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

March 30th 2012

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

Bioethics info-net

A Newsletter of Kenyatta National Hospital–University of Nairobi
Ethics and Research Committee (KNH-UoN ERC)

VOLUME 1, ISSUE 2

FROM THE CHAIRPERSON KNH-UON ERC

CHAIRPERSON: PROF ANASTASIA N GUANTAI

Welcome to the second issue of the *Bioethics info-net*, the newsletter for the KNH-UoN Ethics and Research Committee. The newsletter continues to educate and inform stakeholders actively involved in biomedical and social sciences research on pertinent ethical issues and updates.

Research is the cornerstone of social, economic and technological development, but to have maximum positive impact it must be vetted, monitored and regulated. KNH-UoN ERC continues to position itself to provide timely leadership and support through training, networks, collaborations and customized services. As we strive to do this, we remain alive to the challenge of ever increasing volume and complexity of research proposals presented to the committee for processing.

To continuously deliver optimally the committee must consistently readjust and re-engineer itself to address factors that may lead to delayed reviews, delayed implementation of research, and loss of strategic opportunities to self and the clients. This is essential as we serve the diverse needs and demands of our clients drawn from local and international sectors.

We appreciate your interest in *Bioethics info-net*, and hope that you will always find it both informative and a useful resource as we all try to develop knowledge and skills in this dynamic field of bioethics. *Welcome aboard*

> *"Research is the cornerstone of social, economic and technological development, but to have maximum positive impact it must be vetted, monitored and regulated."*

KNH-UON ERC MEMBERSHIP RELOADED

The membership of the KNH-UoN ERC was reviewed early this year to not only infuse new blood and expand its diversity, but also facilitate full and fast implementation of its broad mandate. The committee now has a strong team of 19 very active and progressive minded members.

Prof. A.N. Guantai -	Pharmacology and Therapeutics
Prof. C. S. Kigondu	Laboratory medicine (Clinical chemistry)
Prof. M. L. Chindia	Oral & Maxillofacial Surgery
Dr. J.M. Machoki	Reproductive Health
Dr. M. Wasunna	General medicine
Prof. SWO Ogendo	Surgery
Dr. B.K. Amugune	Product Quality assurance
Prof. A. Karani	Nursing Sciences
Dr. John Ong'ech	Reproductive Health
Dr. Nelly Mugo	Reproductive Health
Dr. D.Kibaya	Diagnostic Radiology
Dr. Gladys Mwiti	Social sciences (Clinical psychology)
Dr. Lillian Omutoko	Social sciences
Dr. Irene Inwani	Paediatrics and child health
Mr. L. Nyabola	Public Health and biostatistics
Mr. M. Mudenyo	Medical Records
Prof. Erastus Amayo	Clinical Med.& Therapeutics
Dr. P Muiruri	General medicine
Mrs. W. Morara	Legal Officer

EDCTP SUPPORTS CAPACITY BUILDING IN BIOETHICS

Training needs assessment

Review of research protocols before implementation is now regarded as one of the cornerstones of ethical research involving human participants. Various international and national guidelines also stipulate that ethical approval be a pre-requisite for the commencement of research involving humans. The Kenya National Council for Science and Technology (NCST), http://www.ncst.go.ke/ has outlined guidelines for establishment of ethical review committees (ERCs) in Kenya.

Implementation of approved research protocols, especially in developing countries, is bound to encounter practical challenges that are attributable to research competency and socioeconomic factors. Thus, ethical approval alone does not necessarily ensure protection of the safety and welfare of research participants throughout the research. Hence the need for approved research to be monitored by ERCs. Effective ethical review and oversight of research requires trained human resource and appropriate financial support The operations of these processes are generally hindered by a combination of challenges, including scarcity of resources; inadequate training of members and poor staffing levels.

.

The consequences of such limitations on the ethical review processes range from inordinate delays in processing of proposals to inadequate ethical reviews.
There is limited data on the training needs, functional status and networking among ethics reviews committees in Kenya.
The KNH-UoN ERC in collaboration with National Council for Science and Technology (NCST) carried out a survey of the ERCs in Kenya to determine their operational challenges.
Self-administered questionnaire were distributed to ERCs' Key respondents .

