

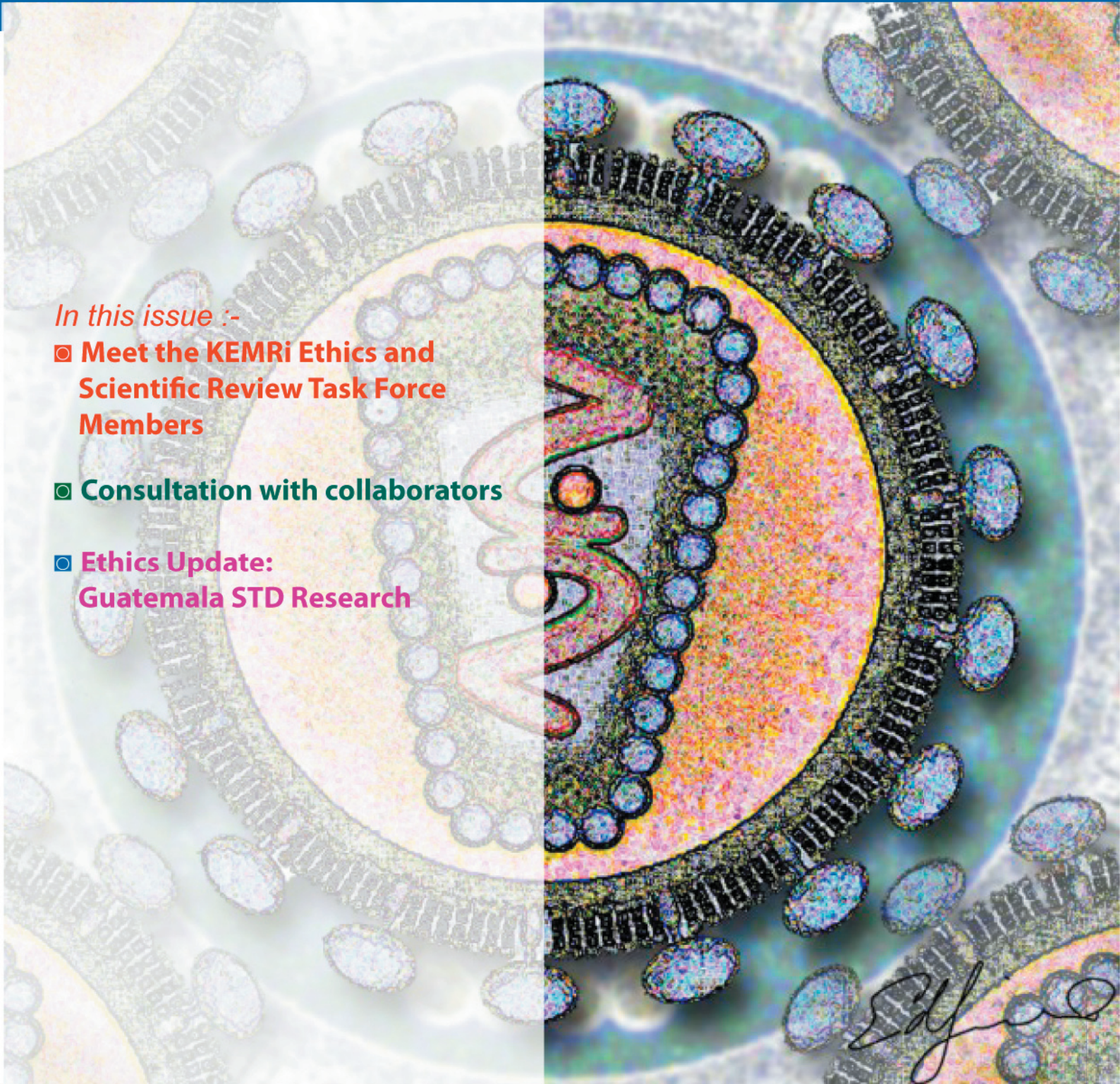
# Kemri BIOETHICS REVIEW



Volume 1, November 2011

*In this issue :-*

- **Meet the KEMRI Ethics and Scientific Review Task Force Members**
- **Consultation with collaborators**
- **Ethics Update: Guatemala STD Research**





