

**GLOBAL HEALTH TRIALS WORKSHOP:  
CLINICAL TRIALS IN UGANDA AND EAST  
AFRICA, FEB 14, 2013**

RESEARCH ETHICS AND CLINICAL  
TRIALS IN UGANDA,  
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# Outline of Presentation

- Research ethics in Uganda,
- Applicable guidelines,
- Research conducted,
- Clinical trials

# Research Ethics in Uganda

- Brief history of health research,
- Evolution of health research ethics,
- Research ethics in the 21<sup>st</sup> century,

# Applicable guidelines

- Belmont Report,
- CIOMS,
- UNAIDS Guidance Principles for HIV Vaccine Trials,
- Uganda National Guidelines for Research Involving Human Subjects, March 2007

# Research Conducted

- Basic
- Epidemiological,
- Socio-behavioural,
- Interventions,
- Operational

# Clinical Trials

- Scientifically beneficial,
- Scientifically and ethically sound,
- Conducted by a competent team of investigators,
- Relevant approvals available, IRB of record,
- Availability of proven efficacious product(s) at end of trials,
- Capacity building

# Examples of impactful trials conducted

- Burkitt's lymphoma,
- HIVNET 012,
- First HIV Vaccine trial,
- Mass treatment of STDs and HIV transmission,
- Safe medical male circumcision,

# Challenges: Experience by the National AIDS Research Committee

- Investigators: competency, Ugandans not involved or adequately committed “absent PI”
- Equipose not clear;
- Later submissions,
- Delayed responses to critique by the committee,
- Shopping around for “friendly” IRB
- Inadequate arrangements of product availability at end of trial;
- Tension between career development, financial gain, community benefit