A total, of 30 institutions participated in the survey, and out of these, only 23 had active ERCs. Among the institutions with ERCs, majority of them (68.2 %) provided teaching, clinical and research activities. Membership of ERCs ranged from 3 to 16 members with diverse representation. One had a community representative and three had pharmacists while most had clinicians, scientists, bioethicists, legal experts and religious representatives. Four ERCs had only one member trained in Bioethics. Three ERCs had 2 members trained in bioethics and three ERCs had 3, 5, and 8 members trained in Bioethics respectively. Some had no members trained in bioethics.
Many ERCs met frequently, and had the operational guidelines in place.

Regarding areas for improvement, many ERCs felt that they should diversify their membership and receive more financial resources and administrative personnel and capacity building through regular training. In fact all ERCs surveyed expressed need for bioethics training for their members for an average of five days. Major challenges mentioned included, members untrained in Bioethics, conducting training for ERCs members, monitoring and evaluation of approved research. Other challenges were, developing standard operating procedures (SOPs, reviewing of protocols on special topics , providing services to stakeholders and timely review.

Acknowledgement; This survey was carried out with financial support from EDCTP

Bioethics training for ERC members:

Currently it is illegal to carry out research in Kenya without ethical clearance. The offence is punishable as provided for in Science and Technology repeal Act Cap 250 of the Laws of Kenya. The country hosts many public and private academic, research and service institutions engaged or with the potential to engage in research. Resarch protocols from all these institutions will require vetting by approved /accredited review boards. A survey to assess the status of review boards and the training needs in bioethics revealed that there are limited number of institutional review boards in Kenya whose members have been trained in Bioethics. At the same time, there are institutions with a wish to establish their own review boards and therefore desire to have core staff to be trained to kick start the process. EDCTP was once again gracious to identify with this need and sponsored an Ethics and Research training workshop in January 15TH -18TH , 2012 at Kenya School of Law, Nairobi, Kenya .
This workshop targeted ERC members from Kenyan institutions and although it is impossible to train all the deserving members in one workshop, it is hoped that those trained would lead the capacity building campaign in their committees on the principles of Bioethics.

OBJECTIVES : Objectives of the training workshop were:

- To train members of ERCs in Bioethics.
- To create a network of ERCs in Kenya.
- To assess challenges facing IRBs in Kenya regarding training opportunities.

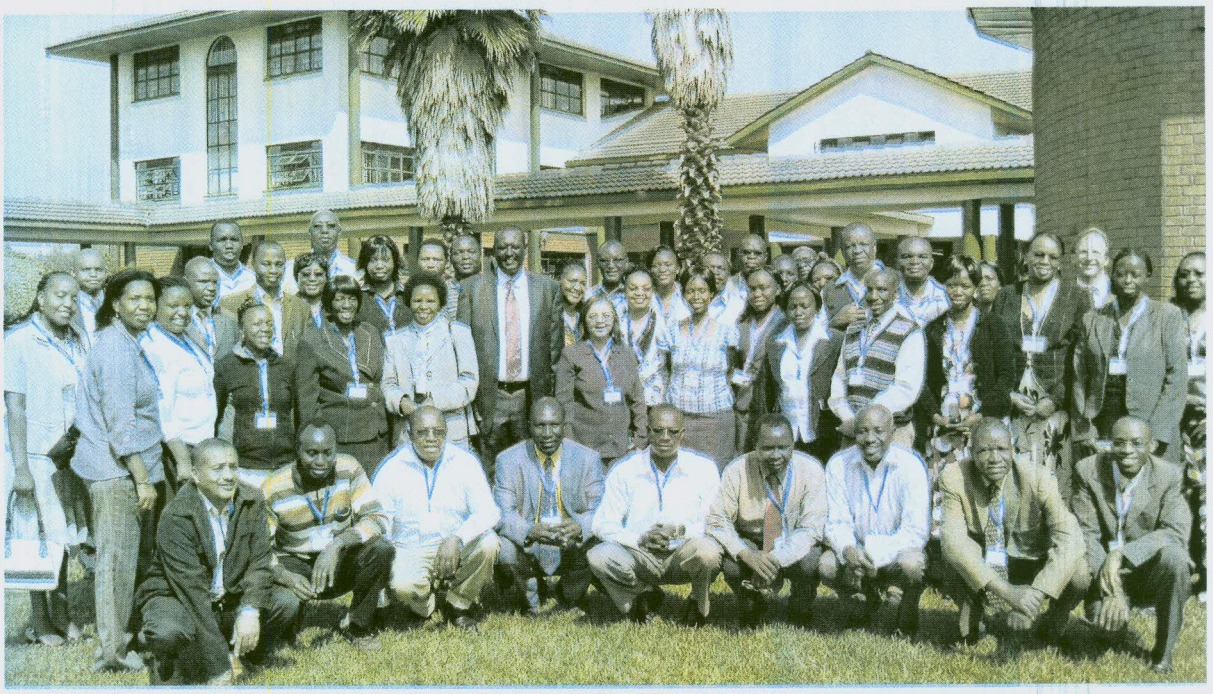
CHIEF GUEST: MR RICHARD LESIYAMPE, CEO Kenyatta National Hospital opens the workshop

