

Newsletter of the

**AFRICAN MALARIA NETWORK
TRUST (AMANET)**

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EDITORIAL

A historical conference was held in Arusha, Tanzania in February 1995, whereby malaria researchers from Africa, Europe and the USA agreed to form the African Malaria Vaccine Testing Network (AMVTN) whose mission was to prepare Africa for planning, undertaking and coordinating malaria vaccine trials. As was expected there were many doubting Thomases who maintained that there were too many obstacles such as unavailable candidate malaria vaccines and weak African-led malaria research institutions that lacked capacity to undertake malaria vaccine trials at internationally acceptable scientific and ethical standards. They strongly argued against the AMVTN mission.

Much has changed over the last eight years. As expected malaria vaccines designed to protect short-term travellers have been tested and re-tested even in Africa. But unexpectedly, the formerly neglected asexual stage malaria vaccine candidates, which stand best to benefit the residents of malaria endemic areas have attracted public interest from several European governments, the EC and the US government, so that several antigens have recently been developed and produced using the current good manufacturing practice (cGMP) and are vying for testing at African-led test sites.

The last eight years have also witnessed a determined growth in capacity strengthening of African malaria researchers. Through relentless efforts the AMVTN, which was later succeeded by the African Malaria Network Trust (AMANET) mounted short-term training workshops in order to build capacity essential for evaluating malaria vaccine candidates meeting international quality standards. AMVTN/AMANET has over these years trained over 400 African scientists and associated personnel in important areas such as health research ethics, good clinical practice and data management in intervention trials. Others have been trained in design and methodology of malaria vaccine trials and in molecular biology and immunology of malaria vaccine development. Recently, African scientists in AMANET-sponsored workshops developed Standard Operating Procedures for Good Laboratory Practice and for Ethics Review Committees.

Over and above the development of individual competencies, AMANET has embarked on an all-round institutional capacity strengthening, which is best exemplified by the Centre National de Recherche et de Formation sur de Paludisme (CNRFP) of Ouagadougou, Burkina Faso. The AMANET Secretariat is proud to profile CNRFP in this issue of the AMANET Newsletter.

Over these years CNRFP (formerly CNLP) scientists have participated in many of the AMVTN/AMANET training activities. Due to epidemiological, personnel and other considerations, CNRFP was a natural choice for a future malaria vaccine trial site, but lacked partnership with an established northern institution. Working closely with the AMANET Secretariat, CNRFP was able to undertake a needs assessment backed by an earlier site characterization followed by an expert pre-trial external audit. When a malaria vaccine candidate became available for Phase Ib testing, CNRFP scientists rose to the challenge. Working under the co-sponsorship of AMANET with the assistance from the European Malaria Vaccine Initiative (EMVI) they prepared the study protocol, case control forms (CRFs), informed consent forms and other essential trial documents. These were considered and approved by the AMANET Scientific Coordinating Committee which then permitted the start of the trial, provided national ethical clearance was granted. The AMANET capacity-strengthening grant to CNRFP included a line item for the establishment and operation of a national ethics review committee, which we are glad to mention, has now been formed and is running well. Furthermore, a Data Safety Monitoring Board (DSMB) has also been established.

The participation of CNRFP in a malaria vaccine trial surely confirms the wise decision made eight years ago to start preparing African-led research institutions for undertaking malaria vaccine trials. Without that decision and its dedicated follow-up, the testing would have been done elsewhere.

