



# Ethics Consultative Meeting

WHO Headquarters, Geneva

11 June 2007

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# 1. Introduction

On 21 July 2006, the EDCTP Assembly approved a change in the EDCTP strategy for implementing joint calls, brokering initiatives, and joint member state-African activities – the joint programme activities. The strategy focuses on integrated clinical trial grants that incorporate components of networking and capacity building. For this reason, EDCTP will no longer launch most of the small individual calls on networking and capacity development as been done previously.

However, there has been a general consensus from the EDCTP secretariat, ethics scientific review committee and EDCTP constituencies, that capacity strengthening for research ethics in Africa should be handled separately. This is partly in view of the potential conflict of interests and the recognition that ethics is a discipline with its own research agenda, better supported separately from specific research projects.

The aim of this meeting was to obtain recommendations on how best EDCTP should continue to support ethics in Africa. More specifically, the meeting aimed to:

- Discuss whether EDCTP should continue launching open calls on ethics in Africa
- Determine possibilities of collaboration between EDCTP and other organisations
- Determine how EDCTP should strategically target specific regions in Africa that urgently need capacity strengthening in ethics
- Determine how EDCTP should best support PABIN to become an effective coordinating office for ethics in Africa.

The meeting was chaired by Dr Joan Box. Dr Box has also been serving as the chair of EDCTP ethics scientific review committee. She had worked at the UK Medical Research Council for over 30 years and as Clinical Research and Ethics Liaison Manager for the last 5 years, until her retirement in September, 2006.

## 2. Other Participants

**Dr Marie-Charlotte Bouésseau**

Technical Officer, Ethics and Health Unit of the World Health Organization (WHO)

**Dr Juntra Karbwang**

Scientist, Special Programme for Research and Training in Tropical Diseases (TDR) of WHO.

**Prof. Wen Kilama**

Managing Trustee, African Malaria Network Trust (AMANET)

**Prof. Carel Ijsselmuiden**

Director, Council on Health Research for Development (COHRED)

**Ms Sandra Realpe**

Ethics Officer, The Global Forum on Bioethics in Research

**Prof. Sandy Thomas**

Director, Foresight, Department of Trade and Industry, Office of Science and Innovation of the UK government

**Jacob Leverage**

The Wellcome Trust

**Dr Aissatou Toure**

Developing Countries Coordinating Committee (DCCC) member, EDCTP

**Prof. Juhani Eskola**

Partnership Board member, EDCTP

**Dr Annaléne Nel**

Chief Medical Officer, International Partnership for Microbicides (IPM)

**Prof. Peter Folb**

Chief Scientist, Medical Research Centre in South Africa

**Mrs. Coumba Touré**

Technical Officer, Initiative for Vaccine Research of WHO-UNAIDS

**Dr Zarifah Hussain Reed**

Scientific Officer, Initiative for Vaccine Research of WHO

**Prof. Beyene Petros**

Executive committee member, Pan African Bioethics Initiative (PABIN)

**Prof. Charles Mgone**

Executive Director, EDCTP Secretariat

**Dr David Coles**

Joint Programme Manager, EDCTP Secretariat

**Dr Michael Makanga**

Capacity Development Manager, EDCTP Secretariat

**Ms Vanessa de Oliveira**

Project Officer, EDCTP Secretariat

### 3. Updates on Ethics Activities in Africa

Several organisations presented various activities that they are undertaking in strengthening health research ethics in Africa. These includes EDCTP, WHO, AMANET and PABIN. Please refer to annexes 3-9 for the presentations and summary of these activities. In these presentations covered the following points:

1. Currently EDCTP has €2,500,000 to be spent between now and 2010 on supporting ethics activities in Africa.
2. Experience with the NEBRA project (annex 10), which has surveyed the legislative framework and organisation of Research Ethics Committees in the 15 African countries involved, has shown a wide variation in their structure and functions.
3. WHO surveys have shown that there is some duplication in training, monitoring, and coordination of research ethics committees (REC) and that better coordination is necessary. It was agreed that there was a need for such coordination to help provide some standardisation but not necessarily aiming at uniformity since different models suit different situations. It was also agreed that both quantitative and qualitative data were required. Distance learning in ethics is being developed.
4. WHO/TDR has conducted several Standard Operating Procedures (SOPs) workshops and developed a self-assessment tool. It is necessary to establish in-country and in-region structures to monitor changes. Countries are encouraged to assess and accredit themselves. RECs are approved for 3 years, with annual reports on progress. Personnel are trained to do this assessment. It is repeatedly found that ethics is the weakest point of clinical studies. (Refer to annexes 4 and 5).
5. AMANET (annexes 6 and 7) has a considerable record in training in human research ethics (247 individuals so far have been trained) and in GCP (162 individuals). Workshops have been conducted on RECs SOPs. There is a web-based course (refer [www.amanet-trust.org](http://www.amanet-trust.org)) and internet discussion has been set-up. Investigators are trained in human research ethics. Advanced training in human research ethics is planned.
6. PABIN (annexes 8 and 9) aims at achieving a concerted African ethics voice, with African leadership, representing Africa on SIDCER. Their strategic plan includes helping national health authorities, advocacy, providing operational guidelines, translating guidelines and coordination of ethics activities. PABIN needed a further 3-5 years to put these efforts on a strong footing.
7. Since 2007, UNESCO has been supporting a programme for **Assisting Bioethics Committees**, which aim to reinforce the bioethics infrastructure in Member States through establishing national bioethics committees and enhancement of the functioning existing committees; and a second project entitled '**Ethics Teacher Training Course**' which is mapping existing ethics teaching programs in UNESCO Member States – describing the various programs, discussing them in expert meetings and making them available in the 'Global Ethics Observatory'. UNESCO has expressed interest in meeting EDCTP to discuss these programmes and explore ways of collaboration on ethics capacity building in developing countries.

It was also noted that NIH, who had taken the lead in supporting REC training in Africa, continued to be a major funder of such activity and that the Global Forum on Bioethics annual meeting in June 2007 will focus on **Fostering the Research Ethics Infrastructure in the Developing World** – which was also highly relevant to EDCTP.

## 4. Priority Ethics Activities

It was recognised that ethics could be supported in a number of different ways, including providing training, strengthening RECs/IRBs themselves and strengthening expertise in ethics in higher education institutions. Therefore EDCTP should consider what distinctive contribution it should make within its scope and priorities. It was suggested that the greatest contribution would be to ensure that there were sufficient, functioning, local RECs where EDCTP planned to support research, to enable this to undergo proper ethics review. This might in some cases require EDCTP to support establishing or strengthening committees, in others ensuring that members were adequately trained – but it was not thought to be primarily an EDCTP role to build up higher education departments in ethics or to provide courses in writing grant applications, although there was undoubtedly a need for this in some situations. It was therefore recommended that the funding available for ethics should not be subdivided into separate calls for strengthening RECs, training, or for coordination, as had been done in the past, but funding should be retained in one ‘pot’ to support the applications of any type judged most worthy of support. This should enable EDCTP to focus its activities where the impact would be greatest. Participants welcomed the fact that the criteria for support included the scientific quality of the applications.

It became clear that a mapping exercise would be desirable to help EDCTP and other stakeholders judge what activities to support, and where such support could best make a difference. This mapping should find out which organisations were doing what and where in supporting ethics in Africa, and identify gaps and how these might best be addressed, so that EDCTP could use this as a background to decision-making. For example, it was pointed out currently there is an ongoing support that is being provided by a variety of organisations for a number of training courses. Therefore, EDCTP should focus its efforts where such support in training is lacking.

The mapping exercise should be used to determine whether essential standards were being met, rather than superlative, ideal ones, and should be linked with institutional development plans thus also serve as part of the capacity development process. WHO and NEBRA have mapped ethics review activities in several countries already, AMANET is currently mapping some 40 committees and UNESCO plans to map training courses. There is a need to include this experience and to establish a registry, with particular reference also to the WHO experience in HIV/AIDS. It was noted that mapping would be very time-consuming as data not only needed to be collected, but also kept up to date.

In discussing who might best undertake such mapping, it was noted that there was a need to ensure a wide ownership so that the product could be useful for other organisations as well as EDCTP. It was thus suggested that it was pragmatic to appoint an individual or a team with no competing commitments to have the primary responsibility for ensuring that the mapping exercise was carried out effectively and efficiently. Whilst this could be someone appointed to an organisation like WHO, it was recognised that there were advantages if an African institution took the lead in collecting data through working with people on the ground. Thus, whilst the mapping should be done at the regional level, there should be centralised coordination. It was noted that EDCTP would support nodes of excellence and that this could help in the mapping exercise.

There were problems with launching an open call for this exercise, as the competitive nature of such a call would not help the need for collaboration on the work. First it was important to establish what should be mapped by key organisations and then there might be some regional competition, or an organisation could be commissioned to do the work. The chair emphasised and all agreed that it was important not to allow too much of the available funds to go towards this mapping exercise since it was intended to be a means to the end of deciding what else should be supported rather than an end in itself.

Although a mapping exercise was needed, all agreed that EDCTP should also, in parallel launch open calls for proposals for ethics including support of capacity development.

## **5. Potential Collaborations**

Several organisations had already expressed interest in collaborating with EDCTP, including UNESCO, European Forum on Good Clinical Practice (EFGCP) and WHO. This was very much welcomed. It was noted that there had been recent major changes in EFGCP and it was said to be no longer dominated by commercial organisations and interests. It was agreed that although collaboration with NIH and other organisations on ethics activities could prove extremely valuable, EDCTP should not lose sight of its own objectives to ensure that there is adequate ethics review capacity in places where it funds clinical trials, complementing existing activity where appropriate.

The suggested mapping exercise would also provide an overview of activities that could be worked on in collaboration. Nevertheless, it was agreed that EDCTP should take the lead in approaching some of these organisations immediately to explore possibilities for joint calls or other forms of collaborative working, rather than wait for the mapping to be completed. It was clear that UNESCO and EFGCP would welcome being contacted in the near future.

Working with other organisations could help in tackling some areas where ethics review capacity is still very weak or non-existent.

## **6. Targeting Specific Regions in Africa**

It was recommended that strong ethics committees should be available to review research in locations where EDCTP has or will have clinical trials running so that responsible research is supported. Targeting should not only be geographical but based on need. National ethics committees could not be expected to take care of everything

It was important to focus on the operation of how ethics committees work in practice, rather than on training only. EDCTP should focus on where clinical trials are being conducted and where there are inadequate or weak ethics committees. Applicants for support of ethics activities as well as those planning trials should be required to state in their proposals what local ethics review is already in place and where there are gaps.

It was noted that some Francophone and Lusophone countries do not have basic documents needed in their own language. NECs and IRBs should be supported to have the basic resources needed. It was also suggested that although there were more ethics committees in Anglophone countries, many of these lacked the expertise in ethics and philosophy that was sometimes more apparent in their Francophone counterpart. This could be remedied by developing better networking between RECs. It was therefore suggested that EDCTP should support a networking call on ethics. It was also suggested that in view of the disadvantages imposed on Francophone and Lusophone countries in applying for grants in English. Support for grant writing could in some instances be valuable.

EDCTP should support some regional forums in Africa to address regional ethical issues, exchange information and provide a platform for networking. Such a forum could be held as a satellite meeting at the Global Forum on Bioethics.

## 7. Supporting PABIN

It was suggested that PABIN should be well placed to provide support to help make national ethics committees in Africa operational but that it was important to make a success of their planned activity, such as the annual meeting, first.

It was suggested that EDCTP could support PABIN to build capacity to hold meetings for a specific purpose e.g. an annual forum to address especially complex ethical issues, provide a platform to exchange information and share expertise, address how to close the gaps in Africa, avoid duplication, or raise awareness of ethical issues. Some doubts were expressed about whether PABIN was best placed to undertake accreditation activities – it might be better to be helping RECs to meet the standards required for accreditation, rather than judging them.

PABIN could provide a storehouse of information about ethics in Africa through the development of a database and providing training. It was suggested that EDCTP support its secretariat so that it is administratively strong enough to carry out these functions.

One criticism was made about how the membership is created in that it should be based on country rather than on individuals because it is heavily Anglophone at the moment. It was currently active in some 26 countries.

It was suggested that PABIN might be one of the organisations in a position to take a lead in mapping ethics activities being supported in Africa.

