have the resources to obtain further treatment. Participants who receive medications on which they are physiologically dependent (e.g., opiate agonists) may require an extension of the protocol, a transfer to another medication with cross-tolerant properties, or a tapering off of the experimental medication, before their treatment can be terminated (Gorelick et al., 1999; Lieberman, 1996). Ethical questions concern whether investigators are responsible for re-engaging treatment drop-outs, offering alternative treatments to participants responding poorly to experimental conditions, providing services for participants who are discovered to have relapsed during a follow-up assessment, or identifying community clinicians that might provide affordable postexperimental treatment.

Drug Abuse Research Involving Racial and Ethnic Minority Groups

Racial and ethnic minorities are disproportionately affected by the negative social and health consequences of drug abuse including HIV/AIDS, deteriorating health, lack of health care, and high mortality rates (Beauvais, Reardon, Wallace, & Price, 2000; Buka & Kington, 2001). Sociocultural sensitivity, including the ability to place behaviors studied and ethical practices employed within a sociohistorical context must be a critical component of risk–benefit calculations when research involves ethnic minority study participants in substance abuse and associated HIV risk (Fisher, Pearson, Kim, & Reynolds, 2002; Singer et al., 1999). As part of the U.S. Public Health Service's health disparities initiative, NIDA (2001) has initiated programs to describe, understand, and remedy the disproportionate negative consequences of drug use and related HIV risk for racial and ethnic minorities. Involvement of racial and ethnic minorities in drug abuse research is essential if treatments are to adequately reflect sociocultural factors contributing to personal and community resilience and vulnerability to addiction and HIV risk behaviors. In the language of bioethics, such involvement serves the principle of distributive justice by ensuring that the benefits and burden of drug abuse research are fairly distributed among individuals living in the United States.

Along with the scientific, social, and personal benefits that can be obtained from these laudable efforts come the risks of group stigmatization, exploitation, and harm that has marked episodes of historical medical neglect and abuse in research with racial and ethnic minorities in the United States, which are typified by slave medical experiments and the Tuskegee syphilis study, birth control testing in Spanish-speaking communities, and the Barrow Alaskan Native alcohol study (Foulks, 1989; Jones, 1993; Texas State Historical Association, 2002). This unfortunate history has spawned a suspicion of research and treatment among many racial and ethnic groups (Reverby, 2001). For example, some ethnic minority leaders have interpreted needle exchange programs and blinded seroprevalence studies as a form of genocidal neglect (Fairchild & Bayer, 1999). Others believe that the true intent of research is to inflict rather than study the HIV virus (Fisher & Wallace, 2000).

Participant Perspectives on Research Risks and Benefits

Funding for illicit drug use and HIV risk research is often driven by economic and political concerns (e.g., urban crime, welfare dependency, health care costs) framed by the perspectives of those who do not suffer

from these disorders. Research risks and benefits may be judged differently when viewed through the lens of persons with drug addictions. Recent efforts to gather participant perspectives suggest that recruitment of vulnerable populations, including historically oppressed groups and persons at high risk for HIV/AIDS, may be compromised by participant concerns about group stigmatization and mistrust of research (Fisher & Wallace, 2000; Foulks, 1989; Fullilove & Fullilove, 1993; Herek & Glunt, 1988; Swanson & Ward, 1995; Thomas, Pinto, Roach, & Vaughn, 1994). Concerns about invasion of privacy in response to questions about sexual and illegal behaviors, inflicted insight when a participant is told his or her HIV/AIDS status, and a sense of abandonment in the absence of adequate postexperimental follow-up have also been reported (Fisher, 2003a; Fisher & Wallace, 2000; Fullilove & Fullilove, 1993; Stevenson et al., 1993). Experiences with inadequate medical care in underserved communities lead some participants to question the value and validity of drug and HIV testing as part of experimentation (Fisher & Wallace, 2000).

Group stigmatization. Racial and ethnic minority concern over group stigmatization has also received little attention in research risk analysis. Descriptive data on drug addictions and related HIV risk behaviors in racial and ethnic and economically distressed communities has sometimes been used publicly to support racial or socioeconomic stereotypes despite data indicating these disorders cut across cultural groups and socioeconomic strata. Failure to consider whether prospective participants regard group depreciation as a potential cost of research participation may be asking ethnic minority or disadvantaged members of society to unjustly bear research risks (Fisher et al., 1997; Kilpatrick, 2000; Norton & Manson, 1996; Oetting & Beauvais, 1990; Ponterotto & Casas, 1991; Sampson, 1993; Zuckerman, 1990).

