



UNIVERSITY OF NAIROBI  
COLLEGE OF HEALTH SCIENCES  
P O BOX 19676 Code 00202  
Telegrams: varsity  
(254-020) 2726300 Ext 44355

November 15th 2011  
Volume 1, Issue 1



KENYATTA NATIONAL HOSPITAL  
P O BOX 20723 Code 00202  
Tel: 726300-9  
Telegrams: MEDSUP, Nairobi

# Bioethics info-net

## Overview

### What is Bioethics?

Welcome to this newsletter, a newsletter with a difference. It marks the first ever attempt in Kenya to disseminate bioethics information through the print and electronic media. The issues that the discipline of bioethics deals with are as diverse as there are human activities and hence the most practical definition that can assist readers to understand the role and the importance of bioethics in society are essential. Making a decision in bioethics takes into account not only the type of research and methodology to be applied but also the environment within which the research is carried out.

Bioethics can simply be summarized as *a field of study concerned with the morals (ethics) of research and implications of the research outcomes on the stakeholders current and future.*

*Bioethics Info-Net aims to raise the bar of biomedical research Locally and Internationally by Informing, Networking and Strengthening ethics and research committees and researchers*

*Let us therefore adopt bioethics as the ethics of all that affects life.*

In this and other preceding issues, this newsletter will endeavor to expound further on the meanings and the practice of ethical decision making in the country and elsewhere. This first issue has been made possible through the support of the European and Developing Countries Clinical Trials Partnerships (EDCTP Grant CB.10.41302.024). It is an initiative of the oldest ethics and research review committee (ERC) in Kenya *the Kenyatta National Hospital (KNH) and University of Nairobi (UoN)-ERC*

## About KNH/UoN-ERC

**K**enyatta National Hospital and University of Nairobi Ethics and Research Committee (KNH/UoN-ERC) has been in existence since 1974. The committee was initially set up to serve the University of Nairobi, and Kenyatta National Hospital. However, its mandate has expanded overtime time due to increased national and international demand for credible ethics /scientific review process and oversight of research. In 1979, the Science and Technology Act established the National Council for Science and Technology (NCST) to coordinate and advise the government on all research carried out in Kenya, hence providing oversight on bio-medical research. Over the years, the NCST has mandated institutional ethics review committees including KNH/UoN-ERC to review and approve research involving human subjects for and on its behalf.

The KNH/UoN-ERC has 37 years of experience and hands-on skills in the review of wide range of scientific health research including academic, operational, epidemiological, translational and clinical research. It has a membership of at least 17 eminent persons drawn from academia, clinical practice , lay public, legal and social sciences.

Currently KNH/UoN-ERC processes over 450 research proposals from local and international researchers. With this immense wealth of experience, it is imperative that the committee spearheads capacity building in bioethics in Kenya through appropriate trainings and information dissemination. This is the first attempt by the oldest ethics review committee in the country to reach out to the general pub-

lic through a newsletter. We aim to inform, generate debate and share from the long experience of the committee with all Kenyan public.

However sustained support of Key partners, collaborators and genuine friends and well



*A section of KNH/UoN-ERC members in a group activity*

wishers will be critical to the effective delivery of this mission.

For more information on KNH/UoN-ERC visit our **Website:** [www.uonbi.ac.ke/activities/KNHUoN](http://www.uonbi.ac.ke/activities/KNHUoN)

*“We aim to inform, generate debate and share from the long experience of the committee with all Kenyan public.”*

## Understanding Bioethics

### Principles of Bioethics

*“There are millions of people who would willingly volunteer to participate in research if only they are assured of respect, safety and protection.”*

*A.N Guantai, 2011*

The governing principles of bioethics are three and these should be followed by all the bioethics committees and researchers. In brief they are:

**Autonomy**- The right to choose

**Beneficence** - Acting in the best interest of the patient (**Non-maleficence**- do no harm)

**Justice** - Ensuring fairness and equality in the distribution of risks and benefits..

These terminologies will be elaborated on further in subsequent issues of this newsletter.

### The Role of the NCST in ethics review

The structures that Kenya adopted for the management of science, technology and innovation includes the NCST at the apex, and implementing institutions. All authority is from the Cabinet and is exercised through the ministry of Higher Education, Science and Technology.

The mandate of the NCST is to advise the Government on matters of science and technology, and promote and coordinate its development. It is made up of 12 eminent scientists and Permanent Secretaries of line ministries. The council operates through committees mostly created under section 6 of the Science and Technology Act. One of the committees is the National Bioethics Committee (NBC). The NBC has a membership of seventeen persons from different professional backgrounds. It conforms to the recommendations of UNESCO, WHO and other guidelines that have been adopted worldwide. It is charged with the role of coordinating ethics review in the country. Ethics review in research is conducted on delegated authority from the NCST. The NBC processes accreditation of institutional ethics review committees, monitors their activities and arbitrates on various issues emanating from institutions. Institutional ethics review committees on their part review research protocols and monitor research activities that they have approved. They make annual reports to the NBC which are useful for sharing experiences and

ensuring growth in bioethics.

National guidelines for general consideration of ethics are prepared by the NBC. The current guidelines were prepared in 2004. There are several specific guidelines that are the responsibility of different institutions that also have a role in research clearance. Such institutions include; the Pharmacy and Poisons Board, National Environmental Management Authority, Kenya Wildlife Service, and departments in some ministries. The guidelines are specific and address only relevant issues for example, the Pharmacy and Poisons Board has guidelines for the conduct of clinical trials.

