



# EDCTP Stakeholder Meeting on Ethics

## Online Consultation Feedback

### 1 Introduction

In preparation for the meeting, EDCTP has set up an online consultation to gather views from stakeholders. The end result is expected to be a concrete set of recommendations through an open consultative process that involves a broad range of stakeholders from academia, industry, foundations, non-governmental organisations, civil society, governments and other interested parties working in the field of ethics.

The comments and recommendations will inform discussions at the respective meetings and where appropriate contribute to EDCTP strategy in this field. The feedback from the online consultation is presented in this document as they have been submitted. These will also feature in the final meeting report.

### 2 Online Consultation Feedback

#### **Dr Adebayo Adejumo**

University of Ibadan, Nigeria

#### **Current status of the field**

The need for ethics regulation within the context of emerging health and research issues can not be over emphasized. Despite the availability of local and international research ethics guidelines, adherence to ethical codes in human research is still worrisome. Available literature point to low level of research integrity among researchers, sponsors, and other stake holders in many parts of Sub-Saharan Africa. The impact of poor funding of research, need for focus on emerging health challenges, standard of care in international clinical trials, and domestication of research ethics regulation among others deserve greater attention in the sub-region.

#### **Future Directions**

- Domestication of research ethics guidelines
- Intensification of training of researchers, ethics committee members, students, and research communities
- Standardisation of research ethics committee activities in line with global practices
- Increased funding of research ethics committees, and other research ethics activities in training institutions
- Enforcement of research ethics regulations
- Training of research ethics committee laymen

#### **The role of EDCTP**

- Harmonisation of research ethics guidelines and organisations in the sub-region
- Funding of research ethics training activities
- Advocacy for support of research ethics regulation and enforcement by regional governments
- Inclusion of research methodology, and research ethics in the training curriculum of all health related disciplines and postgraduate programmes

#### **Ms Loren Becker**

Global Health Technologies Coalition at PATH, United States

#### **Current status of the field**



- Redundancies in ethics committee review (e.g., institutional, local, national)
- Requirements that EC and NRA reviews occur consecutively instead of parallel
- Lack of coordination among ECs on meeting cycles and review timelines
- Limited human resources to manage both technical and administrative aspects of review
- Lack of established and enforced timelines for review
- Lack of incentives for efficiency in ethics review of clinical trials.

#### **Future Directions**

- Increase support for mechanisms for collaborative review of new protocols by NRAs and ECs across countries
- Develop and implement a common training curriculum to be used across capacity building initiatives
- Develop sustainable financing approaches for supporting NRA and EC activities
- Develop sustainable financing approaches for supporting EC activities.

#### **The role of EDCTP**

- Support/facilitate mechanisms for joint reviews among ethics committees across centers and countries for multi-country trials. A first step would be to conduct several pilot joint reviews with an eye toward assessing the benefits and risks of joint review (e.g., timelines, financial costs) from multiple perspectives. Partners for this would include the WHO, product developers conducting multi-country trials, relevant ethics committees
- Support coordination and alignment across ethics review capacity building initiatives in Africa. Key aspects of this could include building curriculum consensus and developing/supporting an accreditation scheme for ethics reviewers/ committees. Partners for this would include a host of regional and disease-specific capacity building initiatives (e.g. AMANET, IRENSA, SARETI), as well as global initiatives such as The Global Health Network, Harvard's Multi-Regional Clinical Trials Center.

#### **Dr François Bompert**

EFPIA/Sanofi, France

#### **Current status of the field**

Similar issues as in the rest of the world: challenges posed by the informed consent process in an increasingly complex legal and regulatory environment, data confidentiality, personalized medicine, etc. In addition: issues related with the vulnerability of patients, healthcare systems and personnel and ethics committees.

#### **Future Directions**

Ensure that African ethicists and health professionals are involved in discussions around "cutting edge" issues such as those regarding data confidentiality, use of genetic information, Big Data, personalized medicine etc.

#### **The role of EDCTP**

Ensure dialogue between Africa and Europe on all ethical issues, involving European Commission structures, the WHO, the World Health Association, but also representatives of the private sector and patients associations. Regarding short- to medium- term objectives, a priority should be to simplify informed consent processes, with a focus on the key information that are necessary for participants to make a true, informed, decision.

#### **Dr Elizabeth Bukusi**

Kenya Medical Research Institute, Kenya

#### **Current status of the field**

There is lack of implementation of what is known to work, lack of robust systems of follow up and lack of research to determine both new treatment options as well as operational and translational research to address the gaps which have been identified.



### **Future Directions**

Operational and translational research that can be scaled up to practice. Strengthening of health systems to meet the challenges of health care in areas with the greatest need.

