

KEMRI BIOETHICS REVIEW



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From the Director

Welcome to the second issue of The KEMRI Bioethics Review, the quarterly electronic publication on Bioethics. Bioethics is an increasingly important and imperative consideration in all research, particularly in biomedical research that involves human subjects.

As scientific advances propel breakthroughs in medical technology at a dizzying pace, urgent questions arise about how to address and regulate these breakthroughs in an ethical manner for the benefit of humanity.

While technological innovations engender of the promise of potential for benefits, we have to be rightly wary of potential negative effects. The role of bioethics is to weigh the balance between potential benefits versus potential hazards and make the call on what is ethical, just and in the best interests of humanity.

The number and range of research handled by the Institute has increased, as has the awareness that of the need to adequately address novel bioethical issues in the varied and increasing complex research areas. In this light KEMRI has embarked on a process building its capacity in bioethics so as to achieve the Institute's



primary mission which is to improve human health and quality of life through research, capacity building and service delivery. The first step in this process has been to examine the current review system in KEMRI with a view of restructuring it where necessary to make it more effective and efficient.

In this issue we shall describe on how the current research review process functions at KEMRI, and provide details about the approval process. We shall also introduce the members of the KEMRI Ethical Review Committee.

We appreciate your interest in The KEMRI Bioethics Review, we hope that you will find this issue informative and a useful resource to help you understanding the current review system.

Solomon Mpoke, PhD
Director, KEMRI

Research Regulatory Process in KEMRI

By Dr. Elizabeth Bukusi, the Deputy Director Research & Training

KEMRI is the premier biomedical research institution in Kenya. The Institute was established by an Act of Parliament in 1979 as the national body responsible for carrying out health research in Kenya (www.kemri.org). Under this Act, KEMRI is responsible for: conducting biomedical research; collaborating locally with other organizations and institutions of higher learning in training programmes and on matters of relevant research; liaising with other research bodies within and outside Kenya to carry out similar research; disseminating research findings; and working together with the Ministry responsible for research, the National Council for Science and Technology, and the Medical Science Advisory Committee on matters pertaining to research policies and priorities.

The KEMRI has ten research centres that focus on different areas of national and strategic importance. The centres are mandated to emphasize and articulate research on the following areas of focus: biotechnology, clinical, geographic medicine, global health, infectious and parasitic diseases control, microbiology, public health, respiratory diseases, traditional medicine and drugs, and virus research.

KEMRI also has the Eastern and Southern Africa Centre of International Parasite Control (ESACIPAC), mandated with strengthening research and control programmes on parasitic diseases in the eastern and southern Africa region, covering Kenya, Uganda, Tanzania mainland, Zanzibar, Malawi, Zambia, Zimbabwe and Botswana. In addition the KEMRI Graduate School of Health sciences hosts the Institute of Tropical Medicine and Infectious Diseases (ITROMID) in collaboration with Jomo Kenyatta University which offers masters and PhDs in health sciences.

KEMRI has grown to become one of the leading health research institutes in Africa with demonstrated success in conducting collaborative biomedical research and producing exceptional scientists. From informal discussion with colleagues from the National institutes of health, the KEMRI review system mirrors the NIH system where institutes have a central IRB which has focus on human subjects protection (<http://www.niehs.nih.gov/research/clinical/join/ohrc/index.cfm>).

All research activities carried out by the Institute's centres have to be vetted and approved by the Centre Scientific Committee (CSC).

