Ethical Dilemmas and Standards in Research with Drug Users

Kaveh Khoshnood
&
Kevin Irwin
Yale School of Public Health

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Take Home Message (1)

Current **ethical principles** do not:

A) adequately *identify* ethical dilemmas arising in field-based research with out-of-treatment drug users

B) nor do they offer *pragmatic guidance* on resolving these dilemmas
Take Home Message (2)

1. There is a need for the development of specific ethical guidelines for field-based research involving active drug users in international settings.

2. We must provide incentives and venues for researchers to document not only their research outcomes but also their research experiences, particularly regarding ethical issues.
Why/How Did we Get Interested in this Issue?

- Confronted thorny ethical dilemmas in conducting field based HIV prevention research in US

- As we expanded our research to international settings, new ethical issues emerged
What Did We Do?

1) Document our own research experiences

   Ethical dilemmas created by the criminalization of status behaviors: Case studies from ethnographic field research with injection drug users. *Health Behavior and Education*. 2002; 29: 30-42.

2) Applied for funds to investigate this issue further
   a) Domestic Research Study (Donaghue)
   b) International Research Study (CIRA)
“Generic” Ethical Dilemmas in Drug Use Research

- Illegal nature of drug use and related activities can result in a variety of risks to subjects and staff
- Stigma attached to illicit drug use
- Drug Use is a highly personal and emotionally charged behavior
- Vulnerability of drug users creates potential for their exploitation in research
Selected Ethical Dilemmas: Study Participants

- Risk of arrest and incarceration
- Achieving Informed Consent and “voluntary participation” under desperate circumstances
- Rise of unrealistic expectations from the researchers
- Unforseeable Challenges resulting from field-based research
Selected Ethical Dilemmas: Study Staff (1)

- Risk of physical harm or arrest
- Stigma of working with “Junkies”
- Assisting participants in procuring or using drugs
- Risk of relapse for former IDUs
- Blurring of personal/professional boundaries
Selected Ethical Dilemmas: Study Staff (2)

- Observing a significant risk behavior by study participant (unprotected sex, sharing syringes, etc)
- Learning of study participant’s intention to hurt someone
- Damage to social relationships and social standing of staff in the community due to unanticipated problems in the study
Should We Pay Drug Users for Participation in Research?
Does paying drug users undermine informed consent?
Informed Consent: Coercion or undue influence

“An investigator shall seek consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence” (emphasis added)

Does Payment to drug users for participation in research constitute “coercion” or “undue influence”?

Is money special?
Additional Ethical Challenges in Drug Use Research in International Settings

- No or little tradition of research with drug users.
- No or inexperienced IRBs.
- No or limited medical (including drug treatment) and social service resources.
- Extremely punitive law enforcement against drug use.
- Competing agendas of funders, researchers, participants, local IRBs and partners.
Is there any help out there for researchers to resolve these ethical dilemmas?!
Overarching Guiding Principles for Ethical Conduct of Research

1. Respect for persons
   (ensuring voluntary & informed consent)

2. Beneficence/non-maleficence
   (do good, minimize harm)

3. {Distributive} Justice
   (fair distribution of benefits & risks)
Ethical Guidelines versus Research Experience

Ethical guidelines provide principles that can guide human subject research,

But,

• What about research experiences? What actually happened and how were ethical dilemmas resolved?

• How do we know what worked and what didn’t work?
Don’t Ask, Don’t Tell!

- Drug Researchers often confront and deal with thorny ethical issues; however these experiences are rarely reported or made accessible to other colleagues.

- There are perceived disincentives for researchers to openly discuss these experiences that could make them vulnerable to reprisals from funders, regulatory agencies or those who find such research objectionable on moral, ideological and political grounds.
Expanding the Ethical Discourse (1)

- What were the researchers’ experiences with local NGOs, police, government officials, IRBs and general community?

- How was the adequacy of informed consent ensured?

- How was the material inducement (incentive) for participation in research determined and negotiated?
Expanding the Ethical Discourse (2)

- How did the investigators deal with lack of essential social and medical resources to refer drug users to?

- What were the programmatic and policy implications of the research?

- Were there significant “adverse events” in the research setting (i.e., local partners, local community) beyond individual research participants?
The Way Forward:

Researchers

- Assemble multidisciplinary teams that includes ethicists and social scientists.

- Report and publish research experiences and best practices, not only outcomes.

- Develop community consultations in setting local standards.

- Build capacity of both US based and international IRBs.

- Consider programmatic and policy implications of your research; before, during and after your study.
The Way Forward: *IRBs*

- Seek resources to increase the capacity to review protocols involving field-based research with active drug users in international settings.

- Identify and actively recruit individuals with expertise in this area to serve as permanent or ad-hoc members of your IRBs.
The Way Forward:  
**Funders/ Regulatory agencies**

- Encourage researchers to share their experiences with thorny ethical challenges with the larger scientific community.

- Remove disincentives for researchers to openly discuss ethical challenges they encounter in their work.

- Provide funding to increase the capacity of both US and international IRBs to review research protocols involving active drug users.
The Way Forward: *Editors/Organizations*

- **Create venues (special issue of Journals, conferences, websites, etc.)** for researchers to document their research experiences and discuss the ethical issues encountered and how they responded to or resolved them.

- **Consider the creation of an International Harm Reduction Research Ethics Committee** that can serve as a clearing house and resource to offer technical assistance.
A Call for Transparency

• Recent attacks on harm reduction oriented research by those who oppose us on ideological and political grounds should not scare us into a defensive posture.

• Instead we should use this as an opportunity to set the record straight and state clearly and forcefully that we have nothing to hide and our research is legitimate and worthy of support by public funds.
“Promoting and protecting human rights is inextricably linked with promoting and protecting health. Ethics and human rights derive from quite similar, if not identical, core values”

Jonathan Mann