## 8. Summary of Recommendations

1. It is vital that high quality ethics review of clinical research being funded by EDCTP was undertaken by ethics committees in the host countries. Therefore strengthening ethics review capacity in countries and areas where EDCTP was supporting clinical trials should be a primary focus.
2. EDCTP should continue to launch open calls for proposals in order to help strengthen ethics review capacity in Africa and these should not be tied to specific topics thus that support could be given where it was thought likely to be most effective in achieving the above aim.
3. Collaboration should take place, where possible, to avoid duplication and where there would be added value to EDCTP, and action should be taken quickly to explore which collaborative links would be useful.
4. EDCTP should encourage applications from geographical areas known to have inadequate ethics review capacity. Applicants should be asked to describe the existing capacity and the gaps that are require to be filled.
5. Mapping for establishing who is supporting what and where is urgently required. This should be undertaken by an individual or a single organisation, but should have wide ownership through a central coordination mechanism and take account of mapping activity already undertaken or currently in progress.
6. The report of the meeting should be circulated for comments to the whole group, who should be encouraged to continue networking and exchanging views and ideas on how best to develop this subject further.

# Annexes

## Annex 1: Agenda



### Agenda

The sequence of Items may be changed at the start of the meeting

Agenda items	By	Timelines
<i>Meeting Commences/Coffee</i>	<i>All</i>	<i>08:30</i>
1.0. Welcome	Charles Mgone (EDCTP) and Joan Box (Chair)	08:40 – 09:00
2.0. Approval of the Agenda	All	09:00 – 09:10
3.0 Tour de table		09:10 – 09:15
4.0. Brief updates on ethics activities in Africa supported by: <ul style="list-style-type: none"> <li>○ WHO</li> <li>○ AMANET</li> <li>○ PABIN</li> <li>○ EDCTP</li> </ul> (with brief written, pre-circulated summaries for each of these)	Marie-Charlotte Bouésseau/  Juntra Karbwang  Wen Kilama  Beyene Petros  Michael Makanga	09:15 – 09:25 09:25 – 09:35 09:35 – 09:45 09:45 – 09:55
<i>Coffee break</i>	<i>All</i>	<i>09:55 - 10:10</i>
4.0 Discussion on priority ethics activities	All	10:10- 10:40
5.0 Discussion on potential collaborations between EDCTP and other organisations	All	10:40 -11:00
6.0 Discussion on how EDCTP should target specific regions in Africa that need capacity strengthening in ethics	All	11:00 – 11:20
7.0 Discussion on how EDCTP should best support PABIN to become an effective coordinating office for ethics in Africa	All	11:20 – 11:40
8.0 Chairs remarks on 4.0-7.0 discussions	Chair	11:40 - 11:55
9.0 EDCTP funding strategy and procedures	Vanessa de Oliveira	11:55 – 12:05
10.0 Recommendations on how to proceed in the implementation of the priority activities taking into account time lines	All	12:05 - 12:35
11.0 Summary of recommendations	Chair	12:35-12:45
<i>End of meeting</i>	<i>All</i>	<i>12:45</i>
<i>Lunch</i>	<i>All</i>	<i>12:45 – 13:30</i>

## ***Annex 2: Comments from the Scientific Review Committee***

### **Summary Ethics SRC comments**

In order to encourage wide consultation in preparation for this meeting, the chair person of EDCTP's ethics Scientific Review Committee (SRC), Dr Joan Box Bayes, requested all SRC members for feedback on how they thought EDCTP should continue to support the development of research ethics review capacity in Africa. This was done in view of the new EDCTP roadmap and also taking into account the experience of other like minded organisations. Below is a summary of their comments.

All SRC members who responded felt that:

- EDCTP should continue to launch open calls on ethics;
- EDCTP should target specific countries where few ethic committees are active and encourage the creation of ethics committees in French and Portuguese speaking countries;
- EDCTP should collaborate with other organizations like AMANET, NIH (Forgarty training initiatives) and UNESCO in order to avoid duplication and strengthen efforts;
- Continued support for PABIN will be beneficial in the long term.

Other suggestions:

- EDCTP should promote better grant writing – the quality of the applications is sometimes jeopardised by poor writing skills;
- The open calls should not be limited to establishment or strengthening of existing committees, but open to other capacity building initiatives that may be relevant in specific institutions as may be identified by the applicants. For example, many African researchers lacking training in research ethics are a result of the absence of research ethics teaching departments in African institutions of higher learning. Such Institutions of higher learning where biomedical research involving human participants also occurs, may consider establishing research ethics teaching departments a priority over establishing research ethics committees;
- EDCTP could create a database of research organizations recognised by ministries in each country in order to identify institutions that have not received any support in the past;
- EDCTP may further wish to scrutinize the PABIN administrative structure with the view to consider supporting a full time dedicated secretariat (persons that are not employees of other organizations within their countries as is the case at present). This could also include looking into establishing a permanent physical location for the PABIN secretariat as opposed to the current rotating office hosted in local institutions.

### **Feedback from Dr Pauline Mwinzi**

1. To discuss whether EDCTP should continue launching open calls on ethics in Africa

I think EDCTP should continue launching open calls on ethics in Africa for a given duration of time, which will then be reviewed and either extended or terminated depending on impact and need. The open calls can be made more inclusive, not limited to establishment or strengthening of existing committees, but open to other capacity building initiatives that may be relevant in specific institutions as may be identified by the applicants. For example, many African researchers lacking training in research ethics are as a result of the absence of research ethics teaching departments in African institutions of higher learning. Such Institutions of higher learning where biomedical research

involving human participants also occurs, may consider establishing research ethics teaching departments a priority over establishing research ethics committees.

2. To determine possibilities of collaboration between EDCTP and other organizations

Collaboration with organizations that have made a continent-wide impact so far e.g AMANET and a couple of Forgarty training initiatives (e.g. IRENSA, SARETI) needs to be encouraged to avoid duplication of efforts. A database from these organizations on what they have achieved so far would help identify areas for future emphasis.

Earlier initiatives by Forgarty for example have produced a number (almost 100) of research ethics scholars in various countries and institutions of higher learning and EDCTP could build on these efforts to move them to the next level. For example, the efforts by one Ames Dhai (a graduate of the Forgarty-sponsored IRENSA program University of Cape Town) establishing the Steve Biko Bioethics unit at the University of Witwatersrand, is a good example that these graduates can take up training others, locally –but need further support. Not all African Universities have the resources that the University of Witwatersrand has availed Prof. Dhai. Support to further utilize the expertise already developed by these ongoing programs would complement and build on their ongoing activities.

3. To determine how EDCTP should target specific regions in Africa that need capacity strengthening in ethics

Through local ministries of health, and use of databases from NEBRA and AMANET, EDCTP could pursue to register/create a database of research organizations recognized by such ministries in their countries, to identify institutions that have not received any support in the past. Most of current initiatives so far have mostly benefited Anglophone Africa, and there is therefore a special lack of capacity-building opportunities for Francophone and Lusophone African countries.

4. To determine how EDCTP should best support PABIN to become an effective coordinating office for ethics in Africa?

Continued support for PABIN will be beneficial in the long term. Further to the previous grant awarded to PABIN, EDCTP may further wish to scrutinize the PABIN administrative structure with the view to consider supporting a full time dedicated secretariat (persons that are not employees of other organizations within their countries as is the case at present). This could also include looking into establishing a permanent physical location for the PABIN secretariat as opposed to the current rotating office hosted in local institutions. This will enable PABIN to fully focus on delivering on proposed goals.

**Feedback from Dr Leopold Lehman**

Dear Joan,

Thank you very much for your message.

I find it very good that further thought went on in EDCTP headquarters to support ethics in Africa.

As a member of the EDCTP ethic's SRC, I was honoured and proud to bring inputs in a field where there is yet very little achievement in Africa, especially in Central Africa.

The launching of open calls on ethics in Africa by EDCTP was initializing a process of strengthening local resources. It was very appreciable that a wide majority of sponsored projects was furnished with training activities. Sponsoring these projects was an assurance for the development of expertise in ethical review in Africa.

Many researchers in central Africa still write projects and are unable to submit them because ethical review committees are lacking or not functioning. This shows that the presence of functioning committees is still a bottle neck for clinical research activities in Africa.

Institutional and/or National review boards were the first institutions to be set to improve this situation. English speaking countries are ahead in the creation of such committees but French speaking countries are still left far behind. The later should therefore be encouraged.

PABIN is actually the strongest institution in Africa in this field. Their proposal reviewed by EDCTP was planning a variety of training activities.

Following this remarks, I will suggest the following:

- EDCTP should launch open calls on ethics as previously done and target specific countries where very few ethic committees are active. This is the case of most French speaking countries in central Africa.

- EDCTP should promote seminars on ethics in some universities of needy countries through PABIN in Collaboration with African and European experts. The trained persons by EDCTP/PABIN programs could remain as focal points for the creation of institutional ERC.

My opinion is that the sudden interruption of the former program was inopportune but continuing EDCTP's action through PABIN by supporting its networking and training activities could be very useful to promote ethics review capacity in Africa.

I hope that my comments will bring a little help.

### **Feedback from Prof Stuart Rennie**

1.) I believe that open calls should be continued, rather than attaching ethics capacity projects to specific research projects; the sustainability (and credibility) of the ethics projects depends on them being integrated in local institutions, not married to specific research initiatives. Over the last year, I have witnessed a great interest in EDCTP's open calls from those I know that work on research ethics and bioethics in Africa: the interest and need is there. However, mechanisms should be in place to mitigate some of the shortcomings seen in the first round of open calls. Some applicant institutions were unfamiliar with the craft of grant writing, and this lead to difficulties in evaluating and accepting proposals. There seems to be a need for more direction and mentoring from the EDCTP, because of weak grant-writing capacity. Perhaps the application forms should be more directive and force the applicants to provide greater detail and think through their training programs (and collaborative relationships) more carefully, and the EDCTP office could act as grant application facilitators via email or by putting more 'grant-writing enabling' resources on the EDCTP website. In short, open calls with conditions that enhance the possibility of higher quality submissions and a potentially higher acceptance rate.

2) The most obvious collaborative partner for ethics capacity building would be the National Institute of Health/Fogarty International Centre initiative, and its funded projects in Cape Town, Pretoria, Kinshasa, Cairo and Ibadan. (Disclaimer: I am project manager of the Kinshasa project). The less collaboration between the EU and US initiatives, the greater the danger of what is seen often in 'development' circles: mutually detrimental competition and replication. In my view, the Africa-based NIH projects are very open to and interested in potential collaboration with EDCTP; it is an agenda item on the next Fogarty network meeting in October. A priority in Africa is teaching of ethics within higher education institutions (including biomedical research institutions), and in this regard UNESCO would also be a good partner for EDCTP.

3) One way of targeting regions is to either use existing data about needs for ethics capacity building (such as NEBRA project or other research over the last few years) or to devote resources to generate more data on existing needs. There is much that is not known. However, it is common knowledge that Lusophone and Francophone regions have largely been neglected by all known research ethics capacity initiatives to date, and therefore one could strongly encourage submissions from these regions. Obviously, targeting in ethics

capacity should also be coordinated with existing knowledge about research activity in Africa. Perhaps we could establish conditions of 'high priority areas' e.g. high priority areas would be places in which (a) there is known to be little existing ethics capacity, (b) increasing volume of research involving human participants and (c) socio-economic and political circumstances affecting health and supporting the need for biomedical research but also increase vulnerability of research participants.

4) The best ways for EDCTP to support PABIN would be to (a) help further articulate PABIN's short- and longer-term goals, (b) carefully monitor and evaluate PABIN's activities against a background of benchmarks (c) provide logistic and human resource support where weaknesses are identified and (d) assist in finding/suggesting collaborative partners/organizations that can strengthen PABIN's (and EDCTP's) mission. At the moment, it is not yet clear (to me) how PABIN will oversee the various EDCTP funded activities in Africa, what the oversight will involve (site visits, semi-annual reports?), or how the establishment of national chapters of PABIN in selected countries contributes to this coordinating function. Each specific EDCTP project leader should know what PABIN (as a coordinating office) expects from them, and in what ways PABIN (and through them, EDCTP) may assist them.

#### **Feedback from Prof Jan Helge Solbakk**

### **UNESCO**

13 May 2007

To: Joan E. Bayes

From: J.H. Solbakk, Chief Bioethics Section  
Division of Ethics of Science and Technology  
Social and Human Sciences Sector  
UNESCO, Paris

#### **A brief note on UNESCO's bioethics activities in developing countries**

Among the different bioethics activities of UNESCO's Division of Ethics of Science and Technology in developing countries, I will restrict my description to two activities I believe could represent *future platforms of collaboration between UNESCO and EDCTP in the field of ethics capacity building in developing countries*:

#### **1) The first project activity is entitled 'ABC – Assisting Bioethics Committees':**

The project started in 2007 and aims at reinforcing the bioethics infrastructure in Member States through the establishment of national bioethics committees, and, once they are established, through the enhancement of the functioning of committees.