W L Kilama

AMANET MANAGING TRUSTEE

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J B Rugemalila and S B Sirima

Introduction

The Centre National de Recherche et de Formation sur le Paludisme (CNRFP) formerly known as the Centre National de Lutte Contre le Paludisme (CNLP), is part of the Secretariat General of the Burkina Faso Ministry of Health. It was founded in 1982 with financial and technical support from the Directorate General for Co-operation to Development, Italian Ministry of Foreign Affairs (DOCS-MAE). The centre has close research links with (among many others) the Institute of Parasitology of the University of Rome 'La Sapienza' (ISTPAR); Department of Molecular, Cellular and Animal Biology of the University of Camerino, Italy; European Union; World Health Organization Special Program for Research and Training in Tropical Diseases; London School of Hygiene and Tropical Medicine; West African Onchocerciasis Control Program; Department of Immunology of the University of Stockholm; Imperial College of the University of London; Swiss Tropical Institute in Basel; Institute of Biochemistry of the University of Lausanne; and University of Notre Dame in Indiana, USA. The centre is one of the two leading malaria research institutions in the country, the other one being Muraz Centre at Bobo Dioulasso.

Institutional Mandate

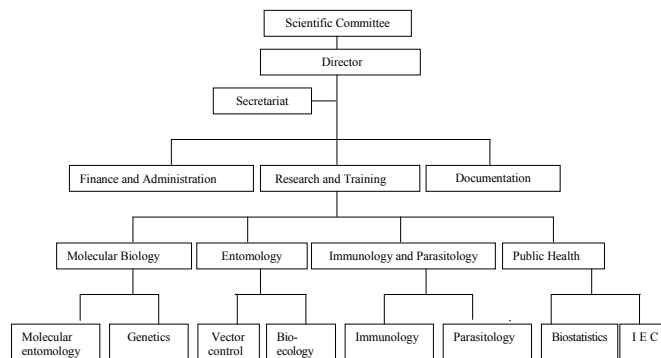
The centre was founded to guide the development of the national malaria control programme and to support its implementation. The mandate of CNRFP is therefore i) to participate in the formulation, implementation, supervision, and evaluation of the national malaria control programme; ii) to carry out operational and basic research for the identification of new malaria control tools and adapting existing ones to the local conditions; and iii) to provide training on malaria to healthcare providers and scientists from Burkina Faso and other African countries.

National Public Health Importance of Malaria

Malaria transmission in Burkina Faso is hyperendemic, occurring throughout the year peaking during the rainy season from June to October. The major vectors are *Anopheles gambiae ss*, *An. arabiensis*, and *An. funestus*. Malaria accounts for at least 15 000 deaths among the estimated annual 8 million cases, placing it among the national priority diseases. *Plasmodium falciparum* is responsible for more than 90% of malarial infections. The malaria transmission pattern in the country is one of the reasons for selecting CNRFP among the early three institutions to receive AMANET grants for capacity strengthening to establish malaria intervention trial sites. The other two institutions are the Centro de Investigacao em Saude da Manhica (CISM) of Mozambique and Institute of Public Health of the Muhimbili University College of Health Sciences (IPH MUCHS) of Tanzania. CISM and IPH MUCHS have all-year-round transmission and are located in mesoendemic and holoendemic malaria areas, respectively.

Institutional Organogram and Research Capacity

According to a recent external audit conducted in September 2002 as an assessment of the capacity of CNRFP to carryout phase 1b MSP3 malaria vaccine trial, the organizational structure of the centre is as shown in the following organogram:



At the apex there is the Scientific Committee, which makes policies whose implementations are supervised by the Director of the centre. There are seven sections namely: 1) Finance and Administration 2) Data Management, 3) Health Information Education and Communication (IEC); 4) Molecular Biology; 5) Entomology; 6) Immunology and Parasitology; and 7) Public Health. The laboratories for Entomology, Parasitology, and Immunology, are well equipped for performing various sophisticated investigations on large number of specimens. Following the audit, further improvements have been made on the laboratories, including setting up of quality control systems. Other facilities include an insectary, modern facilities for data management and analysis, a local-area-network (LAN) of 30 personal computers with Internet facilities, a small library, an administrative unit and a mechanical workshop. The research capacity of the centre is being further developed through the three-year AMANET grant. The grant will enable CNRFP to collect morbidity and mortality data on a selected demographic surveillance community, determine immune responses to *Plasmodium falciparum* antigens, undertake renovations and upgrading of laboratories, procure laboratory equipment and supplies and provide short- and long-term training to scientific and technical staff.

