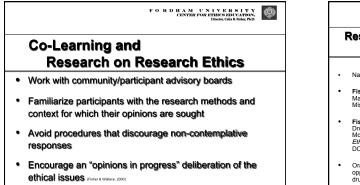


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Goodness-of-Fit Requires Co-Learning

- 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

Minimizing Research Vulnerability Through Co-Learning		
INVESTIGATOR	PARTICIPANT	
 Knowledge base 	Health priorities	
 Scientific method 	Cultural values	
 Testable hypotheses Ethical procedures available to protect participant rights and welfare 	 Fears and hopes about the general or specific scientific enterprise The real world context in which hypotheses will be studied 	



Use qualitative and quantitative methods

PORTURANT CONTRACTORY EXAMPLES

- 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-intevention studies on HIV risk: Perspectives of street drug users. Substance Use & Abuse.

www.fordham.edu/addictionethics

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Threats to Reasoned RCT Participation Decision

- 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)

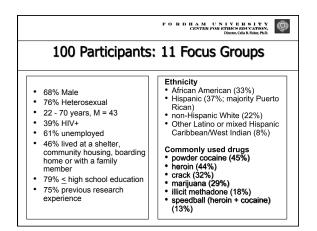
Appelbaum PS, Lidz WL, Grisso T. Therapeutic misconception in clinical research: Frequency and risk factors. IRB: Ethics & Human Research 2004;26(2):1-8.

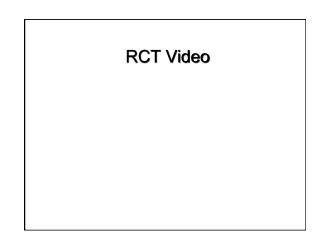


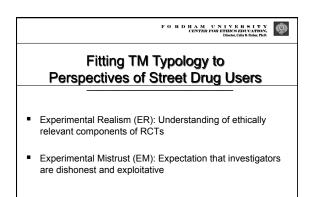
Key Goodness-of Fit Ethical Issue

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









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:

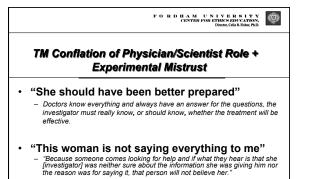
 "It's like she's [the investigator] more interested in if their study gonna work. That's what we need you for. We need you to be a guinea pig, to take this stuff and see if it works for you."

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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"

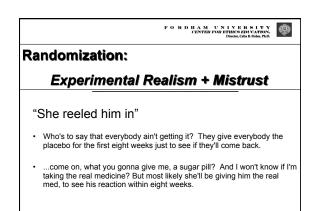


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Random Assignment & Placebo

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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Ri	sks of Placebo:
	Experimental Realism
•	"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.
	"Recourse you will not know if he guit because he had will

 "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."

Placebo:
TM + Addiction Beliefs

"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

- 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

- 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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 Fisher, C. B. (2003). A goodness-of-fit ethic for informed consent to research involving persons with mental retardation and developmental disabilities. Mental Retardation and Developmental Disabilities Research. Reviews, 9, 27-31.
 Fisher, C. B., & Ragsdale, K. (2006). A goodness-of-fit ethics for multicultural research. In J. Trimble and C. B. Fisher (Eds.) The handbook of ethical research with ethnocultural populations and communities (pp. 3 26). Thousand Oaks, CA: Sage Publications.
 Fisher, C. B. & Goodman, S. J. (2009). Goodness-of-Fit Ethics for Non-Intervention Research Involving Dangerous and Illegal Behaviors. In Buchanan, D., Fisher, C. B., Gabie, L. (Eds.) Research With High-Risk Populations: Balancing Science, Ethics, and Law. (pp. 25-46). Washington DC: APA Books.
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