The project consists in the setting-up of two taskforces of experts – one English-speaking and one French-speaking – with practical experience in ethics committees from 12 countries. Within the next three years they will assist 6 English-speaking and 6 French-speaking Member States in need of bioethics committees at national level.

The project is organized in three phases:

- (1) provide practical recommendations in order to establish national bioethics committees in 12 Member States;
- (2) support national bioethics committees, once established, in developing appropriate working methods and operational procedures; and
- (3) improve the functioning of bioethics committees, once operational, through evaluation and training.

Till date we have been assisting two Member states in establishing National Bioethics Committees - Togo and Ghana - and four other Member states have requested our assistance in this endeavour: Malawi, Madagascar, Jamaica and Gabon.

*The project was originally planned as a three years project. Through extra budgetary funding it is our hope to be able to continue this project in other Member States in need of setting up bioethics committees. We hope EDCTP will consider this project as a possible basis for future collaboration between EDCTP and UNESCO in the field of building ethics capacity in developing countries.*

## **2) The second project activity is entitled 'Ethics Teacher Training Course':**

The Ethics Education Program of UNESCO is mapping existing teaching programs in the area of ethics in the Member States of UNESCO. The various programs are described, discussed in expert meetings, and made available in the Global Ethics Observatory ([www.unesco.org/shs/ethics/geo](http://www.unesco.org/shs/ethics/geo)). Experiences concerning the contents, intensity, methods and materials of existing programs are therefore publicly accessible and can be exchanged among experts. Teachers who want to initiate ethics teaching can find suggestions and ideas in the database. The quality of ethics teaching programs, however, also substantially depends on the quality of the teachers. Ethics teaching can be made much more influential and attractive for students if they are involved by a highly qualified, stimulating and inspiring teacher.

This course is set up to provide training to ethics teachers with the purpose to enhance their skills and abilities in the field of bioethics. It aims particularly on training a younger generation of teachers so that ethics teaching programs in the near future can expand and improve in all Member States of UNESCO.


### **Objectives**

1. To introduce the students to the means and resources of teaching bioethics
2. To teach the students the methodologies and methods of teaching bioethics
3. To assess and provide feedback on the students' demonstrations of teaching skills under the guidance of experienced teachers

Till date this course has been piloted in one Member state (Romania) in 2006. The format has been changed on the basis of the evaluation of the students. The second course will take place in Kenya in July 2007.

Through extra budgetary funding it is our hope to be able to continue this project in other Member States in need of training a young generation of ethics teachers. We hope EDCTP will consider also this project as a possible basis for future collaboration between EDCTP and UNESCO in the field of building ethics capacity in developing countries.

**Annex 3: Presentation EDCTP**



**European and Developing Countries  
Clinical Trials Partnership (EDCTP)**

## **Supported Ethics Activities**

Vanessa de Oliveira  
Ethics Consultative Meeting  
Geneva, 11 June 2007



**EDCTP Supported Ethics Activities  
in Africa**

EDCTP is committed to improving compliance with internationally accepted standards for ethical review and has supported the following:

- An African coordinating office that oversees activities in clinical trial ethics through the formation of a coordinating committee with representation from all relevant players
- Ethics training in Africa through courses and seminars
- Promotion of the establishment and strengthening of National Ethics Committees (NEC) or institutional review boards, which are competent and independent through the African Office of the EDCTP.



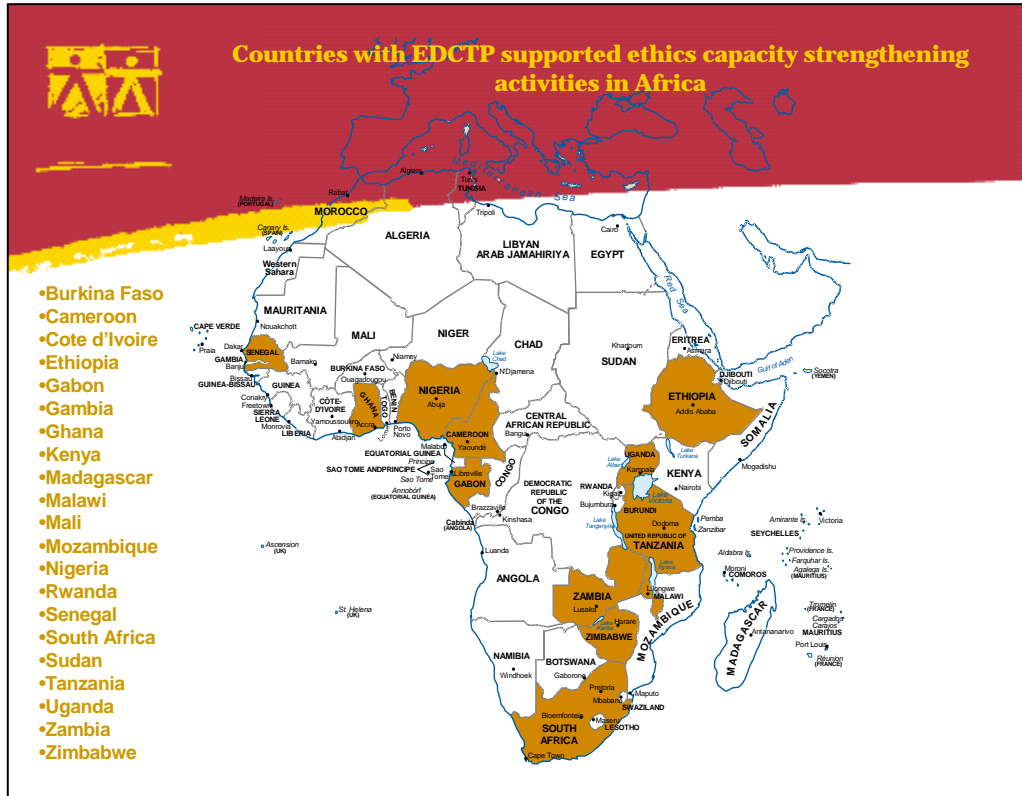
## Support for Courses and Seminars

GRANTEE	BUDGET	LOCATION
1. University of Stellenbosch	€ 69,926	South Africa
2. MRC (Zimbabwe)	€ 98,700	Zimbabwe
3. AMANET	€ 99,800	Tanzania
4. University of Malawi	€ 98,123	Malawi
5. Cardiff University	€ 94,800	UK
6. Institut de Droit de la Santé	€ 98,700	Switzerland
7. Vienna School of Clinical Research	€ 100,000	Austria
8. Nigerian Institute of Medical Research	€ 78,000	Nigeria



## Establishment/Strengthening of National Ethics Committees & Institutional Review Boards

GRANTEE	BUDGET	LOCATION
1. Navrongo Health Research Centre	€ 50,000	Ghana
2. MRC (Zimbabwe)	€ 48,400	Zimbabwe
3. University of Malawi	€ 50,000	Malawi
4. University of Ibadan	€ 49,957	Nigeria
5. Makerere University	€ 50,048	Uganda
6. PABIN	€ 100,000	Ethiopia



**Available Funds for Ethics 2007 - 2010**

Product based topic	Start funding procedure*	Reserved budget EDCTP-EC	Expected MS contribution	Total
Malaria vaccines	01Q07	14.500.000	14.500.000	29.000.000
Malaria treatment	02Q08	9.000.000	9.000.000	18.000.000
Malaria and Pregnancy	01Q08	9.000.000	9.000.000	18.000.000
TB vaccines	01Q07	11.750.000	11.750.000	23.500.000
TB treatment	01Q09	14.000.000	14.000.000	28.000.000
HIV vaccines	02Q07	7.000.000	7.000.000	14.000.000
HIV treatment	01Q08	6.500.000	6.500.000	13.000.000
HIV microbicides	01Q08	6.000.000	6.000.000	12.000.000
Support environment for clinical trials in Africa				
Nodes of Excellence	01Q08	10,000,000	TBD	
Regulatory Affairs	04Q07	640,000	TBD	
<b>Ethics</b>	<b>04Q07</b>	<b>2,500,000</b>	<b>TBD</b>	
Senior Fellowships	04Q07	3,600,000	TBD	



## European and Developing Countries Clinical Trials Partnership (EDCTP)

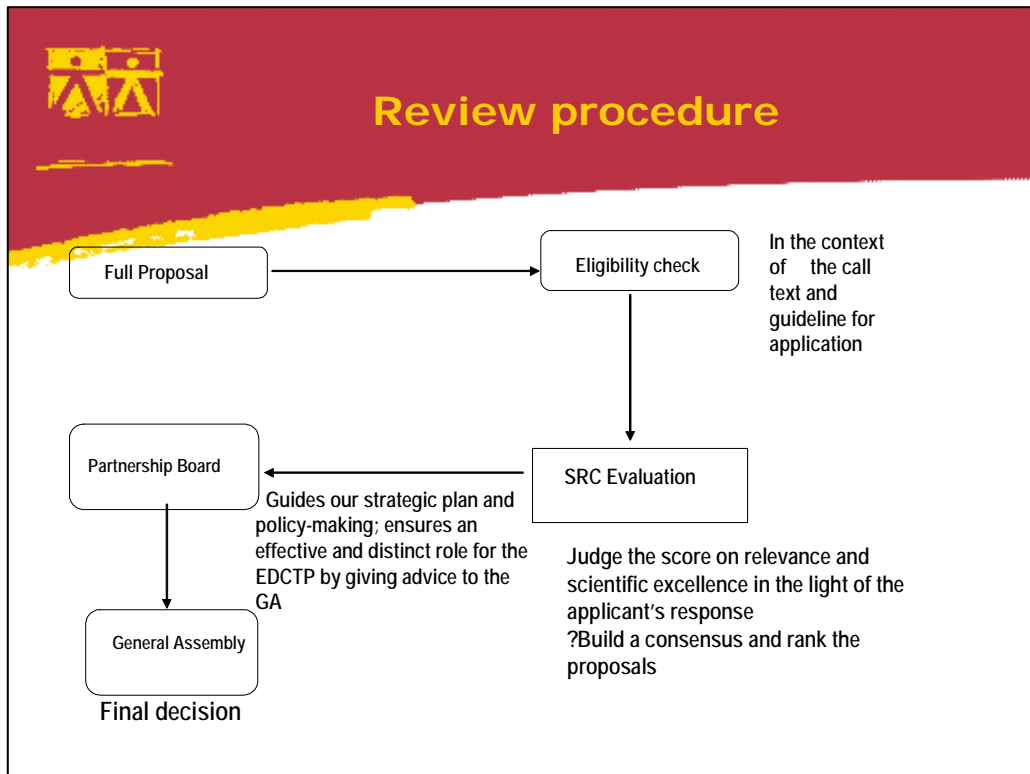
# Funding Strategy and procedures



## EDCTP Funding Procedure

### Selection Criteria

- I. **Excellence** (feasibility, impact, innovativity, quality and record of applicants, quality of the proposed set up)
- II. **EDCTP Relevance** (public health relevance for developing countries, adequacy of proposal in context of the call)
- III. **Partnerships** (contribution to improved north-north, north-south, south-north and south-south collaboration)
- IV. **Capacity Building** components (training aspects)
- V. **Project Management** (representation of required expertise, appropriateness of budget)





## Strategy 2007-2010 New projects

- Large project approach with a focus on products:
  - Clinical trial
  - Networking
    - Exchange visits
  - Capacity Building
    - Infrastructure
    - Training of staff working at site
    - Training of African scientists (PhD-Postdoc)
    - Building capacity at less developed sister site
  
- In addition investments in ethics, regulatory affairs and nodes of excellence will be targeted at countries where EDCTP funded sites are located



## EDCTP Funding Procedures: Call for Proposals

- Call for proposals:
  - Open call of EDCTP together with MS
  - Co-funding arrangement is up to participating MS and differs per MS
    - Some countries have made a cash contribution to EDCTP
    - Other have reserved a budget at their home institution
    - Some countries need to do their own review
    - Others are able to use EDCTP's review procedure
    - Some countries have restrictions: only spent on local or own national scientists or only spent in Africa
  - Applicants need to contact European Networking Officers who can advice on the procedure in their country
  - African applicants can contact DCCC members
  - Project partner tool can help find partners



