

# **Roundtable A**

## **Informed Consent**

### **From Theory to Practice**

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# The divided landscape of informed consent

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## The Spirit:

- ◆ Agreement between researcher & participant
- ◆ Dialogue
- ◆ Improves conduct of research
- ◆ On-going process

## The Reality:

- ◆ Requirement for enrollment
- ◆ One-way communication
- ◆ Legal and regulatory compliance
- ◆ One-time event

# Emergent Agreements

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- ◆ Informed Consent is a process
- ◆ Language & terms at appropriate level
- ◆ Conveying right amount of information
- ◆ Use of supplementary materials
  - Booklets, videos, fact sheets, flip charts
  - Drama, song, dance
- ◆ Signature & witness options
- ◆ Appropriate reimbursements

# Comprehension assurances: initial and on-going

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- ◆ Requirements
  - enrollment
  - on-going
- ◆ Costs and benefits of on-going monitoring
- ◆ Options for comprehension checks

# Partnerships with community

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- ◆ Community understanding of “research”
- ◆ Opportunities to work in partnership
- ◆ Benefits of working with community

# Norms and Values

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- ◆ Norms for women's autonomy may infringe on principal of Respect for Persons
- ◆ Partner consent/assent/notification
- ◆ Community views on trial approach to partner notification

# Social and Psychological Harms

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- ◆ Consequences of testing
- ◆ Stigma associated with HIV and/or TB research
- ◆ Rumors

# Essential Elements of Informed Consent

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- ◆ Description of *research & participant's participation*
- ◆ Description of *reasonably foreseeable risks*
- ◆ Description of *expected benefits*
- ◆ *Advantageous alternatives* to participation
- ◆ Explanation of *confidentiality*
- ◆ Explanation of *compensation for injuries*
- ◆ *Whom to contact* about the research & participants' rights
- ◆ Explanation that participation is *voluntary*