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## Through the Community Looking Glass:

How street drug users perceive ethical issues in randomized clinical trials for drug addiction

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*Celia B. Fisher, Ph.D.*  
*Marie Ward Doty Chair and Professor of Psychology*  
*Director, Center for Ethics Education*  
[Fisher@Fordham.edu](mailto:Fisher@Fordham.edu)

**American Public Health Association**  
**Philadelphia**  
**November 10, 2009**

## Presenter Disclosures

Celia B. Fisher

The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

"No relationships to disclose"

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## Vulnerabilities of Street Drug Users

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Medical Vulnerabilities	Social Vulnerabilities
<ul style="list-style-type: none"> <li>• Impulsivity</li> <li>• Cravings</li> <li>• Cognitive impairments</li> <li>• Co-morbid psychiatric disorders</li> <li>• Associated health problems <i>[Hepatitis, HIV, malnutrition, TB]</i></li> </ul>	<ul style="list-style-type: none"> <li>• Minority status</li> <li>• Poverty</li> <li>• Social Stigma</li> <li>• Illegal behaviors <i>['boosting', sex for money, selling/buying drugs]</i></li> <li>• Dangerous social network</li> </ul>

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## Goodness-of-Fit Ethics

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Alternative to assumptions that street drug addiction vulnerabilities pose unique challenges that can only be resolved through:

- **Under-protection:** *Mis-applying waivers of human subjects protections (e.g. fully informed consent)*
- **Over-protection:** *Mis-applying assessment of research risk (e.g. prohibiting monetary compensation)*

Fisher (1997, 1999)

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## Goodness-of-fit Ethics Defines Research Vulnerability as...

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- The **joint product** of participant characteristics and the research context, and
- The extent to which a participant's rights and welfare are jeopardized or protected by specific actions of scientists within a specific experimental context.

Fisher (1997, 1999)

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## GFE: Reducing Research Vulnerability

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Vulnerability is reduced when research procedures are fit to participant characteristics

- *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?*

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

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### Goodness-of-Fit Requires Co-Learning

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- The translation of Belmont principals into best fitted ethical practices cannot be achieved simply through the moral reflections of scientists and IRBs.
- Moral discourse between scientist and participants is an essential means of fitting these principles to participant characteristics and research methods

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### Minimizing Research Vulnerability Through Co-Learning

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<b>INVESTIGATOR</b>	<b>PARTICIPANT</b>
<ul style="list-style-type: none"> <li>• Knowledge base</li> <li>• Scientific method</li> <li>• Testable hypotheses</li> <li>• Ethical procedures available to protect participant rights and welfare</li> </ul>	<ul style="list-style-type: none"> <li>• Health priorities</li> <li>• Cultural values</li> <li>• Fears and hopes about the general or specific scientific enterprise</li> <li>• The real world context in which hypotheses will be studied</li> </ul>

Fisher (1997, 1999)

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### Co-Learning and Research on Research Ethics

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- **Work with community/participant advisory boards**
- **Familiarize participants with the research methods and context for which their opinions are sought**
- **Avoid procedures that discourage non-contemplative responses**
- **Encourage an "opinions in progress" deliberation of the ethical issues** (Fisher & Wallace, 2000)
- **Use qualitative and quantitative methods**

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### Research on Addiction Research Ethics Video Stimulated Focus Groups

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- National Institute on Drug Abuse (NIDA) (RO1-DAO15649)
- Fisher, C. B., Oransky, M., Mahadevan, Singer, M., Mirhej, G & Hodge, G. D. (2008). Marginalized populations and drug addiction research: Realism, Mistrust, and Misconception. *IRB: Ethics & Human Research*, 30, 1-9.
- Fisher, C. B., Oransky, M., Mahadevan, Singer, M., Mirhej, G & Hodge, G. D. (2009) Do Drug Abuse Researchers have a Duty to Protect Third Parties from HIV Transmission? Moral Perspectives of Street Drug Users. In Buchanan, D., Fisher, C. B., Gable, L. (Eds.) *Ethical and Legal Issues in Research with High Risk Populations* (189-206). Washington DC: APA Books.
- Oransky, M., Fisher, C. B., Mahadevan, M., & Singer, M. (in press). Barriers and opportunities for recruitment for non-intervention studies on HIV risk: Perspectives of street drug users. *Substance Use & Abuse*.

[www.fordham.edu/addictionethics](http://www.fordham.edu/addictionethics)

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### Threats to Reasoned RCT Participation Decision

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- Failure to Understand Elements of RCT Research
- Therapeutic Misconception
  - Incorrect belief that individualized needs will be taken into account in RCT condition assignment (TM1)
  - Conflation of physician/scientist role (TM1)
  - Unreasonable expectations of medical benefit from research participation (TM2)

• Appelbaum PS, Lidz WL, Grisso T. Therapeutic misconception in clinical research: Frequency and risk factors. *IRB: Ethics & Human Research* 2004;26(2):1-8.

