



# Challenges of Prevention Research

- Complex study designs;
- Multisite, international trials involving thousands of participants;
- Most participants are healthy “at-risk” volunteers;
- HIV infection is a necessary study endpoint;
- Results are affected by user behavior; and
- Studies involve culturally sensitive topics:
  - Sex and stigma.
  - Gender and power.



# Vexing Prevention Research Issues

- When is it unethical to use a placebo in an HIV prevention trial?
- What should be included in the HIV prevention package provided to all study participants?
- Do researchers or trial sponsors have an obligation to provide access to HIV treatment and care for seroconverters?
- Is there an obligation to provide new prevention tools to trial participants once the trial ends?



# Post-Trial Access

- What should be provided to research participants after their participation in a trial has ended?
- What, if anything, should be made available to others in the trial community or country?
- Upon whom does any legal and ethical obligation fall?



# Justice

Applying principles of justice to research, a study must:

1. Distribute the risks and benefits of research fairly across communities;
2. Be fair in choosing who to recruit; and
3. Protect vulnerable groups.



# Justice

Justice also requires that a trial not harm a community or an individual. A study should instead provide some benefit.

1. The research address health problems of concern to the trial communities; and
2. The treatment is made reasonably available to the study population after the research is completed.

# Post-Trial Access to Research Results

- What constitutes reasonable availability?
- Would requiring the provision of post-trial benefits deter much-needed research?
- Could providing post-trial access could create an undue inducement for individuals and communities?
- Does post-trial access create or exacerbate inequalities within and between communities based on differential access.



# Post-Trial Access to Research Results

There is a broader meta-ethical principle that we must always consider:

**“Ought Implies Can”**





# Post-Trial Access to Research Results

Return research results to individuals and communities in ways that are appreciable and contextualized.

Consider other ways in which post-trial benefits should be provided to the participants and the community.

- Education and training.
- Building research and clinical capacity.
- Providing equipment and other resources.