### **The role of EDCTP**

EDCTP should fund additional research in all relevant fields. EDCTP should also leverage on position to work with relevant stakeholders for advocacy and for pushing for change, implementation and focus in the countries hardest hit.

### **Prof. Christian Burri**

Swiss Tropical and Public Health Institute, Switzerland

### **Current status of the field**

Independent ethics committees in Africa received major training over the past decade and in my opinion the understanding of the ethical issues is much better than in many other regions (e.g. India, CIS states). However, the committees are still underfunded and work inefficient due to sub-optimal management processes and a lack of understanding of their service role.

### **Future Directions**

- In view of the above statement, training on managerial issues will be key to speed the processes up and make them transparent, predictable and credible. User fees should be calculated on the basis of the effective needs to run a functional committee and allow discrimination between research and commercial studies. IECs should be supported in establishing practical and workable charters
- Independent Ethics committees should also be advised on how to cooperate with drug regulatory authorities (see regulatory affairs stakeholders meeting).

### **The role of EDCTP**

- To continue the pursued strategy of ethics grants and nested grants within the projects, but with a particular focus on management
- An external analysis of the function of EDCTP funded ethics committees covering the number of projects reviewed, the existence of a correct charter and particularly the performance (timelines) should be commissioned to allow improvement.

### **Prof. Anne Buvé**

Prince Leopold Institute of Tropical Medicine-ITM, Belgium

### **Current status of the field**

- There is still a paucity of well functioning ethics committees in several countries sub-Saharan Africa
- By well functioning I mean: well organised and with sufficient competent members.

### **Future Directions**

- Training in research ethics, not only for biomedical research but also social sciences research in the area of health and health systems research
- A body that has the mandate to carry out audits of RECs with the aim to strengthen capacities and to achieve more equal quality of advises provided by different RECs (to avoid "shopping around").

### **The role of EDCTP**

- Fund training courses or attendance of training courses
- Fund research into the functioning of ethics committees
- Fund research on ethical issues. A top priority should be research on informed consent and the interactions between researchers and communities.

**Dr Pamela Claassen**

University of Namibia

**Current status of the field**

Quality health care for the most pressing issues such as:

- HIV/AIDS
- Malaria
- Maternal Deaths

Socio-economic context:

Poverty, Unemployment, Gender-based Violence, Rural/Urban Health Divide

Environmental unpredictability: climate change:

- Floods/droughts that affect economies as well as socio-economic health issues
- Malaria mutations

**Future Directions**

- Continuous HIV and malaria intervention programmes
- Responsible conduct of all health professionals to do the right thing when it comes to health practises
- Accountability of health practises
- Engaging in collaborative research activities that include comparative studies.

**The role of EDCTP**

- Capacity building in research ethics professionals
- Training IRB members and chairpersons
- Training IRB managers and administrators
- Institutional awareness campaigns of responsible research conduct in developing conduct
- Frameworks to measure, monitor and evaluate responsible research conduct.

**Prof. Alice Desclaux**

Institut de Recherche pour le développement (IRD), France

**Current status of the field**

Ethics committees have been set up and overall formal ethics issues have been considered, but particular issues related to vulnerable populations must still be discussed and managed.

**Future Directions**

Developing ethics for vulnerable populations such as: women (including pregnant women); children; socially vulnerable population; the elderly. A particular commitment to gender equity should be a priority.

**The role of EDCTP**

Develop networking with ethics committees, social scientists, ethicists, European medical scientists, representative of vulnerable populations. Ethics for health research in children and women, with adaptation to local cultures and societies, should be considered a priority.

**Dr Christiane Druml**

Medical University of Vienna, Austria

**Current status of the field**

The key issues are:

- Internationalisation of research
- Special needs of health research in Africa
- Specific issues regarding the cultural aspects therefore needing specific rules - it is not "one size fits all", but it is important to apply bioethics principles with focus on the specific



needs

### **Future Directions**

It is necessary to think globally and to find a system which fits all African countries for capacity building as well as for the system of research ethics committees thus permitting research with the highest standards for the benefit of the African population.

### **The role of EDCTP**

EDCTP is an important player in this field and should strive to streamline with its means (via its program and its funding) the ethical review procedure. EDCTP should also collaborate with UNESCO, especially the ABC program of the International bioethics Committee of UNESCO and of WHO

**Prof. Pierre Effa**, Pan African Congress for Ethics and Bioethics (COPAB), Cameroon

### **Current status of the field**

See my Paper at the 5th Meeting of European Commission International Dialogue on Bioethics, Brussels, September 17, 2013

### **Future Directions**

Priorities should be, implementation and capacity building of Regulatory bodies in each Member State of African Union with a continental coordination at the level of African Union Commission.

