



Addiction Research Ethics and the Belmont Principles: *Do Drug Users Have a Different Moral Voice?*

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Drug Use Research: “Vulnerabilities of Hidden Populations”

- *Health and economic vulnerabilities*
- *Cognitive vulnerabilities*
- *Social and legal vulnerabilities*



Belmont Principles

Protection of Human Subjects in Research

- Beneficence and Nonmaleficence
- Respect for Persons
- Justice

Nuremberg Code, 1946

Universal Declaration of Human Rights (UN) 1947

Declaration of Helsinki, WHO first issued in 1964

Belmont Report US 1979

CIOMS International Ethical Guidelines for Biomedical Research

Involving Human Subjects first issued in 1993



Additional Principles

- Integrity
- Fidelity and Responsibility

American Anthropology Association, 1998

American Medical Association, 2001

American Psychological Association, 2010

American Sociological Association, 1997

Public Health Leadership Society, 2002



“Foundational Principles Often Conflict”

(National Commission, 1979)

Beneficence & Nonmaleficence

- Ethnography → *Fidelity and Responsibility*
- HIV Partner Research → *Respect*
- Treatment Research → *Justice*



Goodness-of-Fit Ethics

(Fisher 2002, 2004; Fisher & Goodman, 2009; Fisher & Ragsdale, 2006)

Vulnerabilities of everyday life must be distinguished from research vulnerability; Research vulnerability is joint product of participant characteristic and research procedures

- *What special life circumstances may render participants more or less susceptible to research risk?*
- *Which aspects of the research design may create or exacerbate research risk?*
- *What procedures can be implemented to reduce such risks*



Ethical Principles Through a Participant Lens

- Privileged status of principles is contextually based
- Do established principles reflect how participants view the moral world of research?
- Lack of understanding → over/under-estimation
 - Risks & benefits
 - Personal agency
 - Fair access to research



GFE: Co-Learning

Fisher, 1999, 2002

Investigator

- Knowledge base
- Scientific method
- Testable hypotheses
- Ethical procedures available to protect participant rights and welfare

Participant Expertise

- Health priorities
- Cultural values
- Fears and hopes about the general or specific scientific enterprise
- The real world context in which hypotheses will be studied



Evidence-Based Research Ethics

AIMS OF STUDY

- Which ethical principles do street drug users apply in their moral justifications for resolving specific types of addiction research ethics dilemmas?
- Do these precepts correspond to Belmont and other traditional research principles?
- Do street drug users apply these precepts rigidly or on a case-by-case basis sensitive to the contextual nature of each ethical dilemma?



Recruitment

- Inclusion Criteria:
 - Illegal drug use past 30 days (other than alcohol, marijuana)
 - Previous drug use research participation
 - English proficiency
- Recruitment: shelters, harm reduction centers, methadone mobile distribution sites



Participant Characteristics (N=90)

Demographics

- 51% Male
- Age range: 18 – 61 (M = 34.7)
- 42% PWID
- 22% MSM
- 21% Caring for child 21%
- 55% unemployed
- 54% lived at a shelter, community housing, boarding home or with a family member
- 68% \leq high school education
- 66% History incarceration

Ethnicity

- 31% Black non-Hispanic
- 34% Hispanic (PR)
- 31% Non-Hispanic White
- 1% Other

Commonly used drugs

- cocaine (34%)
- heroin (26%)
- crack (47%)
- Amphetamine (100%)
- street methadone (14%)



Procedure

- 3 Addiction Research Scenarios — “Retrospective Responsibilities”
- Scenarios read to participants
- Mixed method: 4-point Likert-type scale response to scenario question followed by narrative rationale
- Coding: Inter-rater agreement = 94%, 89%, 96%



Principles of Co-Learning Focus Opinions on Scientific Ethics/Values/Morality

- Purpose of Study: *“to improve the way drug use and related HIV risk research is conducted by learning what community members think about everyday moral dilemmas and specific ethical challenges faced by researchers.”*



Principles of Co-Learning Define Research

- Research Defined. “A *research study* is conducted by a researcher when he or she wants to understand why things happen the way they do, how people think and feel about issues, or what kinds of treatments may or may not work.
- For example, a researcher who wants to understand why people get addicted will ask participants to fill out surveys or interview drug users about their drug use.
- Or a researcher who wants to test whether a new treatment to reduce drug use works will recruit individuals, who use drugs, to participate in a study to test the treatment.