Fig 1: The figure shows the feed into the SSC

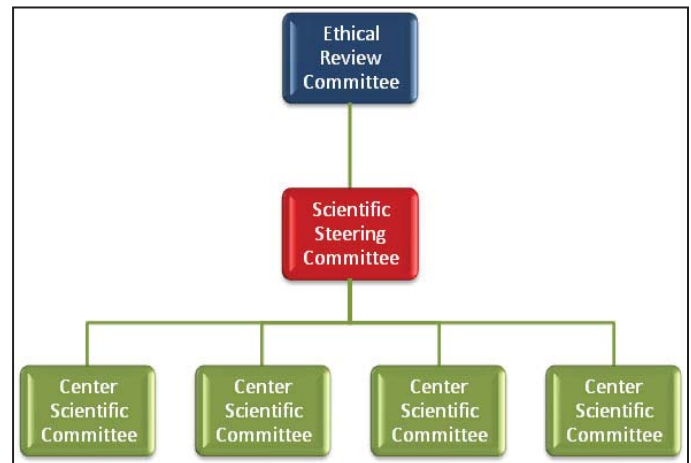
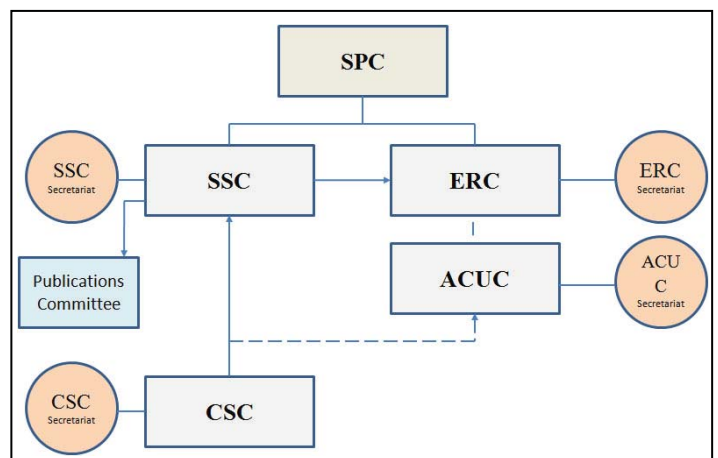


Fig 2: Proposals review process and relational structure of KEMRI's Scientific Committees



Key
 CSC: Centre Scientific committee
 SSC: Scientific steering committee
 ACUC: Animal Care and Use committee
 ERC: Ethical Review Committee
 SPC: Scientific programs committee

The CSC appraises the research proposals before they are forwarded to the institute's central committee - the Scientific Steering Committee (SSC). The SSC, which consists of Assistant Directors, Centre Directors and Heads of KEMRI's six research programs including

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the, ITROMID Coordinator reviews the scientific content of research proposals and to confirm whether: the research uses procedures consistent with sound research design, which do not unnecessarily expose subjects to risk; the research is likely to answer the proposed question, the knowledge reasonably expected to result from the research has scientific importance, there is provision for capacity building and to ensure that proposals reflect an acceptable level of scientific rigor and merit prior to ethical review

On approval, the proposals are forwarded to the Ethics Review Committee (ERC) which provides the final approval before implementation of research can begin. Proposal that involve animal use are submitted to the Animal Care and Use Committee (ACUC) at the same time as they are forwarded to the SSC. The ACUC has oversight for the use and care of animals which are used for experimentation.

The KEMRI ERC, which consist of 10 members, has 5 of the members external to KEMRI and 5 members who are KEMRI staff. Of these staff, four are part of the secretariat which is headed by the Secretary. The KEMRI ERC also undertakes reviews for investigators not affiliated with KEMRI. These external reviews currently constitute up to 15% of new proposals. The figure below depicts the current system of Ethics regulation review at the institute. From October 2011 a onetime protocol processing fee of USD1000 was levied for all for review of all applications submitted by investigators who are not affiliated with the institute.

The highest committee of research regulation at KEMRI is the Scientific Programs Committee. This is a board of management committee charged with the responsibility of providing strategic direction for the science at the institute.

Meet the KEMRI Ethical Review Committee (ERC) Members

Mr. Ambrose Rachier

Mr. Ambrose Rachier is the Chair of the KEMRI Ethics Review Committee (ERC) and has been a member of the KEMRI ERC since its inception more than thirty years ago.

He holds a Bachelor of Laws Degree from the University of Dar-es-Salaam and a master of Laws Degree from the university of Nairobi where he majored in Law and Medicine with emphasis on Bioethics. He also holds a Certificat Pratique de Langue Francaise from the University of Madagascar.

