



# **Addiction Research Ethics and the Belmont Principles: *Do People Who Use Drugs Have a Different Moral Voice?***

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# Belmont Principles

- Beneficence and Nonmaleficence
- Respect for Persons
- Justice

*Belmont Report US 1979*

*Code of Federal Regulations 45 CFR 46 Protection of Human Subjects 2009*

*Federal Nuremberg Code, 1946*

*Universal Declaration of Human Rights (UN) 1947*

*Declaration of Helsinki, WHO first issued in 1964*

*CIOMS International Ethical Guidelines for Biomedical Research*

*Involving Human Subjects first issued in 1993*

# Persons Who Use Drugs

## “Social Vulnerabilities”

- *Economic*
- *Physical and Mental Health*
- *Transient Cognitive (intoxication, withdrawal)*
- *Legal*
- *Social*

# Vulnerability: The Definitional Problem

- CFR 46.111a(3) and 46.111b: Vulnerable populations require additional safeguards to ensure “selection of subjects is equitable” and not subject to “coercion”
- What are research specific vulnerabilities?
- What safeguards are required?

# Goodness-of-Fit Ethics (GFE)

(Fisher 1999, 2002, 2004, 2014, 2015; Fisher & Goodman, 2009; Fisher & Ragsdale, 2006; Fisher & Yuko, 2016; Mastly & Fisher, 2008)

- Social Vulnerability  $\neq$  Research vulnerability
- Research vulnerability = failure to fit ethical procedures to participant characteristics
- Reducing research vulnerability requires familiarity with participant strengths as well as frailties
- *Empirical data is critical to identifying research ethics relevant population research assets and susceptibility to harm*

# Goodness-of-Fit Ethics



**Failure to distinguish between vulnerabilities in participants' lives and research vulnerabilities can jeopardize participant autonomy and lead to under- or over estimation of research risks**

# Importance of Participant “Expertise” Community Advisory Boards

## Science Establishment

- Ethical principles
- Regulations
- IRB & PI experience
- Traditional ethical protections

## Participants

- Moral values
- Trust in the scientific enterprise
- Implementation in real world contexts
- How ethical decisions will affect their rights and welfare



# “Foundational Principles Often Conflict”

(National Commission, 1979)

## Conflicts with Beneficence

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

# GFE: Ethical Principles Through a Participant Lens

- Do established principles reflect how participants view the moral world of research?
- Is the privileged status of a specific principle contextually based?

Lack of understanding → over/under-estimation

Risks & Benefits

Personal Agency

Fair Access to Research

# AIMS OF STUDY

- Which ethical principles do PWUD apply in their moral justifications for resolving addiction research ethics dilemmas?
- Do these precepts correspond to Belmont principles?
- Do PWUD 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

# Participants (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%)
- Amphetamines (100%)
- Street methodone (14%)

# Obtaining Participant Perspectives

- Research defined prior to scenarios
- 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%

# Scenario 1: Legal Risk

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.

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

# Scenario 2: HIV Partner Risk

- 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 the 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.

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



# Scenario 3: Random Assignment

- 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

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

# 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
<b>"If Terry was so concerned about her kid, she wouldn't be doing drugs and hiding from the cops in the 1<sup>st</sup> place if you ask me."</b>	<b>"John is a grown adult who can let Chris know if he wants. So no [Dr. Alba] should not tell Chris."</b>
<b>"[Terry] is grown and [should] know ....the consequences."</b>	<b>"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."</b>
	<b>"John has a right to his privacy."</b>
	<b>" If your going to do something that will hurt people's lives, confidentiality does not apply anymore."</b>

# 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.
<b>"You should obey the law...no matter what it is. It is what keeps society going".</b>	<b>"If you promise me to keep my info safe, then you should not go back on it."</b>	<b>"Everybody should follow rules because otherwise there will be no order. So yes, [Mary] should be punished for that."</b>
<b>"As a human being [Dr. Jones] should help out Terry, but since she is at a job she should obey the law."</b>	<b>"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."</b>	<b>"Dr. Ross should have considered that Mary was trying to help, but since she did break the rules she should be fired I feel."</b>

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

# Persons Who Use Drugs are Moral Agents

- PWUD 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

# Goodness-of-Fit Ethics Lessons Learned

# Individual and Professional Responsibility

- PWUD see themselves as responsible for the consequences of their actions
- They hold researchers to a higher standard of moral excellence

They expect investigators to

- Uphold professional standards
- Act as role models
- Avoid blurring of roles

# GFE and Ethnographic Research

## **Researchers conducting ethnographic research should**

- clarify personal v. professional role expectations during informed consent,
- revisit these expectations during the course of the research relationship and
- avoid blurring of professional and personal boundaries

# Relationships of Trust and Care

- PWUD value participant-scientist relationships based on trust
- They value scientist and participant obligations based on “contractual” agreements made during informed consent
- Believe some moral ideals supersede professional obligations, including protecting children, saving a life, and helping the needy

# GFE and Confidentiality

- Prior to study determine the limits of confidentiality based on harms that can be anticipated in the population and resources available to assist if reporting is necessary
- Clearly specify extent and limits of disclosure during informed consent—simply stating disclosures may occur if there is evidence of “harm to self or others” is not sufficient
- Assuming a protective stance over participants without considering their own definitions of autonomy may lead to dignitary harm.

# Justice & Fairness

- Most PWUD believe random assignment is a fair process for distributing the benefits and burdens of research
- They expect investigators to act fairly and to take responsibility for those who work for them
- The reasons for random assignment should be explained during informed consent



# 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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