

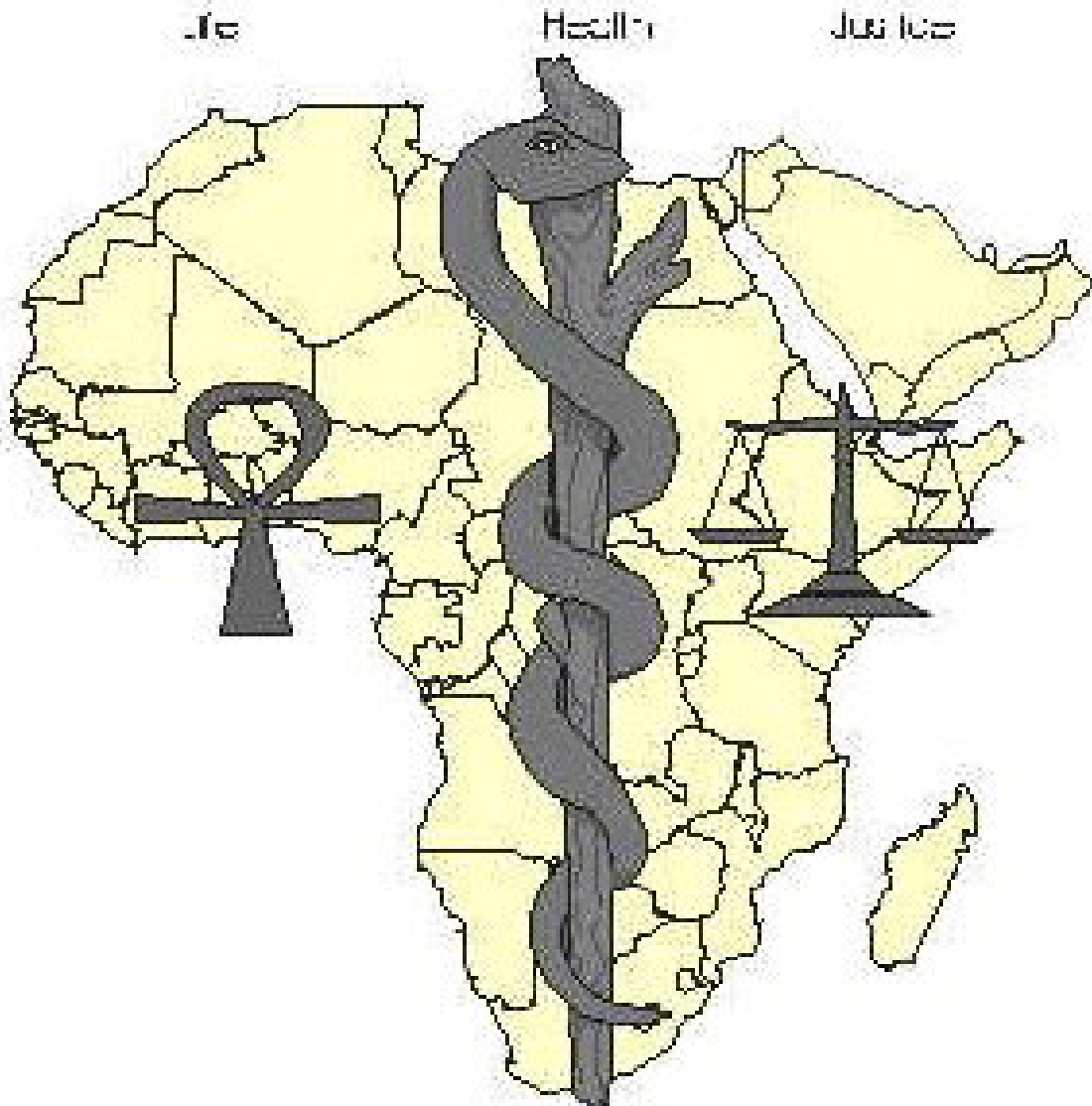
Pan-African Bioethics Initiative (PABIN)

Third Conference

Good Health Research Practices in Africa

28-30 April 2003

United Nations Conference Hall, Addis Ababa, Ethiopia





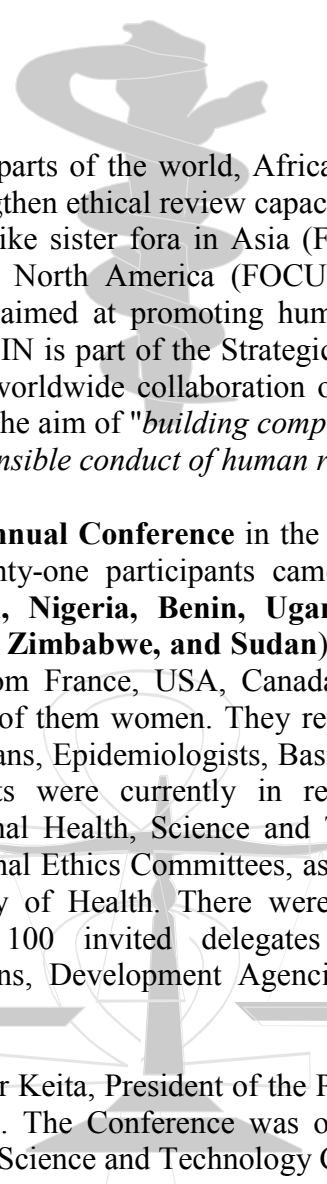
Pan-African Bioethics Initiative (PABIN)

28-30 April 2003
Addis Ababa, Ethiopia

Report on Meeting

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2. Background
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 - b. Previous Conference
3. Conference Programme
4. Summary of the deliberations at the Conference
5. List of Participants

Summary



Based on experiences in other parts of the world, African researchers launched a Pan-African regional forum in 2001 to strengthen ethical review capacities within countries. The Pan-African Bioethics Initiative (**PABIN**), like sister fora in Asia (FERCAP), Latin America (FLACEIS), Eastern Europe (FECEIS) and North America (FOCUS), is constituted as an independent, nongovernmental organization aimed at promoting human subject protection based on good ethical review procedures. 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*".

PABIN conducted its **Third Annual Conference** in the UN Conference Hall in **Addis Ababa** on **March 28-30, 2003**. Twenty-one participants came from **14** African countries (**South Africa, Tanzania, Cameroon, Nigeria, Benin, Uganda, Mali, Zambia, Cote d'Ivoire, Burkina Faso, Ghana, Kenya, Zimbabwe, and Sudan**) other than the host country, **Ethiopia**. International partners came from France, USA, Canada, Belgium and the WHO. Ethiopian participants numbered 104, 12 of them women. They represented 48 different institutions and were a mix of Lawyers, Clinicians, Epidemiologists, Basic Scientists, Veterinarians and Private Practitioners. Most participants were currently in responsible positions as Members of Parliament, National or Regional Health, Science and Technology Councils, as members of Institutional, Regional or National Ethics Committees, as Heads of Departments, Institutions or various Teams of the Ministry of Health. There were three former Ministers (and a vice Minister) of Health. Over 100 invited delegates of Embassies, Non-Governmental Organizations, civic associations, Development Agencies and Universities took part in the opening ceremonies.