Mr Rachier is also a member of the Aga Khan University Ethics Review Committee. In addition to this, he serves as the Chairman of the HIV and AIDS Tribunal, a quasi-judicial body established under the HIV and AIDS Prevention and Control Act. The HIV and AIDS Tribunal has the jurisdiction to hear cases and complaints arising under the Act, particularly matters pertaining to violation of human rights. This includes discrimination and stigmatization of people living with HIV or AIDS. In this capacity Mr. Rachier has handled sensitive cases touching on ethics law and human rights arising from workplace, domestic and research ethics scenarios.



Mr. Rachier is an advocate of the High Court of Kenya for 37 years standing and has throughout his legal career been engaged in private practice. In his practice he has handled varied aspects of law and has for many years distinguished himself in the practice of property law and law and medicine. The Law Society of Kenya has benefited immensely from his vast experience as a resource person in these fields of law inviting him to provide lectures in its Continuing Legal Education programmes.

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He has mentored many lawyers in the Council of Legal Education Pupillage Programme.

Mr. Rachier has been instrumental in the empowerment of other Ethics Review Committees by offering training to members of newly established Ethics Review Committees including the AMREF Ethics Committee and the Aga Khan University Ethics Review Committee. He has received training on Research Ethics from various Universities including the Universities of Witwatersrand, Washington and Harvard. He served as the UNESCO consultant for Kenya on documentation of data on global ethics, an exercise that entailed the study and gathering of sources and contents of ethical rules in Kenya including ethics of medical practice as well as ethics of research.

Mr. Rachier has been a lecturer at the Kenya School of law for 23 years where he taught Land law and conveyancing. He has also taught Environmental Law at the University of Nairobi. He has also attended many international conferences where he delivered many papers. He contributed a chapter in the book "AIDS IN

KENYA" and a "Mental Health Handbook" with Prof. David Ndeti. He has published various papers on Law and Ethics and Law and HIV and AIDS.

Mr. Rachier has for many years consulted for Kenya Medical Association in which capacity he has given many lectures on ethics of medical practice on such controversial subjects as euthanasia, death and dying, abortion, advance wills, ethics of organ transplantation to mention but a few.

Mr. Rachier was a member of the committee which developed the sessional paper on AIDS in Kenya, a policy paper that was adopted by Parliament as a guide to numerous ethical issues and concerns. He was also the chairman of the Government appointed task force on HIV and AIDS Law. He was recently the consultant for the Ministry of Lands on reform of land laws.

Mr. Rachier's major hobby is jogging. He loves football and is the current Chairman of Gor Mahia Football Club. He is married with many children.

Prof. David Musyimi Ndeti

Prof. Ndeti graduated with a MBChB (University of Nairobi), DPM (London University) and Membership of the Royal College of Psychiatrists, UK (MRCPsych) and later elected Fellow of the same College (FRCPsych). He also holds a Doctorate in Medicine (MD) from the University of Nairobi and is currently registered for a Higher Doctorate of the University of Nairobi (DSc) at the University of Nairobi.

He is a full Professor of Psychiatry, University of Nairobi, where he has served for four terms as Chairman of the Department and is credited with initiating five innovative programmes. Prof Ndeti is the Founder of Africa Mental Health Foundation (AMHF), the premier Mental Health Research Organization in East and central Africa.

Prof Ndeti is the Vice-Chair of the African Division of the Royal College of Psychiatrists UK and the Secretary of the Section on Psychiatry in Developing Countries, World Psychiatric Association and a member of the Council on



Brain and Cognitive Sciences, based at the Harvard, a part of Global Agenda Councils based in Switzerland and World Economic Forum. This body is tasked with advising Governments on emerging issues. He sits on Editorial Boards of several Journals in Psychiatry and related disciplines based in USA, Europe and South and West Africa.