Informed Consent

Informed consent to research must be informed, rational, and voluntary (Freedman, 1975). Meeting these requirements is often difficult in drug abusing populations. Intoxication or withdrawal symptoms can produce temporary impairments in consent capacity. Cognitive deficits from long-term substance abuse, HIV/AIDS-related dementia, comorbid psychiatric disorders, or psychological symptoms associated with addictive disorders outside the circumstances of intoxication such as cravings and impulsivity can compromise informed and rational consent (Adler, 1995; Cohen, 2002). Economic resources strained by the purchase of illicit drugs or failure to hold a job may compromise the voluntary nature of participation when cash incentives are offered; as might dual role relationships that emerge when service providers participate in research recruitment efforts (Miller & Rosenstein, 1997).

Some have argued that denial and other psychological characteristics of illicit drug users who do not seek treatment is evidence that they lack the information or decision-making capacity to make an informed decision about research participation. Studies testing the efficacy of heroin prescriptions raise similar concerns. Charland (2002), for example, argued that because addicts suffer from a compulsive need to seek and use heroin, they are incapable of making a rational decision regarding participation in research that will offer free and legal heroin. According to Charland, consent impairment is of two kinds: (a) The compulsion to obtain heroin precludes voluntary choice, and (b) intoxication and withdrawal symptoms compromise the ability to comprehend choices. Yet, at least one study demonstrated that injection drug users are as competent to consent to an HIV vaccine trial as nondrug users (K. Harrison, Vlahov, Jones, Charron, & Clements, 1995). At present, the principle of fairness suggests that all individuals with drug addictions cannot be assumed to lack consent capacity.

Determining Consent Capacity

In a recent survey of National Institute on Alcohol Abuse and Alcoholism and NIDA-funded projects, McCrady and Bux (1999) reported widespread uncertainty and disagreement among investigators regarding application of federal guidelines for informed consent to drug-abusing populations. Investigators used a range of consent procedures for participants with drug addictions: (a) objective tests of cognitive capacity, (b) reading or item review methods for increasing understanding, and (c) testing for comprehension. However, tools to assess a prospective participant's level of consent capacity do not resolve how to determine the level of capacity that should be required for autonomous consent (Dresser, 1996; Fisher, 1999). For example, impulsivity and tendencies toward risk taking associated with addictive disorders may lead to underestimations of risk in illicit drug users who are nonintoxicated and otherwise cognitively competent at the time of consent (Cohen, 2002).

Language. Federal regulations require that informed consent information be presented in language that is understandable to the participant (DHHS, 2001). When drug abuse and HIV risk research involves individuals with minimal education or from ethnic and cultural groups with different language proficiencies, language preferences, and communica-

tion styles, misrepresentation or misunderstanding of consent information can occur. Efforts to select the most appropriate language may be insufficient if study participants are embarrassed to reveal their discomfort with English. The use of translators can address many language barriers, but investigators must ensure that interpreters are competent to perform the service and do not have a personal relationship with the study participant that might lead to exploitation, coercion, or violations of privacy (Fisher et al., 2002; Marshall, 1992). Interpreters apply their own value meanings to dialogue; therefore, transparency of perspectives among the investigator–participant–translator consent triad is important (Marshall, 1999; Putsch, 2002).

Predefining the Nature of the Study in Ethnographic and Observational Studies

The open-ended and exploratory nature of ethnographic interviews and participant observations may make it difficult during informed consent to predefine the exact nature of information that will be obtained (Marshall, 1992). The emphasis on discovering emergent themes through qualitative interviews by definition means that the investigator does not know beforehand all the topics and information that will arise during discussions. To protect the safety and privacy of both researcher and IDU individual, an agreement is often reached during informed consent about which activities will and will not be witnessed (Singer et al., 2000). However, the investigator conducting observational field research involving street drug use will not be able to identify during informed consent unexpected illegal or other behaviors that a prospective participant may not wish to be observed.

Health Care Beliefs and RCT

RCTs also raise issues of consent clarity. A common misconception of study participants is that involvement in a study providing treatment will produce therapeutic benefits, when the purpose of most studies is to test whether the treatment is effective (Appelbaum, Roth, Lidz, Benson, & Winslade, 1987). The therapeutic misconception may be compounded for participants from some cultural backgrounds who value deference to medical authority (Marshall, 1999). Confusion may also arise when individuals are unfamiliar with the nature of random assignment. For example, in one study on participant perspectives, some adolescents believed that they would be able to talk their way into the treatment arm of a placebo control trial (Fisher & Wallace, 2000).

