

PROCEDURE FOR ETHICAL CLEARANCE OF BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS IN TANZANIA

Ikingura, J.K. and Kitua, A.Y.

Background

All research involving human subjects should be conducted in accordance with three basic ethical principles, namely *respect for persons, beneficence and justice*. It is generally agreed that these principles, which in abstract have equal moral force, guide the conscientious preparation of proposals for scientific studies.

Respect for persons incorporates at least two fundamental ethical considerations, namely:

Respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect of their capacity for self-determination; and protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Beneficence refers to the ethical obligation to maximize benefits and to minimize harms and wrongs. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to safeguard the welfare of the research subjects.

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research. (1) (CIOMS/WHO, 1993.

Introduction

Like elsewhere in the world, health research investigators wishing to work in the United Republic of Tanzania should be aware of ethical, legal and regulatory requirements for research on human subjects in their own countries as well as in Tanzania. No national ethical, legal or regulatory requirements should be allowed to reduce or eliminate any of the protections for human subjects set forth in the Helsinki Declaration (HD). (2)

The control and coordination of health research in Tanzania is the responsibility of the National Institute

for Medical Research, (NIMR), through its National Ethics Committee namely: the Medical Research Coordinating Committee, (MRCC). The Institute was established by the Parliamentary Act No.23 of 1979, with the functions to monitor; control; coordinate; and evaluate health research undertaken in the country. It is the MRCC which deals with both scientific and ethics review of research proposals and provides approval for the conduct of health research in the country. (3)

However there are other institutions in the country that undertake health research. These are: Muhimbili University College of Health Sciences; Tanzania Food and Nutrition Centre; Tropical Pesticides Research Institute; Consultant and Regional Hospitals; Health Systems Research Unit of the Ministry of Health; Zanzibar Ministry of Health; University of Dar es Salaam; University College of Lands and Architectural Studies; Non health sectors (Water, Local Government; Community Development; Social Welfare; and Non Governmental Organizations).

All these institutions may form institutional Ethics Committees to approve health research to be conducted within their institutions, so long as the mechanisms used to oversee that ethics are observed are put in practice follow the international and national guidelines (soon to be available) on the formation and conduct of committee activities (4). However they are obliged to forward to NIMR copy of the research proposal approved by the institutional Ethics Committee for information, and for national ethics clearance in case of research involving external collaborators. The Tanzania Commission for Science and Technology is charged with the overall coordination of all research in Tanzania and is the only institution which may grant research permit to external investigators. (5)

Procedure for Ethics Clearance of Health Research Proposals in Tanzania

The Medical Research Coordinating Committee is the body within NIMR that deals with both scientific and ethics review and approval of research proposals involving human subjects at the national level. Clear and exhaustive guidelines have been developed for use by reviewers to ensure that all matters concerning scientific soundness and ethics consideration of the proposal are dealt with properly and uniformly. The MRCC meets once

every three months. Any research proposal received by NIMR for the purpose of clearance is sent to three competent reviewers of the subject of interest. They are requested to use the review guidelines and send their comments within two weeks. Once comments from reviewers are received, they are presented at the next MRCC meeting and members of the Committee make their final decision based on the reviewer comments and additional observations by the members.

The Secretariat is alert to ensure that there is no conflict of interest for the particular study to anyone of the reviewers or members of the committee. Comments from the Committee are sent to the addressee of the proposal, the Principal Investigator (PI), to indicate that the proposal has been cleared or not. In any case whenever a proposal is denied clearance, the PI of the proposing team will be given clear indication as to the reason why the proposal could not be cleared and will be requested to make necessary amendments and resubmit the proposal for clearance.

Role of the National Ethics Clearance Committee (EC)

The purpose of an EC in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety, and well being of all actual or potential research participants.

The committee should provide independent, competent, and timely review of the ethics of the proposed studies. In their composition, procedures, and decision-making, the team needs to have independence from political, institutional, professional and market influences. They need similarly to demonstrate competence and efficiency in their work. (6)

ECs are responsible for carrying out the review of the proposed research before the commencement of the research. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received approval by establishing a monitoring mechanism.

Role of the Institutional Ethics Committee (IEC)

Institutional Ethics Committee have similar roles to that of the national ethics clearance committee, but operate within institutional boundaries.

