Ethics Committee Perspective

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IRB/IEC

- Established to safeguard the rights, safety and well being of human research subjects

- The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial

ICH-GCP
‘A trial should be conducted in compliance with the protocol that has received prior IRB/IEC approval/favourable opinion’

ICH–GCP
• The ethics committee has an ongoing responsibility for the ethical conduct of research,……………

• Subjects must not be entered into the trial until the relevant ethics committee (s) has issued its favorable opinion on the procedures.

WHO-GCP
Importance of IRB Capacity Building

- IRB is responsible for human subject protection in research
- IRB is an important stakeholder in research
- IRB provides a system of check and balance in research
- Good IRB procedures contribute to quality data
Challenges

- Limited opportunities for training of ethics committee members
- Insufficient resources to create the infrastructure for ethical research
- Ethics and regulatory systems not well developed
- Limited legal framework for the oversight of clinical trials in many countries
- Low community knowledge about research
  - Comprehension level of IC; Low level of literacy; research versus treatment (Therapeutic misconceptions)
- Very weak post review process
- Lack of regulations about health research in many settings
- Weak institutional support for ethics committees
- Limited funding of African ethics initiatives, forums
Developing capacity in ethical review in Africa

- **Pan-African Bioethics Initiative (PABIN)**
  - founded in January 2001 at a pan-African conference

- PABIN is part of the Strategic Initiative for Developing Capacity in Ethical Review (**SIDCER**), a worldwide collaboration of institutions and people interested in promoting ethical review, with the aim of *"building competent, independent, in-country decision making for promoting the responsible conduct of human research"*. 
Public sectors

WHO/TDR, OHRP, ICMR

Private Sectors
- IFPMA
- WIRB

NGO – EFGCP
- PATH
- MFES

SIDCER

FERCAP
National Chapters

FLACEIS
National Chapters

FECCIS
National Chapters

PABIN
National Chapters

FOCUS
National Chapters
Activities: Embedding quality into ethics review by running the SIDCER Recognition Program for ethics committees

SIDCER Recognition Programme
- Launched in Ethiopia in 2006
- Conducted in Zanzibar, Madagascar, Liberia, Uganda, Ethiopia, DRC

Objective:
- to measure and provide accountability for the quality and effectiveness of ethical review worldwide.

- A SIDCER recognition certificate provided to an IRB/IEC is a sign that the highest standards of ethical review in clinical research are being met.
TOOLS

- Operational Guidelines for Ethics Committees That Review Biomedical Research
- Operational Guidelines for Surveying & Evaluating Ethical Review Practice
- SIDCER Self assessment Tool
- Standard Operating Procedures (SOPs) templates for IEC/IRB

ACTIVITIES THAT SUPPORT IEC/IRB RECOGNITION PROGRAMME

- Human Subject Protection Course
- IEC/IRB SOPs writing workshop
- SELF EVALUATION
  - SIDCER EC self assessment tool.doc
- Site Survey and evaluation
Conducting the SIDCER/PABIN Ethics committee recognition program
- AHRI/ALERT ERC, Addis Ababa University
- Faculty of Medicine IRB (2009)
- Uganda Virus Research Institute (UVRI) ERC (2010)
  - others ongoing (DRC, Ethiopia, Liberia)

National Chapters
- ETBIN
  - Capacity building of ethics committees in Universities in Ethiopia
Summary

- Capacity building is a priority to promote best practices in ethical review
- Mobilization of resources for sustainability of efforts towards strengthening ECs
- Collaborations of all stakeholders for a common goal
- Strengthening of Initiatives such as PABIN and its national Chapters in Africa

Thank You!