## EDCTP Funding Procedures: Brokering

- **Brokering:**
  - Funding a project without an open call
  - Potential situations to choose for brokering:
    - Limited number of MS are interested/have expertise
    - Limited number of products
    - Limited number of suitable and available sites in Africa
  - Decision to take this approach will be taken in close collaboration with funders
  - Procedure: Development of brokering action plan that should lead to an eligible application
  - Application form and review will be identical to open call except that there are no other projects for comparison

**Annex 4: Presentation WHO**



# Research ethics in Africa EDCTP- WHO meeting

Geneva 11 June 2007

**Dr Marie Charlotte Bouésseau**  
Ethics, Trade, Human Rights and health Law



## Overview

1. Lessons learnt from NEBRA
2. ETH on going activities in research ethics in Africa
3. Suggestions for future collaboration





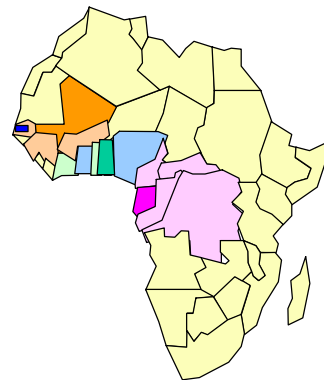
# 1. Lessons learnt from NEBRA

*Networking for Ethics on Biomedical Research in Africa*



## Objective of the project

- Survey in 15 African countries describing the current situation of RECs, existing regulations, resources and needs
- Elaborate a matrix for national strategic plans aiming the strengthening of ethical review of research involving human beings





## Major needs identified

Different kinds of RECs to be considered:  
IRBs, national (? one model)

- **Clarification and coordination** of functions
- Institutional **legitimacy** of RECs (follow up of decision taken by RECs)
- Better **coordination** of existing initiatives concerning quality improvement of RECs (training activities, monitoring of RECs)



## Major needs identified (cont.)

- Better knowledge and enforcement of **domestic laws and regulations** by all relevant stakeholders of research for health
- Need for **harmonization** of norms without uniformization
- Need for **sub regional networking** (language)





## Comparative approach

(See NEBRA report part 3)

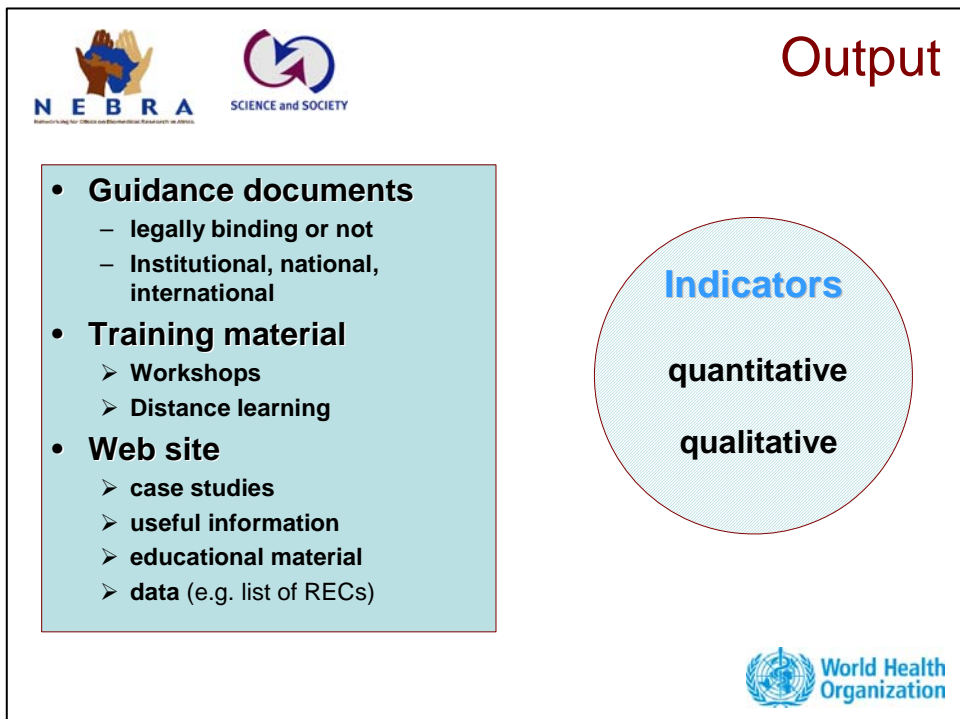
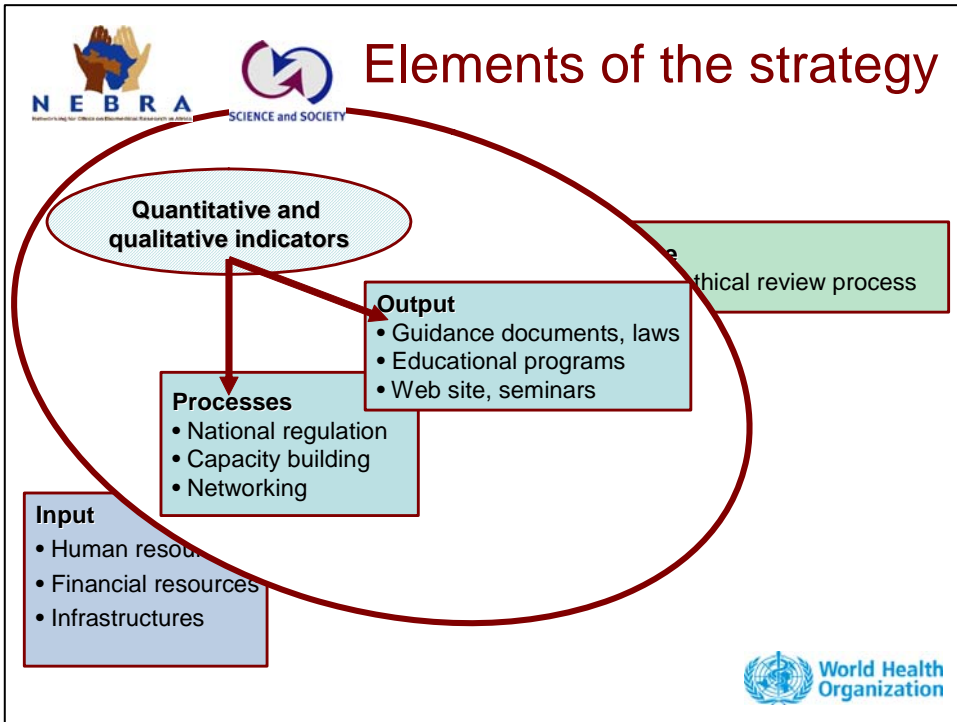
- Disparity of situation
- Diversity of systems
- Transition and rapid changes  
(data need to be regularly up dated)
- Difficulties to enforce existing regulations



## Towards national strategies to strengthen research ethics

- Specific objectives
- Expected results / Time
- Human, institutional and financial resources







*"NEBRA a cet avantage particulier d'avoir collecté des informations sur les expériences réussies et non réussies de la sous-région de manière à proposer des solutions endogènes. Les résultats préliminaires présentés en juillet dernier à Bamako et assortis de recommandations, suggèrent des propositions concrètes adaptées aux pays concernés et dont la mise en œuvre devrait indubitablement contribuer à améliorer la situation. "*

**Dr Flore Gangbo, Ministre de la Santé du Bénin,**



## **2. ETH on going activities in research ethics in Africa**





## Training activities

- Ibadan (Feb 07) - EDCTP
- Tunis (March 07) – collaboration with RHR
- Ouagadougou (July 07) – PATH and RHR
- Gabon (07) – EDCTP



### TRREE for Africa – EDCTP

- » To increase knowledge and skills /research ethics and strengthen partnership
- » Training material available in November 2008

[http://trree.org/site/en\\_trree\\_home.phtml](http://trree.org/site/en_trree_home.phtml)



## Global Forum on Bioethics in Research

- A venue for delegates from developing and developed countries to debate the ethical issues surrounding international collaborative research
- A discussion is based on concrete cases
- Next forum will take place in Vilnius, Lithuania, and will focus on 2 main issues:
  - Fostering the research ethics infrastructure in the developing world / transition societies
  - Ethical aspects of mental health research
- A satellite meeting will be organized to address issues related to vaccine research (IVR with Ethics and Health)



### 3. Suggestions for future collaboration



#### 1. Capacity strengthening

- Avoid conflicts of interests (sponsoring of research / training of RECs)
- Complement to what is already existing
  - collect data concerning workshops and distance learning courses
  - provide tools for trainers in ? languages e.g. casebooks
  - evaluate long term impact

#### 2. Normative issues

- Collaboration with countries for the elaboration of national strategy (see Gabon)
- Collect and up date data on existing regulations



#### 3. Networking

- Collect and up date information about RECs in African countries
- Consider the possibility of a network of national committees eventually linked with Global summit (see collaboration WHO/UNESCO in EMRO)
- Consider the possibility of sub regional network (language) to facilitate the exchange of material and information, critical analysis of experiences, etc.



## ***Annex 5: Summary of activities WHO***



### **WHO Ethics and Health Initiative**

on going activities on research ethics in Africa

#### **Mission**

Ethics and Health Initiative was launched October 2002 by the Director General

- To provide a focal point for the examination of the ethical issues raised by activities throughout the organization, including the regional and country offices
- To develop activities regarding a wide range of global bioethics topics

*What are our main objectives?*

- To develop WHO **policies** and strategic approaches, ensuring ethical standards and analyses are included.
- To **strengthen capacity** in the Member States, enabling professionals and the public to incorporate ethics into their work.
- To collect and disseminate **information** on different aspects of ethics and health.
- To contribute to **international debate** on ethics and health, in collaboration with international organizations (governmental and non governmental), and academic centers.

*How do we work?*

Providing support

- at the three levels of the Organization for analyzing the ethical aspects of health.

- To the Member States through tools and guidelines for incorporating an ethical analysis into health services delivery, health research, and public health activities.

## Activities on research ethics in Africa



*What have we learnt from Networking for Ethics on Biomedical Research in Africa?*

(see NEBRA final report p. 90 to 103)

- In the project area (15 countries of Western and Central Africa) the regulatory situation varies as well as the ethical review system:
  - Some countries have specific legislation (e.g. Gabon), others have legislation with implications on health research (often not well known), others have draft bills or decree(e.g. Benin), others have decrees (e.g. for the creation of ethics committees in Burkina Faso).
  - Two major options exist for Research Ethics Committees (RECs): Institutional Review Boards (IRBs) or National Ethics Committees (NECs). The specific responsibilities of NECs can differ (review of protocols, normative role, function of coordination, etc.).
- The situation is characterized as "transition" and would require regular up dating (some data of NEBRA survey have already changed).
- A better knowledge and enforcement of existing domestic laws would be needed. Clear regulation establishing the ethical review process and functions of ethics committees is also required in many countries.

*What should be a national strategy to strengthen ethical review of research?*

- Three pillars:
  - Strong RECs
  - Clear regulations
  - Regional and sub regional networking activities
- Characteristics:  
Reasonable, transparent, inclusive, responsive, accountable
- Components:
  - Specific objectives
  - Expected results
  - Time frame
  - Human institutional and financial resources

*What could be done?*

1. Country collaboration to formulation national strategic plans
2. Capacity strengthening
  - Provide tools for trainers (basic module) in the countries
  - Work on indicators to evaluate long term impact of training activities
3. Normative issues
  - Collect and up date information on existing regulations in African countries
  - Work with countries on harmonization of regulations
4. RECs networks
  - Collect and up date information about RECs in African countries
  - National committees (link with Global summit)
  - Sub regional network: exchange of material and information, critical analysis of experiences, etc. in different languages.