## EDITORIAL COMMITTEE

Dr. Elizabeth Bukusi *Editor In chief*

Dr. Christine Wasunna

Dr. Kizito Lubano

Dr. Charles Obonyo

Ms. Caroline Kithinji

Mr. Mohamed Abdi

Ms. Everlyne Ombati

Welcome to the first issue of the *The KEMRI Bioethics Review*, a Kenya Medical Research Institute quarterly electronic publication on Bioethics. *The KEMRI Bioethics Review* is about cutting-edge bioethics. The main objectives of this newsletter are to promote human dignity as the foundation of bioethics; to provide high-quality, up-to-date information; and to facilitate the participation of researchers and scientists within and outside the Institute in ethics and policy debates.

KEMRI is a state corporation established through the Science and Technology (Amendment) Act of 1979, as the national body responsible for carrying out health research in Kenya. It is charged with the responsibility of: conducting biomedical research; collaborating locally with other organizations and institutions of higher learning in training programs 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 of Public Health and Sanitation, and the National Council for Science and Technology on matters pertaining to research policies and priorities.

KEMRI has grown from its humble beginning 32 years ago to become a regional leader in human health research. The Institute currently ranks as one of the leading centres of excellence in health research both in Africa and globally. The Institute collaborates with other relevant organizations within and outside Kenya in the furtherance of its mission *"In Search of Better Health"*.

The volume and complexity of research conducted at KEMRI has significantly increased in recent years. As a consequence of this desirable growth, the current review systems for facilitating conduct of research have experienced persistent constraints arising from lack of adequate capacity to process an increased number of research proposal submissions. To address this challenge, it has become necessary to restructure and expand our office facilities, strengthen the secretariat staff, and services to enhance efficiency and to ensure ethical and competent review of protocols submitted to the Institute.

KEMRI expects that the research it supports will be of high ethical standards. To this end, an efficient regulatory system that sustains and encourages good ethical practice in biomedical, clinical, behavioral and social research within the institute is highly desirable. Furthermore, the growing range and sophistication of research requires a regulatory framework that will make ethical requirements more explicit and provide a frame of reference for new and established researchers in social sciences, interdisciplinary research involving social science, biomedical and clinical research. The framework will improve quality, access,



consistency, efficiency, and capacity for ethical review of research involving human subjects.

To respond to this need, KEMRI has established an Ethics and Scientific Review Task Force to review the current scientific and ethical review system. The Task Force will oversee the process of revolutionizing the regulatory process at KEMRI, transform communication system between the regulatory committees and scientists, build capacity for scientific review of diverse portfolio of research, expand ethics education training for research, and improve on timelines for protocol turnaround.

This is indeed an exciting time for KEMRI. My special thanks go to the entire KEMRI scientific fraternity for maintaining a competitive edge in human health research, and to the new leadership endowed with enormous energy, excitement, and ideas—a desire to make things happen and to hit the ground running. I have no doubt the newly appointed Ethics and Scientific Review Task Force will act quickly and professionally on a broad spectrum of issues on bioethics—each one of monumental proportion, toward an efficient scientific and ethical review system in KEMRI.

Strengthening the ethics regulatory systems is key to scientific development of any research institute. As we now live in an interconnected world where human dignity is often threatened by the lack of basic health necessities, each one of us should contribute towards mitigating this threat. The KEMRI Bioethics Review is pleased to be your regular source of information on this exciting journey. I wish you all an enjoyable reading.

Solomon Mpoke, PhD  
Director,  
**Kenya Medical Research Institute**

How to contact us:  
The KEMRI Bioethics Review  
ADILI-The KEMRI Bioethics Center  
P.O. Box 54840-00200  
Nairobi,  
Kenya  
[bioethics@kemri.org](mailto:bioethics@kemri.org)  
<http://www.kemri.org>

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## Word from the Chair of the KEMRI Ethics and Scientific Review Task Force

### Dr. Elizabeth Anne Bukusi

On behalf of the KEMRI management, I feel honored to have the opportunity to chair a highly motivated and dedicated Task Force team who have been working relentlessly for the last ten months to oversee the restructuring of the research regulatory process and to spearhead the implementation of a new, improved, and efficient system within the Institute. It is my pleasure to welcome the team and you, the reader, to this first edition of *The KEMRI Bioethics Review*.