The Honorable Ibrahim Bubaker Keita, President of the Parliamentary Union of Africa spoke at the opening of the Conference. The Conference was opened by H.E. Ato Mulugeta Amha, Commissioner of the Ethiopian Science and Technology Council.

The Conference discussed the following themes in the next three days:

- Expressing values in guidelines and research practices
- International guidelines and their application in the African context
- Increasing international understanding of in-country needs for human subject protection
- International research collaboration
- Quality assurance in ethics for research
- Measuring quality in research
- Accreditation in health research
- Expectations in achieving international cooperation in human subject protection

There was an appreciation for the need to strengthen ethical review capacities in the different nations in Africa and for education to be essential for this purpose. Participants called on countries that have not yet done so, to develop national guidelines integrating international research expectations into national practices in the African context. While formation of ethical committees was to be strongly encouraged, the need for Quality Assurance of ethical review and measurement of such quality was indicated to be a challenge to be faced at the same time. The role of PABIN in the next years would be to strengthen such capacity in Africa and represent the voice of Africa in ethics on the global scale.

Decisions taken at the Conference included:

The structure of PABIN will be based on representation by national chapters. The Ethiopian Bioethics Initiative (ETBIN) was recognized as the first national chapter of PABIN. Its by-laws were recommended as templates for sister chapters in Africa.

A physical Secretariat will be established for PABIN to run its daily activities and serve as document center. A bid will be floated for selection of candidate institutions.

The next meeting will be held in Benin in 2004.

Background

The following document was distributed before the meeting as background to the Conference:

This conference is the fourth in a series of international regional conferences contributing to the International Cooperative Project on Best Practices in Health Research. The aim of the project is to advance a global dialogue on Best Practices in Health Research. The project develops out of a concern to establish good ethical practices based on the development of systematic ethical review that supports ethical insight and responsibility on the part of researchers, sponsors, and government agencies. The project grows out of the international partnerships developed by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER).

This conference carries forward the work of the Pan-African Bioethics Initiative (PABIN) with regard to capacity-building for ethical review and the promotion of the protection of human subjects. This is a follow up of PABIN conferences held in Pretoria and Cape Town. It also brings together the work of several international workshops held by the African Malaria Network Trust (AMANET) in conjunction with PABIN.

The current discussion on the responsible development of research projects and the care required for research participants and their communities' forms a general framework for the conference. The conference explores current international guidelines for ethics and Good Clinical Practice, and their effect on national legislation, guidelines and research procedures.

Conference Background

This conference follows on the past two years of activities by PABIN. The programme is developed against a background of meetings and preparations that include the following:

- A Pan-African Workshop on Standard Operating Procedures for the Ethical Review of Health Research, organized by AMANET & PABIN in collaboration with Makerere University, SIDCER, & EFGCP (Entebbe, Uganda, 17-21 February 2003)
- AMANET Workshops on Ethics in Health Research in Africa, (Kisumu, Kenya, 23-27 April 2001; Addis Ababa, Ethiopia, 10-12 December 2001; and Khartoum, Sudan; 12-16 January 2003)
- Ethique et qualité en recherche clinique, organised by INSERM in collaboration with PABIN, French Institutions, EFGCP, Institut Pasteur, Espace-Ethique Méditerranée, Association pour l'Aide à la Médecine Préventive, Institut de Recherche pour le Développement, Faculté de Médecine Paris Sud (Pari XI), Fondation d'Entreprise GlaxoSmithKline-France (Paris, France, 21-23 October 2002)
- AMANET Combined Training Workshops on Health Research Ethics and GCP (Pretoria, South Africa, 3-4 July 2002; Libreville, Gabon, 30 September to 4 October 2002) International Symposium 2002: Good Ethical Practices in Health Research in Africa, Organised by PABIN in collaboration with EFGCP, WHO TDR, AMVTN, DHHS USA, INSERM France (Cape Town, South Africa, 23-24 February 2002)
- Workshop on Developing Ethical Review in Light of Contemporary Issues in Biomedical Research Ethics, PABIN (Medical University of South Africa, 8-9 November 2001)
- Seminar on Ethical Review Committees in Africa organised by TDR WHO in collaboration with AMVTN, CBS, EFGCP, & CIOMS (Lusaka, Zambia, 29-31 January 2001)

- Meeting on Planning a Workshop on Ethical Review in Africa (WHO, Geneva, 17 March 2000)
- Seminar on the Ethical Review of Biomedical Research in African Countries, organised by TDR WHO & AMVTN (Arusha, 5 November 1999)
- Seminar on Health Research Ethics, AMVTN (Arusha, 1-4 November 1999)
- Workshop for Establishing a Forum for Educating Members of African Ethical Review Committees, CBS, EFGCP & OAU (Organization of African Unity, Brussels, Belgium, 12 April 1999)

Conference Objectives

The primary objective of the conference is to examine ways to promote good ethical practices in health research in Africa. A major consideration is the value and effect of international guidelines on health research practice. Within this framework, the following specific objectives will be pursued:

- Examining and improving human subject protections in health research in Africa;
- An examination of operational procedures for ethical review in Africa;
- An examination of substantial issues affecting ethical review in Africa
- The relationship between investigators and ethics communities in Africa
- A review and discussion of specific ethical issues arising in the context of guidelines and their effect on health research practices (e.g., the use of controls in clinical trials and the availability of products following research);
- An examination of the quality assurance standards and procedures throughout the development of health research project;
- The applicability in Africa the ICH and WHO Guidelines on Good Clinical Practice and their relation to existing or developing national guidelines;
- The impact of the WHO TDR *Operational Guidelines for Ethics Committees That Review Biomedical Research and the implementation of the companion guideline Surveying and Evaluating Ethical Review Practices* (2000);
- The applicability of the WHO TDR Companion Guideline *Surveying and Evaluating Ethical Review Practices* (2002);
- The development of international guidance on Standard Operating Procedures for ethical review;
- The consideration of an African approach to accrediting ethical review committees.

Conference Outcomes

The meeting will aim to achieve outcomes for further actions in the following areas:

- The contribution to a study on the impact of international and national guidelines on health research practices in Africa.
- An analysis of the strengths and weaknesses of current guidelines;
- Suggestions for considerations in the development of future guidelines;
- The outlining of a systematic approach to addressing human subjects protections in international and national research in Africa.

