Designing Research on Research Ethics

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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)

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What is Evidence-Based Research Ethics (EBRE)

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

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What is Empirical Research on Research Ethics [ERRE]?

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

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Research Ethics Pyramid

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Applying Research Ethics Criteria To the Design of ERRE

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Will your study inform investigators, IRBs, or other research stakeholders on how to design or evaluate whether studies…

- Will enhance health or knowledge (Social Value)?
- Apply sufficient methodological rigor (Scientific Validity)?
- Apply inclusion/exclusion criteria based on scientific objectives *not* convenience, vulnerability or privilege (Fair Selection)?
- Adequately minimize risk and maximize benefit (Favorable risk-benefit ratio)?

Will your study inform investigators, IRBs, or other research stakeholders on how to design or evaluate whether studies…

Develop population sensitive procedures to ensure informed, rationale & voluntary consent (Respect for autonomy)?

Ensure contextually relevant confidentiality protections (Respect for privacy)?

Adequately monitor participant well-being (Participant Welfare)?

Have sought and acquired adequate stakeholder involvement (Inclusivity)?

Will Your Study Help Interpret and Apply Federal Regulations or Organizational or International Guidelines?

For example

- U.S. 45CFR46 Protection of Human Subjects in Biomedical and Behavioral Research
- HIV Prevention Trials Network (HPTN) guidance document
- UNAIDS/WHO Ethical Considerations in Biomedical HIV Prevention
- CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects

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 administrative responses to participant complaints in HIV prevention studies (Underhill)

1. Lay of the Land
Description of Stakeholder Opinions/Beliefs

- African American women's evaluation of risks and benefits of group versus mHealth delivered HIV preventions (Broaddus)
- Peruvian FSW's post-experimental attitudes toward HPV research risks and benefits (Brown)
- Attitudes of Thai parents and youth toward YMSM participation in HIV related research (Guadamuz)

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2. Ideal v. Reality

- Extent to which sponsors of Kenyan PrEP study provide participants post-trial access to Truvada (Njuguna)
- Extent to which IRBs employ current standards for confidentiality protections for HIV recruitment involving social media (Curtis)
- Challenges to providing standards of prevention in a multinational HIV vaccine trial (Sachdev)

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; IRBs should follow state mature minor laws in approving guardian permission waivers
Justice	Monetary compensation should not be provided to drug using populations to protect them from exploitation	Drug using populations must be provided equal compensation for research participation and the same respect for their right to use the funds as persons who do not use drugs

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

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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

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