The vision of the Review Task Force is to build capacity in ethics training for both members of the ethics review committees and for investigators at the Institute. The aim is to establish an independent bioethics unit at KEMRI and ensure that it is appropriately staffed, trained, resourced, and entrenched within KEMRI's structures to oversee efficient research regulatory processes at the institute. This will be achieved by:

- Creating an independent bioethics unit at KEMRI charged with the responsibility of conducting an institute-wide audit of the current ethics review system to understand the challenges faced by different players. The bioethics unit will be established in consultation with collaborators who have expertise in running independent bioethics units and multiple committee models of Institutional Review Board (IRB) review. A survey will be conducted to collect comprehensive information that will guide the restructuring of the ethical review process. Consensus will be built by developing a proposal (board paper) to submit to the KEMRI board of management seeking to establish the bioethics unit. Once approval is obtained from the board of management, the bioethics unit will be established within the Institute to oversee the ethical review process. Review guidelines for the committees will also be developed
- Improving communication by setting up an electronic review system to expedite and improve efficiency for submission and review of protocols. This will enhance timely submission of protocols, reporting and communication.
- Building capacity for scientific review in the Institute by promoting ethics education, training of research scientists and the current IRB members within KEMRI and the graduate students, as well as

instructing reviewers on how to conduct specialized review of highly complex protocols.

To realize our goals the objectives of the task force are as follows:

- To suggest appropriate and feasible restructuring of the ethics and scientific review mechanism, including setting up of a unit to perform this function.
  - To comprehensively review the adequacy of the current research regulation system within KEMRI for processing the current work load and make recommendations.
  - To build consensus within the Institute for any changes proposed.
  - To initiate and coordinate the implementation of approved changes.
  - To make any other recommendation that will help improve ethics and scientific review mechanism in the Institute.
  - To suggest possible methods of increasing capacity for scientific and ethics review including training.
  - To raise funds for the implementing changes and suggest ways of sustaining any suggested changes
- I encourage you to support the growth of this newsletter. Submit an article, a commentary, questions, or news briefs for our next issue so that the *KEMRI Bioethics Review* can continue to deliver high quality work. Until then, enjoy your copy of the KBR.

## Meet the KEMRI Ethics and Scientific review Task Force Members



**Dr. Elizabeth Bukusi** is a Chief Research Officer and the Deputy Director Research and Training in KEMRI. Her primary areas of interest in research focus on sexually transmitted infections, reproductive health, and HIV prevention, care and treatment. In 1995, she established the Research Care and Treatment Program (RCTP) at the Kenya Medical Research Institute (KEMRI) in collaboration with Dr. Craig Cohen (UCSF). In addition to conducting research, the goal of the program is to enhance local capacity to conduct socio-behavioral and biomedical research and provide HIV care through training and infrastructure development. In addition to her substantial experience in conducting research in Kenya as well as providing HIV care, mentoring and

training different cadres of health care and research personnel, she has an interest in ethics and the development of systems and structures for regulation of research in the Institute and the country. She chairs the Scientific Steering committee (SSC) at KEMRI and oversees of scientific regulation at KEMRI. She has served on the MIRA (Diaphragm) study and the CAPRISA 004 DSMB study and currently chairs the Kenya HIV AIDS Research Coordinating Mechanism (a committee of the National Aids Control Council). She also serves on the WHO Department of Reproductive Health Scientific Technical Advisory Board (STAG).



**Caroline Kithinji** is the KEMRI/ERC Assistant Secretary/Administrator. She is also the joint Secretary of the Taskforce that has been put into place to oversee the formation of a review system at KEMRI to meet the challenge of the increased complexity and number of research proposals submitted for scientific and ethical review.