He has written and edited five books in Psychiatry and Mental Health to target lay people, school children and teachers,

medical students/general practitioners, trauma counselors and cutting edge researchers and scholars in mental health. Two of these books have sections on research ethics. He has written more than 250 articles and book chapters published in Africa, North America and Europe. He serves as a member of KEMRI ERC. He is passionate on Mental Health Research to inform policy and practice with a view to minimizing the treatment gap in the Low and Middle Income countries, which he has coded Vision 2022.

Prof Samuel Sinei

Prof Samuel Sinei graduated with a medical degree, MB; CHB from the University of Nairobi in 1975. Thereafter he worked as a Medical Officer in the Ministry of Health before going back to University of Nairobi for postgraduate training in Obstetrics and Gynecology where he graduated with M.MED in 1981.



He is currently a full Professor at University of Nairobi. He has served as the Principal of the College of Health Sciences, University of Nairobi, and as the Deputy Vice Chancellor, Jomo Kenyatta University of Agriculture and Technology. He has done a lot of research work and published extensively in international refereed journals in the field of Reproductive Health. He has undertaken several short courses in the Bioethics.

He was promoted to the position of Specialist

Obstetrician and Gynecology in the Ministry of Health. In the same year, 1981 Prof Sinei was awarded a WHO scholarship and he proceeded to University of Edinburgh, in the United Kingdom, for further specialization in Perinatal Medicine and Infertility at the Center for Reproductive Biology, Department of Obstetrics and Gynecology. Upon return to the Country in 1982, he took up a teaching position as a lecturer in the Faculty of Medicine, University of Nairobi. He has undertaken several short courses in the field of Reproductive Health including at John Hopkins University and University of Washington.

Prof. Sinei is the immediate past Chair of the KEMRI, ERC and remains as member of the committee. He currently works with KEMRI/ Walter Reed Project HIV Research Program as the Deputy Director overseeing Management and Program Operations. He is actively involved in HIV research and is a principal investigator and associate investigator of a number of Walter Reed Army Institute of Research (WRAIR) and AIDS Clinical Trial Group (ACTG) protocols.

Prof. Sinei has served in several national and international advisory and management boards.

Prof. Anna Kagure Karani

Prof Karani is an Associate Professor of Nursing Education at University of Nairobi since 2008. She obtained her doctrate in 2002 from University of Nairobi. She has a wide experience in clinical work in hospital and in community work as well as extensive experience in teaching and research work. She has more than 50 publications in peer reviewed journals and books.



Prof. Karani has received several awards for promoting community work and nursing education. These awards include: the Head of State Commendation (HSC) which she was awarded during the 40th celebration of Independence on 12th December 2003; the Wharton Fellows Program in Management for Nurse Executives by Johnson & Johnson awarded in 2008; Recognition Award for Dedication & Excellence for providing training on HIV/AIDS by Marquette University, School of Nursing in 2003; International Council of Nurses Certificate for Continuing Education in 1999; gold medal for services at the 4th All Africa Games in 2009; and Recognition of

Commitment, Diligence and Long Service by National Nurses of Kenya in 2009' among others. She is currently the Chief Nursing officer for St. John Ambulance Kenya, the Vice Chair of the Nursing Council of Kenya, Lead Trainer for Leadership For Change for International Council of Nurses (ICN) Kenya.

She is a member of both Kenyatta National Hospital/University of Nairobi and the KEMRI, ERC. She also serves as the Chief Editor of the Kenya Nursing Journal. She was the coordinator post-graduate programs and head of Education/Administration School of Nursing Sciences University of Nairobi. Prof Karani is an external examiner to nursing programs in the region and has initiated some collaboration with local, regional and international nursing programs.

Dr. Monique Wasunna

Dr Wasunna is the Assistant Director, Research; at the KEMRI. She has served as Director Centre for Clinical Research from 1996 to August 2007 and more recently, was the Director KEMRI in an acting capacity from August 2007 to May 2009. Currently, Dr. Wasunna heads the Drugs for Neglected Diseases Initiative (DNDi) Africa. DNDi is a not-for-profit drug development organization based in Geneva. DNDi Africa office is housed within KEMRI.