Conference Format

A three-day conference consisting of discussion in plenary sessions and workshop groups, with a focus on the examination of the value and effect of ethics and GCP guidelines in Africa. The following themes will be discussed:

- Expressing Values in Guidelines and Research Practices
- The international Guidelines and the African Research Contexts
- Expressing Research Values in National Guidelines
- Increasing International Understanding of In-country Needs for Human Subjects Protections
- Ethics Quality Assurance for Research Participants
- National Considerations and International Concerns for Accreditation in Health Research

Conference Participants

The participants are African researchers and ethics committee members as well as international guests from leading research institutions involved in research in Africa.

Conference Languages

The languages of the conference are English and French

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The Third PABIN Conference is a follow-up of an earlier PABIN meeting in South Africa reported on below in *The Lancet*:

THE LANCET • Vol 359 • March 16, 2002 • www.thelancet.com
POLICY AND PEOPLE FEATURE

Africans discuss ethics of biomedical research

Cape Town, South Africa, provided the scenic backdrop for the Third Global Forum on Bioethics in Research held on Feb 21–23, which was followed by the Pan-African Bioethics Initiative (PABIN).

The forum provides a venue in which developing countries have significant input into the ethical debate on international collaborative research sponsored by industrialised countries and done in developing countries. Two thirds of the 110 delegates came from developing countries. Of the 40 countries represented, half were African. The forum is sponsored by the US National Institutes of Health and the Medical Research Councils of South Africa and the UK, WHO, and other international agencies. This year's forum was organised by the UK's Medical Research Council.

The meetings focused on some of the key issues in international collaborative research. These include whether current ethical guidelines constrain or promote post-trial access to drugs, devices, or vaccines; the difficulties in creating ethical guidelines and review processes in developing countries; the standard of care to be provided during trials; traditional medicines; genomics and global health; and culture and informed consent. Participants suggested that we need to move from the discussion on the content of ethical guidelines to their implementation.

Churchill Lukwiya Onen, from the Princess Marina hospital in Botswana, discussed concepts of justice in relation to post-trial access to drugs and devices. He noted that “differences in our interpretation and difficulties in translating research principles into realities must be urgently and amicably resolved”.

A comprehensive picture of the difficulties of doing HIV vaccine trials involving women in South Africa was provided by Douglas Wassenaar of the University of Natal. Women in sub-Saharan Africa carry 82% of the global burden of HIV infection. Their vulnerability to infection is, not surprisingly, affected by their status. This in turn is affected by sexual practices including the decreasing age of sexual debut, dry-sex practices—where foreign material is placed in the vagina to lessen lubrication and create more friction, male refusal to use condoms, a higher incidence of untreated STDs, female inability to behave assertively, transactional sex, and acceptance of multiple partners for males. There has also been an increase in child rape because of the belief that intercourse with a virgin will provide cure STDs.

He noted that fostering voluntary consent is a new ethical agenda in some communities and “would be perceived as a subversive and politically destabilising action”. Women's experiences of consent are likely to be severely compromised and it is these women who may be candidates for HIV trials. Like Onen, Wassenaar called for a transition from aspirational ethical codes to their practice relying on “emancipatory informed and sensitive social-scientific research and action . . . built on the voices of women”.

Godfrey Tangwa of the University of Yaounde, Cameroon, talked about the second scramble for Africa and how the continent presents the biggest and most attractive laboratory for western researchers. Where ethical review committees exist they are inundated with applications. He highlighted the lack of

regulation of research in some African countries, and called for the establishment of strong regional and national regulatory frameworks. This would also enable developing countries to make informed contributions to discussions about international guidelines.

With the greater involvement of genomics in drug development Peter Singer of the University of Toronto, Canada, posited that this science has the potential to increase the global pharmaceutical divide and increase health inequities. This effect, he said, was not unavoidable but much activity was required now. An opinion leader network should be created across different sectors: government, industry, NGO/patient organisations, scientists, and health-care leaders. Participants should familiarise themselves with the current state of genomics technology and frameworks for analysing ethical and legal issues. He called for a Commission on Global Genomics Governance to make recommendations for genome-related issues and activities. He asserted that there was an opportunity for pharmaceutical companies to become positive players.

The forum was treated to a visit to the South African Medical Research Council where the meeting heard from Motlalepula Gilbert Matsabisa. He discussed traditional medicines and a scheme being developed by the Council to try to ensure that any benefit derived from knowledge acquired from local communities about traditional medicines would be shared by those communities.

PABIN is part of the Strategic Initiative for Developing Capacity in Ethical Review, a worldwide collaborative of institutions and people interested in promoting ethical review. It was established within the tropical disease research division in WHO. The intention behind PABIN is to “share understandings of good ethical practices between African experts and international organisations involved in research in Africa” and the meeting continued discussion of the issues raised during the forum.

Participants from African countries discussed the difficulties they face in creating rigorous ethical review processes. The lack of regulation of ethical review and unavoidable conflicts of interest arising amongst the small number of people with the skills to be members of ethics committees were consistent themes. Formal academic training in ethics is limited and, in many countries, non-existent.

Donna Knapp van Bogaert of South Africa talked about the challenges of corruption, which she said thrived in environments of poor governance, and were exacerbated by poverty. She described the politicization of research, noting that in some states research could only proceed if it was authorised by a particular individual. People may be appointed to boards for factors unrelated to their knowledge or experience. It may be exceedingly difficult to act as a whistleblower, she said.

While the challenges of creating ethical guidelines and processes for research are significant in industrialized countries, fundamental issues arise for developing countries that may not have sufficient resources to create the infrastructure for ethical research. All participants agreed that it is crucial that support continues for initiatives such as PABIN.

Bebe Loff

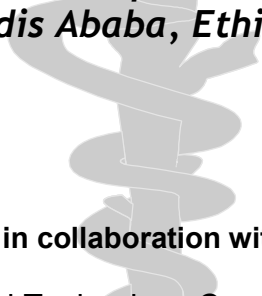


Pan-African Bioethics Initiative **(PABIN)**

An International Conference on Good Health Research Practices in Africa

28-30 April 2003
Addis Ababa, Ethiopia

in collaboration with



Ethiopian Science and Technology Commission (ESTC), FDRE
Ministry of Health (MoH), Federal Democratic Republic of Ethiopia
Addis Ababa University (AAU)
UNDP/World Bank/WHO, Special Programme for Research & Training in Tropical
Diseases (TDR/WHO)
African Malaria Network Trust (AMANET)
Department of Health and Human Services, USA
European Forum for Good Clinical Practice (EFGCP)
Institut National de la Santé et de la Recherche Médicale (INSERM), France
Fondation Marcel Mérieux (France)
Glaxo Smith Kline (GSK-Belgium)

developed within the framework of the

Strategic Initiative for Developing Capacity in Ethical Review
(SIDCER)



An International Conference on Good Health Research Practices in Africa Pan-African Bioethics Initiative (PABIN)