Caroline is a trained scientist with a BSc in Zoology and Biochemistry and a Masters in Medical Parasitology from the University of Nairobi and the London School of Hygiene and Tropical Medicine, respectively. She undertook a one year course in Bioethics that included a six month period to carry out a practicum at the Johns Hopkins School of Public Health. Caroline is very passionate about 'informed consent documents', particularly their length, readability and the accurate translation.



**Dr. Norbert Peshu** is a Chief Research Officer at the KEMRI Centre for Geographic Medicine Research - Coast (CGMR-C). He is also a PI in one of the largest collaborative research program which is a collaboration between KEMRI and The Wellcome Trust.

Over the past four years he has been involved in a collaborative HIV/AIDS research and care programme between KEMRI/IAVI and University of Washington, which has resulted in the establishment of the comprehensive care and research Clinic at Kilifi District hospital and the establishment of HIV/AIDS/STI clinic in Mtwapa. These two facilities have had a major impact on the care and preventive services

towards HIV/AIDS in Kilifi District.

He is a member of the KEMRI Scientific and Publication Committee and has served as a member of Data and Safety Monitoring Board in two vaccine studies in Kenya. He also serves as a member of Kilifi District Health Management Board.



He has attended training in Research Leadership, Management and Ethics. He is a member of the working group for UNAIDS/WHO guidance on research ethics in biomedical HIV prevention trials and the UNAIDS/AVAC guidance on good participatory practices.

Dr. Peshu is also member of the KEMRI Internal Research Grants Awarding and Management Committee; the data and safety committee of LEAP study (Leishmaniasis study); and the KEMRI Ethics and Scientific Review Task force.



**Dr Sammy M. Njenga** is the Director of Eastern and Southern Africa Centre of International Parasite Control (ESACIPAC) at Kenya Medical Research Institute (KEMRI). He is also the Secretary of KEMRI Scientific Steering Committee (SSC).

He obtained a BSc (Hons) degree in Zoology and Biochemistry from University of Nairobi in 1990 and then joined KEMRI in 1991 as a Research Assistant. He successfully competed for Indian Council for Cultural Relations (ICCR) MSc Scholarship Award, through Kenya's Ministry of Education in 1995 and proceeded to Guru Nanak Dev University, Amritsar, Punjab. He was awarded an MSc (First Division) degree in Molecular Biology and Biochemistry in 1997 and returned to

KEMRI where he participated in lymphatic filariasis research. He was nominated for Bill & Melinda Gates Foundation PhD Scholarship Award, through Lymphatic Filariasis Support Centre, Liverpool, UK in 2001.

Dr Njenga registered for PhD at the Liverpool School of Tropical Medicine and conducted research studies on lymphatic filariasis in Malindi district, Coastal Kenya. He was awarded a PhD degree in 2005. Since earning his PhD, Dr Njenga has successfully competed for several research grants on Neglected Tropical Diseases (NTDs). In November 2008, he was awarded a prestigious postdoctoral fellowship by European Foundations Initiative for NTDs (EFINTD) to conduct research on schistosomiasis, soil-transmitted helminths, and lymphatic filariasis in Kwale district, Coastal Kenya. He is often invited by World Health Organization (WHO) as Temporary Advisor at NTDs technical consultative meetings. He has published widely in peer-reviewed journals.



**Christine Wasunna** is a Senior Research Officer at the Centre for Clinical Research, KEMRI and a member of the Biotechnology Research Programme. Dr Wasunna is broadly interested in understanding the genetic and environmental contributions to variation to susceptibility to diseases.

She is the Assistant Secretary to the Ethics Review Committee and to the Scientific Steering Committee. Since 2006, Dr. Wasunna has focused her attention on biomedical ethics, human subjects' protections, and has expertise in the ethical conduct of human investigations specializing in genetic studies of African populations. She is currently a member of MALARIAGEN's International Data Access Committee and Secretary for two regional networks: Network for Ethics

Review Committees and Regulatory Authorities in East and Southern Africa and the Africa Research Ethics Network.

Dr Wasunna has also been instrumental in the establishment of the National Clinical Trials Registry through partnership with the Pharmacy and Poison's Board, Kenya. As a member and Secretary of the Task Force, she has participated in the development of the data collection tools for the evaluation of the current review system and proposed models for managing research proposals from pre-approval to post-approval so the SSC and ERC secretariat can keep up with the increasing submission activity.