PARTICIPANTS :

A Total of **58** participants attended the two and half days workshop.
The workshop was organised by the University of Nairobi - Kenyatta National Hospital Ethics and Research Committee (KNH-UoN -ERC) and facilitated by trained ERC members drawn from it with additional support from NCSTand Kenya medical Research Institute (KEMRI).

The participants came from the following institutions: Aga Khan University Hospital, Gertrude's children's Hospital, Kenyatta National Hospital/University of Nairobi/ Ethics Research Committee, Kenyatta University, Jomo Kenyatta University of Agriculture and Technology, Coast Provincial General Hospital, AMREF, ICIPE, Pwani University, Mombasa Polytechnic University College, Great Lakes University of Kisumu, Moi University, University of Eastern Africa - Baraton, Catholic University of East Africa, The Presbyterian University of East Africa, Kakamega Provincial General Hospital, New Nyanza Provincial General Hospital, Masinde Muliro University of Science and Technology, Maseno University, Kijabe Hospital, Chuka University College, Kenya Methodist University, Nairobi Hospital and the National Council for Science and Technology

A Section Of Participants Keenly Following The Presentations



GROUP PHOTOGRAPH (EDCTP Workshop January 15TH -18TH , 2012)

Pretest and post test evaluations

The participants' knowledge increased with the score of 54% in the pretest and 81% in the post test.

Workshop evaluation by the participants and suggestions

Overall the participants found the workshop to be well run with good presentations. Unfortunately, some participants missed hot baths in the mornings.

KEY SUGGESTIONS:

The participants suggested the following:

1. Increase the duration of training to five days to allow more interactions, discussions and networking.
2. Have an all inclusive workshop for social scientists.
3. Have follow-up training for the participants.
4. The training workshops could be replicated in other institutions.
5. National Council for Science and Technology (NCST) should be in the forefront in organizing training, addressing challenges and strengthening networking of ERCs in Kenya.
6. An international face to the training was suggested to share experiences.

Participants hoped that other opportunities will arise to have more members of ERC trained in the near future.

EDCTP BIOETHICS WORKSHOP
FREQUENTLY ASKED QUESTIONS (FAQs)

The following key questions were captured during the rich discussions

1. Do you need ethical approval for social studies just like clinical studies?
2. What do you do with waste from research?
3. What is the role of ERCs on international explorations e.g oil extraction?
4. How is bioethics re-informed?
5. Is there an ERC on animal studies?
6. What is the role of ERC on Herbalist Research?
7. What is the action of ERC on supervisors who don't review research protocols?
8. What is the role of ERCs on bio-repositories?
9. When reviewing international protocols involving local people, do ERC need to review the proposal?
10. How do ERC manage confounding factors in clinical trials?
11. When do the ERCs get informed about a malpractice in clinical trials?
12. What is the role of MSMB and ERCs in approving herbal medicine?
13. Can recruitment be done on the basis of verbal consent?
14. Is there an over-researched community? Any ethical issues?
15. What should be done on consenting mature minors and what is the age cut?
16. What is the role of ERCs on samples that are shipped outside the country?
17. What happens to people in a community with a particular condition ?
18. When a data collection tool is changed slightly, do you send the whole proposal or just the tool for ERC approval?
19. Can we have an act of Bioethics?
20. How can an ERC member be protected from the CEO of the same organization?
21. Can you outsource for IRB review?
22. How can ERC members be motivated?
23. How do we incorporate traditional concepts in drug proposals?
24. How do we inform the community of extended longitudinal studies?
25. How do ERCs ensure they get final research report?
26. How can the money given to volunteers/participants in various studies in a community be standardized?
27. How do ERCs monitor the reviewed proposals ?
28. Is it possible to network/collaborate on ERCs activities on monitoring and evaluation?
29. Is it ok for the ERCs to do spot checks on an ongoing research project?

