



AFRICAN MALARIA NETWORK TRUST

Ifakara Health Research and Development Centre Institutional Review Board Training Workshop

29-31 March 2005, Dar es salaam, Tanzania

Workshop Report

Sally Mtenga and Roma Chilengi

The Ifakara Health Research and Development Centre (IHRDC) which was founded in 1957, is a not for profit, independent, district based health research and resource centre. The IHRDC is established to carry out research on topics perceived to be local priorities, to support those planning health systems, and to help members of the local community to achieve better health. Over the years the main activities have included basic, laboratory, clinical, health systems and social anthropology research in malaria, tuberculosis, schistosomiasis and other infectious diseases of public health importance. Of recent, the increased number of activities at the institution has necessitated improvement on the operational strategy.

One of the areas that required revamping is the Institutional Review Board (IRB), charged with responsibility of ensuring ethical conduct of research. In this regard, IHRDC requested the African Malaria Network Trust (AMANET) for technical assistance in the process of reconstituting the IRB. This is the report of the three-day IRB training workshop that was organized and hosted at the IHRDC Dar es Salaam office from 29 to 31st March 2005.

Participants

Name	Background/affiliation	Role in IRB
Dr Charles Mayombana	Senior Scientist, IHRDC	Member
Mrs Sally Mtenga	Social scientist, IHRDC	Secretary/member
Dr Boniface Jullu	Laboratory scientist, IHRDC	Member
Mr Benedict Ngakuka	Retired school teacher, Ifakara	Member
Mr Ally Hussein	Librarian, IHRDC	Member
Mr Shabani Zambo	Retired army officer, Bagamoyo	Member
Mrs Joyce Ikingura	Ethicist, National Ethical Committee	Member
Peter Mayunga	Retired accountant, Bagamoyo	Member
Dr Roma Chilengi	AMANET	Facilitator

Day 1

The session was officially opened by Dr Salim Abdulla, standing in for the IHRDC director Dr Hassan Mshinda. He welcomed participants and asked them to give a brief introduction of themselves. This was followed by a brief background about the Center

with an aim of letting the new participants to know what IHRDC has been doing in the area of health research and interventions. He explained that the aim of this workshop was to have a common understanding on guiding principles with regards to research ethics and empower all the IRB members so they participate fully in the reviewing of the research protocols. Another major objective was to improve the existing standard operating procedures to be able to meet national and international guidelines of research ethics. Further, to accommodate physical and professional expansions that IHRDC is currently undertaking.

The first topic was on history of research ethics & major ethical guideline codes. Dr. Chilengi began by giving a justification for biomedical research. Distinction was made between research and medical practice in that research is not routine treatment but rather experimentation and involves human subjects. Though there is need to accept research as important to human kind, it is also important to safeguard the welfare of the human research subjects. This session gave the following major historical highlights:

- The Hippocratic Oath- *“Physicians should “abstain from whatever is deleterious and mischievous”;*
- Thomas Paracelsus- *“Before proceeding with therapeutic innovation, a physician ought to consult with peers”;*
- William Belmont- *“The need for experimentation, voluntary consent, & discontinuation”.*
- Prussian Directive- *“Consent and information provision in research”*
- Nazi Germany- *“Examples of the human atrocities”*
- Nuremberg declaration- *“The first ethical code and the”*
- Helsinki declaration – *“The main basis of modern ethics /research guidelines”*
- Belmont report- *“The three fundamental ethical principles”*

The historical background was followed by sessions on guidelines for operations of ethics committees. The WHO guideline for operations of ethics committees was presented as a sample guide. Under this section the facilitator argued that there are many important international guidelines (ICH, GCP, FDA, EMEA etc), but it is also important to have consideration for the national guidelines without overlooking different local and cultural aspects.

However in developing SOPs, it is critical to integrate the fundamental international principles so as to be comprehensive in catering for collaborative research..

The group worked on improving their current IRB SOP by integrating important elements from the WHO ethical guideline. This led to a number of modifications, which would be submitted to the national committee for approval after the IHRDC administration ratifies them.

Day 2

Mrs. Ikingura from National Institute of Medical Research (NIMR) started the day with sharing experiences of national ethics committee in its composition, election process and the execution of different ethical issues. It was learnt that all research involving non-Tanzanian collaborators need to obtain national approval, which involves authorization

permit for the external collaborators through the Tanzania Commission for Science and Technology.