### **The role of EDCTP**

Partnership between EDCTP and COPAB will certainly bring appropriate answers to concerns outlined above.

Indeed, COPAB is the Ethics Network of African Union. COPAB proposes the establishment and operation of African Platforms on Ethics especially in the areas of intervention of EDCTP. For example: the African platform on ethics in clinical trials and guidelines for health research, on good clinical and pharmaceutical practice, on public health, particularly the evaluation of health policies, on research on HIV/AIDS.

COPAB program also provides:

- Certification on Ethics Review in partnership with WHO
- Training on Ethics and Bioethics at the Pan African University in partnership with UNESCO and international cooperation.

**Mrs Najet Hadhri**

Institut Pasteur de Tunis

### **Current status of the field**

The most limitations are the lack of legal frame and regulation.

### **Future Directions**

We must increase awareness about ethical issues and multiply training sessions in these fields.

### **The role of EDCTP**

- Giving training facilities for African researchers and IRB 's officer to visit a old ethic structure
- Build specialised network
- Reinforce on line training opportunities

**Prof. Carel IJsselmuiden**

COHRED, Switzerland

**Current status of the field**

- Lack of quality control, standardisation, user-accountability
- Lack of capability for RECs to deal with rapidly growing complexity of research collaborations
- No attention paid to role and relevance of REC Administrators as opposed to REC members.

**Future Directions**

- Africanisation of SOPs, ICH guidelines
- Change-over to cloud-based service provision
- Development of virtual consultancy function - not all RECs can possible have all expertise needed
- Regional standardisation
- Mechanisms for RECs to convene in a virtual space to decide on multi-centre trials
- Accreditations mechanisms, nationally, regionally (? continentally)

**The role of EDCTP**

- COHRED is a key alliance
- Need continental harmonization with other large funders in this field: NIH FIC, Wellcome Trust, national universities in Africa
- Create awareness of need for ICH, cross-border collaboration

**Mr Bather Kone**

African Union Commission, Nigeria

**Current status of the field**

Effective commitment and involvement of regional intergovernmental organisations, self financial contribution in capacity building.

**Future Directions**

Effective and efficient political support of the regional organisations to African capacity development.

**The role of EDCTP**

Support building networks and networks experience exchange North-South and South-South.

**Prof. Mariana Kruger**

Stellenbosch University, South Africa

**Current status of the field**

- Multi-institutional review of international collaborative research.
- Ethics regarding biobanks and intellectual property rights
- Research ethics guidelines for public health research
- Research ethics guidelines for research with traditional medicines
- Addressing healthcare priorities of communities in research agenda.

**Future Directions**

- Continuous capacity building in research ethics
- Harmonisation of ethics review in multi institution ethics review in international collaborative research.

**The role of EDCTP**

- Sponsorship of education programmes in research ethics



- Conference for networking purpose
- Assistance with the development of national ethics guidelines.

**Ms Katherine Littler**

Wellcome Trust, United Kingdom

**Current status of the field**

Complexity of ethics review systems, especially when conducting multi site studies where there are differing and often conflicting expectations/rules in different countries and at the consortia level. There is a need to engage with ethics review bodies.

**Future Directions**

There is a lot of good work taking place in building ethics capacity (including in initiative such as H3Africa) it would be good to learn how to make these efforts more joined up.

**The role of EDCTP**

The major funders are a key stakeholder group.

There is a need to tap into initiatives that are working to make the approach to ethics review less "sliced" - brining the disease-specific initiatives and networks together - would be a great way to build on current capacity and share lessons learnt.

**Dr Lucinda Manda-Taylor**

College of Medicine, University of Malawi

**Current status of the field**

One of the key challenges and limitations facing health research ethics framework in sub-Saharan Africa is the lack of a unified voice or practice. While great strides have been taken in the establishment of ethics committees on the continent, ECs seem to function in isolation. Previous proposals of setting up regional bodies like PABIN (Pan-African Bioethics Initiatives), seem to have lost the momentum and steam they once possession to steer the research ethics dialogue and agenda in Africa. Because of this, ethics committees seem to function in isolation. This brings forth the need for ECs to come together and share their experiences and observations, with the aim of updating themselves and refining their functions. One example where coming together can hold share experiences and observations is through organizing meetings and workshops for research ethics committee administrators. For example, in 2011, MARC hosted (through funding provided by the EDCTP) the First African Conference for Administrators of RECs. Of the feedback provided by participants was the need to have a training body in Africa that would draft a curriculum, and offer continued professional development and accreditation of Research Administrators in Africa. Similar to what PRIMR does in the USA. It would be a great achievement if this idea was followed through as it would enable IRB Administrators to continually accredit themselves and update themselves on current and topical issues in research ethics.