Dr Wasunna is a physician and an infectious disease and tropical medicine specialist. She holds a Bachelor of Medicine and Bachelor of Surgery degree from the University of Nairobi. Her postgraduate training in medicine was at the London School of Hygiene and Tropical Medicine, University of London where she obtained an MSc and a PhD in medicine and a diploma in Tropical Medicine and Hygiene from the Royal College of Physicians of London. She is a Fellow of the Royal Society of Tropical Medicine and Hygiene, and member of the Kenya Medical Association and Kenya Association of Physicians.

Dr Wasunna is a World Health Organization (WHO) certified Clinical Monitor with recent retraining by Clinical Research Africa (CRA) in research monitoring in 2010. She has had several trainings in Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) by WHO and CRA. In 2003, Dr Wasunna took an advanced course in Ethics at the University of Washington, USA. In 2010 and 2011 she was trained by UNESCO in bioethics as a member of the National Bioethics Committee. She is also certified by the Collaborative Institutional Training Initiative (CITI) after successfully completing the online course on protection of human subjects in research.

Dr Wasunna is a member of KEMRI Scientific Steering Committee, KEMRI Ethics Committee, Kenyatta National Hospital and University of Nairobi Ethics and Research Committee, and a member of the Kenya National Bioethics Committee. She also serves as a member of the Pharmacy and Poisons Board Expert Committee on Clinical Trials. She is a co-author of the Kenya National Ethics Guidelines, produced by the National Council for Science and Technology.

In 2008, Dr Wasunna was appointed by the Director General, UNESCO, as a member of the International Bioethics Committee (IBC), a



position she holds to date. IBC is a body of 36 independent experts that follows progress in the life sciences and its applications in order to ensure respect for human dignity and freedom. It was created in 1993. During this period at IBC, Dr Wasunna has contributed to the publication of two IBC reports namely: Report of the International Bioethics Committee (IBC) on Social Responsibility and Health; Report of IBC on the Principle of Respect for Human Vulnerability and Personal Integrity.

Dr. Wasunna's research interest is primarily focused on clinical trials in visceral leishmaniasis, malaria and HIV. From 2003 to date, Dr. Wasunna has been a member of the Leishmaniasis East Africa Platform (LEAP). LEAP is a clinical research platform that brings together scientists and institutions in East Africa to develop clinical trial capacity to bring new treatment options to neglected visceral leishmaniasis patients in the region. Dr. Wasunna co-ordinates all LEAP activities in the region supported by DNDi. She has published her work totaling over 60 manuscripts in peer reviewed journals.

NEWS FLASH

The KEMRI ERC was recently accredited by the National Council for Science and Technology (NCST) for another three years, that is from January 2012 to January 2015. To date, the NCST has accredited 11 committees in Kenya. Other accredited Ethics committees include Kenyatta National Hospital/ University of Nairobi, Kenyatta University, Kenya Methodist University, Moi University/Moi Teaching & Referral Hospital, ICIPE, Pwani University College, Chuka University, Aga Khan University Hospital, AMREF and the Institute of Primate Research.

Eng. Alexander M. Mbugua

Eng. Alex has been working in the Engineering industry for over thirty-eight years. He has broad based experience having undertaken numerous projects in the field of Civil and Structural Engineering.

Eng. Alex Mbugua founded Base Plan Associates in August of 1996 and since then he has specialized in design of civil and structural engineering design in reinforced concrete, steel structures and frames and highway bridges. He is the Principal Engineer of Base Plan Associates and serves to oversee, evaluate, approve and coordinate within all projects.

He has been a team leader in design and supervision of high-rise office blocks, housing developments and industrial projects in various parts of Kenya, Tanzania, Uganda, Rwanda and South Sudan. As a consultant, he has been tasked with helping project teams bring innovative, sustainable outcomes to our infrastructural development in civil engineering design of housing schemes entailing design of road network, storm water collection and disposal systems including design of box

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culverts for road works and airports in Kenya and Malawi.