Conference Programme

Day 1 Monday, 28 April 2003

- 08:00 - 9:00** **Registration**
- 09:00 - 09:30** **Opening Addresses**
- Chifumbe Chintu, Chairman, PABIN
H.E. Ato Mulugeta Amha, Commissioner, Ethiopian Science and Technology
Commission, Ethiopia
WHO Representative to Ethiopia
Office of the Secretary General African Union (AU)
- 09:30 -10:00** **Keynote address:**
- The Application of Cultural Values and Ethical Principles to Health Science
Research Dr. Yayehiyrad Kitaw, Ethiopia (unable to attend)
- Developing a Pan-African Approach to Research Ethics: The PABIN
Contribution to SIDCER (Strategic Initiative for Developing Capacity in Ethical
Review) Dr Juntra Karbwang (WHO/TDR, SIDCER Secretariat)
- 10:00 - 10:30 Group Photo & Coffee Break
- Plenary Session 1: Expressing Values in Guidelines and Research
Practices***
- Chairperson:** **Beyene Petros, Ethiopia
Achille Massougboji, Benin**
- Rapporteur:** **Mulu Muleta**
- 10:30 - 11:00 Research Values and Research Practice: The Need for Education and Guidance
in Support of Research
Douglas Wassenaar, University of Natal, South Africa
- 11:00 -11:30 Decision-making in Ethics: Challenges to Ethics Committees when Reviewing
In-country and International Proposals
Wen Kilama, African Malaria Trust Network (AMANET)

11:30 - 13:00 **Working Groups, Session I: Examining the Current Challenges to Human Research Protections**

Chairpersons: Fisseha Haile Meskal (ETBIN, Ethiopia);
Yemane Teklai (ESTC, Ethiopia);
Howard Engers (ETBIN, Ethiopia)

- What are the interests and needs of patients/subjects and potential research participants?
- What questions (ethical, scientific) are common to the research environment?
- What mechanisms do researchers currently have available to resolve challenges in the research environment? Of these, which mechanisms are most often used? Which are most successful? Which provide the least satisfaction?

13:00 – 14:00 Lunch Break - National Hotel

Plenary Session 2: International Guidelines and Their Application to the African Context

Chairperson: **Faiza Mohammed Osman, Sudan**
Pierre Effa, Vice Chairman, PABIN (Cameroon)

Rapporteur: **Abera Geyid**

14:00 - 15:00 Reports from Session I of the Working Groups and Plenary Discussion

15:00 - 15:30 An examination of operational procedures for ethical review in the region: How are we doing in the implementation of the Operational Guidelines?
Paul Ndebele, Zimbabwe

15:30-16:00 Tea Break

16:00 - 16:30 Surveying and Evaluating EC Practices in African Countries
Wen Kilama and Joas B. Gugemalila, Tanzania

16:30 - 17:30 **Roundtable Discussion I: The Application of International Guidelines to African Research Needs**

Moderator: Francis Crowley (EFGCP); M. Bouesseau (WHO)
Panel: Adeyinka Falusi, Nigeria; Achille Massougbojji, Benin;
Banson Barugahare, Uganda; F. Debois, France;
Wen Kilama, Tanzania; Eyassu Mekonnen, NECC.

17:30 - 18:00 Presentation by other Invited Organizations
A. Falusi, African Health Research Forum
Damen H/Mariam, Ethiopian Public Health Association.

19:00 Reception at Ghion Hotel

Day 2: Tuesday, 29 April 2003

Plenary Session 3: Expressing Research Values in National Guidance

Chairpersons: Adeyinka Falusi, Nigeria

K. Doucoure, Mali

Rapporteur: Fisseha H. Meskal

8:30 - 10:30 **Round Table Discussion II: Country reports on current systems of National Guidance for human subject protection**

Panelists: Representatives from various African countries:
Tilahun Teka, NECC, Ethiopia; A. Mwinga, Zambia; C. Mgone, Uganda; O. Bindi, Mali; P. Tindana, Ghana; A. Sinei, Kenya; A. Falusi, Nigeria; A. Massougbojji, Benin; P. Effa, Cameroun; R. Kingamkono, Tanzania; Abera Geyid, Ethiopia; P. Ndebele, Zimbabwe; D. Wassenaar, S. Africa; F. Osman, Sudan

10:30 - 11:00 Coffee Break

11:00 - 12:30 **Working Groups, Session II: Integrating International Research Expectations into National Practices**

Chairpersons: Gilles Landrison (Counselor, French Embassy);
Getachew Aderaye (Addis Ababa University);
Tilahun Teka (NECC, Ethiopia).

- What are the current needs for in-country guidance on human subject protections?
- How do current international guidelines assist in developing in-country guidance, education programmes, and regulatory structures?
- Which international engagements would most assist the development of in-country protections for research participants?

12:30 - 14:00 Lunch

Plenary Session 4: Increasing International Understanding of In-Country Needs for Human Subjects Protections

Chairpersons: M. C. Bouesseau, WHO
Jemal Abdulkadir, Ethiopia

Rapporteur: Eyassu Mekonnen

- 14:00 - 15:00 Reports from Session II of the Working Groups and Plenary Discussions
- 15:00 - 15:40 Report from National Medical Associations in Africa Regarding Their Support for Research and Ethical Review
Representatives of National Medical Associations: F. Osman, Sudan; Joseph Kahamba, Tanzania; K. Doucoure, Mali; Adem Ali, Ethiopia.
- 15:40 - 16:20 Tea Break
- 16:20 - 16:40 Specific Concerns for Paediatric Research in African Countries, Lulu Muhe, Ethiopia
- 16:40 - 17:50 **Roundtable Discussion II: The International Researcher: Partnership and Decisions**

Panelists: J. Karbwang, WHO; F. Crawley, EFGCP; Melody Linn, NIH; M. Bouesseau, WHO; Yemane Teklai, ESTC; Damen H/Mariam, Ethiopian Public Health Association; J. Simpure; Bouyou-Akote, E. Nkandu, Zambia; F. Hirsch, INSERM
- 18:00 - 19:30 PABIN Business Meeting
a) Chairman's Report
b) Report by the treasurer
c) Report by Officers
d) PABIN Chapters By-laws
e) Election of Office Bearers
- 19:30 Cultural Evening at Crown Hotel
(Transportation from Ghion Hotel at 19:00 hours)

Day 3: Wednesday, 30 APRIL 2003

Plenary Session 5: Quality Assurance in Ethics for Research Participants

**Chairpersons: Rose Kingamkono, Tanzania
Eyassu Mekonnen, Ethiopia**

Rapporteur: Abraham Aseffa

08:30 - 10:00 **Round Table discussion III: Quality Control and Assurance Systems for Health Research**

Panelists: Adanech Kidanemariam, Ethiopia; F. Debios (Fondation Merieux), France; R. Carpentier, Canada; J. Karashani, Zambia; B. Barugahare, Uganda; A. Massougbodji, Benin;