**Future Directions**

To date, EDCTP has done a great job at helping countries establish functional ethics committees that have written guidelines and standard operation procedures in place. In addition, funding has also gone to helping ethics committees deliver lectures and trainings to faculty, members of ethics committees and other national stakeholders on the subject of human participant protection in research, research ethics and good clinical practice. These activities have gone a long way to ensuring that researchers and research governance officers protect the rights, safety and well-being of research participants.

In the next phase of EDCTP 2, I would like to suggest that we build to this capacity by also helping institutions in LDCs to buttress their regulatory documents and policies. Of particular interest to the College of Medicine, University of Malawi, is the need to develop a policy document on Intellectual Property Rights. As more and more scientists in Malawi collaborate





with partners in HICs testing novel drugs, or even designing new interventions, creations, scientific discoveries there is a need to position the College in a position that ensures that the benefits of research and the inventions that arise are not lost. And, ethics committees have a role to play in this area. For instance, ethics committees can:

1. Advise university researchers on the ethical use of IP in research
2. Ensure university researchers address IP issues through the ethical application process
3. To ensure university researcher' awareness of policies and procedures
4. To ensure university human research ethics policies and procedures on IP are considered and updated when required

(source: <http://www.waikato.ac.nz/research/ro/ethics/Appendix%204%20-%20Intellectual%20Property%20in%20Research.pdf>)

These need to be built into the guidelines on health research at the College of Medicine, University of Malawi.

### **The role of EDCTP**

EDCTP needs to continue partnering with RECs on the continent, Regulatory authorities in different countries, Research Support Centre at Universities and other funding agencies like NIH, Fogarty, WHO who are interested in building the capacity of research ethics on the African continent.

### **Dr Jean-Baptiste Mazarati**

Rwanda Biomedical Center, Rwanda

#### **Current status of the field**

- Human Resources: There aren't enough skilled people to carry on such research
- Funds: Where human resources is there, there is lack of funds
- Medical Ethics is a new area in Sub-Saharan Africa, which does not ease research
- Infrastructure: Most ethics committees do not own infrastructure where they independently conduct their business.

#### **Future Directions**

- Empower multiples health workers associations and laboratories in Africa so that they initiate operational research
- Help educate Health-related stakeholders through workshops, short or long term training in Ethics and bioethics
- Educate patients and all beneficiaries of health care to know their rights
- Initiate studies that foster the understanding of Health issues in Africa
- Partner with European Research institutions to help Africa take its own share in Global Health initiatives
- Promote African Solutions or approaches to Global Health delivery wherever they have succeeded.

#### **The role of EDCTP**

- The first key players are the different ethical committees all around Africa: They badly need funds to stand strong, monitor and evaluate research they approve. They need training in various aspects of ethics in order to refine their work
- Help Ethical Committees institute and train local IRBs that relay their work in various institutions
- Second key players: Medical associations and researchers in different public health institutions
- EDCTP should ensure that various Ethical Committees have enough funds to do their job. It should organize rotational training camps in various areas of Ethics for Ethical committees members.



**Dr Wilfred Mbacham**

University of Yaounde, Cameroon

**Current status of the field**

These need to be universal in principle but context specific given the myriad of cultural differences that exist.

**Future Directions**

Firstly, the ethical concerns need to be debating many times for a common understanding of what the issues are. Secondly there needs to be online course and now webinars on ethics that allow a central authority to teach the issues without adulteration of facts or methodology etc.

**The role of EDCTP**

- Sponsor IRBs for a continuous education and review of projects
- Organise online courses and webinars for various needs for the IRB
- Key players - DAAD, WHO, Wellcome Trust, NIAID

**Dr Boitumelo Mokgatla-Moipolai**

COHRED, Botswana

**Current status of the field**

1. The ever increasing scope, complexity and amount of health research in Sub Saharan Africa has resulted in a greatly increased and increasing need for sound ethical review structures and functions within these countries, and for greatly increased efficiencies in ethical review processes
2. The greatly varying ethics review processes, hence lack of harmonisation in the ethics review process
3. Poor research ethics infrastructure, particularly in view of administration which tends to be a major bottleneck to research ethics committees' efficiencies.  
Lack of capacity and well developed information management systems - leading to long turn around times / waiting periods
4. Lack of coordinated and standardised training (basic training) and continued training /advanced training, this should be matched with the new developments in health research e.g. Genomic research, HIV Vaccine trials.