Scenario 1: Hold Ss Drugs

For months Dr. Jones conducts street interviews on problems faced by poor female drug users raising young children. —including sharing her own parenting stories with participants

Just prior to an anticipated police raid, Terry, a female participant asks Dr. Jones to hide her drugs for fear her child will be taken away.

Dr. Jones does not know whether or not she should break the law and hide the drugs for Terry.

4-point Likert-type scale: In this situation, how important is it for Dr. Jones to obey the law?

Why is it important/not important?



Scenario 2: Disclose HIV Status

- Dr. Alba hangs out with street drug users interviewing them about HIV risk.
- Through interviews he learns that one participant, John, is intentionally hiding his sero-positive HIV status from and having unprotected sex with another participant, Chris, who Dr. Alba knows to be seronegative
- Dr. Alba tries to convince John to tell Chris about his HIV, but John refuses and reminds Dr. Alba that during informed consent he promised to keep everything confidential

Dr. Alba does not know whether he should tell Chris that John is HIV positive.

4-Point Likert-type question: In this situation, how important is it for Dr. Alba to keep his promise to John?

Why is it important/unimportant?



Scenario 3: Fire Assistant

- To test an experimental medication for cocaine addiction Dr. Ross will follow research guidelines that say the best way to know if a medicine really works is to randomly assign half the people the medication and half a sugar pill called a placebo.
- Mary, one of Dr. Ross's research assistants, volunteers at a clinic for homeless persons who are desperate to quit their cocaine addictions
- Mary makes an exception to the guidelines by putting all the homeless individuals into the medication group

In this situation, how important is it for Dr. Ross to fire Mary for making an exception to the guidelines?

Why is it important/not important?



Theme 1: *Beneficence*

Investigators should strive to do good and prevent harm

- Maximize scientific knowledge
- Protect research participants and others from harm

Case 1: Hold Drugs	Case 2: Disclose	Case 3: Fire Asst
"I don't care if Dr. Jones is a researcher... Terry could lose her kid... So she should try to help Terry."	"Chris could die then [Dr. Alba] will never be able to live with that."	"This would violate the integrity of the study and would not necessarily help the addicts since the medicine's effects are yet unproven."
"[Hiding the drug] would perpetuate a risky situation for the child without necessarily helping Terry."	"Dr. Alba should tell Chris because that is only the right thing to do, That goes beyond the duties of a researcher's promise to keep confidentiality	"Dr. Ross should make an exception... because in this case [Mary] is not just breaking the rules, she is trying to help those people."



Theme 2: Respect

Participants

- Are responsible for the choices that they make
- Have the right to knowledge that will affect their safety or
- Have a right to privacy.

Case 1: Hold Drugs	Case 2: Disclose HIV
"If Terry was so concerned about her kid, she wouldn't be doing drugs and hiding from the cops in the 1 st place if you ask me."	"John is a grown adult who can let Chris know if he wants. So no [Dr. Alba] should not tell Chris."
"[Terry] is grown and [should] knowthe consequences."	"If Chris had some sense, he would have done some homework of his own and found out for himself. It is not Dr. Alba's job."
	"John has a right to his privacy."
	"If your going to do something that will hurt people's lives, confidentiality does not apply anymore."



Theme 3: Justice

Fairness requires investigators

- Ensure equal research opportunity
- Eliminate bias
- Make up for historic and current health disparities.

Case 3: Fire Assistant

“Everyone should be treated the same which is why the guidelines were that way.”

“When you make exceptions like that you are not giving everyone an equal chance.”

“By firing Mary Dr. Ross did the right thing because he is saying that he does not support preferential treatment.”

“Because nobody ever does anything for people that are homeless. They deserve exceptions.”



Theme 4: Relationality

Researchers and participants are in relationships that obligate investigators to:

- maintain participant trust
- honor the reciprocity of relationships where both “get and give”.