Valuable information was discussed on how the national ethics committee would interact with IRBs, what can be done to improve inter-IRB communication, examples of “IRB shopping” and matters pertaining to the legal mandate of ethics committee. It was learnt that the national committee was handling in excess of 20 proposals monthly and lessons learned in meeting the challenges were discussed. The session continued with looking at establishing a system of ethical review; it was emphasised that the critical pathway of the protocols needs to be streamlined. The IRB needs to clearly stipulate in the SOP what kind of expertise it will need and how they will be engaged; how the investigators would get relevant information on the procedures to follow, establish a communication strategy that respects the set timelines and estimate the cost implications for their operations so that resources are appropriately allocated.

It was emphasised that the IHRDC ethical committee needs to have a strong collaboration with other ethical committees especially the national committee. The need for independence was also raised in that the IRB should not suffer undue pressure from administration or the scientists, but rather should adhere to guidelines once established. However, the IRB procedures should also be flexible, being responsive to demands of expedited review when appropriate.

The discussion on informed consent emphasised the fact that it should be a process and not a one off event. There is therefore need to have a mechanism of providing feedback to the participants whenever new information comes up or if there is a change in the research procedure. The IRB members need to make sure that, the information given in the informed consent is comprehensive enough and is in the language, which can be understood easily by the research participants, especially uneducated ones. Obtaining “true informed consent” was presented as the greatest challenge for investigators, and the IRB needs to evaluate that information package before approving the research.

The elements of informed consent according to GCP were discussed, highlighting that it must all be in a language to be understood by the participant, and adequate time must be allowed for information, comprehension and decision making. It is particularly important the participant knows that this is research, appreciate the risks involved, understand the benefits, accept the expected responsibilities and volunteer to participate without undue coercion.

Beyond this, the question of the IRB responsibilities, and how can it ensure that they are fulfilled was addressed. The cardinal obligation being that the participant’s rights, safety and well being are protected. It was pointed out that ethical approval should not be seen as a “blank cheque” to the investigators, but rather an approval of only activities strictly stipulated in the protocol.

The IRB therefore should have a way to ensure that the investigators are actually doing only what they approved, and this is the need for procedures to address the question of

ethical oversight. Strategies to help follow up on approved activities were discussed, and they would include:

- Requirements for regular progress reports, and penalties for non compliance;
- Requirements that all clinical trials be monitored by independent experienced clinical monitors;
- Requirements for Data Safety and Monitoring Boards (DSMB) to be set up for all randomised controlled trials;
- Random un announced inspection checks by IRB;
- Feedback information from the participant community;
- Obtain institutional backing to follow up with disciplinary measures if needed.

The discussion was followed by further review of the SOP and again relevant amendments and proposals were made in the light of the topics discussed.

Day 3

The third day began by an overview on the topic on the “IRB’s meeting and decision-making process”. There is need for well-coordinated communication to the IRB members with regard to documents to review, meeting place and time. The schedule should preferably be drawn ahead of time, logistics prepared and quorum requirements considered to avoid time wastage. The secretariat needs to have basic office facilities to allow for printing, communication, filing, and a secure meeting room.

Full decisions on protocols should only be made during meetings, and other earlier decisions otherwise made through conference calls or mail should be reviewed. Elements of the protocol to be considered were presented beginning with the statement “bad science is unethical” therefore scientific review should also be adequate. In reviewing research protocols it is important to pay particular attention when special groups of vulnerable populations are targeted.

The IRB must adopt a mode of reviewing protocols which must be followed. The decision making process should also be preset; whether by consensus or voting, but it must be clearly written in the procedures and adhered to.

It is important to take time for other business including the time to assess the progress of the IRB, reviewing all operational costs and welfare of the IRB members besides making decisions on protocols.

The issue of dealing with ethical misconduct was discussed starting with the various definitions: “Misconduct means fabrications, plagiarism or any serious deviation from accepted scientific practices in proposing, conducting or reporting research”. The IRB needs to understand the environment, under which misconduct happens, and this may include excessive personal financial incentives for subjects; overworked investigator or study team; excessive work demands for staff or investigator and previous successful fraudulent behaviour. Other important issues to look out for include high staff turnover, complex protocols, extremely slow subjects accrual, rapid subject accrual and inadequate investigator qualification.

Approaches to prevention were discussed in a stepwise manner from primary, secondary and tertiary prevention.

The final activity was to come up with a plan of action for the next steps in order to complete the SOP revision exercise, steps to improve the composition of the IRB, and draw an annual schedule of the meeting dates to be included in the SOP.