**Future Directions**

1. Building long-term sustainable review infrastructure: Information management systems, to ensure the quality of review, overcome the administrative challenges, reduce the awaiting / review period significantly, improve the research ethics committees efficiencies even with low human resources
2. Harmonisation of research ethics review process
3. Standardised Research ethics training.

**The role of EDCTP**

EDCTP should consider investing in the research ethics review infrastructure - information management systems. The latter will address multiple problems such as; harmonisation of review processes, capacitating less capacitated research ethics committees (RECs), reduce the review periods and improving the RECs efficiency.

**Ms Marion Motari**

WHO/AFRO, Congo

**Current status of the field**

Lack of adequate institutional capacity for the conduct of research ethics

**Future Directions**



Creation of stronger regional networks, facilitation of joint reviews (inter-country) as a mechanism for capacity building, human resource development/regular training opportunities, harmonization of practices

#### **The role of EDCTP**

- WHO is a good partner - due its wide representation and access to ministries and other players at national level
- Proposed mechanisms for collaboration - joint capacity building activities, developing guidelines, annual Africa health research ethics symposia, publications etc.
- Priority for funding: Capacity-strengthening initiative for national and institutional ERC, paying special attention to vaccine trials.

#### **Dr Paul Ndebele**

Medical Research Council of Zimbabwe (MRCZ), Zimbabwe

#### **Current status of the field**

African countries are still operating at different levels when it comes to research ethics. Some countries do not have frameworks that are supported by law. The area of Research Ethics Committee administration also requires attention, as the majority of administrators have not received any formal training. A lot of RECs in Africa still have paper-based systems that are not reliable. There is need to move to electronic systems that make the work of RECs easy.

#### **Future Directions**

1. Training for Research Ethics Committee administrators. There is need for the development of a formal course for administrators
2. Ensuring that all African countries have legislations that adequately support research ethics frameworks
3. Promotion of electronic submission and management systems across Africa is also necessary.

#### **The role of EDCTP**

EDCTP can provide resources for supporting a course for REC administrators across Africa. EDCTP can also facilitate a programme of mentorship whereby REC admins from African institutions can work with RECs in Europe for on-the-job-training. EDCTP can also assist countries that do not have legislations that support the operations of RECs. Funds can be provided to support the processes that will lead to the development of such pieces of legislation. EDCTP can also work with African Union to influence change in the area of research ethics across Africa.

#### **Mrs Francine Ntoumi**

Fondation Congolaise pour la Recherche Médicale (FCRM)[Congolese Foundation for Medical Research], Congo

#### **Current status of the field**

Develop expertise of ethics committees' members in reviewing research protocols and organize themselves regionally to get support from national governments.

#### **Future Directions**

Regional networking and support.

#### **The role of EDCTP**

Financial support for training and networking.

**Dr Aceme Nyika**

Public Health Projects in Africa (PHPAfrica), Zimbabwe

**Current status of the field**

The key issues are (i) sustainability of institutional and national Ethics Committees, (ii) weak national regulatory authorities, (iii) inadequate empirical research to enable evidence-based ethical review processes, (iv) sharing of biological specimens in international collaborative research, (v) need to harmonize ethical and regulatory processes, etc.

**Future Directions**

(i) Enhancing self-sustainability of Ethics Committees, (ii) promoting harmonization of ethical and regulatory processes, (iii) promoting African-driven development of ethical and regulatory frameworks for sharing of specimens and data and (iv) funding Bioethics empirical research.

**The role of EDCTP**

EDCTP should consider funding long-term projects which incorporate sustainability strategies as part of the specific objectives. Health-related projects should be used as platforms for empirical Bioethics projects since in general they may not be conducted as stand-alone projects. Thus there should be interaction among the funders of health-related projects so as to make them multi-disciplinary and include Bioethics research components. There should also be interaction with relevant arms of the national governments in order to enhance collaboration and chances of sustainability after the funding ends.

**Dr Opokua Ofori-Anyinam**

GSK, Belgium

**Current status of the field**

- Trained personnel (scientists and non scientist for biomedical research)
- Commitment (without being paid lots of people will not work)
- Solution giving (most say what they don't want but don't provide solutions or alternatives)-
- Clarification of the role of the bodies as not only problem finding but also solution based approach
- Fora for discussions on dogma.

**Future Directions**

- Develop a solution and teaching framework for African scientists
- Include curricula in training in universities and research organisations
- Develop with research communities (internally and externally) questions that dog research and provide fora for solution finding- have a plan for 1-3 years and clear objectives and few but detailed questions
- Work with organisations like welcome trust to develop guidance documents.