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### Key Goodness-of Fit Ethical Issue

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***Are Concepts of "Understanding" and "TM" Observed in Middle Class & Hospitalized Populations Fitted to Street Drug Users?***

- Health Disparities
- Social marginalization
- Personal and collective experiences of past medical or research abuses

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## 100 Participants: 11 Focus Groups

<ul style="list-style-type: none"> <li>• 68% Male</li> <li>• 76% Heterosexual</li> <li>• 22 - 70 years, M = 43</li> <li>• 39% HIV+</li> <li>• 61% unemployed</li> <li>• 46% lived at a shelter, community housing, boarding home or with a family member</li> <li>• 79% ≤ high school education</li> <li>• 75% previous research experience</li> </ul>	<p><b>Ethnicity</b></p> <ul style="list-style-type: none"> <li>• African American (33%)</li> <li>• Hispanic (37%; majority Puerto Rican)</li> <li>• non-Hispanic White (22%)</li> <li>• Other Latino or mixed Hispanic Caribbean/West Indian (8%)</li> </ul> <p><b>Commonly used drugs</b></p> <ul style="list-style-type: none"> <li>• powder cocaine (45%)</li> <li>• heroin (44%)</li> <li>• crack (32%)</li> <li>• marijuana (29%)</li> <li>• illicit methadone (18%)</li> <li>• speedball (heroin + cocaine) (13%)</li> </ul>
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## RCT Video

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## Fitting TM Typology to Perspectives of Street Drug Users

- Experimental Realism (ER): Understanding of ethically relevant components of RCTs
- Experimental Mistrust (EM): Expectation that investigators are dishonest and exploitative

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## Understanding Treatment Uncertainty

Experimental Realism

- *"There aren't any guarantees. You don't know if it's gonna work or not. It's just a chance you're taking."*

Experimental Realism & Therapeutic Optimism:

- *"I would take the chance, too. If I wanted to really get off of this mess, this other drug, I would take it."*

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## Understanding Treatment Uncertainty

Experimental Realism + Experimental Mistrust:


- *"It's like she's [the investigator] more interested in if their study gonna work. That's what we need you for. We need you to be a guinea pig, to take this stuff and see if it works for you."*

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## Roots of Experimental Mistrust

History of Health Discrimination

- *Don't you think that every time you go in the doctor's office they are experimenting on you?*
- *AZT aspect...I mean, all I kept seeing was my friends dying and they were guinea pigs in a certain sense too"*


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**TM Conflation of Physician/Scientist Role +  
Experimental Mistrust**

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- **“She should have been better prepared”**
  - *Doctors know everything and always have an answer for the questions, the investigator must really know, or should know, whether the treatment will be effective.*
- **“This woman is not saying everything to me”**
  - *“Because someone comes looking for help and if what they hear is that she [investigator] was neither sure about the information she was giving him nor the reason was for saying it, that person will not believe her.”*

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**Random Assignment & Placebo**

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Experimental Realism

- *“She is professional enough to explain to him that over and over...This is a trial. You may not end up with the medicine.”*
- *“But if you sign up for it and you know it can be a placebo or not, and if you’re willing to take that and accept that then it’s all good.”*

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**Randomization:**

**Experimental Realism + Mistrust**

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“She reeled him in”

- Who’s to say that everybody ain’t getting it? They give everybody the placebo for the first eight weeks just to see if they’ll come back.
- ...come on, what you gonna give me, a sugar pill? And I won’t know if I’m taking the real medicine? But most likely she’ll be giving him the real med, to see his reaction within eight weeks.

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**Risks of Placebo:**

**Experimental Realism**

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- *“When people find out they’ve taken the placebo, it makes them regret, after -- ‘Oh my God, I’ve been taking the placebo, and it worked’. Well, no it didn’t.*
- *“Because you will not know if he quit because he had will power or because of the placebo. You will never know if the medicine actually works or not.”*

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**Placebo:**

**TM + Addiction Beliefs**

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“Mental Will”

- They are doing an experiment to find out about what kind of attitude people have in the program; if it works psychologically with the placebo or if it works with the real medicine.
- What I see is that this is a way of knowing if the person had a psychological will, a mental response or if he had a true reaction.


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**Implications for Goodness-of-Fit Ethics**

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- Experimental Realism (understanding) is not the same as believing in the honesty of the information provided (Experimental Mistrust).
- A “reasoned” RCT participation decision is linked to histories of health disparities & research exploitation.
- Therapeutic misconception is linked to experimental mistrust & addiction beliefs.
- RCT consent procedures must be fitted to address distrust based on health disparities and TM influenced by addiction beliefs.


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**Conclusion:  
Ethics Through the Community Lens**

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- Participants are experts on their own lived realities and interpretations of research risks and benefits.
- Investigators and participants have mutual investment in valid and ethical drug addiction research.
- They may have different perspectives on the value, validity, risks and potential benefits of research.
- The responsible conduct of research must be informed by these different perspectives.
- Participant perspectives must inform but not dictate ethical decisions of investigators.

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[http://www.bioethics.gov/reports/past\\_commissions/nbac\\_mental2.pdf](http://www.bioethics.gov/reports/past_commissions/nbac_mental2.pdf)
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