**Dr. Gerald M. Mkoji**, Chief Research Officer and Assistant Director (Training and Communication) at KEMRI, is a parasitologist with expertise in schistosomiasis and other snail-borne parasites, with special interest in schistosome epidemiology, control strategies, diagnostics, snail biology. He has more than 20 years post-doctoral research experience, has written more than 60 scientific publications, has several years' academic experience involving teaching and mentoring graduate students, and 12 years of leadership and management experience. He has served as Director, Centre for Biotechnology Research and Development, KEMRI from 1999-2011 and as acting Deputy Director (Research & Training between 2009 and 2011. He has

also acted as the Chair for KEMRI's Scientific Steering Committee (2009-2011), and served as Secretary for Scientific Steering Committee (1999-2004), as Secretary for KEMRI's Publications Committee (1995-1997), and as Chair, KEMRI's Animal Care and Use Committee (1994-1997). He is currently the Chair of the KEMRI's Intellectual Property and Technology Transfer Committee, and a member of KEMRI's Scientific and Ethical Review Task Force.



**Dr Charles Obonyo** is a Principal Research Officer at the KEMRI's Centre for Global Health Research (CGHR) based at Kisumu. He joined KEMRI in 1991 as a Clinical Officer and has risen through the ranks to his current position. In 1997, he completed a Master's Degree course in Clinical Epidemiology at Erasmus University at Rotterdam in The Netherlands and in 2006, obtained a PhD from Utrecht University in the same country. In 2001 he attended a 2 weeks training on Ethical Issues in International Health Research at Harvard School of Public Health, USA. Dr Obonyo has served as the Secretary for the Centre Scientific Steering Committee (2003-2006) at the CGHR. He has a keen interest in health research ethics and has attended several short courses on the same.

Besides research at KEMRI, Dr Obonyo is an Adjunct Associate Professor at the Great Lakes University of Kisumu (GLUK), a part-time Lecturer at the School of Public Health, Maseno University and also an adjunct faculty member for the Vienna School of Clinical Research. Dr Obonyo is the Chair of the GLUK Ethics Committee (since January 2010), and also serves as one of the two representatives for Sub-Saharan African on the Cochrane Developing Countries Network. He has co-edited a book on the Kenyan Malaria Program Performance Review and authored 20 research papers published in peer reviewed journals. His publications focus on severe pediatric malaria epidemiology, childhood vaccines, blood transfusion, antimalarial drug resistance, HIV-malaria co-infections, post-election violence and treatment of schistosomiasis. His current research interests include systematic reviews of health interventions, public health ethics, publication ethics and evaluation of new drugs for treating Malaria and Schistosomiasis. Dr Obonyo is a member of the Editorial Committee for the KEMRI Bioethics Review newsletter and also a member of the KEMRI Taskforce on Scientific and Ethics Review.





**Mr. Abdi** is the head of ICT department in the Institute. His duties and responsibilities include the development of ICT policies and strategies; coordination of all ICT programs and staff matters.

He holds a Bachelor of Science degree from Egerton University, Njoro, Kenya and a Master of Science degree in Computer Applications from Hohai University, Nanjing China. Mr. Abdi has a wealth of experience spanning over 15 years in project management and planning, training and development programs. He has attended numerous courses both locally and overseas on Strategic Planning and Management, Project Planning and Management and Strategic leadership development programs. He is also a member and a fellow of the Computer Society of Kenya and a Microsoft Certified Systems Engineer. Mr Abdi serves

as a technical expert in the KEMRI Ethics and Scientific Review Taskforce.



**Margaret Rigoro** is an Advocate of the High Court of Kenya and the Ag. Senior Principal Legal Officer, KEMRI who joined the Service of the Institute in November, 2007 as an Administrative Officer II in the office of Deputy Director (A&F) and mandated to advise on legal issues in the Institute. She has a Bachelor of Laws Degree (LLB Hons) from Moi University, Eldoret and a post-graduate diploma in Laws at the Kenya School of Law.. She has been exposed to research in case law and preparation of a hearing in both angles as a litigation and defense counsel, taking witness statements, client interviewing etc.