His unique engineering background gives him the ability to analyze the microscopic structural interactions of a project, while overseeing the

macroscopic progress of it. He is affiliated with the Engineers Registration Board of Kenya, The Institution of Engineers of Kenya, The Architectural Association of Kenya and KEMRI in which he has served as a Member of the Ethical Review Committee since for over 25 years.

Eng. Alex is registered with The Engineers Registration Board as a Consulting Engineer. He is a member of the Institution of Engineers of Kenya (I.E.K), and the Architectural Association of Kenya (Council Member of the Engineers Chapter- A.A.K)

Prof. Peter Mageto

Prof Mageto is an Associate Professor of Theological Ethics and Head at the Department of Theology and Pastoral Studies at Daystar University. He obtained his theological degree from St. Pauls' United Theological College (Now St. Pauls' University). He has a Master's and PhD in Theological Studies in Ethics and Society from Garrett-Evangelical Theological Seminary/ Northwestern University in Evanston, Illinois, USA.

He served as an Assistant Professor at the University of Evansville, Indiana, USA for two years. In August 2006, he joined Daystar University's Faculty of Postgraduate Studies and a year after he was appointed as Acting Coordinator responsible for the Master of Arts in Communication and Master of Arts in Christian Ministries. During this period, he mentored and



supervised a number of students undertaking thesis work.

In 2010, he was appointed as the Head of Department, Theology and Pastoral Studies. He has done a lot of research work and published in areas of HIV/ AIDS, ethics in higher education, part-timing in universities and clergy ethics.

He serves as a member of the KEMRI ERC and as Chair of the Ecumenical Symposium of East African Theologians. He has undertaken short courses in

ethical research, ethics review through KEMRI. He currently works with Daystar University, Nairobi, and serves in various national and regional boards.

Dr Juma Rashid

The Director of the Centre for Clinical Research at KEMRI has traditionally served as the Secretary of the ERC. He received his MBChB, MMed in Internal Medicine degrees from the University of Nairobi, in addition to the Certificate of Tropical Medicine.

His research focuses on drug development for Leishmaniasis. These investigations have increasingly led him into developing his interests in pharmacokinetics. He was the Project Manager for DNDi's Leishmania East Africa Platform (LEAP) in Kenya. He is a World Health Organization/Tropical Disease Research (WHO/TDR) certified clinical monitor and has overseen several clinical research studies in the East African region.



He is a safety monitor for the Phase III trial of the most clinically advanced malaria vaccine candidate i.e. RTSS, to date. He has served on the board of several national bodies including the Drug Registration Evaluation Committee, the National Pharmacy and Therapeutics Committee and the Pharmacy and Poisons Expert Committee on Clinical Trials. From August 2007 to February 2012, he served the Secretary for the Ethics Review Committee and was instrumental in the

development of the current ERC Standard Operating Procedures. He contributes regularly to professional and scientific journals and has published several articles in peer reviewed journals.

Streamlining Ethics Review in Kenya

By Simon Langat - Chief Science/Secretary, National Council for Science & Technology

Most researchers have known for a long time that research protocols have to be subjected to a process of ethics review. The process begins with the researchers and more particularly the principal investigators going through a process of self check. One needs to ensure that the protocol will pass through the authorization committees in minimal time. Committees use an established method of ascertaining that the proposed research manipulations will not harm the recruited participants in any way besides other requirements. Such procedures need to be standardized across the country.

In Kenya, NCST is the government organ that is mandated to ensure that the standards for responsible conduct of research in the country are upheld. It is in the interest of the public, researchers, participants, communities and collaborators that ethical standards be maintained to a high degree. According to the Science and Technology Act, Cap 250, laws of Kenya, the NCST is charged with a mandate to provide advice to the government, coordinate and promote the development of science,



Dr Simon Langat from the National Bioethics Committee (NCST)

technology and innovation agenda in the country. The Council operates through a series of committees that develop policy documents that are then used to inform national policy. One such committee is the National Bioethics Committee (NBC) that addresses ethics issues in research and policy making.