Look out for answers to these and other questions in the next issue !!

AWARD OF CERTIFICATES

All the participants were given certificates of attendance at the end of the workshop. Facilitators likewise were given certificates of appreciation for their commitment and quality presentations.

[Above] A Facilitator, Mr Ambrose Rachier receiving a certificate from Prof Guantai as other facilitators Prof Kigondu, Prof Bhatt, Dr Monique Wassuna look on with appreciation.

[Right] A participant receiving a certificate of participation from Prof K M Bhatt-Chair of The National Bioethics Committee.

TAKE HOME SUPPORT MATERIALS:

A CD containing all the presentations was made available to the participants so that they could pass on the information to other members of their committees. A folder containing hard copies of essential reference documents was also given to each participant

ACKNOWLEDGEMENTS :

The needs assessment survey leading to this report was undertaken by Prof. K. Bhatt, Prof. C Kigondu, Prof. A Guantai, Dr. S Langat and Dr. M Oyaro. We are grateful to the institutions that participated. The statistical analyses were done by Wycliffe.

The project was generously funded by EDCTP grant number CB.10.41302.024

Competing interests: None

ETHICAL PRINCIPLE OF AUTONOMY:

Autonomy is synonymous with independence. In research, it is the capacity of the research participant to make an un-coerced decision to participate in research after comprehensively being informed about the study. This decision **must be respected.** Autonomy therefore underpins the principle of **respect for persons.**

Autonomy is one of the basic principles of ethics in research involving human participants. Research participants must have opportunity to know about risks and benefits of participating in a particular research before consenting. It is an obligation on the part of the investigator to respect each participant as a person capable of making an informed decision regarding participation in any research. The investigator must ensure that the participant has received full disclosure of the nature of the study, the risks, benefits and available alternatives. There must be adequate dialogue and opportunity to ask questions. The principle of autonomy resulted in requirement of informed consent. The informed consent document is the most important document in a research project. It is a contractual agreement between the researcher and the research participant that must be fully documented and signed by the parties and witnessed. It must be fully adhered to and implemented in spirit and letter to ensure autonomy and hence respect of research participants.

How autonomous are the research participants?

Despite knowledge of history of atrocious experiments done during Nazi era and existence of the Nuremberg code, Helsinki declaration, CIOMS guidelines and many other guidelines regarding research in humans, there are still many violations of the basic ethical principles including autonomy. Often the disclosure to the research participants is not adequate. The expected risks are not fully explained and availability of alternative treatment is also not disclosed. Sometimes the research participants rights are down played. One of the most important mechanisms particularly in clinical trials which limits autonomy is the therapeutic misconception.

"There must be adequate dialogue and opportunity to ask questions."

Often the participants, particularly from socially and economically disadvantaged groups, over estimate the benefits and overlook the possible harms developing despite receiving detailed information. This misconception can lead to disastrous consequences. In the HIV vaccine some participants change their behaviour having a false sense of security and yet they know that the vaccine is justified and not really protective until proven.

In economically and socially compromised individual, it is often not possible to know the voluntary nature of participation particularly when gifts and unrealistic high re-imbursements are done for transport. In very poor communities or health facilities with limited resources, the participants enroll for any trial to have some kind of medical care.

Competence of participants is important to give consent where a participant is not competent to provide consent a legal guardian may provide consent if it is in the best

interest of the participant. In certain emergency situations the participant may not be capable of giving consent autonomously, where waiver or consent by guardian is acceptable, for example foetus or a person in coma. It is also important that the researchers also selects participants with more favourable risk/benefit ratio even if these individuals are less able to give autonomous consent.

In some communities the head of the household decides on behalf of the participant to enter any research, however universal principles of ethics still apply and no participant should be enrolled unless the final decisions is by the individual participant.