Scientific and Technical Staffing

The scientific and technical staffing of the centre is as follows:

Specialty	Scientists	Technicians
Physicians	5	-
Epidemiology	2	2
Paediatrics	0	-
Parasitology	1	4
Entomology	3	5
Immunology	1	3
Molecular Biology	1	1
Biostatistics	-	1
Sociology	1	-
Pharmacists	1	1
Demography	1	-
Project Administrator	1	1

Following the recommendations of the external audit, CNRFP is in the process of establishing an independent Institutional Ethics Review Committee (IERC). Furthermore, appropriate technical and scientific workers have also been trained in good laboratory practice (GLP), good clinical practice (GCP), standardization of immunological assays and the writing of standard operating procedures (SOPs). The central policy of CNRFP and its partners has been the transfer of skills from the foreign scientists participating from the earlier field and laboratory activities to Burkinabe scientists, aiming at developing a critical mass of national scientists who are able to run the centre. This process is now at an advanced stage because currently the centre is running well without any foreign staff on a permanent basis.

Field Facilities and Scientific Achievements

In 1994, CNRFP set up a demographical surveillance programme on a community of about 90 000 people in 150 villages in Ziniaré District and in 1999 at Balonguen Village in Bazega District. The village of Balonguen is located 50 km South of Ouagadougou. The community has a Village Health Post with facilities for first aid and a maternity ward staffed by a traditional midwife. There is a government dispensary at Kalguin about 5 km away on the Ouagadougou-Accra Highway. The dispensary has recently been renovated through the AMANET grant for capacity strengthening. The renovation provided among other things a roof to the main building and an inpatient ward. The Bazega District Hospital is about 8 km from the Kalguin Dispensary, and is accessible by road. Among the major scientific achievements and research areas of the centre are an up-to-date demographic surveillance system of a malaria endemic community, management of severe and non-complicated malaria, clinical and epidemiological profiles of severe malaria. Other major research areas are malaria control by impregnated materials, human genetic factors related to malaria control, immune responses, the genetics of malaria vectors and parasites, vector behaviour and susceptibility to insecticides and *Plasmodium falciparum* drug susceptibility.

**AMANET WORKSHOP ON HEALTH RESEARCH
ETHICS IN AFRICA, 12-16 JANUARY 2003,
KHARTOUM, SUDAN**

C S Mgone

Workshop justification

Currently there is considerable interest in health research ethics. This interest follows the promise of biomedical sciences developing new vaccines, drugs, diagnostics and therapeutic products for the treatment, management, prevention and control of the many ailments that afflict humans. However, this requires testing and experimentation including in humans, to demonstrate safety, efficacy usefulness, acceptability, tolerability and effectiveness. There is a worldwide concern and conviction that there is a need for protecting the rights and welfare of research participants, especially that of vulnerable groups and individuals. Ethical concerns are particularly important in Africa where trial participants may easily be exploited because of the immense disease burden and inadequate health care, widespread ignorance, human rights abuses and weak or absent regulatory health research ethics mechanisms. Therefore there is an urgent need to ensure that international standards for

designing, conducting and reporting trials are met. AMANET, whose mission is to build capacity in the testing of malaria interventions, particularly malaria vaccines has given prominence to the training of African health researchers and their associates in health research ethics. These aspects are usually not taught in academic institutions.

Objectives

The main objective of the workshop was to provide an educational framework for the understanding and appreciation of the principles of health research ethics with special emphasis on their application to the African situation. This was realized through plenary sessions and group discussions on topics concerning basic ethics, current international guidelines on health research and intervention trials and on good clinical practice (GCP) principles.

Advertisement of the workshop

As in the past, the workshop was extensively advertised through the AMANET newsletter, its website and through several listservers. The target groups for the workshop were middle- and senior-level scientists working in African institutions, especially malaria scientists, members of ethics review committees, data safety monitors, members of national regulatory authorities, study monitors, research sponsoring agencies and editors of biomedical journals.

