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# Clinical Trials Roundtable on Developing Guidelines for Health Research in Africa

## A Report from the Science with Africa Conference – Improving African Participation in Global Research & Development

Submitted by Francis P. Crawley

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The following meeting report is from the Science with Africa Conference held in Addis Ababa, Ethiopia, on 6 March 2008.

The meeting was presided over by *Abdul-Hakim Elwaer*, Director, Department of Human Resources, Science & Technology, African Union and *Aïssatou Gueye*, SRO-North, United Nations Economic Commission for Africa. The meeting was moderated by *Avril Doyle*, Member of the European Parliament, and attended by more than 70 leading experts from African, European, and US organizations involved in health research in Africa as well as national, African, and international political organizations.

### Discussion Summary

This roundtable discussion was based on an invited proposal for 'Developing Guidelines for Health Research in Africa' coordinated by *Francis P. Crawley*, Executive Director, Good Clinical Practice Alliance – Europe (GCPA) in collaboration with the United Nations Economic Commission for Africa (UNECA) and the African Union (AU), with technical advice from Intelligence in Science (ISC), Brussels.

The discussion began with opening remarks from the Moderator, *Mrs Avril Doyle*, Member of the European Parliament, in which she stated that there is a direct link between investment in research and development. She suggested that it would be rewarding for all parties involved if sufficient funding was invested to enable stronger collaboration between the best scientists in the south and those in the north. She observed that there has been a strong commitment by the European Union to health research in developing countries, as evidenced in the creation of funding mechanisms such as the European and Developing Countries Clinical Trials Partnership (EDCTP). She emphasized that the EU

insists that clinical trials that contravene the established ethical guidelines in developed countries should not be allowed to be implemented in developing countries: low standards of ethics and science in health research are not acceptable in any setting.

*Dr Pierre Effa*, President of the Cameroon Bioethics Society (CBS) and Vice President of the Pan-African Bioethics Initiative (PABIN), thanked the organizers for the invitation to participate in this roundtable discussion and expressed his appreciation for the work already begun. He discussed the need for the project to consider a pan-African conference on bioethics inviting leading African institutions involved with health research. The project on developing health research guidelines for Africa should strongly consider the role of health research and ethics in achieving the Millennium Development Goals<sup>1</sup> in Africa, specifically those related to public health (e.g. reducing maternal and child mortality and combating major diseases including HIV/AIDS and malaria). The challenge of this project is to take into consideration socioeconomic and cultural differences of specific communities, regions, and countries in Africa.

A road map to engage the participation of all stakeholder African institutions, governments, the AU Commission and Pan-African Parliament will be established within the project to ensure that there is the political will to develop and implement these guidelines. Collaborators in the project are also planning several workshops on ethics contributing to the development of guidelines for health research in Africa. The need for a pan-African law promoting health research and protecting human participants emphasized in the proposal for this roundtable discussion is of key importance.

1 More information on the Millennium Development Goals can be found at <http://www.un.org/millenniumgoals/>.

## Presentations

There were several presentations by experts involved with health research, mainly from Africa but also from Europe and the US.

The Nigerian experience with developing capacity for health research, particularly clinical trials, was presented by *Professor Ifeoma Okoye*, the Chairperson of the Association for Good Clinical Practice in Nigeria (AGCPN). She explained that the AGCPN came into existence through a series of activities that included the creation of the GCP initiative, sustainable institutional review boards (IRBs) all over Nigeria, advocacy to policy makers to obtain political will and a regulatory framework. The AGCPN works in partnership with the National Agency for Food and Drug Administration and Control (NAFDAC) and the National Health Research Ethics Committee (NHREC). She emphasized the need to develop harmonized health research guidelines in Africa on GCP, Good Laboratory Practice (GLP) and clinical trials that are robust but not hostile to foreign collaborators, and suggested that the Nigerian experience should be used as a template. Education is key, and she called on the project to develop a web-based training programme on ethics for investigators.