Participant Perspectives

Substance abuse research raises a fundamental ethical question: How do we balance our moral obligation to respect the dignity and autonomy of persons with drug abuse problems to consent to research with the obligation to ensure that ill-informed or incompetent choices do not jeopardize their welfare or leave them open to exploitation? Accurate appraisals of consent capacity include knowledge about the motivations of persons who volunteer and why they may be willing to subject themselves to varying degrees of research risk (Fins & Miller, 1997). Fair consent outcomes also require attention to the characteristics, life experience, knowledge base, and attitudes toward proxy consent and decisional advocacy of prospective participants (Fisher, 2002, 2003b). Failure to understand conditions under which drug abusers perceive consent procedures as intrusive or anxiety provoking can jeopardize recruitment and voluntary consent (Singer et al., 1999; Stevenson et al., 1993). The knowledge derived from the proposed project will help investigators understand these concerns.

Confidentiality

Research on drug abuse and related HIV/AIDS risk behaviors elicit sensitive information about mental and physical health and illegal activities that if disclosed could place participants or their family members in social or legal jeopardy. Once participants have agreed to share such information, investigators must ensure that confidentiality practices are consistent with the informed consent agreement. There may be situations for which routine procedures for ensuring confidentiality (subject codes, secure storage and limited access, disposal of unnecessary information, supervision of research personnel, anonymous data collection) do not provide sufficient protections. For example, IDU individuals asked to keep diaries of a variety of high-risk behaviors may not be capable of keeping these diaries private, especially when they are intoxicated. Data collected on use or selling of illicit drugs or other illegal activities may be subject to subpoena stemming from criminal investigations or custody disputes. In these circumstances an investigator can apply for a Certificate of Confidentiality under 301[d] of the Public Health Service Act, providing immunity from any government or civil order to disclose identifying information contained in research records. The Certificate does not override state child abuse reporting laws (see Hoagwood, 1994; Melton, 1990).

Disclosure in Cases of Harm to Self or Others

Participants with drug addictions may reveal suicidal ideation or other life-threatening behaviors (e.g., use of a toxic inhalant to get high) that require disclosure of confidential information to practitioners or family members. Procedures for determining and managing these situations include valid assessments of risk, interviewers trained to recognize indicators of suicide, and protocols for managing suicidal risk and for hospitalization if necessary (Pearson, Stanley, King, & Fisher, 2001). In some instances, confidentiality policies must be informed by state and local law. All 50 states mandate mental health professionals to report suspected child abuse (Child Abuse Prevention and Treatment and Adoption and Reform Act, 1972), and reporting laws apply to researchers in at least 13 states (Liss, 1994). Some states also require reporting maternal substance abuse as a form of child endangerment (Andrews & Patterson, 1995; Garcia, 1993; M. Harrison, 1991).

Although there has yet to be case law for research, investigators need to consider whether their relationship to a research participant meets the criteria of "duty to protect" laws (i.e., *Tarasoff v. Regents of the University of California*, 1976) that require informing a third party of the prospect of harm if one has (a) a "special relationship" with the prospective assailant, (b) the ability to predict that violence will occur, and (c) the ability to identify the potential victim (Appelbaum & Rosenbaum, 1989). "Duty to protect" obligations pose additional ethical complexities when harm to others is interpreted to apply to behaviors associated with the spread of the HIV/AIDS virus (Loue, 2000). Given that federal guidelines require disclosure of confidentiality and reporting obligations during informed consent, it is of some concern that McCrady and Bux (1999) found that only 50% of drug addiction scientists informed participants that indications of child abuse, suicide, or homicide would be disclosed and the procedures that would be followed. In addition, even when informed of such risks, the language that often appears on consent forms (e.g., "confidentiality will be protected unless disclosures are required by law") may not be informative for populations who are not familiar with these laws (Fisher et al., 2002).

