

Role of PABIN and ETBIN in promoting the National Research Ethics Review System

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Ethical Review Capacity needs

- Research is the key to development
- Globalization and the challenges to health research – the 10/90 disequilibrium
- Protection of the research participant
- Decision making
- Understanding ethical dilemmas
- Consensus view point
- Ethical review structures

Ethics is a moral responsibility of all

• Right or wrong?

– Legal implications

• Basic principles: Independence, Pluralism, Competence, Transparency

• Integrity, fairness, knowledge, respect for human dignity

• Stakeholders: Researchers, Ethics Committee members, research participants

– all for the best interest of the research participant

• Capacity building a common responsibility and no one's protected sphere

• Civic Initiatives have a role

International initiatives

• Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

– build competent, independent, in-country decision-making for promoting the responsible conduct of human research.

• FORA: Asia (**FERCAP**), Latin America (**FLACEIS**), Eastern Europe (**FECEIS**) and North America (**FOCUS**)

– to strengthen ethical review capacity within countries

– to share the complexity of cultural variations, national laws, local medical and research practices, and local knowledge

– to develop similar structured approaches to address their specific needs.

Overseas Spending by U.S. Pharmaceutical Companies

The Body Hunters:

Exporting Human Experiments

- Where Profits and Lives Hang in the Balance:

“Finding an Abundance of Subjects and Lack of Oversight Abroad, Big Drug Companies Test Overseas to Speed Products to Market”

Washington Post – December 17 - 22, 2000

Concern for Ethical Review in Africa?

- **Heavy burden of disease; therefore greatest need for health research in Africa**
- **Vulnerable populations**
 - **Diseases**
 - **Ignorance**
 - **Poverty**
- **Need to support and guide conscience of investigators**
- **To provide public assurance**

•GREAT NEED FOR GOOD ETHICAL REVIEW IN AFRICA

Concern for Ethical Review in Africa?

- **Limited African regulatory infrastructure**
 - Variable Regulations and Codes
 - Shortage of competent personnel
- **Overburdened regulatory infrastructure**
- **Limited capacity for ethical review**
- **Limited capacity for monitoring**

- **Lack of experience, self-confidence?**

Pan African Bioethics Initiative

- **Established in 2001 in Lusaka, Zambia**
- **Held three Conferences to date**
- **Officers:**
 - C Chintu (Zambia), P Effa (Cameroon)
 - B Petros (Exec Committee member)
 - Organized Training workshops and meetings with AMANET, INSERM, EFGCP, etc.

Current activities of PABIN

- **Physical Secretariat in Addis**
 - Secretariat services to Executive Committee
 - Organizing Annual Conference
 - Running a website
 - Disseminating information
 - Communicating with ECs and Fora
 - Fund-raising
- **EDCTP application in progress with WHO, AMANET, INSERM for EC survey, networking, training**

Ethiopian Bioethics Initiative (ETBIN)

- **Established on January 21, 2002 with 24 founding signatories at ALERT**

- Secretariat at AHRI
- Organized the Third PABIN Conference with ESTC and NECC, April 28-30 2003 in Addis Ababa
- Recognized as the first National Chapter of PABIN on April 30, 2003

ETBIN Governance

Membership:

- Open to all Ethiopians or persons residing in Ethiopia who share the objectives of ETBIN
- Ordinary members are required to pay a membership fee
- Membership must be renewed biennially

Officers:

- Chairperson, Vice-Chairperson, Secretary, Treasurer, Education Officer, Communications Officer, and 3 additional Executive Committee Members.
- elected for a period of four years from among the Ordinary members participating in the General Assembly.

Finance:

- composed of membership fees, contributions, gifts, grants, research funding, or other sources of funding

Serving ETBIN Officers

The following were elected for a period of two years on 21 January 2002:

- Dr. Beyene Petros (Chairperson)
- Dr. Fisseha H/Meskal (Secretary)
- Dr. Abraham Aseffa (Communication Officer)
- Prof. Jemal Abdulkadir (Member)
- Dr. Abera Geyid (Member)
- Ato Asrat Hailu (Member)
- Dr. Mekuria Lakew (Member)

ETBIN Objectives and roles

- **providing a forum** for regular meeting and discussion on bioethics in Ethiopia;
- **preserving and promoting the Ethiopian traditions in ethics** and bioethics within the contemporary discussions on issues in bioethics;
- **improving communication among ethics committees** (ECs) reviewing biomedical research (including health, behavioural, and social science research) in Ethiopia;

ETBIN Objectives/Roles

- fostering education in bioethics and the training of members of ECs
- promoting and assisting the development of ethical committees
- acting as an Ethiopian collaborating centre for fostering ethical review
- organizing national meetings and symposia

ETBIN Objectives/Roles

- **assisting with the implementation of standard operating procedures for ethical review** in the country, taking into consideration the *"Operational Guidelines for Ethics*

Committees That Review Biomedical Research" and its complimentary guideline: *"Surveying and Evaluating Ethical Review Practices.*

- facilitating the development of national fora for members of ECs in Ethiopia;
- Coordinating information flow and responses on the subject of bioethics.**

Current status ETBIN

- Registration at the Ministry of Justice in process
- Grant received from NORAD to support initial activities
- Members active in creating and using for a for ethics discussions and training
- General Assembly to be called soon
- Call for membership

Issues in Research Ethics: examples

- Community consultation
- Informed consent process
- Placebo (the control arm)
- Standard of care
- Compensation, insurance and indemnity
- Post study responsibilities

Issues in Research Ethics

- Intellectual property rights
- Utilization of research results in public health
- Standard of ethical review and evaluation of ECs
- Capacity building
 - Training
- Needs driven research
- National ownership of research

Have a say in Research Ethics

- Get your proposals reviewed
- Serve in ECs

Contribute to a higher standard of ethics

- Join ETBIN**
- Join PABIN**