Participants

Enthusiasm to attend the workshop was very high as underlined by 103 applications that had requested participation. Among these, 28 were selected and attended the workshop. These came from 12 African countries including ten from the host country Sudan, three each from Nigeria and Tanzania, two each from Cameroon, Ethiopia and Ghana and one each from Democratic Republic of Congo, Kenya, South Africa, Uganda, Zambia and Zimbabwe.



Programme

The workshop programme comprised a mixture of core plenary sessions presented by facilitators and group discussions and presentations from the participants. The topics included the philosophy on the African concept of a person and traditions in health care, history of the development of ethics in health research, ethical issues on clinical trial designs, informed consent, international guidelines, use of archival specimens, use of human tissues and the role of principle investigators and other researchers and sponsors after completion of research projects. The mixture of lectures and group discussions ensured guided interactive

participations from both the participants and facilitators.

Expected outcomes

The workshop aimed at increasing awareness, knowledge and advocacy of health research ethics. The expected outcomes of the workshop were:

1. Improvement in health research ethics awareness and knowledge among workshop participants
2. Empowerment of participants in strengthening and improving of health research ethics review committees (HRECs) where they existed and establishing them if lacking
3. Enabling participants to acquire good management skills and coordination of HRECs at all levels including at institutional and national levels
4. Improved knowledge on the composition, selection, training and continuing education of members of HRECs.

Evaluation

Workshop organization, conduction, appropriateness and effectiveness were evaluated using a self-administered questionnaire on the first and on the last day. The evaluation on the first day was mainly on administrative matters such as accommodation, meals and time allocation of topics that might have required immediate rectification at the beginning of the workshop. The initial and final evaluation and feedback was mostly positive. On the first evaluation most of the participants indicated that they were very much pleased with the general organization and plan of the workshop and no changes were required. The final evaluation showed that generally over 85% of the participants found the workshop of very good standard, relevant, and effectively met its objectives.

Acknowledgements

The workshop was jointly organized by the African Malaria Network Trust (AMANET) and the Institute of Endemic Diseases of the University of Khartoum (IEND) and hosted by IEND. The Danish International Development Agency (DANIDA), the Dutch Ministry of Foreign Affairs (DGIS) and the European Commission (DG-Research) provide core funding to support AMANET Secretariat.

**AMANET/PABIN WORKSHOP ON STANDARD
OPERATING PROCEDURES FOR HEALTH
RESEARCH ETHICS COMMITTEES IN AFRICA,
17-21 FEBRUARY 2003, ENTEBBE, UGANDA**

***M Kawuma, S L B Kajuna, M Tembo, A G Falusi,
C S Mgone***

Introduction

The workshop was jointly organized by the African Malaria Network Trust (AMANET) and Pan-African Bioethics Initiative (PABIN) in collaboration with the Clinical Research Centre of the Makerere University, the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) and the European Forum for Good Clinical Practice (EFGCP). It aimed at contributing to the development of reference standard operating procedures (SOPS) for

African health research ethics review committees. This was in fulfillment of the AMANET mission of strengthening capacity, performance and impact of malaria research and development (R & D) and training institutions as well as that of PABIN of promotion of ethical review of biomedical research studies in Africa. The workshop focused mainly on the implementation of the WHO/TDR (2000) Operational Guidelines for Ethics Committees that Review Biomedical Research.

Rationale and broad objective

The pace of health research undertaken in Africa is increasing as a result of increasing interest in health issues as well as the increase in many new candidate disease control tools that arise from biomedical research and require testing in disease endemic countries (DECs).

Specific objectives

Within the framework of the broad objective of the workshop of developing high ethics review standards for Africa, the following specific objectives were pursued:

- ❖ Establishment of standard procedures for ethics review
- ❖ Strengthening of the roles of Chairpersons, Secretaries and Administrators of Ethics Review Committees (ERCs)
- ❖ Contribution to the development of African national ethics review systems in accordance with standardized international reference
- ❖ Contribution to the development of international reference SOPs for ERCs
- ❖ Promotion of training in ethical review procedures and networking of participants
- ❖ Preparation of ERCs for audit, inspections, registration and accreditation
- ❖ Fostering of the ongoing implementation of the WHO/TDR Operational Guidelines for Ethics Committees that Review Biomedical Research (2000) with a view towards introducing into practice the WHO/TDR companion Guideline Surveying and Evaluating Ethical Review Practices (2000).