## ***Annex 6: Presentation AMANET***



### **AMANET Strengthens Health Research Ethics in Africa**

**Wen L. Kilama**

**Managing Trustee**

**AFICAN MALARIA NETWORK TRUST**

Tanzania Commission for Science and Technology Building

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AMANET

[www.amanet-trust.org](http://www.amanet-trust.org)



## **Contents**

- Introduction
- History of AMANET in Strengthening HRE in Africa
- Recent AMANET achievements in Strengthening HRE in Africa
- New AMANET project on Strengthening Institutional Capacities in HRE in Africa
- Summary

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## History of AMANET Strengthening HRE in Africa

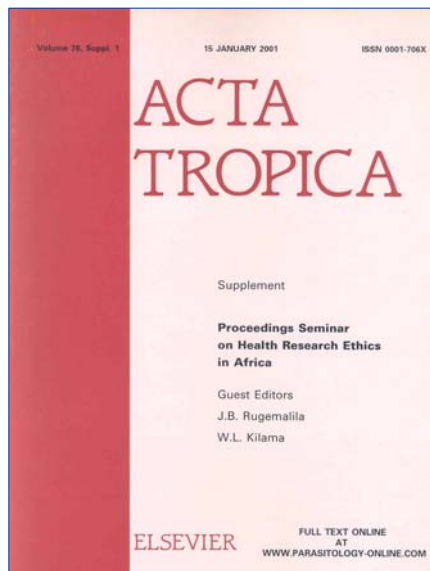
- Ethics a major concern since inception as AMVTN in 1995 Ref.
- AMVTN Seminar on HRE, Nov 1999, Arusha, Tanzania
- 54 participants from 34 countries

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[www.amanet-trust.org](http://www.amanet-trust.org)



Supplement:  
Proceedings  
Seminar on  
Health Research  
Ethics in Africa,  
Acta Tropica,  
Vol 78, Suppl. 1,  
15 Jan 2001



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## Recent AMANET Achievements in Strengthening HRE in Africa

Health Research Ethics (9+)	Total trained
2001( Kisumu, Kenya), 2001(Addis Ababa, Ethiopia), 2002(Pretoria, S. Africa), 2002(Libreville, Gabon), 2003(Khartoum, Sudan), 2003(Yaoundé, Cameroon), 2005(Dar es salaam, Tanzania), 2006, 2007 (Dar es salaam, Tanzania)	<b>+247</b>
<b>Participating countries:</b> Benin, Burkina Faso, Cameroon, Egypt, Ethiopia, Gabon, Ghana, Kenya, Madagascar, Malawi, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Sudan, Tanzania, The Gambia, Uganda, Zambia, Zimbabwe	
Good Clinical Practice (6)	Total trained
1998 ( Accra, Ghana), 2000( Bagamoyo, Tanzania), 2004 (Ouagadougou, Burkina Faso), 2003( Bagamoyo, Tanzania), 2005 (Zanzibar, Tanzania ), 2006( Bagamoyo, Tanzania)	<b>162</b>

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## Other HRE Training Activities

- SOPs for HRE Committees, Entebbe, Uganda, 2003
- Advanced Bioethics Workshop, Zanzibar, Tanzania, 2004
- Writing SOPs for HRE Committees, Dar es salaam, Tanzania, with OHRP, 2005
- Pilot Workshop, AMANET Web-based Course, Dar es Salaam, Tanzania, 2006

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## AMANET Free Web-based Course on HRE [www.amanet-trust.org](http://www.amanet-trust.org)

- Since October 2006
- **345 registered** so far
- **78 successfully completed**, received certificates



Ethiopia (5), Nigeria(15), Rwanda(4), Malawi(4), Zambia (1), Gambia (4), UK (1), USA (1), South Africa (1), Uganda (1), Kenya (8), Tanzania (9), The Netherlands (1), Scotland (1), Austria (1), Mali (3), Cameroon (1), New Zealand (1), Ghana (12), Zimbabwe (2), Gabon (1), Norway (1)



## New AMANET Project: Building Institutional Capacities in HRE in Africa

- Strengthening ethical review process at African research institutions
- Training Investigators in Human Research Ethics
- Fostering and promoting discussion, and debate on HRE from an African perspective



## Strengthening ethical review process at African research institutions

- Baseline survey of institutional ERCs
- Training Workshops in HRE (6 English, 2 French)
- Develop Harmonized SOPs for Ethics Review Committees
- Strengthen institutional ERCs

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## Strengthening Institutional Ethics Review Capacities

	Yr I	Yr II	Yr III
Equipments, furniture, office supplies			
Developing SOPs (manuals) for the Committee			
Travel costs for oversight, EC members, etc			
Setting up data base and archives			
Allowances (administrators, reviewers, training, sitting allowances, etc)			
Communications (e-mail, telephone & fax, internet access)			
Salaries for EC Secretariat staff			
Conducting seminars for investigators			
Public education (including outreach) on HRE			
Field visits by Committee (in-country)			
Consultancy			

**The 20 institutions will benefit from the AMANET vast experience with international bank transfers.**

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## Typical workshop content

- Overview of the history of ethics in health research;
- Ethics codes and guidelines
- Ethics Committees: responsibilities, composition, functions and operations
- Review and discussion of ethics principles guiding health research and their application within African settings
- Qualifications, roles and functions of the sponsor, principal investigator and monitor
- Ethics considerations in the design of health research projects
- Analysis of risk/benefit in health research
- What is owed to research participants and communities
- Role and conduct of informed consent in health research
- Standard of care and fair distribution of benefits and burdens
- Examination of current ethics review mechanisms in Africa
- Availability of products following research, including the issue of patents
- Role of regulatory agencies in health research



## Training Investigators in Human Research Ethics

Starts Mid-2008, 5 workshops ,being developed. Candidates must possess basic ethics certificate. Contents might include:

- **Responsibilities of researcher, and sponsor, mentorship**
- **Ethics of research design**
- **Ethics in epidemiological studies**
- **Ethics in public health interventions**
- **Informed consent, and design of consent forms**
- **Health research record management and confidentiality**
- **Study management, data handling and safety issues**
- **Ethics in trials of traditional medicines**
- **Research with particularly vulnerable groups**
- **n-s, and s-s health research collaboration**
- **Conflict of interest**
- **Misconduct in health research**
- **Research with animals**



Fostering and promoting discussion, and debate on HRE from an African perspective

The e-discussion will cover:

1. **Brief case studies**
2. **Ethics Dilemmas**
3. **Ask the Expert/Ethicist**

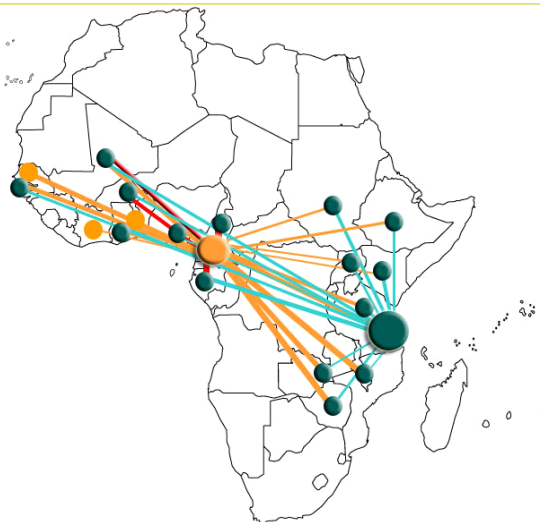
**Coordination:** Sub-hub in Yaoundé, Cameroon

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## AMANET HRE Network



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## Milestones

- Published report from a **Baseline Survey** of competences of 40 African ethics review committees
- **At least 240 members** of ethics review committees/IRBs/IECs trained in Health Research Ethics
- A Workshop held on **Harmonization of Standard Operating Procedures** for Ethics Review Committees/IRBs/IECs. SOPs developed
- **Strengthened capacity** in **20** institutional ethics review committees
- **At least 150 investigators and scientists** trained in health research ethics
- An interactive **electronic discussion forum on bioethics** issues in Africa established by November 2007

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## SUMMARY

- AMANET concerned re HRE in Africa since inception in 1995
- Proceedings 1999 Seminar on HRE in Africa published 2001, Acta Tropica
- Trained +300 Africans in HRE,+ 200 planned
- Ethics for Investigators module
- Trained 200 Africans in GCP
- Web based basic HRE course underway; planning French version, advanced course, GCP
- Electronic debate and discussions re HRE
- Strengthening 20 African Ethics Review Committees

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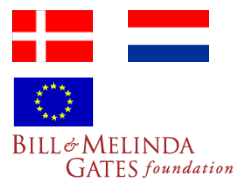
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## Acknowledgements

- AMANET is grateful to:

DANIDA, Dutch Ministry of Foreign Affairs, EC's Directorate General Research, EC's AIDCO, The Gates Foundation



- AMANET has also received assistance from:

EDCTP, WHO-AFRO, WHO/TDR, AU, SIDA/Sarec, GSK, Wellcome Trust, US-NIH, US-NIMR, US-OHRP



## ***Annex 7: Summary of activities AMANET***

### **AMANET Strengthens Health Research Ethics in Africa**

Wen L. Kilama, African Malaria Network Trust, PO Box 33207, Dar es Salaam, Tanzania Email: [wkilama@amanet-trust.org](mailto:wkilama@amanet-trust.org)

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#### **Summary**

African Malaria Network Trust (AMANET) has prioritized capacity strengthening in Health Research Ethics (HRE) since its inception. AMANET evolved from the African Malaria Vaccine Testing Network (AMVTN), which was formed in 1995. In November 1999, AMVTN organized an historic *Seminar on Health Research Ethics in Africa*, Acta Tropica 2001, Vol 78 (Supplement 1), 126 pps; it drew in 54 participants from 34 African and European countries and the USA.

Ever since the Arusha HRE Seminar, AMANET has reached out across Africa, covering both Anglophone and Francophone countries. Overall, nine (9) workshops on *Health Research Ethics in Africa* have been organized, attracting close to 300 participants. To promote networking, conscious efforts are made to bring together Anglophone and Francophone participants. These AMANET training workshops have been held in Kenya (2001), Ethiopia (2001), South Africa (2002), Gabon, (2002), Sudan (2003), Cameroon (2003) and Tanzania (2005, 2006 and 2007). Participants were drawn from Benin, Burkina Faso, Cameroon, Egypt, Ethiopia, Gabon, Ghana, Kenya, Madagascar, Malawi, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Sudan, Tanzania, The Gambia, Uganda, Zambia, and Zimbabwe. Countries with more than ten HRE workshop participants include Burkina Faso, Cameroon, Ethiopia, Gabon, Ghana, Kenya, Nigeria, and Tanzania. Two workshops on developing SOPs for ECs were also organized, as was one advanced bioethics course.

In order to meet the ever increasing demand in HRE, AMANET with EDCTP funding recently launched a web based course in HRE in English; preparations for a French version are at an advanced stage.

A recent four year grant from the Bill and Melinda Gates Foundation will fund eight HRE workshops for members of ethics committees (two in French); five HRE workshops for investigators are also planned. With the Gates Foundation grant, AMANET will also strengthen the ethical review process of twenty (20) institutional Ethics Committees (EC) so as to provide them with essential equipment, furniture and supplies, develop standard operating procedures, set up centralized databases, improve communications, strengthen oversight of studies, and engage in public outreach programs.

The Gates grant will also foster debate and discussions on the internet on HRE from an African perspective. Case studies and ethical dilemmas faced by African ECs will be circulated electronically to a wide audience including EC members and the ensuing debates and discussions will be compiled for submission to a coordination centre, the Yaoundé Sub-hub, for analysis by expert ethicists. In addition, 'Ask the Expert/Ethicist' program will enable the audience to ask questions regarding ethical dilemmas and challenges encountered in the field. Compiled replies will be put on the AMANET and PABIN websites.

Moreover AMANET has been actively involved in training investigators in Good Clinical Practice (GCP). To date, six (6) GCP training workshops have been held in Ghana (1998), Burkina Faso (2004), and Tanzania (2000, 2003, 2005 and 2006), benefiting 162 participants. A web-based GCP course is planned.

## ***Annex 8: Presentation PABIN***

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

### **Activities, Achievements, and Challenges of PABIN**

Beyene Petros

PABIN Executive Committee member

Ethics Meeting EDCTP

11 June 2007

Geneva

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

### **Outline**

#### **1. PABIN**

- History
- Strategic plan

#### **2. Achievements**

- Conferences and training activities
- Secretariat
- National chapters
- Developing collaborations
- Fundraising

#### **4. Challenges**

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

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

- PABIN was founded at a pan-African conference on ethics in health research in January 2001 in Lusaka, Zambia
  - Conference organized by WHO/TDR following on an initiative taken by AMVTN (later AMANET) in 1999
- 40 participants representing 15 African Countries
  - (Benin, Cameroun, Ethiopia, Gabon, Guinea, Ivory Coast, Kenya, Liberia, Morocco, South Africa, Sudan, Tanzania, Uganda, Zambia and Zimbabwe)
  - in addition Belgium, France, the Philippines, Switzerland and United States of America were represented.

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

### **PABIN is linked in a global forum**

- Strategic Initiative for

Developing Capacity in  
Ethical Review  
(SIDCER)  
– Asia and Western Pacific  
(FERCAP),  
– former Russian states  
(FECCIS),  
– Latin America (FLACEIS),  
– Pan African Bioethics  
Initiative (PABIN)  
– North America (FOCUS).

