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?
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 should 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.