Participants

Among the 40 selected participants from various African countries, 37 from 10 countries namely Cameroon, Ethiopia, Ghana, Kenya, Nigeria, Sudan, Tanzania, Uganda, Zambia, and Zimbabwe were able to attend. They were chairpersons, secretaries and administrators of Ethics Review Committees from universities and research institutions.

Facilitators

Prof. Wen W Kilama, AMANET/PABIN, Tanzania; Banson Barugahare, Makerere University, Uganda; Paul Ndebele, Medical Research Council, Zimbabwe; Opokua Ofori-Anyinam, GlaxoSmithKline Biologicals, Belgium; Francis P Crawley, EFGCP; Sirinart Vasanavathana, Regional Office, FERCAP, Thailand; Prof. Charles Mgone, AMANET Secretariat, Tanzania.

Programme

The workshop program included mostly practical sessions that followed a few lectures. There were five introductory lectures including guidelines for writing of SOPs, values and importance of SOPs and their role in health research ethics committees. In the eight practical sessions that were conducted, participants were randomly divided into

three groups, which discussed and adapted various SOPs and guidelines based on the FERCAP SOPs and International Network for Cancer Treatment and Research (INCTR) protocol review and guidelines.

Workshop outcomes

The goal of the workshop was that the knowledge gained would be used by participants for:

1. Training and providing certification for in-country surveyors of ethics review practices
2. Contribution towards the translation and in-country adaptation of the WHO/TDR guidelines on surveying and evaluating ethics review practices
3. Contribution towards the development of in-country and regional standards for accrediting ethics review committees
4. Contribution towards the development of international standards for the protection of human research participants

Evaluation

Using a structured questionnaire, the participants evaluated the workshop organization and activities and made suggestions to the hosts for future improvements where it was necessary. The quality and contents of the workshop were highly relevant to the needs of participants. The host organizing committee's service was very outstanding.

Workshop proceedings

The proceedings consisted of presentations and mostly discussions in groups as well as plenary sessions focused on development of reference standard operating procedures for ethics review committees in Africa. The following themes were covered:

- Session 1: The value of SOPs in achieving independence and competence in ethical review
- Session 2: Preparation of terms of reference for Ethics Committees
- Session 3: SOP for constituting Ethics Committees
- Session 4: SOP for application submission and initial review
- Session 5: SOP related to participants' rights and protection
- Session 6: SOP for resubmitted applications, expedited review and emergency meetings
- Session 7: SOP for amendments, adverse events, follow-up in ethical review, protocol termination and final report review
- Session 8: SOP for administering Ethics Committees
- Session 9: Preparation for audit, inspection and Ethics Committee registration and accreditation
- Session 10: Establishing initial and ongoing education for members of Ethics Committees

Within these themes, shortcomings of ethics practices in Africa were highlighted. These included lack of standard operating procedures and legislation, inadequate membership, corruption and absence of auditing procedures. These shortfalls underlined the basis and scope of the workshop.

It was agreed that objective and uniform specifications in review of protocols is achievable when the ethics review system is guided by SOPs. Through this process, decisions of IEC/IRB remain consistent from one institution to another including among different countries in Africa. It was also stressed that to be effective SOPs must be simple to understand and use and be subject to regular review.

The central role of ethical review in health research was outlined as

protection of the rights, safety and welfare of human participants. In effecting this role, the ethical principles for biomedical research including the performance of ethics review committees were discussed. The reference document for discussion was the WHO/TDR (2000) Operational Guidelines for Ethics Committee that Review Biomedical Research. After summary presentation, it was noted that several countries did consult these guidelines though very few had adapted them to their national ERC/IRB settings. The ERC/IRB in various countries were encouraged to adapt the guidelines, as they are very helpful in guiding the establishment of ERC/IRB, defining their roles, and in decision-making, documentation and archiving.

