



FORDHAM UNIVERSITY  
THE JESUIT UNIVERSITY OF NEW YORK

THE CENTER FOR ETHICS EDUCATION

Celia B. Fisher, Ph.D., Director

# Designing Research on Research Ethics

Celia B. Fisher, Ph.D.

[Fisher@Fordham.edu](mailto:Fisher@Fordham.edu)

Fordham University

HIV Prevention Research Ethics Institute

July 8, 2013



# What is Research Ethics ?

- ★ Procedures for the planning, conduct, and reporting of research “that protects the interests of the public, the subjects of the research, and the researchers themselves” (Kalichman, 2009)



# Research Ethics Principles

## Belmont Principles

- ★ **Beneficence and Non-maleficence**—do good and do no harm
- ★ **Respect**—protection of participant autonomy and privacy
- ★ **Justice**- fair distribution of research benefits and burdens



# Clinical Research Ethics Criteria

Emanuel, Wendler & Grady (2000)

1. Value—enhancement of health or knowledge
2. Validity—methodological rigor
3. Fair selection—based on scientific objectives *not* convenience, vulnerability or privilege



# Clinical Research Ethics Criteria

Emanuel, Wendler & Grady (2000)

4. Favorable risk-benefit ratio—risks minimized, benefits maximized (clinical equipoise; standard of prevention, post-experimental care)

5. Independent Review—unaffiliated review (objective, evidence-based, informed)



# Clinical Research Ethics Criteria

Emanuel, Wendler & Grady (2000)

6. Informed consent—**informed, rationale & voluntary** (therapeutic misconception, cultural conceptions of autonomy)

7. Respect for enrolled participants—**privacy protections, right to withdraw, monitoring their well-being**



# Regulations & Guidelines

★ U.S. 45CFR46



# What is Evidence-Based Research Ethics (EBRE)

- ★ Judicious use of empirical data to inform the design, evaluation, and implementation of *Research Ethics*





# What is Empirical Research on Research Ethics [ERRE]?

- ★ Studies designed to provide the empirical foundation for *Evidence-Based Research Ethics [EBRE]*



# Research Ethics Pyramid

Research  
Ethics

Evidence-  
Based Research

Empirical Research on  
Research Ethics



# Categories of ERRE

Adapted from Koh (2009)



# 1. Lay of the Land

## Description of Current Practices

- ★ Physician ART prescribing behaviors involving drug using versus non-drug using populations (Hettema)
- ★ The extent to which opt-out measures are sufficiently understood by women going for pre-natal care in South India (Madhivanan)
- ★ IRB responses to participant complaints in HIV prevention studies (Underhill)



# 1. Lay of the Land

## Description of Stakeholder Opinions/Beliefs

- ★ Participants' evaluation risks and benefits of a peer delivered drug use intervention study (Kostick)
- ★ FSW's post-experimental attitudes toward IPV research risks and benefits (Brown)
- ★ Familiarity of IRBs and investigators with confidentiality protections for HIV recruitment involving social media (Curtis)



## 2. Ideal v. Reality

- ★ IRBs appropriately apply the minimal risk definition to adolescent sexual health survey research  
[ § 46.102i: Definitions: Minimal Risk]
- ★ Offering free treatment does not compromise voluntary participation in HIV vaccine research in underserved communities [ § 46.111 Criteria for IRB approval of research]
- ★ Parole boards do not take into account a prisoner's research participation in making parole decisions  
[ § 46.305(6) Additional IRB duties where prisoners are involved]



## 3. Improving Human Subjects Protections

- ★ Enhancing informed consent for research on over-the-counter HIV tests in Appalachia (Basta)
- ★ Improving knowledge of rights to sexual reproductive health services among adolescents in South Africa (Thokoane)
- ★ Developing a culturally appropriate research training CITI module for American Indian/Native Alaskan communities (Pearson)



## 4. Changing Ethical Norms

Principle	Norm	Change
Beneficence/ Nonmaleficence	Special protections against research exploitation are necessary for prisoners defined as any individual involuntarily confined or detained in a penal institution.	The regulatory definition of prisoner must be broadened to reflect the fluid nature of detention and imprisonment so that prisoners participating in treatment studies are not cut-off from treatment immediately upon release from prison
Respect	Guardian permission is an essential protection for children involved in research	Guardian permission is a barrier to essential research on LGBT sexual health;; an independent youth advocate is a reasonable alternative mechanism
Justice	Vulnerable populations must be protected from burdens of research	Vulnerable populations must be provided equal access to benefits of research





# ERRE and the Fallacy of "Is to Ought"

## Empirical Facts

- ★ Describing what "is"
- ★ Comparing what "is" (*reality*) to the "ideal" (*ethical ideals*)
- ★ Interventions to match the real to the ideal
- ★ Changing ethical norms

## Interpretive Fallacies

- ★ Perceptions = reality
- ★ Ideals are universally held by stakeholders
- ★ The "is" should dictate the "ought"
- ★ Regulations and guidelines have the specificity or breadth to



# Designing ERRE Requires

- ★ Familiarity with relevant federal regulations, international guidelines, and organizational ethics codes
- ★ Familiarity with the Belmont principles and current moral arguments for their application to specific research practices
- ★ Experience necessary to identify current challenges to the implementation of human subjects protections
- ★ Respect for value of stakeholder perspectives
- ★ Openness to new ways of addressing these challenges



# References

- Dubois, J. D. (2008). *Ethics in mental health research: principles, guidance, and cases*. Oxford: Oxford University Press.
- Fisher, C. B. (2011) Addiction Research Ethics and the Belmont Principles: Do Drug Users Have a Different Moral Voice? *Substance Use & Misuse*, 46, 728-741.
- Kalichman, M. (2009). Evidence-based research ethics. *AJOB*, 9, 85-87.
- Koh, A. A. (2009). *The role of empirical research in bioethics*. *AJOB*, 9, 59 – 65.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). *The Belmont Report: Ethical Principles and Guidelines for the protection of human subjects of research*. <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>
- Sieber, J. E. (2004). *Empirical research on resarch ethics*. *Ethics & Behavior*, 14, 397-412.