Professor Okoye was asked if there are currently specific strategies in place for assisting study participants who do not always fully understand the research content during the informed consent process, for example, in genetic research. She replied that, in such instances, schematic representations are used or the services of an interpreter employed.

The issue of what constitutes coercion in trial recruitment was also raised, in terms of potential participants placing absolute trust in their treating physicians. While this phenomenon does exist, the AGCPN are reported to be extending their advocacy to the grassroots where information is being made available to participants on their rights.

A workshop participant wanted to know if there are mechanisms in place to ensure that the samples collected are only used for the analysis indicated in the research proposal and not shipped to Europe for unrelated research. The response was that there is a statement in the information sheet on type of analyses to be done and scientists have also been trained nationwide to comply with the contents of the informed consent forms. Furthermore, the question was raised as to whether, apart from clinical trials, ethical guidelines for social research have been considered. The initial proposal for this roundtable and project foresees the inclusion of social scientists in the development of GCP guidelines and other African health research guidance.

*Francis P. Crawley* gave a presentation on behalf of *Professor Ames Dhai* of the Steve Biko Center for Bioethics at the University

of the Witwatersrand, South Africa. The presentation discussed the South African experience of establishing a robust set of guidelines for the conduct of clinical trials. South Africa has had GCP guidelines in place since 2000 and these were further revised in 2006. The current guidelines are similar to the International Conference on Harmonisation (ICH) and World Health Organization (WHO) GCP guidelines. However, they contain specific considerations for the South African context; for example, the Principal Investigator (PI) of the clinical trial must be a resident in South Africa, stressing the importance of the ownership of research and capacity building. The participants were also informed about several sets of guidelines developed in South Africa since 2000, including the 2006 guidelines for biotechnology research. It has been reported that while the guidelines exist, there remain challenges with their implementation.

Mr Crawley stressed that within the context of this project, the project partners were focused on the process of implementation as part and parcel of the process of drafting the guidelines. He referred to his experience in developing global guidelines for health research and ethics in Europe and Asia, as well as with the WHO, Joint United Nations Programme on HIV/AIDS (UNAIDS), Council for International Organizations of Medical Sciences (CIOMS) and World Medical Association (WMA). He stressed that writing guidelines was not the only challenge, but that their actual implementation is vital to their success. The need to obtain political will to ensure the implementation of the guidelines when they become available is fundamental.

The moderator then requested that participants consider why pan-African guidelines on health research were needed and reflect on what specific guidelines might be developed.

*Professor Joseph Ochieng* of the Forum for Research Ethics in Uganda (FREU) and Makerere University presented the Uganda National Council for Science and Technology *National Guidelines for Research Involving Humans as Research Participants*.<sup>[1]</sup> He remarked that the guidelines promote free choice for the research participants and facilitate researchers performing their roles as scientists, thus, contributing to the development of high-quality research. The Ugandan guidelines address issues relating to the following: rights and welfare of research participants; regulatory oversight of research projects; establishment, function and review procedures of IRBs; ethical considerations in the review of research protocols; the informed consent process; standard of care during research; responsibilities of the investigators, sponsors and host institutions; monitoring and reporting; human biological materials storage, use and future exploitation; publication and dissemination of results; and prescribed penalties for noncompliance.

*Dr Christine Wasunna* of the Kenya Medical Research Institute spoke on health research ethics in genetics research. In Africa the main challenge facing this kind of research often concerns the ability to explain to rural participants what a gene is. Furthermore, studies usually generate large sets of complex data that threatens to invade the privacy of families, communities and, particularly, ethnic groups; hence the absolute need for confidentiality. Dr Wasunna said the project being launched at this workshop should give special attention to genetic research questions when drafting guidelines for health research in Africa.

*Dr Richard Hubbard* of Pfizer spoke on international clinical trials in low resource countries. His presentation focused on the globalization of clinical trials, reflecting on the current environment (increasing complexity of studies, competition for investigators and subjects), ethics and ethics committee considerations, global industry clinical trials, societal benefits of doing more trials in low resource countries, corporate commitment to ethical research following the ICH GCP guidelines and the *Belmont Report*. He also discussed the existing Pfizer policy on global clinical trial standards, Pfizer's current investigators' training programme and the future of Pfizer's international clinical trials programme (i.e. ensuring the maintenance of high ethical standards, focusing on capacity building, training, accreditation and local collaboration).