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

**PABIN's strategic plan: action items**

- Developing an overview of existing ethical review committees within the African Region and maintaining a **registry**
- Developing competent in-country **ethical review systems**
- Contributing a concerted **African voice** to the international discussions on ethics and science in health research

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

**PABIN's strategic plan: action items...**

- Assisting national health authorities in Africa with the development of **national guidelines for ethical review**
- Developing educational programs in ethics and GCP that are integrated into **university curricula**
- Establishing national systems for **accrediting** health research ethics review committees in Africa

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

**PABIN's strategic plan: action items....**

- Acting as an information exchange and meeting ground between African researchers and ethicists as well as an **interface** between Africans engaged in health research and the international community

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

**Achievements: Structure building**

- **Membership**
  - 324 members (Jan 2007), 26 countries
  - Kenya 51 Sudan 26
  - **Ethiopia 50 Tanzania 24**
  - **Nigeria 31 Ghana 24**

- **Cameroon 28** Uganda 14
- S. Africa 26
- National Chapter formation ongoing
- ETBIN, CAMBIN, NIBIN, TABIN
  - Under formation (SUBIN, GABIN, etc.)
  -

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

### **Achievements: Forum building**

- Communication with Ethics Review Committees in Africa and PABIN members
  - EC Survey (2003) and ongoing with AMANET (2007)
  - Executive Committee meetings (Cape Town, Addis Ababa, Zanzibar, Blantyre, and last one on Jan 19-20, 2007, Addis Ababa)
  - Executive Committee Telephone Conference, March 2007
- Annual Pan-African Conference Organization
  - Fifth Conference: June 2008 (Call out for venue)
  - Fourth Conference in Yaoundé, Cameroun, “Millennium Development Goals and Health Research Ethics in Africa”, June 5-7, 2005
  - Third Conference in Addis Ababa “Good Health Research Practices in Africa”. United Nations Conference Hall, Addis Ababa, Ethiopia, 28-30 April 2003.

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

### **Achievements...**

- SIDCER Recognition Programme
  - Launched in Ethiopia in 2006
  - Plans for Tanzania, Kenya, Uganda (WHO/TDR fund)
  - Plans for West and Southern Africa (EDCTP/other funders/?)
- Ethics training
  - WIRB training to obtain experts for capacity building
  - University curriculum
  - Web based training (AMANET course)
  - Plan for regular course at the International Training Division, ALERT
- Ethics Committee strengthening
  - Experience in Ethiopia
- Guideline translation
- National forum for discussions on ethical dilemmas

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

### **Achievements...**

- Fund raising
  - EDCTP applications

- Bill and Melinda Gates Foundation (AMANET/PABIN)
- Advocacy
- African Union
- WHO/TDR
- AMANET
- WHO
- NEBRA
- SARETI
- NIH
- Fogarty
- Ministries of Health
- National Assembly of Cameroon
- AHRI/ALERT
- Ethiopian Science and Technology Agency
- UNESCO, among others

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

### **PABIN EDCTP African Union collaboration for ethics capacity building in Africa**

Dr Pascoal Mocumbi, High Representative of EDCTP, and the PABIN Secretariat the Office of the Commissioner for Social Affairs, African Union, Addis Ababa

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

### **Workshops with PABIN participation: 2001-...**

- Workshop of Ethics Review Committees in Africa (Lusaka, Zambia 29-31 January 2001);
- Workshops on Ethics in Health Research in Africa:
  - » Kisumu, Kenya, 23-27 April 2001;
  - » Addis Ababa, Ethiopia 10-12 December 2001,
  - » Khartoum, Sudan 12-16 January 2003, and
  - » Yaounde, Cameroon 15-19 September 2003.
- Combined Training Workshop on Health Research Ethics and GCP, Pretoria, South Africa, 22-26 July 2002.
- Combined Training Workshop on Health Research Ethics and GCP for Francophone African Countries, Libreville, Gabon 30 September to 4 October 2002

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

### **Workshops with PABIN participation:...**

- Workshop on Standard Operating Procedures for Ethics Review of Health Research in Africa, Entebbe, Uganda, 17-21 February 2003.

- Workshop on GCP for African Clinical Monitors, Ouagadougou, Burkina Faso, 20-24 October 2003.
- A Pan-African Workshop on Standard Operating Procedures for the Ethical Review of Health Research, Makerere University (Entebbe, Uganda, 17-21 February 2003)

Pan African Bioethics Initiative **P A B I N** Réseau Panafricain de Bioéthique

#### Workshops with PABIN participation: ...

- 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)
- PABIN has also been represented in other workshops and meetings for example:
  - A workshop on Partnership for Enhancing Human Research Protection held on 31st May to June 4th 2004, Blantyre, Malawi. A total of 74 participants from 9 African countries (Botswana, Ethiopia, Ghana, Kenya, Malawi, Tanzania, Uganda, Zambia and Zimbabwe attended.
  - A Conference on Ethical Aspects of Clinical Research in Developing Countries held on 20-22 March 2002, Accra, Ghana. 48 participants from Benin, Cameroon, Egypt, Ghana, Kenya, Malawi, South Africa, Tanzania, Uganda, and Zimbabwe attended.

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#### Workshops with PABIN participation: -...

- Health Related Biotechnology in Africa: ethical, legal and social implications (ELSI) of transfer and development organized by TDR/WHO in collaboration with West African Bioethics Program; Ibadan, Nigeria, 4-8 April 2006

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#### Challenges and response

- Funds: minimum of three to five year support
  - Network (among/with members and national chapters)
- Closer links with ethics initiatives
- Advocacy for appropriate recognition and support

- National Chapters
- Support initially; can secure sustainable structures and funding mechanisms on their own
- More and wider
- Executive Committee
- General Assembly and elections
- Secretariat
- Strengthening and networking

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- Africa is a complex environment with different levels of appreciation of needs for ethics capacity strengthening
- Pan African efforts always take long to take root
- Multiple players
- An African voice in ethics requires African leadership and grass root mobilization – it should not be done by proxy
- PABIN represents an independent African effort for an African Voice and its growing pains are pains of resource limitations: not of vision; and of efforts to be truly independent – with own program and tools, however slow the growth
- PABIN seeks support to serve as an umbrella and coordinate ethics activities in Africa

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### Acknowledgement

- WHO/TDR
- AMANET
- EDCTP
- World Health Organization
- African Union
- Ministry of Health, Ethiopia
- National Assembly of Cameroun
- Armauer Hansen Research Institute/ALERT
- ETBIN, CAMBIN, NIBIN, TABIN
- Ethiopian Science and Technology Agency
- UNICEF
- And many other contributors to the Conferences Organized by PABIN over the years

## ***Annex 9: Summary of activities PABIN***

### **INTRODUCING PABIN**

PABIN is a pan-African organization whose fundamental **aim** is to strengthen ethical awareness and discussion across the continent. The **vision** of PABIN lies in ensuring the promotion of health through research and the protection of research participants and their communities. The PABIN **mission** is directed toward building competent and independent in-country decision-making structures for health research. It is primarily focused on the development of strong national **ethical review systems** as well as providing regional **Good Clinical Practice** standards and training. PABIN is composed of leading members of the African research and ethics communities, and it acts as an interface between these communities and international organizations and research projects.

PABIN's **strategic plan** includes the following:

1. Developing competent in-country **ethical review systems**
2. Developing an overview of existing ethical review committees within the African Region and maintaining a **registry**
3. Contributing a concerted African voice to the **international discussions** on ethics in health research
4. Assisting national health authorities in Africa with the development of national **guidelines** for ethical review
5. Developing **educational programs** in ethics and GCP that are integrated into university curriculum
6. Establishing national systems for **accrediting** health research infrastructures in Africa
7. Acting as **an information exchange and meeting ground** between African researchers and ethicists as well as an interface between Africans engaged in health research and the international community

PABIN is currently administered by an **Executive Committee** composed of 11 members from 9 countries. It is registered in Zambia and its physical Secretariat is hosted by the Armauer Hansen Research Institute, a government research facility within the All-Africa Leprosy TB Rehabilitation Training Centre (ALERT) in Addis Ababa, Ethiopia. To date, PABIN has **324 members in 26 countries** including Kenya (51), Ethiopia (50), Nigeria (31) Cameroon (28), Sudan (26), S. Africa (26), Tanzania (24), Ghana (24) and Uganda (14). Members are encouraged to form **National Chapters**. Currently, recognized chapters exist in **Ethiopia** (ETBIN), **Cameroun** (CAMBIN), **Tanzania** (TABIN) and **Nigeria** (NIBIN) and more are being formed (**Sudan, Democratic Republic of Congo, Ghana, Zambia, Kenya, etc.**) in response to recent calls by the Executive Committee.

#### **Achievements of PABIN to date**

PABIN is a young pan-African initiative struggling to take root in a setting of high diversity and resource limitations. It relies heavily on the dedication and commitment

of pioneers whose vision is to realize the dream of an informed African voice in

ethics. Its primary task has been to provide a **forum** where Africans can meet and establish networks amongst themselves, and with international partners, while developing understanding of principles of ethics and consulting on current dilemmas. It has promoted discussions on international guidelines (ICH-GCP, Helsinki Declaration, WHO Operational Guidelines for Ethics Committees, etc) and encouraged Africans to express their views from the perspective of local cultures, beliefs, ethical norms and practices with the purpose of protecting the rights, dignity and well-being of research participants.

**Providing a Pan-African Ethics Forum:** Four Pan-African Conferences (Lusaka Jan 2001, Cape Town Feb 2002 Addis Ababa March 2003, Yaoundé June 2006)

**Operational guidelines for ethics review committees:** PABIN involved in Translating the WHO/TDR guidelines into local language (Amharic in Ethiopia); organized with AMANET an ERC SOP workshop

**Training workshops** (in collaboration with AMANET): on SOPs for ERC Entebbe, 2003; Ethics in health research: Kisumu April 2001, Addis Ababa Dec 2001; Pretoria July 2002; Cape Town Feb 2002; (in collaboration with INSERM) Paris Oct 2002; Khartoum Jan 2003; Yaoundé Sept 2003.

**Web-based discussion forum:** [www.pabin.org](http://www.pabin.org) (in process of formation).

**Web-based ethics training:** in collaboration with AMANET, with the active participation of two PABIN Executive Committee members, ongoing

**Ethics University curriculum:** Assisted Medical Faculty, AA University Bioethics Unit in initiating such a curriculum for clinical year students.

**National Ethical Review System building** – Example from Ethiopia (ETBIN)

- National forum to review ethical guidelines
- National guidelines for ethical review, second version developed
- National forum to discuss antiretroviral drug access to research participants
- Training courses in ethical review (medical students, researchers)
- Web supported ethics training course for medical residents in collaboration with University of Oslo (including discussion sessions with trainer)

**National Chapter formation (and legal registration):** Four chapters formed and others are in process.

**Training of African Ethics Committee members** at Western Institutional Review Board in collaboration with WHO/TDR: three Ethiopians trained; serve as resource persons for planned regular ethics course at ALERT Training Centre; further trainees to be selected from other countries

**SIDCER Recognition program for ethical committees:** Launched in Ethiopia through WHO/TDR funds for three Ethics Committees (National, AHRI/ALERT and Addis Ababa University Medical Faculty which together handle over 2/3 of the projects reviewed in Ethiopia) in 2006.

**Communication:** [www.pabin.org](http://www.pabin.org), PABIN Newsletter (Issue 1, June 2007), PABIN brochure, e-mail postings to members (e.g. Calls for elections, 2006; Call for PABIN Conference hosting, June 2007), Teleconference (Executive Committee meeting, March 2007); satellite meetings (executive committee meeting Zanzibar, Blantyre)

**Survey of ERCs in Africa:** First survey conducted in 2003; data obtained on 68 ERCs from 15 Countries in Africa. **Survey form posted on website** for downloading and filling for return to the PABIN Secretariat. This approach demonstrated many limitations. Based on the lessons, a survey tool was developed by AMANET in collaboration with PABIN, and tested in April 2007 and is currently being used with physical visits to ERCs.