Legesse Zerihun, AAU; Yemane Berhane, AAU; Eyassu Mekonnen, NHSTC, Ethiopia; L. Sidibeh, Ghana

- 10:00 - 11:00 Report and Discussion of Recommendations from AMANET/PABIN Workshop on Standard Operating Procedures for Ethics Committees; Entebbe, Uganda
Charles S. Mgone, AMANET
- 11:00 - 11:30 Coffee Break
- 11:30 - 11:45 The Development of a European Approach to Ethics for Health Research in Africa
Francis P. Crawley, European Forum for Good Clinical Practice [EFGCP] & François Hirsch, INSERM
- 11:45 - 12:00 The Canadian Contribution to International Research Ethics
Richard Carpentier, Executive Director, National Council on Ethics in Human Research [NCEHR])
- 12:00 - 13:00 Lunch Break
- 13:00 – 14:30 **Working Groups, Session III: Measuring Quality in Research and Demonstrating Best Practices**
- Chairpersons:** Adem Ali (Ethiopia)
Azeb Tamirat (Ethiopia)
Samuel Sinei (Kenya)
- What aspects of health research require the development of quality systems:
 - How can quality systems be assessed and evaluated?
 - What role should national associations and institutions play in quality assurance: What role should international associations and institutions play?
- Plenary Session 6: National Considerations and International Concerns for Accreditation in Health Research**
- Chairpersons:** **Melody Lin, Director, Office for Human Research Protection (USA); Francis P. Crawley, Secretary General & Ethics Officer, European Forum for Good Clinical Practice (EFGCP).**
- 14:30 - 15:30 Reports from the Working Groups and Plenary Discussions
- 15:30 - 16:20 **Accreditation in National Research Programmes with a View Toward International Assurances**
- Panelists: R. Carpentier, Canada; D. Wassenaar, S. Africa; J. Karbwang; F. Hirsch, INSERM; Francis P. Crawley, EFGCP; Fisseha Haile Meskal, ETBIN, Ethiopia

16:20 -17:20

Round Table Discussion IV: What Expectations should we have for Achieving International Cooperation in Human Subjects Protections?

Panelists: P. Effa, Cameroon; C. Chintu, Zambia; B. Petros, Ethiopia; A. Falusi, Nigeria; F. Crawley, SIDCER; D. Wassenaar, S. Africa; H. Bihonegne, Ethiopia;

17:20 - 18:40

Closing Remarks:

Chifumbe Chintu, PABIN Chairman
Pierre Effa, PABIN Co-Chairman

Closing

Summary of the deliberations at the Conference:

1. *Expressing values in guidelines and research practices*

Douglas Wassenaar (University of Natal, South Africa): spoke on research values and research practice and the need for education and guidance in support of research. He introduced SARETI The South African Research Ethics Training Initiative, Website: <http://shsph.up.ac.za/sareti.htm> and the opportunity for the African region to benefit from the programme in building capacity in ethical review standards. The goals of SARETI are among others to: ● provide advanced, multi-disciplinary education in health research ethics to senior professionals in Africa whose work impacts on health research ethics; ● strengthen institutional capacity to provide health (research) ethics education, development and research in Africa ● increase Ethics Review Committee awareness of ethical issues in health research ● extend the impact of SARETI programs by facilitating the networking of professionals with health (research) ethics training and experience in Africa ● build ethical review capacity and regulatory infrastructure for health research in Africa ● simultaneously advance the benefits of science and the protection of human participants ● assist in the prevention gross human rights abuses and exploitation – in research and otherwise. SARETI provides: 1. Modular Masters Degree (MPH or MPhil or MSocSc - Research Ethics); 2. Intensive Certificate training (3 – 6 months); 3. Ethics Review Committee Training Programs; 4. Workshops & Seminars; 5. African Health Research Ethics Symposium (AHRES) in 2006 - involving PABIN and (all) other FIC programs.

Wen Kilama (African Malaria Trust Network) discussed the challenges to ethics committees when reviewing in-country and international proposals. He stated that Africa “bears the brunt of health problems and as such has the greatest need for health research and therefore ethical review”. The current debates are on community consultation, informed consent process, participatory research, placebo as control arm, medical treatment during research, counseling, and data safety monitoring. He listed issues hardly considered by ethical committees (ECs): poverty, sponsorship, compensation, capacity strengthening, post-study responsibilities, intellectual property rights and utilization of research results in public health. The way forward, he said was to “build capacity of professionals in ethics review, to promote participatory research, mutual trust with ‘guest researchers’ and to promote national ownership of research”.

Working Group reports examining the current challenges to human research protections:

Interest/needs, concern/expectations of patients/subjects and potential research participants:

- relief from suffering, solutions to health problems, contribution to society, safety (no harm), confidentiality, respect, justice, benefits
- information, access to care: individual and community, altruism
- compensation, clarity of ideas
- background knowledge on and public health importance of the research question

Questions common to the research environment:

- independent scientific and ethical evaluation of the research (methodology and relevance), autonomy of the Committee (absence of conflict of interest)
- proper consent after full information, risk:benefit ratio, safety, motivation to young researchers, equity in North-South collaboration, intellectual property rights
- appropriate design reflecting capacity building component, clear agreements on data ownership, memorandum of understanding between institutions
- importance of research in advancing science, continuity

Mechanisms researchers currently have to resolve challenges in the research environment:

- exchange of experience, exchange of samples, e-learning, training
- guidelines, ethical committees
- design research from needs of the environment, empower participants to take informed decision, involve the local community chiefs/traditional leaders continuously and respond to their interests/suggestions
- design participatory research, develop memorandum of understanding and clear agreements early
- common sense - “trop d’ethique tue l’ethique et la recherche”

2. *International guidelines and their application to the African context:*

Paul Ndebele (Zimbabwe) reviewed the current status in Africa in the implementation of the operational guidelines developed by WHO.

Wen Kilama (African Malaria Trust Network) presented a report on a survey conducted to evaluate EC practices in African countries.

Roundtable discussion: The application of international guidelines to African research needs:

What responsibility do we have to produce guidelines and how do we realize these in practice? An asset would be the presence of strong professional associations with Codes of Ethics which provide fora for relevant discussion. Community consent is an important factor in the ethical conduct of research in Africa. International collaboration in research should ensure the early involvement of African partners as equals and avoid last minute add-ons engineered to obtain ethical clearance. The need for an African voice in the preparation of international guidelines was stressed by participants.

3. *Expressing research values in national guidance*

Round table discussion II: Country reports on current systems of national guidance for human subject protection

Ethiopia: The Ethiopian Science and Technology Commission (ESTC) has a 30-member National Health, Science and Technology Council (NHSTC) which provides advice to the Federal Government on policy matters. One of the standing committees of the NHSTC is the National Ethical Clearance Committee (NECC). National guidelines for ethical clearance procedures were issued in 1997. Proposals involving vulnerable subjects, clinical trials, HIV-related studies, export of samples and external sponsorship with funds from abroad require NECC review. Prior approval of proposals from initiating institutional ECs (including those from abroad) are required. Regional ECs are responsible for clearance at State Government level. All ECs have to be registered at the NECC.