Sometimes the potential research participants want the clinician to make decision on their behalf and do not even want to question for fear of having denied good treatment. Exploitation of human subjects has been a major issues particularly in developing countries where often there is lack of proper legal structure to deal with issues pertaining to research with human subjects. An element of coersion and authoritarinism, deceit and undue inducement often infringe the autonomy of human subjects. Professionalism and honesty among researchers is extremely important in order to allow research participants make informed decision.

Can autonomy be compromised and should it be compromised?

One could argue that autonomy is already compromised in research where blinded treatment is given. Here the participants have given up their rights to know which treatment is given and the right to discuss their treatment with the care giver.

Sometimes autonomy has to be compromised for the sake of welfare of the participant. At times there may be a need to use deception when doing research in some exceptional cases to gather relevant information. This of course will require proper justification before allowing such a study.

Sometimes the researchers want to take oral consent. This should only be allowed in very few exceptional cases with proper justification. Without written informed consent there is room for exploitation.

Sometimes the potential participants fear signing informed consent due to misconception that the participants were bound to complete the research and were relinquishing their rights.

It is extremely important that respect for participants autonomy as well as the vulnerability are carefully considered before enrolling in research. No trial should be conducted without proper informed consent of the participant and appropriate documentation of the same.

Which institutions have accredited Ethics Review Committees?

Like in all other areas of public interest, ethics review is a formal activity with rules, norms and procedures. Institutional Ethics Review Committees (ERCs) are accredited by the National Council for Science and Technology (NCST). The processes are accomplished through the National Bioethics Committee (NBC). The NBC is a committee of the NCST established under section 6 of the Science and Technology Act CAP 250, laws of Kenya. During the year, 2011, the NBC developed a process of accreditation to assist in streamlining and standardizing ethics review.

For the first time, the committee sat and considered applications for accreditation in November 2011. Application involves filling a form that provides information on the membership of a proposed committee, diversity among the membership institutions it serves and its operating procedures.

There are currently twelve such committees accredited to review different types of research protocols. The NBC will continue to consider applications as they are received. Accreditation is for a period of three years from the date of notification. Accredited committees are expected to provide annual reports to the NBC and to make special reports whenever there are unusual serious adverse events.

Accredited ERC's with scope of review mandate are as follows:

i) Kenya Medical Research Institute (KEMRI), chaired by Mr A. Rachier,
Scope: to review all nature of protocols,

ii) Kenyatta National Hospital- University of Nairobi, (KNH-UoN) chaired by Prof. A.N Guantai,
Scope: to review all nature of protocols,

iii) Moi Teaching and Referral Hospital, chaired by Prof. E. Were,
Scope: to review all nature of protocols,

iv) Kenya Methodist University (KEMU) chaired by Prof. A. Mutungi,
Scope: to review all nature of protocols,

v) Kenyatta University (KU), chaired by Prof N. Gikonyo,
Scope: to review all nature of protocols

vi) Aga Khan University Hospital, chaired by Dr. P. Simon,
Scope: to review all nature of protocols,

vii) Pwani University IERC, chaired by Dr. T. Rewe,
Scope : to review biological, environmental and social science protocol

viii) Chuka University, chaired by Prof. A. Magana ,
Scope: to review biological sciences protocols,

ix) African Medical and research Foundation (AMREF), Chaired by Dr. M Karama,
Scope: to review biomedical research protocols

x) Institute of Primate Research (IPR), Chaired by Dr. H. Ozwara,
Scope: to review biomedical research protocols involving use of animals

xi) International Centre for Insect Physiology and Ecology (ICIPE) chaired by Dr R. Mukabana.
Scope: to review biological and environmental research protocols.

xii) Gertrudes Children's Hospital, Chaired by Dr Thomas Ngwiri

xiii) Egerton University Chaired by Fr. Raphael G Wanyama

More details about the committees can be found in the NCST website: www.ncst.go.ke

S. K. Langat-Secretary National Bioethics Committee

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 Kigondu**:*
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 Ongeri**,:*
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

Coming Events:

A follow up workshop will be held in May 2012 to receive an update from the trained participants on how they have utilized the knowledge and the future plans they have on bioethics.
Meetings /workshops will be held mid year to roll up plans for the development of the Strategic Plan for the KNH-UoN ERC

In the Next Issue

KNH-UoN Strategic Plan

- Bioethics Frequently Asked Questions and Answers
- Report of the Update workshop
- Principle of Beneficence
- 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
Website: www.uonbi.ac.ke/activities/KNHUoN