**The role of EDCTP**

- Develop a few specific research questions on ethics with regulatory agencies and like minded organisations/bodies and debate issues across the network and create a paper or papers that can be reference documents
- Train ERCs members on research principles
- Develop an auditing document or guideline for ethics committees- allows them to efficiently look and see places for improvement
- Develop curricula ethics in research with like minded bodies and facilitate the circulation in the network for training
- Key players are scientists, regulators, ERCs, students and like minded organisations working on research ethics
- Develop 3 research ethical questions each year and have a debate across the networks- not only with ERCs but within the whole organisations either using computing tools and



also congresses- focus should be on up and coming and not only established continue to train ERCs and fund them within the programmes.

### **Dr Maxwell Otim Onapa**

Uganda National Council for Science and Technology (UNCST), Uganda

#### **Current status of the field**

- The ability of research participants to comprehend the details of ethical implication of their participation in research
- The lack of control of by the participant of the specimens that had legitimately acquired from them during a research
- There is need to carefully document population attitudes to elements of modern scientific research and the consenting process.
- In the areas on Ethical, legal and social implications of biobanking; acquisition, storage and future use as well as transfer of samples seems to be a challenge

#### **Future Directions**

- There is need to develop a framework to guide biobanking and empower research participants to be inform
- Strengthening the IRBs so that they can facility the establishing of frameworks such as biobanking regulations as well as tackling issues of transplants

#### **The role of EDCTP**

- EDCTP should continue availing grants to strengthening research capacity among researchers. Institutions that guide/coordinate and regulate research should also be supported so that they can strengthening their oversights roles. The different institutions and that handle research with ethical implications should be addressed as well
- Mechanisms of collaboration should include EDCTP organized trainings/workshops, scientific conferences
- The area of research that EDCTP should consider funding include strengthening oversight role of the regulatory/coordinating institutions, as well as equipping researchers with research ethics
- EDCTP should consider biobanking.

### **Mrs Alessandra Liquori O'Neil**

United Nations Interregional Crime and Justice Research Institute, Italy

#### **Current status of the field**

Scarcity of resources, doubling of activities, lack of synergy and coordination between North and South and among single governmental institutions, limitations in the capacity to follow up and evaluate effectiveness of programme delivery and capacity building activities

#### **Future Directions**

Increase synergistic approach among intergovernmental institutions and single governments in the delivery of programmes, increase and better distribute resources among local partners, increase evaluation mechanisms and follow up of programme delivery

#### **The role of EDCTP**

EDCTP is in a unique position to continue to deliver its mandate and to continue to increase its leadership role in pooling resources, creating synergistic approaches and in increasing collaboration with intergovernmental partners active in the South and with other EU relevant agencies. EDCTP could also increase its guiding role in providing grants which should include follow up activities and stricter evaluation of programme delivery.

### **Dr Odile Ouwe Missi Oukem**



CERMES, Niger

### **Current status of the field**

Despite efforts being made in the past ten years, Francophone Africa is still lagging behind compared to Anglophone countries. In Central Africa, the situation of Health Research Ethics has been recently described by myself and colleagues (Odile Ouwe-Missi-Oukem-Boyer, Nchangwi Syntia Munung, Francine Ntoumi, Aceme Nyika and Godfrey B. Tangwa ; Capacity building in health research ethics in Central Africa: key players, current situation and recommendations. *Bioethica Forum* / 2013 / Volume 6 / No.1) and much still need to be done, particularly in terms of governance and functioning of RECs. In West Africa, in Niger where I am currently based, the same national ethics committee is functioning since 1999, but obviously members are not trained and there is a need to replace members. In Burkina Faso, the members of a research centre have been replaced, but the training must be started again from scratch. There is a need to improve the governance of health research ethics, the functioning of RECs, and the training of members and potential members in order to increase the critical mass of individuals with minimal education/training in ethics.

### **Future Directions**

1. State of the art in Health Research Ethics in each African country, including information on the number of RECs, the link between RECs in a same country and how they interact, and SOPs describing the functioning of RECs. This has been started with the MARC project, but need to be updated and improved, with an appropriation from the RECs themselves
2. Registration and Accreditation of RECs at the African level
3. Harmonized rules in case of multi sites studies (trials)
4. Systematic Monitoring and Evaluation of ongoing studies by RECs

### **The role of EDCTP**

All points mentioned above are important, but EDCTP can specifically contribute to 1, 2 and 3. More discussion during the Meeting.