Zambia: The School of Medicine in Lusaka has an EC since 1979. It operates on the principles of the Declaration of Helsinki and CIOMS Guidelines. The EC has a fulltime Secretariat and now serves as the national EC. Members come from different professions. Training is provided. SOPs are being developed. A standard fee is received from reviewed proposals. Legal support to the University of Zambia EC may need to be obtained.

Burkina Faso: A nine-member institutional committee composed of different professionals evaluates proposals.

Ghana: There is no national guideline. Ad hoc Committees are formed in the Ministry of Health to review proposals. At Navrongo, a technical committee reviews the scientific content of proposals. Community is consulted and Divisional chiefs are approached. In 2003, Institutional ECs are being established. A country-wide conference was conducted in March 2003 with participants from 9 health institutions. A Ghana Bioethics Initiative is in the process of formation and will assist in the development of national guidelines.

Kenya: There is no national EC. The two medical schools and KEMRI have each their own independent ECs. The need for a coordinating body is felt.

Nigeria: There are 5 registered ECs. There is no coordination, although all base their activities on international guidelines (CIOMS, Declaration of Helsinki, TDR/WHO Guidelines). The University of Ibadan has a 16-member EC (with 8 women). There are plans to establish a national chapter of PABIN in Nigeria.

Benin: There is no national EC. The Institutional EC in the Faculty of Science has 17 members (with 3 women). The EC charges fees for review, which goes to the Institute. There is a problem of compliance by some non-governmental organizations to ethical reviews of projects.

Cameroon: The Ministry of Health has an EC since 1985. The 3rd meeting of the Cameroon Bioethics Society was held in Yaounde in January 2001.

Tanzania: Each of the 4 medical schools have their own ECs. Some of their projects are submitted to the National Institute of Medical Research for review. A national guideline was issued by the Ministry of Health in 2001.

Zimbabwe: The Medical Research Council (established in 1974) has a 14-member committee that reviews all project proposals. Members are appointed for 4 years by the Government from the Ministry of Health, Medical Insurance Industry, medical Associations, etc.). The Drug Control Authority is responsible for matters related to drugs. Fees are charged as percentage of project budget.

South Africa: There are 35 registered Institutional Review Committees. Some of them have received accreditation by the OHRP. National GCP guidelines are available in electronic form to guide the local ECs. There is a national review committee that serves as an appeal body in case of conflict. The national committee approves especial guidelines (e.g. for research issues involving HIV-infection).

Sudan: There are Institutional and National Ethics Committees. For vulnerable populations, a double approval system is instituted.

Mali: has a national EC.

Issues discussed:

- Need for national legal provisions for ECs
- Role of national ECs
- Ethics committee independence
- EC constitution: appropriate representation of the research participants in ECs
- Standard operating procedures for ECs
- ECs review both the science and ethics of proposals: should it be separated?
- Financing ethical review: who should pay? how?
- Follow-up of ethical reviews: how to enforce these
- Training needs in EC: Role of schools in training for EC capacity building (e.g. medical schools)

PABIN is expected to contribute to the further in-depth discussion of these issues and to assist in the development of general guidelines and recommendations.

Integrating international research expectations into national practice:

Current needs for in-country guidance on human subject protection:

- There is a need for national guidelines: diversity in culture, values, interest, economic strength, etc. Example: consent may be understood differently in different cultures.
- African voice is not sufficiently included in the development of the international guidelines
- Surveys need to be done to identify the needs of ECs
- Local institutional guidelines could form the basis for national guidelines
- National guidelines should have a legal backing.
- Political support emanating from priority of research reflecting country public health priority

- Monitoring and regulatory structures are essential components of the ethical review systems

How current international guidelines assist in developing in-country guidance, education programmes and regulatory structures

- Many countries follow in-country and international guidelines. There is however a need to train members of the ECs and young researchers. Ethics training should be put into courses in formal training programmes of universities.
- International guidelines could serve as framework to develop, in-country guidelines that best meet their needs (accommodate the local values, interests, cultural diversity and traditions). These need to be translated into local languages. They need to be tested in the local context to test whether they perform well in country-specific situations. Local guidelines will probably differ in emphasis on certain aspects of subject protection, such as community ownership, capacity building, poverty-related issues,
- Traditional natural medicine has to be addressed and incorporated into guidelines
- The legal framework for monitoring research needs to be strengthened/implemented
- EC shopping has to be prevented by coordinating ECs, e.g. through national ECs

International engagements to assist the development of in-country protections for research participants

- PABIN could organize periodic training programmes, SARETI could provide training for members of ECs.
- International workshops and discussion fora to promote understanding
- PABIN should assist in the development of national guidelines in Africa
- Electronic media
- National and international funding should be sought for ethics capacity building
- International agencies could be involved (UNESCO could assist in matters of training, WIPO in intellectual property rights, PABIN in matters of equity and African voice)

Discussions/remarks:

- Although not satisfactory, Africans were involved in the discussions on the CIOMS Guidelines
- Memoranda of Understanding should be widely employed to regulate North-South partnership in research
- Traditional medicine is given attention in some countries such as in Ethiopia, where the group are represented in the National Council
- Ethics committees should interact with institutions and monitor projects regularly
- WHO could assist in the development of national guidelines for ethical reviews in Africa.
- PABIN should work towards establishing regional guidelines for ethical review.

4. *Increasing international understanding of in-country needs for human subject protection*

Report from the national Medical Associations in Africa regarding their support for research and ethical review:

Medical Association of Tanzania (established 1965) with currently over 1000 members, represented in the National Medical Research Council, in Ethics Review Committees and medical research coordinating committees. Identified constraints: not represented in health institutions, no health research ethics course in the medical school curriculum.

Ethiopian Medical Association: formulated its own Code of Ethics in 1983, which has been revised twice since; does not have its own ethics review committee but members participate in various ECs; is member of the World medical Association and has participated in the Edinburgh declaration.

No formal reports were prepared by other African Medical Associations because of the failure of communication for which the Organizing Committee apologized.

L. Muhe (WHO): highlighted certain concerns for pediatric research in African countries. He referred to the Convention of Human Rights on the Rights of Children (Article 12) under which governments are obliged to respect the dignity and rights of the child. He pointed out areas of particular research difficulties (studies involving newborns, HIV-infection, drug-trials, vaccine trials).

Discussion:

- Dilemma is whom to ask for consent: child, parents, community, all?
- HIV diagnosis is a major problem for studies in small children.
- Should clinical trials be done on children when they can be done on adults, when the target of application is the child?