During the year 2011, the NBC developed guidelines to be used for accreditation of institutional ethics review committees. The earliest institutional ethics committee was

established in 1972 with the advent of the first medical school in the country. For long, only two such committees existed. Today however, there are many universities in the country and research is now carried out in many public and private institutions. The NBC moved to streamline the ethics review and ensure that it is done using the same standards in all institutions. The guidelines are available in the NCST website: www.ncst.go.ke

While not all institutions that are expected to seek accreditation have come forward, it is expected that all who wish to review research proposal will seek accreditation as it indicates the commitment of an institution to carry out credible research.

Capacity Building in Ethics: ERC training

From Dr. Elizabeth Bukusi, the Deputy Director Research & Training

Although the scientific and ethical rationale of protocols could be assessed during the review process, implementation of approved research protocols in the field is bound to encounter practical challenges. Subsequent monitoring of health research requires adequate resources and were trained ERCs. On December 29th 2011, a training was conducted for the KEMRI ERC, at the Fairview Hotel in Nairobi. The training goals for the course were to raise a deeper understanding of protocol deviation and violations.

To begin a dialogue among the ERC members To Suggest key topics and issues to be addressed in future training workshops for the ERC

Overview presentation

The training included presentations on handling protocol deviations and violation from Ms. Caroline Kithinji, ERC Secretariat; ERC Standard Operating Procedures (SOPs).

In addition the ERC members learned about the ADILI Project from Dr. Elizabeth Bukusi, the



Members of the ERC During the ERC training; From Left to right: Dr. Bukusi, Mr. Rachier, Eng Mbugua and Dr. Njoroge

Deputy Director Research and Training.

Members found this training useful and expressed interest of having similar trainings in the future on other areas of interest in research regulation of having similar trainings in the future on other areas of interest in research regulation.

Ethics Update: The Tuskegee syphilis experiment

(Source: Tuskegee Syphilis Study Legacy Committee. 1996-05-20)

The Tuskegee syphilis experiment (also known as the Tuskegee syphilis study or Public Health Service syphilis study) was an infamous clinical study conducted between 1932 and 1972 in Tuskegee, Alabama by the U.S. Public Health Service to study the natural progression of untreated syphilis in poor, rural black men who thought they were receiving free health care from the U.S. government.

The study initially involved 600 impoverished, African-American from Macon County, Alabama – 399 with syphilis, 201 who did not have the disease. The study was conducted without the benefit of patients' informed consent. Researchers told the men they were being treated for "bad blood," a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness." In fact, government officials went to extreme lengths to insure that they received no therapy from any source even when penicillin became the drug of choice for treatment of syphilis in 1947.

In exchange for taking part in the study, the men received free medical exams, free meals, and burial

insurance. Although originally projected to last 6 months, the study actually went on for 40 years. [1]

The 40-year study was controversial for reasons related to ethical standards; primarily because researchers knowingly failed to treat patients appropriately after the 1940s validation of penicillin as an effective cure for the disease they were studying. By 1947, penicillin had become the standard treatment for syphilis. Choices available to the doctors involved in the study might have included treating all syphilitic subjects and closing the study, or splitting off a control group for testing with penicillin. Instead, the Tuskegee scientists continued the study without treating any participants and withholding penicillin and information about it from the patients. In addition, scientists prevented participants from accessing syphilis treatment programs available to others in the area. The study continued, under numerous US Public Health Service supervisors, until 1972, when a leak to the press eventually resulted in its termination. The victims of the study included numerous men who died of syphilis, wives who contracted the disease, and children born with congenital syphilis. [2]

Training Trainers of Trainers

The Centre of Biomedical Ethics and Culture (CBEC), SIUT was inaugurated on October 8, 2004 in Karachi, and remains the only such centre in Pakistan to date. CBEC was established recognizing the need for ethics related education and research in Pakistan that are relevant and

responsive to local cultural and social realities, and the absence of any institution in the country dedicated to this task at a national level.