### **Ms Raffaella Ravinetto**

ITM, Belgium

### **Current status of the field**

Working in resource-limited contexts and with socio-economically vulnerable populations requires a special "ethical effort", in order to appropriately apply the internationally agreed ethical principles in specific contexts, e.g. pertinence of the research for a given community, best standards, benefit-sharing, impact of the research on the local health systems etc. To do so, there is need of strengthening the ethical review capacity (in terms of training and in terms of resources); and of encouraging the communication among different ethics committees that review a same research (to promote mutual learning).

### **Future Directions**

- Structural support (beyond ad hoc training only) to ECs in Sub-Saharan Africa
- Promote South-South and South-North networking among ECs

### **The role of EDCTP**

- Create/facilitate networking platforms for ECs
- Create/facilitate reflection on ethical dilemmas, hopefully resulting in guidance on challenging subjects (e.g., conduct of clinical trials in populations lacking free access to health care)
- Create/facilitate reflection on adequate ethical standards for diagnostic research, cluster randomized trials and other medical research. This last point is also applicable to regulation.

### **Prof. Jan Helge Solbakk**



University of Oslo, Norway

### **Current status of the field**

The lack of a system of independent, robust and well-functioning research ethics committees.

### **Future Directions**

- Allocation of resources to build sustainable RECs. A well-functioning secretariat of each REC is key
- Research ethics training courses for members of RECs
- Capacity building in academic writing and publication ethics targeting young medical researchers.

### **The role of EDCTP**

- By funding research ethics training courses for members of RECs
- By funding training courses in academic writing and publication ethics targeting young medical researchers.
- EDCTP should join forces with UNESCO and WHO in building such capacities

### **Prof. Dominique Sprumont**

Institute of Health Law, TRREE, University of Neuchâtel, Switzerland

### **Current status of the field**

The main challenge is to insure a sustained network of RECs and training programs in research ethics and regulation. There are already important resources available but there is a lack of coordination and connexion between them. In this process, this would also be important to include the therapeutic products and health authorities, such as AVAREF is doing.

Another challenge is to raise the awareness of the researchers, especially from the North, concerning the laws and regulation already in place as well as the existence of the RECs and competent authorities instead of applying a priori US or EU regulation.

### **Future Directions**

More should be put in the networking and coordination of all the activities. There is a lot going on but often in isolation. It would be important to have a clear picture of the situation, identifying best practices and encouraging exchanges between the partners. EDCTP should pay more attention in making sure that all projects bring an added value that is shared among all beneficiaries.

### **The role of EDCTP**

EDCTP should target the countries where the RECs are in greater needs instead of waiting for them to apply. This is interesting to see that there seems to be often the same participants involved in training programs in Africa. The trouble is to find a way to make sure that those who do not come have access to proper training and support to conduct ethical and high quality research projects. This means a change of paradigm in the sense that research ethics projects should not be treated as research projects, putting the stakeholders in a competition but offering them the necessary resources according to prioritized needs.

### **Prof. Godfrey Tangwa**

Cameroon Bioethics Initiative (CAMBIN), Cameroon

### **Current status of the field**

The key issues, in my view, are governance/regulation, capacity-building and infrastructure. The challenges include governing (political) systems, conceptual unfamiliarity with health research ethics, more pressing existential problems, south-north migration, etc.

### **Future Directions**

The three key issues suggested above need to be tackled simultaneously or concomitantly but



with the understanding or awareness that surmounting the challenges would be easier in reverse order.

### **The role of EDCTP**

The EDCTP needs to continue with its past strategies and activities, but to consider lubricating its procedural rules and regulations especially the financial, and to consider expanding its activities to include funding of task forces, deliberative meetings and small conferences, awareness campaigns, etc. Key collaborative players: local NGOs, AU, WHO, parliaments, governments.

### **Dr Aissatou Toure**

Institut Pasteur de Dakar, Senegal

#### **Current status of the field**

- Insufficient critical mass of people trained in health research ethics
- Lack of awareness of general public, civil society and policy in health research ethics issues
- Lack of resources for Ethical Committees (EC) functioning specially for secretariats
- Lack of people specialized in management of ethic committees secretariats
- Very few ethics training opportunities especially for francophone people. No or very few ethics teaching in health related programmes delivered by academic institutions
- Lack of teaching material
- Lack of debates on ethics issues specific to African context

#### **Future Directions**

- Support to secretariat of ethic committees to allow correct functioning
- Developing ethics training
- Developing training in EC secretariat tasks
- Funding of conferences devoted to ethics issues associated to EDCTP area of activities (research on Malaria, TB, HIV) as well as more global issues.