- It was mentioned that attitudinal changes of researchers may be required for the good conduct of research.
- It was emphasized that clinical trials in Africa should be done by Africans for reasons of equity, responsibility, sustainability, capacity building, among others.

Roundtable discussion II: The International Researcher – Partnerships and decisions

Melody Linn (NIH): remarked that US institutions have vast experience in international collaboration, including with Africa. Partnership is to work close to the institutes. International collaboration should be strong in science and based on the approval of country ethics committees as well as that of the collaborating institution. She re-iterated that decision making is a challenge for individual researchers and ethics committees. There must be somebody in the Committee who understands the local condition. From the African point of view, it is understandable that a researcher might question why he/should use US ethical guidelines.

M. Bouesseau (WHO): listed some conditions for partnership: identification of responsibilities of partners, transparency (clear information from ECs), declaration/resolution of conflict of interest, legitimacy of ethics committees. Essential matters in decision making by ECs include

clear decision (positive or negative), pluralism in ECs, integration of scientific criteria, legal approach and professional assurance.

Yemane Teklai (ESTC, Ethiopia): remarked that there should be a standard definition of the “partnership” with clear hierarchy in levels of collaboration based on the principle of equity. He condemned the practice of non-Africans giving ethical clearance for research in Africa without due involvement of the relevant African institutions/researchers. Donor-driven research, often with little relevance to the priority problems in the country, poses a challenge for ethical review. Decision-making in partnerships should include decision on overall design/management of the project on an equal basis, including decision making on the financial allocations, data management and intellectual rights and ownership as well as on responsibility and workload.

Damen Hailemariam (Ethiopian Public health Association): North-South collaboration should be encouraged in principle not least because it is useful for capacity building. Control mechanisms should however be put in place to avoid misunderstandings. The comparative nearness of the North to publishers has often affected authorship. Decision-making should in principle be retained at the “home-level”.

E. Nkandu (Zambia): pointed out common problems in collaborative proposals. Consent forms (from the North) are often long and difficult to translate. Ethical approval in a northern country does not predict (nor guarantee) definite approval in an African country! Health insurance coverage in case of damage to research participants should be the responsibility of the health researchers. Sample use should be restricted to the approved study only.

F. Hirsch (INSERM, France): stated that France does not sponsor proposals which do not involve French as collaborators. There is no EC in France that evaluates proposals to be carried out in the South. France has partnership with West-African countries and supports Ethical review capacity building in these countries. The first Francophone Workshop for Africa took place in Madagascar and Haiti. France works in partnership with PABIN, French Research Institutions and Ministries, EFGCP and several pharmaceutical companies. Similar workshops are being carried out in 2003. he mentioned that there will be a meeting in April 2004 in the context of the Global Forum for Bioethics in Research.

F. Crawley (EFGCP): addressed issues related to responsibility to society individuals. Partnership in decision-making where money is involved and accommodating partners in decision making.

Discussion:

- Is the definition of “international researcher” based on geography or money?
- The need for equitable partnership was emphasized repeatedly
- It was recommended that there should be two PIs in such collaboration: one from the North and the other from Africa for research to be carried out in Africa.
- The consent form should be formulated by the African partners
- Governments should be encouraged to allocate money for research and ethical review capacity building, not least as a gesture of political support for subject protection.

5. *Quality assurance in ethics for research participants*

Roundtable discussion: Quality control and assurance systems for health research

R. Carpentier (Canada) pointed out that demand for quality comes from different sectors: the public, the government, industry etc. Often ECs have difficult decisions to make and have huge responsibilities for the citizen. One such challenge is use of stored samples or tissue. Erosion of public confidence, especially in relation to corporate interest, could make research more difficult. Implementing quality assurance in research will improve quality of research, maintain public confidence and provide a better future for research.

J. Karashani (Zambia) indicated the need for appropriate training of EC members. Funds are often unavailable for follow-up monitoring of approved projects. Lack of good liaison with the Drugs and Poisons Board, who are responsible for importation of medicinal plants, has led to situations where, for example, drugs imported for another purpose are used for research.

B. Barugahare (Uganda) emphasized the need for Africans to demonstrate competence and avoid “being corrupted by the system”. There should be SOPs for ECs and regular monitoring of their activities. He gave a case example from Uganda (where the establishment of a DSMB for a TB drug trial was waived) to illustrate the point.

A. Massougbodji (Benin) noted that there are no common standards of quality. Sponsors require different standards (e.g. the public sector vs. pharmaceutical companies). In addition, the experience of researchers affects standards. The type of research participants is also a factor in expected standards. Defining standards is particularly important in multi-center studies. Which standard should be applied: North or South. A similar issue is what standard to apply for secondary effects of trials that might emerge 10 years later.

E. Mekonnen (Ethiopia) reflected on the various factors affecting quality of research ethics, including competence of researchers, the quality of the study design (how scientific, quality of informed consent, justice, beneficence, Memorandum of Understanding, implementation feasibility of the study results, etc). He remarked that evaluation of competence of researchers and ECs is a big challenge. EC performance can depend on membership diversity, experience, training, integrity, self-confidence, discipline to SOPs, among others. Monitoring could assist quality assurance. Other mechanisms should also be explored to ensure quality. ECs should ensure that African researchers have a say in partnership projects and at the same time protect them from both undue inducement and exploitation.

Discussion:

- Africa does not need to create novel QA/QC mechanisms particular to itself alone. What we need is to adapt the international guidelines of GCP to our context and to strengthen capacity in our institutions through PABIN, AMANET, etc.
- F. Hirsch reviewed the history of efforts to develop quality, assure the authenticity of data and high standards of ethics up to the current concept of Good Practices

(clinical - GCP, laboratory - GLP, manufacturing – GMP, and in preparation: good data management, good ethical review). He emphasized that “there is no ethics without GCP”.

- Further issues addressed were:
 - o Standard of care, rights of seniors and juniors in collaborative research, equity.

Charles S. Mgone: presented a report on the recommendations from AMANET/PABIN workshop on Standard Operating procedures for Ethics Committees (Entebbe, Uganda). Thirty-seven of 40 participants were from IRB members from 10 African countries. SOPs were prepared and it is expected that these will be supported by training, capacity building and advocacy at the national level for adaptation. Follow up workshops are planned.

F. Crawley (EFGCP): gave a sobering talk under the topic: “*(Post) colonialism in biomedical research ethics: wherefore European research ethics?*” He discussed the challenge of human dignity and social justice in an economically and politically unbalanced world. The EFGCP is “engaging a conversation on ethics in research with other regions of the world *largely* through the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)”. He warned against attempts at imposing European rules on African setups and emphasized that “the core of ethics is decision-making”. He re-iterated that the challenge to international health research is to ensure the integrity and quality of a decision. This requires appropriate decision-making structures. “The EFGCP is committed to developing an ethics in international health research that gives priority to *integrity, independence, and competence in decision-making*”, he stated. “This should be the distinguishable international dimension to ethics in health research”.

