

Pan African Bioethics Initiative

**P A B I N**

Réseau Panafricain de Bioéthique

# Ethics Committee Perspective

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**Pan-African Bioethics initiative**

**(PABIN)**

**2012 EU GCP Inspectors Working Group Workshop**

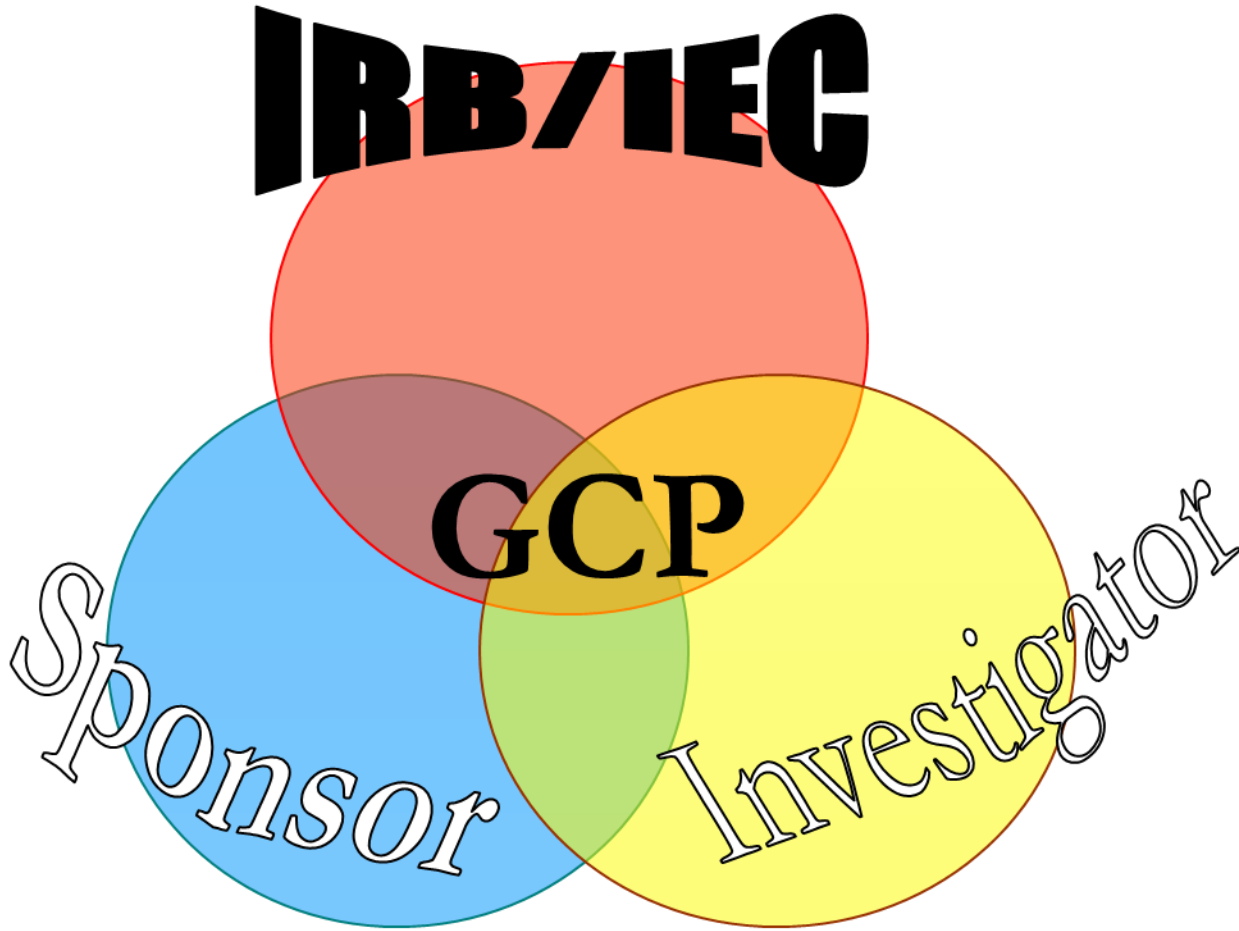
**12-14 November 2012, London**

**IRB/IEC**

**GCP**

*Sponsor*

*Investigator*



# 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.

# 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

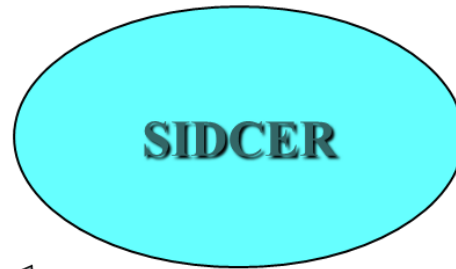
WHO/TDR, OHRP, ICMR

## Private Sectors

- IFPMA
- WIRB

## NGO – EFGCP

- PATH
- MFES



**FERCAP**

**FLACEIS**

**FECCIS**

**PABIN**

**FOCUS**

National  
Chapters

National  
Chapters

National  
Chapters

National  
Chapters

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**

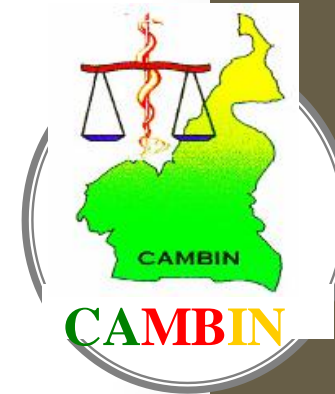
## ACTIVITIES THAT SUPPORT IEC/IRB RECOGNITION PROGRAMME

- **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**



ETHIOPIAN BIOETHICS INITIATIVE  
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# 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!***