Confidentiality and Research Involving Testing of HIV Serostatus

HIV/AIDS disproportionately affects socially or medically vulnerable populations, including ethnic minorities, men who have sex with men, and, increasingly, women and children. OHRP (1993) recommends that for HIV studies, identifiers are not to be recorded when not required by the design of the study (Public Health Service, 1990). Elimination of identifiers may not protect confidentiality when HIV testing is conducted in an HIV/AIDS designated clinic area or if participants are sent to a general clinic at a designated time that patients and hospital staff can correctly infer is for persons from high-risk groups (Perry, 1987). Request for laboratory tests also present confidentiality risks: Referring clinicians may be associated with HIV/AIDS research by laboratory technicians or the nature of the tests may make it clear that HIV antibodies are being examined (Perry, 1987).

Participant Perspectives

Research on drug use and related HIV risks will uncover evidence of these and other health-compromising behaviors that may be unknown to the participant or to others in a position to protect the participant's welfare. Whether to keep such information confidential or disclose it is a daunting ethical challenge for investigators. Confidentiality decisions are complicated by age, gender, and cultural variation in attitudes toward privacy and help-seeking. Historically oppressed populations vulnerable to overreporting to child welfare agencies, racial profiling, or AIDS-based stigma may be distrustful of confidentiality protections or fear disclosure policies (Fisher, Wallace, & Fenton, 2000; Scott-Jones, 1994). Some underserved participants may reveal private information to an investigator in expectation of assistance. Failure to act on such information may inadvertently communicate to these participants that their problem is unimportant or cannot be resolved (Fisher, 1994; Fisher, Higgins-D'Allesandro, Rau, Kuther, & Belanger, 1996; O'Sullivan & Fisher, 1997). Understanding how prospective participants evaluate confidentiality practices is an important resource for drug addiction investigators struggling with these ethical complexities.

Due and Undue Incentives for Research

Federal guidelines permit compensation for effort, time, and inconvenience of research as long as no "undue inducements" are offered to lure people into participating and incentives are not included as a "benefit" in risk-benefit analyses (National Advisory Council on Drug Abuse, 2000; OHRP, 1993). These regulations imply that (a) some inducement is necessary to ensure that sufficient numbers are recruited, and (b) it is possible for investigators to distinguish between "due" and "undue" inducements (Dickert & Grady, 1991; Macklin, 1999). Selecting noncoercive incentives is critical to ensuring the voluntary nature of participation, that research burdens are not born unequally by economically disadvantaged populations, and that in RCT studies the relationships be-

tween clinical researchers and patients and participants do not turn into a commercial relationship (Ackerman, 1989; Dickert & Grady, 1991; R. J. Levine, 1986). Incentives are coercive if they (a) prompt participants to lie or conceal information that would disqualify them from the research or (b) lure into participating those who would otherwise choose not to expose themselves to research risks (Macklin, 1999). The extent to which these criteria are met will vary with the personal characteristics and current needs of prospective participants, underscoring the importance of their perspectives on this important issue.

Monetary Incentives

Monetary incentives for research participation should strengthen generalizability by securing a balanced representation of individuals from all economic levels and cultural communities (Giuffrida & Togerson, 1997; Kamb et al., 1998). However, different economic circumstances may lead to varying perceptions of a cash inducement as fair or coercive (R. J. Levine, 1986). Some institutions adopt a standard compensation rate for all research participation. Others have defined due financial inducements as the amount of money a normal, healthy volunteer would lose in work and travel time or by fair market value for the work involved (Dickert & Grady, 1991; R. J. Levine, 1986; Winslade & Douard, 1992). Monetary incentives for treatment research may also dispel the "therapeutic misconception" (Appelbaum et al., 1987) by clarifying that medical science and medical researchers are most likely to be the primary beneficiaries of clinical research (Koocher, 1991; Macklin, 1999; Ross, Jeffords, & Gold, 1993).

Cash payment for participation in illicit drug use research can create an ethical paradox if it is used by substance abusers to purchase illegal drugs, it encourages them to maintain their drug habits to continue earning research money, or it distorts evaluation of drug use dangers (Koocher, 1991; McCrady & Bux, 1999; Shaner, Eckman, & Roberts, 1995). On the other hand, for those who have difficulty obtaining and holding jobs, the money may be positively perceived as an easy and legal means of obtaining payment for unskilled labor. Policies aimed at addressing this problem include spreading out the payment of full compensation over a period of time, using vouchers, making payments to third parties on behalf of the participant, or withholding payment if a participant is intoxicated or in withdrawal (Gorelick et al., 1999). Such alternatives raise ethical quandaries. On one hand, to deny financial rewards to substance abusers can reinforce economic inequities between drug abusing and nonabusing populations or deny them the right to apply their own value system to life risk decisions (Fisher, 1999). On the other hand, respect for civil liberties can include recognition of individual vulnerabilities and procedures to protect their best interests (Macklin, 1999).