**Advocacy:** PABIN has been presented to international organizations frequently. PABIN is known to the African Union – The Honorable Ibrahim Bubaker Keita, President of the Parliamentary Union of Africa spoke at the opening of the Third Conference (April 2003); PABIN Conference was hosted by the National Assembly of Cameroun (June 2006)- EDCTP High Commissioner, Dr P. Mocumbi and PABIN Secretariat delegation were received by Commissioner Gawanas (AU Commissioner for Social Affairs) (Oct 2004); Executive Committee members discussed with AU Social Commission members (Jan 2007), PABIN Secretariat was invited to participate in the deliberations of the AU Commission on the Africa Health Strategy (Feb 2007).

**Physical Secretariat:** is now carrying out tasks of coordinating PABIN activities.

**Language:** Simultaneous translation is provided at PABIN Conferences and Executive Committee meeting (Jan 2007). Important documents are translated into French for executive committee and members. Website document translations into French have become available recently. The PABIN Newsletter is available in French. Efforts are underway to strengthen communication in French.

**Fund raising:** Major support has come through WHO/TDR. Applications to EDCTP have been submitted three times. An “initial” one-year support of 100,000 Euro to assist Secretariat activities was received in December 2006. Conferences have been supported by multiple funders.

**Networking and partnership:** The future of PABIN depends on its capacity to network and partner. This is in progress.

**Next tasks:** include holding a General Assembly, renewing the PABIN Executive Committee, developing a five year strategic plan, strengthening national chapters, creating/expanding discussion forums, assisting development of regular ethics training programmes in various regions in Africa, strengthening national ethical review committees, assisting formation of national ethical review systems, supporting national chapters in building ethics review committees, developing capacity for surveying and monitoring ethics review committees, working towards sustainable ethics capacity building mechanisms) for promoting good research.

## ***Annex 10: NEBRA report pages***

**Pages 90 – 104 of the final NEBRA report which can be downloaded from [http://trree.org/site/en\\_nebra.phtml](http://trree.org/site/en_nebra.phtml)**

### **3. Comparative approaches and discussion.**

#### **3.1 Legal data component (S1)**

##### **3.1.1 Overview of existing laws in NEBRA survey countries**

The legal or regulatory situation varies considerably in the 14 countries for which data were submitted.

The table on the following page presents these situations in a synoptic manner.

Schematically, the situations are categorised as follows:

Absence of legislation (half of the countries observed).

Existence of legislation dealing directly and specifically with the question of research.

Existence of draft bills concerning this subject.

Creation by decree of a body of the committee type, having the mission of reviewing research protocols.

In addition, one finds that the law, when it exists, may or may not be applied (as in the case of Gabon, for example, where the committee, while established from a legal point of view, seems to have no real existence).

In the countries surveyed, the typical situation is a transitional one, moving towards strengthening of legislative texts. In Togo, the Public Health Code has not yet been passed.. To our knowledge, the draft for this text does not raise the question of research, but sets the deontological foundations of the rights of patients in general. It constitutes a solid basis for later development specific to research. In other countries (Benin or Nigeria), draft laws are at a very advanced stage of preparation. For these two countries, the law replaces the existing one by formalising structures that were initially self-constituted. The two models are different: Benin is progressing towards the establishment of a national committee with broad functions covering clinical and epidemiological research, and research in the areas of traditional medicine. Nigeria, on the other hand, is setting up a national mechanism for regulation and oversight of the work of IRBs and IRCs already established at the local level.

Country	Existence of specific legislation	Application of the legislation	Legislative model	Reference to international texts in the law, in legal texts	Mention of traditional medicine
Benin	DRAFT LAW	N/A	National committee reviewing research protocols	No	Yes – the review system is different
Burkina Faso	DECREE 2002  Code of research ethics being prepared: should result in a detailed legislative document	YES	National committee reviewing research protocols	No	No
Cameroon	DECREE 1987	YES	National committee reviewing research protocols	YES Declaration of Helsinki and “Code of Human Experimentation” (not available)	No
Congo	No legislation according to survey data				
Ivory Coast					
Gabon	LAW 2000	NO	National committee reviewing research protocols	No	No
The Gambia	No legislation according to survey data				
Ghana	No legislation according to survey data				
Guinea	The survey data do not allow for conclusions: the S1 component of the survey was not submitted. A “National Code for Health Research” is mentioned but its status and content are unknown				
Mali	No legislation according to survey data				
Nigeria	DRAFT DECREE	N/A	National committee reviewing research	Yes, in the draft guidelines produced by the National Committee	No (to be confirmed)

			protocols		
CAR	No legislation according to survey data				
DRC	No legislation according to survey data				
Senegal	DECISIO N 2001	YES	National committe e with the mission of overseein g research ethics	No, not directly in the legal text	No, not directly in the legal text
Togo	No legislation according to survey data A draft of a Public Health Code is before the Parliament; the text contains no chapter specifically devoted to research ethics.				

### 3.1.2 Discussion of legal options

A legal framework for research is primordial in the life of a nation: it determines the framework for the guarantee of individual rights. In addition, the restrictive and opposable nature of law provides a reference framework within which actors can position themselves.

The NEBRA survey data show great change in this area for several countries, but also wide variation in progress made: 7 of the 14 countries possess no specific text, and for those countries, the NEBRA survey teams did not report on any project or work in progress concerning the development of legislative tools.

The fact of endowing themselves with functional legal instruments is certainly important for African countries. However, their implementation is neither immediately, nor easily accomplished. This brings us back to a certain number of questions that cannot be answered in this document, but which ought to be raised: will specialised legal cooperation prove necessary? Is there a demand on the part of governments? What are the methods of South-South and South-North cooperation that may prove relevant? The performance of an exhaustive census specifically focused on legal material in all the countries of Sub-Saharan Africa could make it possible to compile what exists in a complete dossier that could be used for an accurate, comparative analysis. Above all, it would be communicated to countries interested in acquiring reflection tools in view of developing their own legal instruments.

Two major options for the organisation of a legal framework for research are brought out by the survey. The first is illustrated by the Nigerian model: it comprises a transversal, normative coverage regulating the operation of delocalised entities within institutions, and therefore based on the principle of subsidiarity. The second, more frequently found in the countries surveyed, which is not in itself significant, depends on the creation of a national body (National ethics committee) having the function of dealing with research protocols in a centralised manner.

In the various documents that could be obtained during the survey, we observe that the texts vary in precision concerning details on the ethical and technical aspects that committees are supposed to review. In particular, references to international texts such as the Declaration of Helsinki do not appear systematically (insofar as it was possible to judge, without any guarantee that relevant documents would be obtained in their entirety, since the method of researching on legislation is not clearly explained for any of the countries).

Moreover, none of the legislative or regulatory texts reviewed refers to specifically African references on fundamental rights or statements specific to research. The question of the choice of basic references to be used in the production of standards for human research at the country level thus seems to remain wide open. In this respect, it is noteworthy that numerous actors who are directly involved in operational committees in different countries, or who hold responsible academic positions, seem quite unfamiliar with the references most frequently cited at the international level.. This would seem to argue in favor of facilitating access to these references by lawmakers or ministerial staff in charge of research, and improving the diffusion and promotion of work accomplished and already available on the specificities of research in Africa.

Beyond these preliminary comments, observations on legal and regulatory data from the NEBRA survey have made it possible to open discussion of the scope of what should be called “research” involving human subjects. This issue, a difficult one worldwide, takes on particular meaning in African countries. Two broad lines of questions may be considered: the first concerns the difference between research and innovation, and the second concerns medicine and traditional practices.

The difference between research and innovation raises a problem that frequently arises in countries of the North. In Africa, economic development and capacity building in the least developed countries brings them access to new techniques and technologies that they had not used in the past. The typical example is found in the practices of MAP or organ transplantation. As a result, these practices are innovative in the context where they begin to be implemented. Should the conditions in which patients have access to some of these practices be subject to particular ethical scrutiny? Should this matter be included within the scope of referrals to a body devoted to research ethics? It is certain that the introduction of newly available techniques in a given country is not always associated with a plan to pursue new knowledge in an organized way. However, the types of ethical questions raised (such as consent, benefit and risk, as well as equity in access to care) show considerable overlap with the range of questions often dealt with by a research ethics committee. Moreover, with regard to the organised production of knowledge, it may be advisable to think about the possible impact of introducing new techniques in a context where they have never before been implemented.

One of the questions raised by the practice of traditional medicine and the search for knowledge in this field, is whether it should come under the same regulatory system as the practice and research of what is known as “modern” medicine. The legislative texts that we have been able to study do not mention traditional medicine, except for the draft bill proposed in Benin. This bill takes it into account, but apparently without requiring that research conducted by a practitioner of traditional medicine be reviewed by the proposed national committee.

Development of the legal or regulatory field of operation must therefore, take into account the spheres of activity or competence of the bodies created for ethical regulation, notably regarding the two lines of questioning raised by reading the survey data

The texts available to us for this survey only rarely discuss the contextual specificities of Africa. Among the paramount issues of this perspective (consent procedures, negotiation with countries providing financial backing, equality of rights, benefits, healthcare standards, etc.), Benin approaches only the question of consent. Foreseeable here are the terms of a potential debate to determine whether these questions should be matter for legislation or whether it would be preferable to entrust them to the attention of committees dealing with research ethics.

To conclude this preliminary discussion, it must be emphasised that the difficulty of applying the law in a clear, efficient and well organised manner shows through the opinions of many committee members and observers. The lack of available means is often mentioned. It is clear that for legal provisions to be meaningful, they must be followed by implementation. This refers back to the operational development of regulatory mechanisms for health in the countries concerned. Nevertheless, regulation of research should not be seen as secondary when it is evident that the stakes involved are clearly those of human rights and the political autonomy of the country. Rather, these issues should be an integral part of efforts to support and develop the tools of public health systems in African countries.

### **3.II. Committee operation (S2)**

#### **3.II.1 Different committee models described in the NEBRA survey**

The NEBRA survey has brought to the fore different models of committees. A first distinction may be made between an institutional model of the IRB or IRC type and the non-institutional national committee model. This distinction may however prove simplistic, particularly when institutional committees evolve towards a national model (as in Benin). In Nigeria, a national committee will supervise institutional committees. In Gabon, the existence of institutional committees creates a phenomenon of functional substitution in the absence of a national committee. It is very rare that the question of committee independence, especially

concerning the institutional model, prompts pejorative comments. According to the great majority of respondents, operational autonomy, irrespective of patronage, is not a problem. A second distinction may be considered, according to whether the committee is entirely national in identity or if, on the contrary, it has a mixed identity. The NEBRA study found two examples of historically combined identity: in the Gambia and Gabon. In the Gambia, the established committee, "The Gambia Government/MRC Joint Ethics Committee", is mixed. As its name indicates, it is based on dual administration by the Anglo-Saxon foundation and the Gambian government. The group interview carried out for the study of this committee brought out no problem of identity. On the contrary, a member even pointed out that the committee makes every effort to prove that it is under MRC control. Finally, let us remember that in the Gambia, it is the only research ethics committee in the country. In Gabon, one of the two institutional committees described, that of Albert Schweitzer Hospital, also has a combined identity for historical reasons dating from the founding of this institution.

Today, the Chairwoman of the hospital (HAS) lives in Germany, with the result that certain dossiers are managed by E-mail. This situation has aroused discussion within HAS. as to whether the organisation of the committee needs to be changed.

A third distinction may be seen in the functions assumed by the structures surveyed. While all of them have the mission of reviewing protocols before their implementation in order to verify their ethicality and most often, their scientific validity, their other actions vary. Thus, not all committees have a role to play during or after research.. The table below recapitulates the data available with regard to committee operations during and after research..

Country	Committee	S2A	Role during research	Role after research
Benin	Ethics Committee of the Faculty of Health Sciences	+	No	No
Burkina Faso	Ethics Committee for Health Research	+	Monitoring. Authority to have the research stopped	No (?)

