Mapping of ethics review and trial regulatory capacity in sub-Saharan Africa

Supporting the Ethics Review Capacity of Health Research in Africa

Health research in general and clinical trials in particular are key to development, health and health equity in Africa. It builds evidence, supports innovation and creates new solutions, technologies and drugs. The conduct of clinical trials is complex - not only in terms of products being tested, but also in balancing scientific and ethical obligations to study populations. The capacity to ethically review study protocols and provide ethical oversight of drug trials is a core component of responsible research systems. Each country and major institution involved in the conduct of clinical trials should have adequate capacity to conduct such ethics review. The MARC project aims to document this capacity in Africa, to promote the strengthening of capacity that exists, and to contribute to the development of African accreditation criteria.

The MARC project aims to develop a map of the capacity to ethically review health research in all African countries where EDCTP operates. The proposal makes provision for an ongoing effort, integration into an existing research system mapping structure to facilitate sustainability and linkage of ethics ‘maps’ to health research system capacity. The partners in the MARC project are EDCTP, COHRED (the Council on Health Research for Development) and the University of Kwazulu-Natal (UKZN) – in particular, the South African Research Ethics Training Initiative (SARETI) located in the School of Psychology of the UKZN in Pietermaritzburg, South Africa.

Background
Currently there is no updated information on ethics review capacity in Africa available. Previous efforts (undertaken by the African AIDS Vaccine Programme (AAVP)) are out of date and comprised mostly contact information and membership, not information on capacity or capacity building needs and programmes. Similarly, the Office for Human Research Protections (OHRP) in the USA lists only those African research ethics committees that have received a ‘Federal Wide Assurance’ (http://ohrp.0nih.gov/search/asearch.asp#ASUR) on the basis of capacity requirements demanded by the US Federal Government. Thirdly, Harvard School of Public Health initiates a ‘Global Research Ethics Map’ which, for now, focuses on countries where the HSPH has ongoing research. It is also not linked to the general health research system, and focuses on issues of importance particularly to US researchers. Lastly, the World Health Organization provides contact information on national bioethics committees, but not on institutional committees nor capacity of such committees.

Rationale
As the EDCTP is committing substantial funding to clinical trials and clinical trials capacity in African countries, it is logical that it should invest resources in providing an up-to-date overview of ethics and clinical trial related regulatory activity that is inclusive of capacity assessment and capacity building assessment. Ideally, such ethics review capacity mapping should be able to link to general research and health research system information, should be ‘ongoing’ rather than ‘ad hoc’, should allow mapping of other ethics review and clinical trials capacity building initiatives, and should form a basis for capacity enhancement through the presentation and use of its data. Lastly, although EDCTP focuses its activities on Africa, the mapping should ideally be integrated into a global map to encourage standardization and ‘south-south’ learning and cooperation.

Method
The MARC project is a three-year programme of Mapping of Health Research Ethics and Regulatory Activities in sub-Saharan Africa – essentially in support of EDCTP funded clinical trial sites and projects but...
with obvious wider applicability. The concept of ‘mapping’ conveys a ‘once-off’ event – which is not what is intended. Instead, the MARC project will link the ‘ethics review capacity’ and ‘ethics review capacity building initiatives’ with COHRED’s Health Research Web platform (HRWeb) which will allow ethics capacity analysis in relation to general research system development, encourage comparisons between countries inside and outside Africa, and which will facilitate the sustainability and knowledge sharing throughout the project.

**Results**

The core deliverables of this project are:

1. A continuously updated (‘self-updating’), systematic map of African research ethics review committees and clinical trial related regulatory activities that is linked to general health research system information of the countries in which the ethics committees are located, and is integrated into a global map of health research systems, and, where possible, linked with other web-based resources in health research ethics.

2. Comprehensive regular reporting on health research ethics activities (capacity programmes and regulatory situation) in sub-Saharan Africa; details to be agreed with EDCTP and other partners.

3. Networking of African regional ethics training initiatives and active research ethics committees through HRWeb and developing the content and display of research ethics committee information in ways that suit the key audiences best.

4. Developing sustainability and capacity, in specific:
   a. agreement on criteria for ethics committee registration on HRWeb
   b. support from donors and research sponsors to demand review by registered research ethics committees
   c. mechanisms for ‘self-funding’, additional donors in place
   d. beginning of an African accreditation mechanism.