Audit was defined as a systematic and independent examination of the research review and approval and the documents of ERC/IRB. The purpose of such an exercise is to determine whether these activities are conducted according to SOPs, GCP, WHO/TDR guidelines, the Declaration of Helsinki and meet all applicable regulatory requirements. Emphasis of an audit and inspection of ERCs should not be on enforcement, but educative leading to the promotion of a better performance and adherence of international standards. Continuing education for members of the Ethics Committee is essential and opportunities are available for that purpose. Funding agencies supporting such training include Family Health International (FHI), WHO/TDR, AMANET/PABIN, National Institutes of Health (NIH), Harvard University and the African AIDS Vaccine Programme (AAVP). It was also encouraged that researchers should include in their proposals a component for capacity building in research ethics for members of ERC/IRB.

Reading materials on current programs for educating members of ethics committee including a draft EFGCP curriculum for educating members of Ethics Committees were used. Additionally, there were presentations on the activities of PABIN and FERCAP to familiarize workshop participants with the work of these regional initiatives. Participants studied the documents and made relevant alterations taking into consideration the African setting. It was anticipated that individual countries would further adapt the SOPs and guidelines according to their national settings and strengthen the operations of ERC/IRB review, approval, monitoring and evaluation systems. It was noted that most of the generic SOPs and guidelines were tailored towards review and approval of clinical trials. Modifications and amendments were made to include other health research areas. The general format of the FERCAP SOPs comprised an approval cover page, table of contents, purpose, scope, policy, responsibilities and a flow-chart.

Participants suggested a variety of courses of action to follow as a way forward, taking into account that each African country has different needs and stages of implementation of ethics review. These suggestions were:

- To maintain networking among participants for mutual support and opportunities for exchange of information and experiences. This could be achieved through the Internet, conferences and training coordinated by PABIN/AMANET followed by impact feedback reports
- PABIN/AMANET to develop an accreditation system for ERC/IRBs for African countries and to ensure recognition with other international accreditation bodies

- PABIN/AMANET to provide training of auditors/inspectors to service the accreditation affiliates in the system
- PABIN to promote local training of trainers (TOT) courses for efficient and economical use of resources
- PABIN/AMANET to offer training scholarships at the high level of Diploma, Masters and PhD and also to advocate the integration of bioethics in national training institutional curriculum
- Participants to advocate the importance of ERC/IRB activities within country under the umbrella of AMANET/PABIN to which ERC/IRB can be affiliated
- Participants to sensitize national authorities on the importance of PABIN in ethics review of health research
- PABIN/AMANET to explore possibilities of launching an African bioethics journal for information dissemination.
- PABIN/AMANET to promote regionally developed proposals for funding workshops, seminars and meetings on ethics research in Africa.

The SOPs and guidelines that were discussed and adapted as generic for African ERCs and IRBs will be made available at the AMANET website. These include the following:

SOP 01 Preparation of Standard Operating Procedures
SOP 02 Distribution of Standard Operating Procedures
SOP 03 Constituting an Ethics Committee
SOP 04 Confidentiality Agreement
SOP 06 Selection of Independent Consultants
SOP 07 Management of Protocol Submissions
SOP 08 Application Assessment Forms
SOP 09 Protocol Review – Expedited Review
SOP 10 Protocol Review – Initial Review
SOP 11 Protocol Review – Resubmission after Initial Review
SOP 12 Protocol Review – Protocol Amendments
SOP 13 Protocol Review – Annual Continuing Review
SOP 14 Protocol Review – Protocol Termination
SOP 15 Final Report Review
SOP 16 Emergency Meeting
SOP 17 Response to Subjects’ Requests Regarding Rights
SOP 18 Monitoring and Evaluation of Serious Adverse Events
SOP 19 Communication Records
SOP 20 Site Monitoring Visits
SOP 22 Maintenance of Active Study Files
SOP 23 Documentation Archive and Retrieval
SOP 24 Maintaining Confidentiality of Ethics Committee Documents
SOP 25 Preparation of Guidelines
SOP 26 Audits and Inspections of the Ethics Committee
SOP 27 Glossary of Terms and Definitions
GL 01 Preparation of Protocol Documents
GL 02 Writing Informed Consent Documents
GL 03 Protocol – Initial Review Application
GL 04 Protocol – Annual Continuing Review Application
GL 05 Protocol – Amendment Submission Form
GL 06 Protocol – Decision Form