#### **The role of EDCTP**

- Funding of networks of ECs (as done for scientific networks)
- Capacity strengthening of EC's secretariat: support for equipment, training
- Funding training for ECs members
- Funding translation of existing training/teaching materials
- Organizing conferences/forums on specific research issues
- Mechanisms of collaboration include closer partnership with stakeholders already acting in health research ethics: WHO, UNESCO (through its Bioethic Program), TRREE, SARETI, COHRED

### **Dr Francois Van Loggerenberg**

The Global Health Network, The University of Oxford, United Kingdom

#### **Current status of the field**

Poor access to training and networking.

#### **Future Directions**

Online training and professional support.

#### **The role of EDCTP**

Leveraging existing ethics capacity to build online resources that can be easily accessed and shared. The Global Health Network is one open-access, free resource that can be utilised by all participants.



**Dr Tine Verdonck**

Institute of Tropical Medicine, Belgium

**Current status of the field**

- Tension between ethics formalities and ethical attitude
- Tension between written and verbal culture
- Lack of emphasis on good (cross-cultural) communication
- Challenge of defining local standard of care
- Lack of transparency about conflicts of interest of researchers
- Pressure on researchers to publish.

**Future Directions**

- Harmonization between European and other global initiatives.
- Open-minded and continuous dialogue about research ethics
- Focus on attitudes rather than on documents.

**The role of EDCTP**

- Promote exchange and dialogue. Bring experts in ethics, researchers, and representatives of vulnerable populations together in a relevant environment
- Do not impose European ethics regulations to a local African setting without a moment's (well-informed) thought
- Learn from double ethics reviews
- Consider exchange of members of ethics committees from Europe and Africa.

**Mr Jef Verellen**

Institute of Tropical Medicine, Belgium

**Current status of the field**

- Most countries have 1 or several ethics committees, but often they are not well equipped to perform a suitable review. Current problems:
  - Timelines for approval too long
  - No or unclear procedures for submission or timelines
  - Procedures not compliant with GCP or WHO guidelines for EC's
  - Workloads too high for timely approval, re-approval and ongoing review
- Members of EC's lack basic knowledge and training in medical/research ethics in general. Proper/sufficient trainings and better know-how should be organized
- No networking among EC's / suitable platforms could improve sharing of practices and information.

**Future Directions**

- Training in ethics, procedures and functioning of IRB's for IRB members (proper expertise is a major concern)
- Set-up of IT based platforms and networks for sharing of information and experiences
- Embedding requirements and coverage of review by EC's in national legislations
- Allocation of resources for proper functioning of national EC's (administration, ample time for review, etc.)

**The role of EDCTP**

See above.

**Prof. Douglas Wassenaar**

University of KwaZulu-Natal, South Africa

**Current status of the field**

There have been huge advances in training and capacity of RECs in Africa over the past decade - obviously requires ongoing effort and attention, but in my view the actual operational



capacity of RECs and REC administrators need attention and structured and strategic support.

#### **Future directions**

Following the above, tailored training for REC administrators and investment in or support of a suitable electronic REC management system would be my priority for the next cycle. This will achieve efficiencies and reduce staffing costs once installed and operational. There are various systems available with different features and cost structures. EDCTP could support a Pan African system which would make a significant continent-wide impact on the efficient review of relevant health research in Africa. As secondary issues there is an ongoing need for initial and on-going training of REC members; much of this could be done cost-effectively by funding additional candidates to attend existing major advanced training programmes already in Africa (e.g. SARETI, ARESA, WAB, MERETI, TRREE, Kenya mostly funded by Fogarty NIH) and by funding some empirical research on topics relevant to research ethics scholarship and development in Africa.

#### **The role of EDCTP**

NIH/Fogarty, Wellcome Trust, African Universities with Research Ethics track records.

#### **Dr Dezemon Zingue**

Centre Muraz, Burkina Faso

#### **Current status of the field**

Key issues: lack of continuous training of IRB members, lack of adequate SOP for IRB, budget for field monitoring of ongoing research, bad planning of activities sometimes, conflict of interests, movement and departure of member for service reason, also it's difficult to obtain ethic expert for local training of IRB members

Challenge and limitations: Obtain budget from the government departure, EDCTP to improve IRB activity, regularly training of IRB members by ethic expert with aid of EDCTP, problem of car for field visit, leadership had to be improve, training of researchers by IRB, connection of IRB and regulatory authority

#### **Future directions**

- Regular training of IRB members by expert
- Car for IRB office
- Annual budget for official IRB
- Fund ethical research

#### **The role of EDCTP**

-continues to support IRB (financially and equipment)  
-support training  
-assure annual support of IRB