Primary objectives of CBEC include serving as an academic and intellectual resource for Pakistan, and assisting in development of individuals sensitive to indigenous issues

and with the capacity to impart ethics education to healthcare communities and beyond. CBEC faculty undertakes constructively critical research that explores the role of cultural and religious norms and socioeconomic realities in shaping value systems prevalent in society. Through its perspectives, the center aims to enrich the predominantly philosophical and secular discourse in contemporary bioethics, and to network with regional and international professionals and institutions involved in similar efforts(1)

Dr Elizabeth Bukusi is the first international student accepted for the Masters in Bioethics program. The two year master's program graduated the first four students in 2011. Dr Bukusi is one of 4 students who are currently pursuing the master's course. The one year PGD runs parallel to the MBE and currently there are 11 scholars from various institutions in Pakistan and one Forensic pathologist from Indonesia. A total of 41 students have graduated from the PGD since inception.

Dr. Farhat Moazam is the founding Chairperson of CBEC, and has had a long academic career. She was the founding Chairperson of the Department of Surgery and the first Associate Dean for Post Graduate Medical Education, FHS, in Aga Khan University, Karachi. Currently she is also a Fellow of the Institute of Practical Ethics and Visiting Professor at the Center for Humanism in Medicine, at the University of Virginia, USA.(2)

Among the similarities Dr Bukusi noticed between Kenya and Pakistan was in the public transport . However the public transport in Paksitan takes

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The Tuskegee Syphilis Study, cited as "arguably the most infamous biomedical research study in U.S. history,"[3] led to the 1979 Belmont Report and the establishment of the Office for Human Research Protections (OHRP).[4]



Tuskegee-syphilis-study doctor injects subject with placebo

(Source: http://en.wikipedia.org/wiki/File:Tuskegee-syphilis-study_doctor_injects_subject_with_placebo.gif)

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4. Office for Human Research Protections (OHRP) (2005-06-23). "Protection of Human Subjects". Title 45, Code of Federal Regulations, Part 46. US Department of Health and Human Services
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WHO Unveils New Standards and Operational Guidance for Ethics Review

The World Health Organization (WHO) has unveiled the latest standards and operational guidelines for ethics review of health-related research with human participants. The guidelines were developed for individuals and organizations involved in health research with human participants, including biomedical, behavioural, social science, and epidemiological research. The guidelines provide guidance to research ethics committees (RECs) on which organizations rely to review and oversee the ethical aspects of research, as well as to the researchers who design and carry out health research studies.

Adherence to these guidelines will help to promote ethical conduct of research and enhance and protect the rights and wellbeing of research participants and communities. The document can be accessed at <http://www.who.int/ethics/research/en/>

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it a notch higher than our 'matatus' as people sit on top of the PSV as well, and they have to pay even if they sit on top.



"Matatu mayhem in Karachi"

(Source: <http://unitednews.com.pk/en/national/>)

For further information on CBEC visit: <http://www.siut.org/bioethics/index.html>

1. <http://www.siut.org/bioethics/index.html>. Accessed on February 25 2012 2.58 pm
2. <http://www.siut.org/bioethics/faculty.html> Accessed on February 25 2012. 3 pm

From the Editor:

The KEMRI Bioethics Review is eager to relay information about ethics activities that occur at KEMRI and elsewhere, on a regular basis, and encourages newsletter submissions from all members of the Institute staff. Please note that the editorial staff reserves the right to edit submitted items.

Wit Corner

A prize will be offered to the first three submissions with correct answers. Answers should be submitted to DDRT@kemri.org

Last Issue's Winners!

- Muriithi Murungi, ICT Officer 1: Information and Communication Department
 - Sarah Nekesah Tembu; Secretary, Assistant Director Administration
1. What is a Federal Wide Assurance (FWA)?
 2. What is FWA number for the KEMRI ERC?
 3. Who is the Chair of SSC
 4. How many members are there in SSC
 5. Who is the current secretary of the ERC

Note: Members of the Task Force and the SSC/ERC secretariats are not eligible for participation in the quiz.

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Partners:

