



AFRICAN MALARIA NETWORK TRUST
First Health Research Ethics Workshop for Ethics Committees and Review Boards
in Africa

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Workshop Report

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AMANET organized a five-day “*Health Research Ethics (HRE) Workshop for Ethics Committees and Review Boards in Africa*” from 28th May to 1st June 2007 at Giraffe Ocean View Hotel, in Dar es Salaam, Tanzania. This workshop was the first in a series of eight similar HRE workshops to be spread in four years in the new AMANET HRE capacity strengthening project funded by the Bill and Melinda Gates Foundation. The thirty three (33) members of ethics review boards and committees who participated in this training came from Burkina Faso, Cameroon, Ethiopia, Gabon, Ghana, Kenya, Malawi, Nigeria, Tanzania, Uganda and Zambia.

The workshop kicked off with a scintillating speech from the guest speaker, Prof Brig. General Yadon Kohi, Director General for the Tanzania Commission for Science and Technology and Member of the AMANET Board of Trustees who set the scene by unpacking the origins and meaning of the word ‘Ethics’. He highlighted the importance of Health Research Ethics in the wake of increasing volumes of health research. In the opening session Professor Kohi and then Professor Kilama captured the basis of ethics and the historical development of health research ethics largely in response to inhuman practices.

Subsequent plenary sessions by Prof Godfrey Tangwa, Mrs Joyce Ikingura, Mr Paul Ndebele, Dr Aceme Nyika, Dr Roma Chilengi and Dr Nditonda Chukilizo zeroed in on philosophical mechanisms of assessing the moral and ethical rightness of an action or research protocol. The four main ethical principles, namely the principles of autonomy, beneficence, non-maleficency and distributive justice, were elaborated as a means of ensuring logical and objective way of assessing the ethical correctness of an action. It was noted that dynamics in health research have an impact on the practicalities of the four ethical principles. Thus risks and benefits could be at individual, family, community or population levels depending on the nature of the research. Nevertheless, the requirement for truly voluntary informed consent remains a cornerstone of ethical health research.

It was made clear right from the beginning of the workshop that Ethics Committees play a major role in ensuring that the welfare and well-being of research participants are protected, and thus they need standard operating procedures that guarantee uniformity, transparency and independency in the review of research protocols.

The informed consent was also unpacked in the context of vulnerable groups of people, who include prisoners, children, pregnant women, handicapped and institutionalized participants, refugees, and impoverished communities. This led to heated debate on whether or not pregnant women are vulnerable. One school of thought was that they are not vulnerable because they are competent individuals who can process information and make rational informed decisions. A second school of thought was that they are vulnerable not in the sense that their decision-making capabilities are limited, but because they carry fetuses which are not yet adults but may be exposed to experimental conditions meant for adults. In addition, many hormonal physiological changes due to pregnancy could render them more vulnerable than adults who are not pregnant. Related to vulnerable groups, it was suggested that resource-constrained institutions should also be considered as a vulnerable group since the need for injection of research funds usually overshadows the need to consider ethical issues.

By the third day of the workshop, issues of standard of care and post-study benefits were flagged as critical aspects of health research that need to be considered if chances of exploitation of research participants are to be minimised. These issues evoked lively discussions on the reality of research being conducted in areas with different standards of care and in resource-constrained settings where products of health research could be unaffordable to the researched communities. Interactive debate on ancillary care during and post study ensued.

After plenary on responsibilities and definitions of sponsors, investigators and Data Safety and Monitoring Boards (DSMB) comments to the effect that the GCP guidelines seem to focus more on the sponsor than other stakeholders were made, and an all-encompassing review was suggested. Towards the end of the workshop, legal and regulatory aspects of health research such as requirements of regulatory agencies and the importance of Material Transfer Agreements (MTAs) were dealt with.

To sum up the proceedings, ethical issues surrounding malaria research were flagged. These included uncertainties surrounding the third generation vaccines that are based on recombinant DNA technology and the adjuvants that may not have been well characterised for use in humans. Potential risks and uncertainties surrounding genetically modified mosquitoes and the use of live vectors to deliver DNA vaccines were also highlighted.