The NCST is in the process of reviewing its activities to improve its efficiency and remain relevant in a changing environment. The S&T Act itself is undergoing re-enactment; most other legal statutes are under review to align them with the constitution. Under the promotion role, the NCST supports research proposals, human resource capacity development and various dissemination activities. The NCST also establishes collaboration with other countries to enable Kenyan researchers meet and work with counterparts in foreign countries.

The NCST is accessible through its website [www.ncst.go.ke](http://www.ncst.go.ke) and its offices in Utalii House, Utalii Lane, Nairobi. The NCST has a secretariat that runs its business and is headed by the Secretary of the NCST as the chief executive. All the work of the NCST's committees is managed by the secretariat.

## Accreditation of Ethics Committees in Kenya

The National Bioethics Committee released guidelines for accreditation of ethics committees. The guidelines are used by institutional ethics committees in preparation for accreditation. Institutions are expected to establish ethics committees following the guidelines. An institutional committee is appointed by the administrative head of an institution. The membership is defined and the minimum number of members is recommended. A lay person is mandatory for all committees. Upon formation, a committee prepares its standard operating procedures (SOPs).

In the past the NCST could only note the existence of committees and several did not in-

form the NCST of their existence. It has become necessary that committees be accredited so as to ensure similar standards are applied in review and composition of committees. The NCST will also develop a data base of persons with experience in ethics review and encourage networking among institutional committees.

Accreditation is for a period of three years and is renewable upon re application. The membership is expected to be dynamic and should accord as many as possible to serve in ethics committees. Accreditation will reinvigorate ethics review in the country and ensure sustainability as the national research system continues to grow.

## Capacity Building in Bioethics in Kenya



*Dr. Langat and Prof Bhatt conducting a Training Needs Assessment Kisumu , Kenya*

The KNH/UON-ERC successfully applied to EDCTP for a grant to support capacity building and strengthening of Ethics Research Committees and networking in Kenya. This project is being implemented by Kenyatta National Hospital and University of Nairobi Ethics and Research Committee in collaboration with NCST.

The project aims at improving the functional capacity, efficiency and expansion of Ethics Research Committees (ERC) in Kenya through training of the members, producing an inventory of all ethics review committees and creating a database of processed research applications in order to minimize duplications. It also plans to create a networking

system with identified external ERCs as mutual partners in upholding Bioethics principles. This local and external networking will enhance ethical review processes in single and multi-site clinical projects in Africa where the burden of disease is high.

The first activity of carrying out a training needs assessment has been completed. The report of the same will be documented in the next issue of this newsletter.

## Your Contribution is very Important

*Special thanks for suggestions and contribution to this issue go to the following:*

**Prof. Anastasia Guantai:** (Editor,)  
*Department of Pharmacology & Pharmacognosy,  
School of Pharmacy, College of Health Science, University of  
Nairobi,  
P.O.Box 19676-00202, Nairobi, Kenya*

**Prof. Kirana Bhatt:**  
*Department of Medicine and Therapeutics,  
School of Medicine, College of Health Science, University of  
Nairobi,  
P.O.Box 19676-00202, Nairobi, Kenya*

**Prof. Christine Kigundu:**  
*Department of Human Pathology,  
School of Medicine, College of Health Science, University of  
Nairobi,  
P.O.Box 19676-00202, Nairobi, Kenya*

**Dr Simon Langat:**  
*National Council for Science Technology,  
P.O Box 30623-00100 Nairobi-Kenya*

**Dr. Micah Ongeru,:**  
*Nairobi Hospital,  
Box 30026-00100, Nairobi-Kenya*

Thank you all for your comments , contributions and suggestions towards this issue.

We look forward to receiving more articles and suggestions that will enrich future issues.

These and any suggestions on this issue may be forwarded any time to :

Prof A.N Guantai: **Email:** [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)

## Coming Events:

The First National Bioethics training workshop for ERC members will be held from 15<sup>th</sup>-18<sup>th</sup> January 2012 in Nairobi.

Limited places are available but it is hoped that at least two members of each IRB will be trained and that the seed that will be sown will have a multiplier effect and hence a positive impact in the quality of ethical review processes in Kenya.

The workshop is expected to attract at least 60 participants drawn from existing ERC's across the country representing research, academic and health institutions. The National Council for Science and Technology (NCST) will be a key facilitator through the National Bioethics Committee (NBC)

## In the Next Issue

- Report on the training needs assessment
- Defining Autonomy
- Outcome of ERCs accreditation process
- Contribution from stakeholder ERC

## Bioethics info-net

Your Voice. Your Choice

KNH/UON-ERC  
UNIVERSITY OF NAIROBI/KENYATTA NATIONAL HOSPITAL – MEDICAL CAMPUS  
COLLEGE OF HEALTH SCIENCES, SCHOOL OF PHARMACY  
P O BOX 19676 Code 00202 NAIROBI, KENYA

Telegrams: varsity  
(254-020) 2726300 Ext 44102/44355  
Email: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)  
Website: [www.uonbi.ac.ke/activities/KNHUoN](http://www.uonbi.ac.ke/activities/KNHUoN)