F. Hirsch (INSERM) described the collaboration of INSERM with West African countries. He presented a list of previous meetings on ethics organized by INSERM (1999 Bethesda, 2000 Yaoundé, September 2002 Libreville, October 2002 the first Francophone Workshop on “*éthique et bonnes pratiques de la recherche clinique*” held in Paris and outlined similar plans for 2003 and 2004. A meeting on “The impact of Intellectual Property Rights on Research and Health Inequity in DCs” is planned for April 2004: 5th meeting in UNESCO (Paris) in the context of the Global Forum in Bioethics for Research.

R. Carpentier (NCEHR, Canada) talked on the contribution from Canada to ethics for health research in Africa. Canada has over 500 ECs including the private committees. There is an accreditation system for ECs.

The role of accreditation was discussed following his talk. Melody Lin remarked that the accreditation systems in Canada and the US are similar. The accrediting body is a non-for-profit body outside the government. No mandate by government is essential. R. Carpentier noted that it would be advisable that the initial steps are taken by the government and further follow-up could be supported by others.

Working Group session III: Measuring quality in research and demonstrating best practices

The following issues were addressed in the discussions:

- All research and ethical review requires quality assurance.
- Mechanism for development of EC standards include provision of certificates, regular systematic reporting, submission of progress reports
- Associations have a role to play to assure quality of EC reviews
- Self-evaluation of ECs
- A point of appeal of EC decisions in the structure, e.g. at the national level
- Registration of all trial sites in a given country and monitoring
- Obligation by researchers to declare prior rejection by any EC
- Training at University level
- Establishment of a clinical site registry
- Effective use of DSMBs

6. National considerations and international concerns for accreditation in health research

Accreditation in national research programs I with a view toward international assurances:

South Africa (D. Wassenaar): Interim National Health Research Ethics Committee accredits all IRBs and ERBs in S. Africa. Unlike in Canada, accreditation is mandatory in SA. In SA, the definition of health research includes all research that involves humans (and not just clinical trials).

Ethiopia (Yemane Teklai): The EC in Ethiopia are organized as institutional, regional and national (NECC). All ECs are expected to be registered by the NECC. There is a national guideline since 1997. In addition, some institutions (such as AHRI) have their own EC guidelines. How effective the system is needs evaluation. There is a need for re-vitalization of EC activities which is currently held back by financial limitations.

The following comments were made during the discussions on accreditation:

Is there a need for double reviews? Is that not a waste of resources? Would an EC report from Addis be acceptable to an EC in Khartoum?

There is a need for accreditation for multi-centre trials (C. Chintu).

What is needed is not ECs but ethical review systems. Legitimacy requires assurance at the public dimension nowadays (F. Crawley).

It is useful to have a list of all ECs and their addresses for reference.

Accreditation of ECs is often pushed by donors.

Is quality assured by establishing new ECs or is it assured better by making the environment in which ECs function more conducive? (F. Crawley)

African countries should apply the two level structure of institutional and national ECs.

The different levels of ECs should have clearly defined roles (institutional, state and federal or national committees) (J. Abdulkadir).

Roundtable discussion IV. What expectations should we have for achieving international cooperation in human subject protection?

P. Effa (Cameroon): “When a question is difficult, do not answer it: ask other questions” – an African saying. Africa is moving out of a bad past into a future. It is better to talk of actions rather than expectations.

C. Chintu (Zambia): Health is not merely the absence of disease. Our expectation is cooperation to protect human rights. Health is a right. We hope that PABIN will harmonize this. “A fool has a basket of answers; picks these up and asks, what is the question for this?”. PABIN should also harmonize guidelines. Our expectation is that harmonization is needed on how we deal with health issues in general, in its broadest sense, not just biomedical. HIV is not just a medical problem... We are born free, and in death, we are all equal.

B. Petros (Ethiopia): In ethics, we begin as equals and continue as equals. We would hope that there is no resistance from EU to accept this basic tenet. We live and thrive in hope. An international cooperation is possible and mandatory. Some of the impediments to cooperation are (not to blame anyone): the North/South divide – not all parties are willing to accept that each of us have something to contribute. Confidence building is a prerequisite; no one is trying to take advantage of the other. We should dispel the notion that ethical clearance is easier in poor countries and cooperate in the proper conduct of research ethics. Inflated opinions about “sovereignty” and “local power” as if all northern proposals have a suspicious agenda harms science. There should be no pre-judging and prejudice when we discuss collaboration in scientific research. The North should support the South to address its priority agenda and not push for its own interest. International cooperation is mandatory. We are doing disservice if we fail to achieve it.

D. Wassenaar (South Africa): A pragmatic and visionary approach is necessary. South-North collaboration is possible and can be enriching. A practical example is the development of the South African health Research Guidelines: southern thinking with materials from the north as resource. The important points to consider here are: local PI included in all aspects of the study, study appropriate to local needs, equal standards of care for all participants, appropriate incentives (equitable in different countries), informed consent tailored to local conditions, protocol differences detailed, identified and justified.

The following comments were made during further discussions:

- The South African example in developing guidelines is an example to emulate (F. Crawley)
- African guidelines for collaboration are needed. PABIN should help develop these. African researchers need to improve their standards to respond to the expectations of partnership with the North (F. Osman).
- PABIN should help challenge existing guidelines that do not accommodate African views or reflect African values. There is readiness among those who worked out these guidelines to work with Africans (Been Petros).
- Gaps for a mutually beneficial research should be filled on both sides reflecting equity, humanity, gender balance, capacity building and mutual contribution Working together is the answer because we are interdependent. Collaboration is not bossing the weaker. Africa should persistently demand equitable treatment. Being equal can sometimes be achieved only through insistence (Adanech Kidanemariam)

- The discussion has ignored a fact: money. Expectation depends more on how and to what level we are interdependent (F. Crawley).

Closing Remarks

Pierre Effa thanked the organizers, participants from Africa, Friends from the North and PABIN members for a successful conference. He thanked the President of the African Parliament, H.E. Aboubaker Keita for the opening address. He stated that important decisions have been made at this meeting:

1. PABIN will in the future be represented by country chapters. Institutions from outside Africa should consult the Executive Committee for representation.
2. An administrative Secretariat will be established to run the organizational activities of PABIN.

Chifumbe Chintu gave the final words. He called for members to bid to host the PABIN Secretariat. He reminded that the Ethiopian Bioethics Initiative (ETBIN) has been admitted to PABIN as a national chapter. He announced that the next PABIN meeting will be held in Cotonou, Benin. He thanked the organizers for an excellent work done and for having demonstrated that PABIN can organize its own meetings. He expressed his hope that the next meeting will be more gender sensitive.

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**3rd Annual Conference of the Pan-African Bioethics Initiative
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