	Institutional Ethics Committee of the Muraz Centre	+	Monitoring.	“Yes, but never used” (S2A). This point does not appear in the official statutory document of this committee.
<b>Cameroon</b>	National Ethics Committee of Cameroon	+	No	No
<b>Congo</b>	<i>N/A</i>			
<b>Ivory Coast</b>				
<b>Gabon</b>	Ethics Committee of the CIRMF (Franceville)	+	No, for lack of means	Sometimes, dissemination of research results to participating populations
	Ethics Committee of Albert Schweitzer Hospital	+	The investigator must report serious adverse events to the EC and provide an interim report on the state of the research.	No response
<b>The Gambia</b>	The Gambia Government/MRC Joint Ethics Committee	+	Monitoring with authority to stop the research	Yes, without details on the nature of the intervention
<b>Ghana</b>	Ghana Health Service Committee	+	Monitoring with authority to stop the research. Occasional visits to the research sites	Calls for final results to be submitted as well as explanation of the way in which results were communicated to participants
	NMIMR IRB	+	Monitoring with authority to stop the research. Occasional visits to the research sites	Calls for submission of final results.
	NHRU IRB	+	Monitoring with authority to stop the research.	No response
<b>Guinea</b>	National Ethics Committee for Health Research	-	?	?
<b>Mali</b>	CNESS	+	Authority to stop the research	Authority to oppose diffusion of research results (without other details)
	FMPOS	-	?	?
	INRSP	+	No response	No response
<b>Nigeria</b>	ABU/ABUTH	+	Monitoring and review of interim results	No (but this would be desirable)
	Gombe FMC IRB	-	?	?
	ISTH ERC	+	No (but should)	No (but should)
	NAUTH	+	No, lack of means, but it would be desirable	No
	National Ethics Review Board	+	N/A. This committee does not review protocols directly, but supervises the others.	
	NPMCP	-		
	UI/UCH IRB	+	Review of interim reports	Ensures that the investigator does follow-up of persons after completion of research
<b>CAR</b>	?	No data		
<b>DRC</b>	CERS-ULPGL	+	Authority for direct	No (cessation of relations

			monitoring (observer) and to stop the research. Possibility of arranging third-party intervention	between investigator and committee)
	Bukavu Univ.	+	No, lack of means	No (cessation of relations between investigator and committee)
Senegal	CNRS	+	Direct monitoring in the field	Follow-up and participation in communicating results to participants
Togo	N/A			

The most striking aspect of this comparison is the variability of monitoring roles during research, and the tasks that may be carried out after the research is completed. For committees that fulfill a function during or after research, we find two possible (not mutually exclusive) positions: one that may be described as noninterventional (for committees that receive data) and the other as interventional (for committees that intervene in the field). Concerning the latter position (field intervention), it should be noted that committee agents may intervene as observers without becoming involved in the relation between investigators and persons consenting to participate in research, or else may intervene directly, for example by playing an active role in the communication of data produced by the research project. It is worth noting that the authority conferred on the committees varies considerably among those surveyed.

Several other distinctions may be made in considering different categories of committees according, for example, to:

- composition (exclusively medical, a combination of healthcare professions, a combination of healthcare professions and persons from outside these professions, or even according to whether or not there is representation of communities concerned by a particular research project);
- whether or not scientific aspects are considered during review of a protocol by a given committee; in this respect, it seems that all the committees look at the question of scientific relevance of the protocols submitted to them, review by an independent scientific committee turning out to be the exception;
- institutional history: certain committees are established within institutions practicing research, others at the national level, independently of institutions; certain committees were founded with the direct intervention of partners of the North (and may still be operating with the latter), while others have arisen from a strictly national initiative.

Other categorisations may of course, be envisaged.

### 3.II.2 Ethical references of the committees

The ethical references used by the committee members contacted are highly varied. Because of the scarcity of data, it is not possible to present statistics or prepare a comparative table in order to bring out the realities of reference use, committee by committee. On the other hand, it is possible to set up a typology based on the fragmentary observations provided by the survey.

The situations that seem to emerge are the following:

1. Absence of specific references for the committee (Example: Benin, where most of the members questioned claim to function on the basis of experience).
2. References established at the same time as the committee, referenced for example in the Rules and Regulations (Example: the Ethics Committee of Albert Schweitzer Hospital in Gabon).
3. Reference to international texts (the most frequent case) that are not specifically African.
4. Reference to African texts dealing with research ethics (no mention).

The first three are the most common situations. It is striking that no specifically African text is mentioned.

This goes back to the question of using the stock of analytical work accomplished (having often led to the production of written material) in the specific context of Africa.

### **3.II.3 Training of committee members**

In general, only a very small proportion of committee members were questioned in this survey. It is therefore impossible to draw conclusions about training at the committee level. Despite this, the demand for training is extremely important from a general point of view. Most of the members responded that they had not benefited from any training in the field of research ethics, and express the wish to do so..

### **3.II.4 Ethics committees and healthcare standards**

The data collected by this survey give the impression that neither the question of healthcare standards, nor that of post-trial treatment access has priority among the various preoccupations encountered by the committees in their work. This is, however, an important specificity of the African countries in the NEBRA survey.

This consideration allows opening the discussion on the possible function of ethics committees with regard to this matter.

### **3.II.5 Links with ethics bodies in countries of the North**

It is also remarkable that in responses collected from committee chairpersons or members, there is almost no mention of ethics bodies in countries initiating or sponsoring research. Is the notion of collaboration, or dual review a subject needing more thorough discussion during follow-up of the NEBRA survey?

### **3.II.6 Networking and data banks**

It is almost universally the case that committees work without sharing their experience with others, whether at the national or international level.

Practical questions concerning the operation, even the survival of the committees, seem - understandably - to prevail over thoughts of networking.

However, from a strategic standpoint, a question needs to be asked: is it not fundamental to strengthen mutual knowledge and the sharing of experience?

More than half of the committee chairpersons or members contacted expressed their wish to see this happen.

### **3.III. Approach to observers' perceptions**

Non-specific country data for the S3 component are in the process of final analysis. The text below constitutes a preliminary approach. This version takes into consideration the following numbers of questionnaires:

7	Benin
5	Burkina Faso
1	Cameroon
5	Congo
14	Gabon
25	The Gambia
11	Ghana
1	Guinea
3	Mali
15	Nigeria
12	Togo

For a total of 99 observers interviewed.

The persons interviewed as observers:

- are citizens of the countries assessed except for five foreign workers in the Gambia (a healthcare professional, a research clinician, a chairman of a research programme and retired epidemiologist, and a student member of a research team).
- They are not members of ethics committees except for two persons of unknown occupation in Gabon.
- In the Gambia, an epidemiologist was a member of an EC and is currently part of a research team. Two research clinicians are members of a research team and were contacted to evaluate a protocol. The chairman of a research programme was contacted to evaluate a protocol and is a member of a research team. A doctor had been a member of an EC. A nurse was contacted to evaluate a protocol and is part of a research team.
- In Burkina Faso, a government representative was contacted to review a protocol.
- Four Togolese citizens are members of a research team and one was contacted to evaluate a protocol.
- In Ghana, 10 of the 11 persons interviewed are members of a research unit, including 4 who were contacted to review a protocol. One observer is a community leader.
- In Guinea, a government representative teaching ethics at the university was contacted to review a protocol and did not respond to the questionnaire.

### **3.III.1 Evaluation of observers' knowledge about the role of ethics committees *Before implementation of a research project involving human participants***

Overall, the responses reveal two major preoccupations on the of the observers. VALIDATION of the protocol is the most frequent comment closely followed by RESPECT OF THE DIGNITY OF PARTICIPANTS AND THE POPULATION.

Concerning the protocol, some specify that it must comply with research ethics as well as with international standards and good practice guidelines. In addition, it must be in line with the needs of the country ("relevance of the research") while respecting sociocultural and religious differences ("by consulting families and community leaders"). One person emphasised that the opinion of a religious leader would be necessary.

Another suggested "presenting the protocol to Parliament" and "to the Minister of Health".

For a few people, validation of the protocol is an opportunity to make suggestions and recommendations.

Again for a few, medical research must sensitise populations and the community to the problem of ethics ("raising awareness about research").

One person stressed that only studies involving human subjects needed ethical approval.

Concerning the participants, consent (mentioned 4 times) must be obtained after providing information on the possible benefits and risks involved ("the person must be a volunteer," "researchers must learn to provide participants with complete information").

In case of problems, there should be provision for compensation.

One of the major concerns about participants is ensuring respect of sociocultural and religious diversity of the population ("respect of the Ten Commandments").

However, one observer believes that the EC "must not play the policeman and block research", and another that the EC "must be independent".

#### ***During implementation of a research project involving human participants***

Most of the responders emphasised the supervisory role that the EC should have: supervision of the progress of research at regular intervals.

They also underline the need for the EC to communicate interim results via reports (annual) or regular progress reports that will keep the community, among others, informed.

Many insist that monitoring in the field (including "surprise" visits) would make it possible to prevent possible "deviations" and would ensure respect of the dignity of participants as well as of the protocol.

One person emphasises the importance of the EC being autonomous, objective and independent.

For two other observers, the EC has no role to play during the research process.

For another, it will suffice to "take inspiration from the ECs of other countries

or the sub-region”.

**After the implementation of a research project involving human participants**

The EC must assess research results (verify respect of the protocol and previously defined objectives) and ensure communication of these results by written report to the target populations. The community could thus be informed of the impact (benefits) of the research and have access to all the advantages it generates.

This report should then be archived and/or communicated to the Ministry of Health.

The observers emphasise that the EC must monitor the fate of the participants.

Two observers point out that the EC has no role to play after completion of the research.

**3.III.2 Concerning international-level documents on standards and directives for research**

**ethics: evaluation of observer knowledge and personal opinions**

The majority of the responses remain very evasive. Few observers are aware of international texts on ethics.

In all, 53 observers out of the 90 interviewed are unable to cite any text.

The most well-known document is the Declaration of Helsinki (cited 25 times).

The Nuremberg Code was cited 9 times and WHO Guidelines 8 times.

The Belmont Report was cited 6 times, the CIOMS 4 times and the Declaration of Human Rights 3 times.

The Hippocratic Oath and the sections on Public Welfare and Protection of Human Subjects of the Code of Federal Regulations (common rule) were cited twice.

Other texts are also put forward, but to a less striking degree: the international

treaty on intellectual property, the Convention on Biological Diversity, the international treaty on Raw Foods of Animal Origin (in relation to food and animal feed), texts on ethics and resuscitation, the Reports of the World

Medical Assembly of Tokyo in 1975, Venice in 1983, Hongkong in 1989 and Edinburgh in 2000.

Also mentioned are the guidelines for good clinical practice, OIS, the

International Ethical Guidelines for Biomedical Research Involving Human

Subjects, the American Psychological Association ethical principles and code of conduct for research on animals and humans (1953-1992), ICH, Good Laboratory Practice, and the Innocenti Declaration.

The majority of observers consider these texts as universal and pertinent because “all human beings are the same no matter what their country of origin”).

However, certain observers think that they should be adapted to social realities and the specificities of African countries.

One person emphasises that funds should be allocated for the study of the behaviour of different ethnic groups with regard to medical research ethics.

**4. Conclusion**

The situation of the 14 countries that could be studied more or less thoroughly proves to be extremely heterogeneous, if not to say unequal.

What should urgently be addressed is the question of countries considered unable to exercise efficient control of research implemented on their territory, and thus obliged to depend on those who finance or conduct such research.

They must certainly be given special attention as a priority.

The dominant notion among the countries surveyed is that of transition. In fact the most frequently observed process is the gradual development of mechanisms for ethical control of research. In general, these start as academic

or institutional initiatives, followed by the creation of a general framework through legislation.

Regulation brings about a radical change in the context when it is made compulsory by the national governing bodies: protocols are subjected to ethical review, not because of obligations generally imposed by entities publishing research results, but out of concern for the protection of fundamental individual rights.

The “ethical function” of ethical committees can be a subject of debate when it concerns research in the African context. The data of this survey indeed show

considerable variation in the understanding of the powers of these committees, whether they have interventional authority or simply the authority to exist.

Should the ethical function of these committees be influenced by the principal known specificities of ethical issues in the conduct of research in Africa? The question arises in view of the mediation role played by certain ethical bodies

when they extend direct invitations to representatives of communities that are potentially concerned by a research project, or when they intervene directly during research (participation in the diffusion of information or even in the consent process), or after completion of research.

This "ethical function" takes on special meaning whenever it becomes definitely political. Indeed, we know that the most vulnerable areas show vulnerability simultaneously in the socio-economic, educational, health, and political realms (the latter in terms of respect of fundamental rights). It so happens that through its interventions, the conduct of a research project is likely to modify the history of the populations concerned. Such intervention may have beneficial or negative effects. It is necessary to consider the potential of these effects above and beyond the medical aspect (even if it may prove very important in terms of access to treatment), because doing research that intervenes in the lives of a vulnerable population always brings consequences other than the production of knowledge. If the practice of research can be seen as an opportunity for collaboration that contributes to sustainable reducing the vulnerability of consenting populations, then ethics committees potentially take on political responsibility.

Even if the data of this survey cannot be representative of a reality that is too incompletely depicted in this document, they may serve as an aid to development and discussion for those in charge of watching over a process involving many actors, from within the committees but also from a broader perspective.