Conclusions

Participants and resource persons found the workshop to be enriching and fruitful since nearly all objectives were realized. The standard operating procedures, which were generally adapted, provided a basis for participants to contribute to the establishing and strengthening of ERC/IRB review systems in their countries. The training stimulated working relationships for networking among participants and in organizing future collaborative efforts in the promotion of ethics review activities in Africa. The workshop participants pledged to implement the WHO/TDR Operational Guidelines for Ethics Review Committees (2000) and the companion Guidelines for Surveying and Evaluating Ethical Review (2000) in the ERC/IRB of their respective countries.

Acknowledgements

The workshop was hosted by the Makerere University, Uganda. Special acknowledgements go to Joel Okullo, Director, Regional Centre for Quality of Health Care; Elly Katabira, Associate Dean, Research, Makerere University, Uganda; Fred Kironde, Head of Department of Biochemistry, Makerere University and their team. Special thanks are given to the PABIN/AMANET administration under the able leadership of Prof. Wen Kilama and his team. The Danish International Development Agency (DANIDA), the Dutch Ministry of Foreign Affairs (DGIS) and the European Commission (DG-Research) provide core funding to support AMANET Secretariat.

What they say about the workshops

Hello everybody,

I finally arrived in Navrongo safely and work is going on smoothly. It was fun and very educative in Sudan. I hope we will meet again very soon.

All the best.

Rita.

Dear Mr Chairman,

Hope all of you are safe home. Thank you everybody. I had a nice time in Khartoum with you. You are great everybody from Khartoum is also great.

Wishing you all the best.

Kind regards

Moges Kassa
Ethiopia.

Hello Everyone,

I hope you are all doing well back home.

I am also doing well here in Ghana. I have started organizing presentations on Health Research Ethics in the various departments in my hospital.

Have a nice day and keep in touch

Dr. Kofi Mensah Nyarko, MD
P.O. Box 8312, Ahensan
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Dear Prof. Kilama,

I have finally managed to clear through my mail and work that was waiting and have a moment to breathe. Thanks for the invitation to the meeting in Uganda. It was a good meeting and I enjoyed meeting old friends and making new ones. I also learnt a lot.

Best wishes

Opokua

Dear Dr. Kilama,

It was a good experience working with you and your team at the last workshop in Entebbe. It is remarkable that so much was packed into so short a time. It was a fruitful outing for me as an Ethics Committee CHAIR. I thank you for inviting me to such a useful Workshop.

Once again, sincere thanks.

Adeyinka G. Falusi

Dear Prof. Mgone,

I hope you are fine. The last meeting in Entebbe was indeed good and educational. These kinds of meetings should be continued and I hope we will meet in the near future on the same issue.

With regards

Dr. Asaminew Girma, from Ethiopia

**AFRICAN MALARIA NETWORK TRUST
CAREER OPPOTUNITY IN HEALTH
RESEARCH**

The mission of the African Malaria Network Trust (AMANET) is to promote capacity strengthening, performance and impact on African malaria R & D and training institutions. Currently AMANET undertakes short- and long-term training of African malaria researchers, infrastructure improvement, equipping research institutions and sponsorship of clinical and field trials of candidate malaria intervention tools. AMANET wishes to recruit a Clinical Trials Coordinator to be based at the AMANET Secretariat in Dar es Salaam, Tanzania, from November 2003.