*Dr Faiza M. Osman* of the Institute of Endemic Diseases (IED) in Khartoum, Sudan, presented on past experience and strategies within the project for the development of African and international cooperation. She referred to the WHO *Operational Guidelines for Ethics Committees That Review Biomedical Research*,<sup>[2]</sup> and her experience in translating the guidelines into Arabic and implementing them into practice and local guidance. She also discussed the use of the WHO *Operational Guidelines for Data and Safety Monitoring Boards*<sup>[3]</sup> within the Leishmania East Africa Platform (LEAP) and Drugs for Neglected Disease Initiative (DNDi) at clinical trial sites in Um El Kher, Sudan; Kassab Hospital, Gadaref State Sudan; Gondar and Arba Minch hospitals in Ethiopia; and the Kenya Medical Research Institute (KEMRI). Dr Osman proposed that the project develop working groups of African and international expertise based on clearly defined objectives.

## Key Issues

The discussion that followed the series of presentations highlighted the following key issues:

- There is a need for strong political support from African leaders who, in turn, have the support of health research experts, and African communities in general, for the development of the relevant legal, regulatory and practical guidance needed to

promote health research and protect human subjects involved in health research.

- Africa needs harmonized pan-African developed (with international support) guidelines and model law(s) for health research covering the areas of GCP, GLP and other health research requirements.
- The GCPA was asked to establish an African and an international secretariat to coordinate African institutions and international collaborators in cooperation with the UNECA and the AU.
- The project for developing guidelines for health research in Africa should concentrate on developing a framework that truly reflects the needs of the African continent for promoting health research and the protection of human subjects.

## Conclusions

The discussion within the roundtable drew the following conclusions:

1. Health research in Africa is a key component to driving health policy and healthcare across the continent. The leadership of the AU and UNECA is of central importance for the development of both pan-African and national approaches to establishing commonly accepted African and international standards for research promotion and the protection of human subjects.
2. Africa should develop its own guidelines for ethics, GCP, and other key areas of health research for the development of investment and outcomes that address the principle African health needs. The project should be developed alongside the ongoing work of the AU (work being carried out by African Health Ministers and African experts) on drawing up a Pharmaceutical Manufacturing Plan for Africa, initiated in Abuja, Nigeria, in January 2005. Model laws regarding ethics in health research should also be developed for consideration by the AU (AU Commission and Pan-African Parliament), national parliaments and governments of Africa. The guidelines and model bioethics law should be developed by experts working in close cooperation with national, African, and international policy makers in health research and health policy in order to ensure their implementation, as appropriate, into national law, regulation, education and practices. The AU and UNECA should provide the leadership needed to create the political will for linking health research to health policy and healthcare through shared African standards.
3. The roundtable has established an African and international cooperative group with an African project secretariat at the CBS in Douala, Cameroon, and an international project secretariat at the GCPA in Brussels, Belgium. Specific working groups will be established for the guidelines and model bioethics law, and a series

of meetings and workshops will be held over the next 24 months to complete the standards and begin the process of implementation.

4. The roundtable participants recognized the need to bring together ethicists, health experts, researchers, regulators, policy makers and politicians for a discussion of the first drafts of the guidelines and model law(s). A pan-African bioethics meeting is being planned for the future with the organisers of the Science with Africa conference.

The conference will have the following objectives in relation to the development of health standards in Africa:

- implement the Resolution of Bioethics from the 32nd Organization of African Unity (OAU) Summit of 1996;<sup>[4]</sup>
- mobilize African strengths for achieving the second step of the Millennium Development Goals in African countries;
- boost health research investment and outcomes for the public health needs of African populations.

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For further information on the Developing Guidelines for Health Research in Africa project, contact Francis P. Crawley, GCPA, fpc@gcpalliance.org.

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