Treatment as Compensation

Providing treatment services as compensation for research participation is not unethical as long as participants are fully aware of available and affordable alternative services. Linking involvement in nontherapeutic research with treatment that immediately follows participation may also provide added benefits to participants by encouraging persons with substance abuse disorders to commit to treatment (Gorelick et al., 1999). However, the inadequacy of primary health care and psychosocial supports in poor communities affected by the drug and AIDS epidemics and their susceptibility to power imbalances between clinical investigator and patient may seriously compromise the voluntariness of participation (C. Levine et al., 1991). Voluntary participation in RCT studies may be compromised if cravings and compulsive disorders produce "internal" coercion (Cohen, 2002) in drug abusers recruited for research on the efficacy of prescription heroin.

Participant Perspectives

There is no consensus on what constitutes ethical compensation for drug addictions research. How prospective participants and community advisory boards across various socioeconomic and cultural communities judge the fair versus coercive nature of specific research incentives can help inform ethical decision making in this challenging area. For example, in a recent study, teenagers and parents from diverse socioeconomic levels judged cash payments as fair reimbursement for surveys on adolescent drug use but were concerned that financial inducements might lead some teenagers to lie to get into a study or prevent them from withdrawing once they agreed to participate. Moreover, ethnic minority respondents were more likely than non-Hispanic Whites to express concern that cash incentives would jeopardize the voluntary nature of participation, undermine altruistic motivations for engaging in research, tempt teenagers to provide false information to become eligible for study participation, or lie in response to survey questions to comply with investigator expectations (Fisher, 2003a).

Conclusions

Investigators generating data on which scientific theory, treatment, public opinion, and public policies and programs involving persons who use illicit drugs are based, face the formidable responsibility of ensuring that procedures meet scientific standards and pro-

tect participant rights and welfare. Federal regulations require investigators to minimize research risks, maximize benefits, obtain informed consent, protect confidentiality, and ensure voluntary participation. However, illicit drug using populations and the research designs to study them present unique ethical challenges for which federal regulations do not provide clear-cut answers. Intoxication, long-term drug use, or advanced stages of AIDS can impair consent capacity. Many people with dependence on and addictions to illicit substances are involved in criminal activities to acquire or obtain money to purchase drugs, making them vulnerable to harm if confidentiality is not adequately protected. HIV infection from syringe and paraphernalia sharing and unsafe sex practices may expose drug users to employment discrimination or social rejection if knowledge of their HIV status is exposed. The need for treatment or for money to buy drugs may heighten susceptibility to coercion tied to offers of free treatment or cash inducements for participation. In addition to research risks related to drug habits and HIV status, many users of illicit drugs are additionally vulnerable because of their disadvantaged economic status, gender, ethnicity, and sexual orientation.

Methods for understanding the epidemiology, social correlates, or efficacy of treatments for drug abuse also raise complex ethical questions. Assessments of drug use or HIV may cause social repercussions or legal liability if such information is disclosed (Des Jarlais & Friedman, 1988; Herek & Glunt, 1988; Perry, 1987). Participants in therapeutic research may experience withdrawal symptoms during detoxification or side effects when experimental medications interact with street drugs (Jatlow, 1999; McCance-Katz, 1999; Morse, 2000; Petrakis & Kosten, 1997). The dissemination of research results may serve to further stigmatize and sustain societal prejudices against historically oppressed racial and ethnic groups (Fisher et al., 2002).

Ethical decision making in illicit drug use research thus requires contextually sensitive interpretations of federal regulations and professional guidelines. Engaging in this system of interpretation, investigators and IRB members have drawn on organizational policies, IRB oversight, and their own moral compass to plan ethical procedures. In recent years drug abuse and HIV/AIDS scientists have pioneered the establishment of Community Advisory Boards to ensure that community concerns are integrated into research planning (Melton et al., 1988). A still untapped resource for guiding research ethics decisions is the opinions and concerns of individuals with the personal vulnerabilities and life situations of those engaged in drug abuse and related HIV risk behaviors (Fisher, 1999, 2003a; Marshall, 1999). Understanding the hopes and fears that persons with drug addictions bring to the research enterprise can help investigators maximize the benefits and minimize the risks of research on substance abuse and related HIV behaviors.

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