Institutions carrying out health research or hosting it are particularly encouraged to have the review committees because these safeguard the image of the institution by ascertaining the quality of the research output and publications.

They also have the obligations of seeing to it that hosted research are undertaken as described in the study

proposals. For each proposal granted institutional ethics clearance, the committees also have the responsibilities of submitting to NIMR a copy of the proposal, the ethics clearance certificate, study progress and final reports, and the resulting publications.

Procedure for ethics clearance at the institutional level
The procedure described above applies here. The composition of the IEC should be made in such a manner as to ensure the competent review and evaluation of all ethical aspects of the research projects received and that tasks can be executed free from bias and influence that could affect independence.

Composition of the National Ethics Clearance Committee (EC)

The composition of the MRCC, which is the functional national ethics committee is as follows:

Chairperson

Director General, NIMR

Secretary

- Director of Research and Training, NIMR
- Tanzania Commission for Science and Technology (COSTECH)
- Muhimbili University College of Health Sciences (MUCHS)
- Medical Association of Tanzania (MAT)
- Ministry of Health, Directorate of Preventive Services
- Ministry of Health, Health Systems Research Unit

The (invitees) observers are two directors and two heads of NIMR institutions, Ifakara Health and Development Centre (IHRDC).

Additional members may be co-opted to participate when it is felt that additional expertise on a subject for which a proposal has been submitted for clearance is necessary.

In order to enhance coordination in research and to link the various research institutions, the Tanzania National Health Research Forum (TANHER Forum) has been created. This body carries the function of promoting the conduct and development of health research in Tanzania and is a complementary body to NIMR in ensuring that the standards of health research are maintained.

The TANHER Forum has an ethics committee which discusses and provide guidelines for ethical and scientific review of scientific proposals in health and is currently in the process of publishing the Tanzanian Ethical Guidelines for conducting research on human subjects.

Procedure for Submitting Proposals for Ethical Clearance by the National Ethics Committee

All proposals sent for ethics clearance must be addressed to:

Director General,
National Institute for Medical Research,
P.O. Box 9653,
Dar es Salaam.

One original and three copies of the proposal are required to facilitate sending the proposal for review. Additionally, all proposals must be accompanied by an ethics clearance fee of US\$ 100 for proposals involving external collaborators, and although until now no charges have been demanded for clearance of local proposals, a decision on introducing such charges and rates chargeable, will be announced soon.

Research Permit

Researchers from outside Tanzania are required to obtain research permit from the Commission for Science and Technology (COSTECH). This permission will only be granted if the proposal has been cleared by NIMR. For this purpose, NIMR informs COSTECH of all proposals cleared by sending a copy of the clearance certificate.

However, foreign investigators must apply for the permit from COSTECH on their own and pay a fee of US\$ 350 for each permit. No foreign researcher is permitted to conduct research in Tanzania without obtaining such a permit.

Currently, the research clearance certificate carries on it the permit from the Ministry of Health to conduct research within the health services and communities under Ministry of Health in the country. However, consent of the involved services and whenever necessary, a memorandum of understanding must be established between the research team and the owner/s of such premises.

Early submission of research proposals is demanded since it may take time to have the review process completed especially where one of more reviewers fail to respond and have to be substituted. NIMR will however make all necessary efforts to minimize the time between submission and review. All in all, full cooperation between the reviewers and the researchers is demanded by NIMR in order to facilitate this process.

References

1. International Ethical Guidelines for Biomedical Research Involving Human Subjects CIOMS, 1993
2. World Medical Association Declaration of Helsinki, October, 2000.
3. Ikingura J.K., *et al.* 1. NIMR Procedure of approving research proposals for ethics clearance, *Tanzania Health Research Bulletin* 3:1, Jan. 2001.
4. Operational Guidelines for Ethics Committee that Review Biomedical Research, *WHO Geneva 2000 (TDR/PRD/Ethics/2000.1)*
5. Kilama W.K., *et al.* Health Research Institutions in Tanzania, *Tanzania Health Research Bulletin*, 1:1, Jun. 1997.
6. Operational Guidelines for Ethics Committees that Review Biomedical Research, WHO, Geneva, 2000.