Case 1: Hide the Drugs	Case 2: Disclose HIV
“Just because she is a researcher doesn’t mean she stops being a friend”	“John trusted him with something personal, so he should not let him down I feel.”
“How can you trust a researcher if the researcher is going around hiding drugs in their bags?”	Because when you agree to participate in a study, you trust the researcher with something very personal. So it is all about trust.”
“You gotta help the person that’s helping her get the data for her research”.	



Theme 5: Professional Obligations

Investigators must

- serve as a model of right conduct;
- maintain professional-personal boundaries with participants;
- preserve the good reputation of the profession;
- ensure the good conduct of other members of the profession.

Case 1: Hide Drugs	Case 2: Disclose HIV	Case 3: Fire Asst.
“Dr. Jones should just do her job and not get involved...That’s getting too personal with your subjects and feels wrong”	“All that is not Dr. Alba’s business if you ask me. He should just stay out of it and not get involved. Informing Chris is not his responsibility.”	[Mary] should have checked with [Dr. Ross] first. How can she take the decision into her own hands like that? She deserves [to be fired].”
“[Dr. Jones] should set an example for Terry, not the other way around.”		“People need to know boundaries especially when it comes to work. Otherwise they do not learn.
“If Dr. Jones gets busted then the research organization she works for ends up looking bad too.”		“if she gets away with it, next time another one of his staff will. So it is important to set examples.”



Theme 6: Rules

Rules have intrinsic moral value--Investigators' are morally obligated to

- obey the law,
- adhere to informed consent agreements with participants,
- follow research guidelines.

Case 1: Hide Drugs	Case 2: Disclose HIV	Case 3: Fire Asst.
"You should obey the law...no matter what it is. It is what keeps society going".	"If you promise me to keep my info safe, then you should not go back on it."	"Everybody should follow rules because otherwise there will be no order. So yes, [Mary] should be punished for that."
"As a human being [Dr. Jones] should help out Terry, but since she is at a job she should obey the law."	"As a researcher, Dr. Alba has a responsibility to both Chris and John. But because he promised John he should keep that end of his professional obligation."	"Dr. Ross should have considered that Mary was trying to help, but since she did break the rules she should be fired I feel."



Theme 7: Pragmatic Self-Interest

- The moral priority in a given situation is to maximize the researcher's own needs and minimize negative consequences to the self.

Case 1: Hide Drugs	Case 2: Disclose HIV	Case 3: Fire Asst.
"I don't think that [Dr. Jones] should break the law....that would end up with her in jail."	"[Dr. Alba] has to follow the rules because he could lose his license"	"What if they, the people who gave him the money for the study come after Dr. Ross? So he is doing the right thing – he is protecting his job."



Do Drug Users Apply Principles Contextually?

Rankings		
Case 1: Hide Drugs	Case 2: Disclose HIV	Case 3: Fire Asst.
Beneficence 26%	Rules 26%	Professional Obligations 26%
Pragmatic Self-Interest 22%	Beneficence 24%	Rules 22%
Professional Obligations 20%	Relationality 18%	Beneficence 20%
		Justice 20%



Drug Users as Moral Agents

- Drug users have the ability and willingness to grapple with complex dimensions of morality
- They share with investigators an appreciation for foundational moral principles guiding research
- These include the Belmont principles as well as principles reflecting a valuing of professional obligation and relationality
- Their application of these principles are contextually sensitive



Individual and Professional Responsibility

- Drug users see themselves as responsible for the consequences of their actions
- They hold researchers to a higher standard of moral excellence
 - Uphold professional standards
 - Act as role models
 - Avoid blurring of roles
 - Treat participants fairly



Relationships of Trust and Care

- Street drug users value participant-scientist relationships based on trust
- Believe some moral ideals supersede professional obligations, including protecting children, saving a life, and helping the needy



Research Ethics Through a Participant Lens

- Research is a moral endeavor
- Participant perspectives are essential to *inform* but cannot dictate ethical decisions
- Participant perspectives lends moral authority to ethical decisions



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Questions/further discussion