CLINICAL TRIALS COORDINATOR

The Clinical Trials Coordinator will be the principal advisor to the Managing Trustee on all matters relating to clinical trials, including planning, execution, monitoring and evaluation.

The main areas of responsibility will include:

- Planning, coordinating and supervising clinical trials in Africa in line with international regulations;
- Participating in the designing of essential trial documents;
- Monitoring adherence to protocol and other documents;
- Preparing minutes of the Trial Sites Development Committee and Expert Committees;
- Filing of regulatory and ethics review documents;
- Preparing SOPs (in collaboration with investigators) for study protocols;
- Supervising needs assessment and site characterization; and
- Undertaking any other duties as assigned by the Managing Trustee.

The ideal candidate should possess:

- A medical degree and a postgraduate qualification preferably at PhD level in community or public health, epidemiology, communicable diseases, biostatistics or similar area of specialization;
- Familiarity with health research ethics issues in Africa;
- Good knowledge and solid experience with ICH/GCP;
- Experience in research supervision;
- Experience in carrying out and monitoring clinical and field trials of interventions; and
- Working knowledge of French.

The position requires an individual with excellent computer skills. Attractive and competitive performance related remuneration package will be offered. Application letter accompanied with detailed CV showing contact address and names of three work/study related referees and all essential documents e.g. certificates, testimonials, etc. should be submitted by e-mail by 1 July 2003 addressed to:

The Managing Trustee,
African Malaria Network Trust,
Tanzania Commission for Science and Technology Building,
P.O Box 33207,
Dar es Salaam, Tanzania.
E-mail: info@amanet-trust.org
Website: www.amanet-trust.org

AMANET WORKSHOP ON HEALTH RESEARCH ETHICS IN AFRICA
Biotechnology Centre, Yaounde 1 University, Cameroon, September 2003
CALL FOR APPLICATIONS

Applications are invited from African physicians/scientists in the employment of African health research, control, and/or training institutions. Applicants must at least be middle to senior level investigators, key members of ethics (or scientific) review committees, study monitors, members of data safety monitoring boards, sponsors of research involving human subjects, members of regulatory bodies or writers/editors of biomedical journals.

Workshop Contents:

1. Introductions, Course Content and Housekeeping
2. History of Ethics in Health Research
3. Ethics Codes and Guidelines
4. Ethics Review Boards/Committees
5. Beneficence/Malbeneficence in Research
6. Respect of Subjects
7. Informed Consent in Research
8. Justice in Research
9. Issues in Study Design: Randomized Control Trials and Placibos
10. Traditional Medicine and Standard Therapy
11. Ethics Issues in International Research
12. Community Benefits and Protections
13. Archived Specimens

Workshop Teaching Methods

The workshop will mainly utilize participatory approaches including lectures, case studies, discussion groups, panels, debates and other interactive teaching/learning methods.

Instructions will be mainly in English, although two of the facilitators will be bilingual (English/ French).

Funding

Selected participants will be awarded scholarships by the African Malaria Network Trust (AMANET), which will cover costs for economy class airfares, tuition and full board. Participants should meet all their other costs.

Applicants wishing to participate in this Workshop should forward the following by e-mail to the addressee below by 1 July 2003.

1. Full name in capital letters, with family name underlined;
2. Date of birth and nationality;
3. Name, full address, telephone number, fax number, and e-mail address where the applicant is employed;
4. Listing of educational qualifications, including date, place and degree(s) obtained;
5. A description in not more than 15 lines of the nature of the current post and any other posts that might have been held in the past and why you need to attend this workshop;
6. Current research interests (not more than 15 lines).
7. A list of scientific publications, especially those relating to clinical/field trials and to the workshop;
8. Names and addresses of two referees (including their telephone, fax and e-mail contacts) who have been requested to provide letters of recommendation which should be sent directly to the address shown below:

All applications must be received by 1 July 2003 by E-mail at the address below:

Managing Trustee, AMANET,
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