She was admitted as an Advocate of the High Court of Kenya in Nairobi and became a Member of the Law Society of Kenya in 2007. Subsequently, she was appointed on permanent terms in the Service of the Institute on

November 27<sup>th</sup> 2007 as an administrative Officer II in charge of Legal Affairs. In her line of duty, she performs the following duties;-

Advises the Director, KEMRI and the Board of Management on diverse legal matters, draft, review and witness legal instruments including research agreements, advice on employment matters, attend court and feedback to the director, offer legal opinion and ensure compliance with statute in the Institute etc.

She is a member of the following Committees of the Institute; Tender Committee, Procurement Committee, Gender Mainstreaming, Complaints handling and Management. She also sits in the Board of Management Meetings and offers advice on legal matters. Recently she attended a conference on National Health Stakeholders at the KICC.

She is ready and willing to assist the KEMRI Ethics and Scientific Review Taskforce to achieve its objectives based on her vast experience of over 4 years as an Advocate of the High Court of Kenya and association in this premier research set up.



**Dr. Geoffrey Rukunga** works as Chief Research Officer and Director of the Centre for Traditional Medicine and Drug Research, Kenya Medical Research Institute. He holds a PhD degree in Pharmaceutical Sciences from University of Strathclyde, Glasgow, U.K.

He has undertaken postdoctoral studies at different times at University of Hohenheim, Stuttgart, Germany; then University of Potsdam University, Germany and Tokushima University, Japan. Dr Rukunga is a Committee member in several KEMRI's Committees including the Scientific Steering Committee (SSC) and Publications Committees among others. He has served as a Secretary to SSC for three years.

Dr Rukunga has received research grants in his research work from many donors among them being: WHO/TDR, WHO/AFRO, Japanese International Cooperation agency (JICA) and National Council for Science and Technology and Wellcome Trust laboratories. Dr Rukunga is a lecturer at Institute of Tropical Medicines and Infectious Diseases (ITROMID) and also serves as a coordinator of Pharmaceutical sciences discipline in ITROMID. He has published 57 papers in peer reviewed journals and has written two books. In his research work he collaborates with International Research Institutes, Government Ministries, National Research Institutes Local Universities and Universities abroad.



**Dr. Kizito Lubano's** Mission is to improve maternal and child health through application of Science, technology and innovation blended with indigenous knowledge to achieve the best outcomes unique to each context.

He is a holder of Bachelor of Medicine & Bachelor of Surgery (MBChB); and Masters of Medicine (MMed) in Obstetrics and Gynecology degrees from the University of Nairobi; Master of Science in Disease Control (MDC) from Institute of Tropical Medicine, Antwerp, Belgium; Diploma in Community-Based Management of HIV and AIDS from Galillee International Management Institute, Israel as well as various certificates in strategic leadership and policy analysis.

He is a career public servant who has worked in the Ministry of Health in various parts of Kenya, including hard-to reach areas in Suba District, Nyanza Province.

He has conducted extensive research in implementation, science and public policy with special interest in health systems and knowledge management and translation.

He is an honorary lecturer at the University of Nairobi, School of Medicine, Department of Obstetrics and Gynecology. He is a guest lecturer at the University of Nairobi Institute of Tropical Medicine and Infectious Diseases (UNITID). He has successfully supervised over 10 Masters students.

He is an honorary consultant at the Kenyatta National Hospital (KNH), Department of Obstetrics and Gynecology.

He is a Principal Research Officer at the Kenya Medical Research Institute (KEMRI) and the Head of Department of Planning, Monitoring & Evaluation.

He serves as the National Coordinator for the Regional East African Community Health-Policy Initiative (REACH-PI), an affiliate of the East African Community (EAC) whose mission is to Access, Synthesize and package Research findings into user-friendly formats such as policy briefs.

Dr Kizito is a member of the Editorial Committee for the KEMRI Bioethics Review newsletter and also a member of the KEMRI Taskforce on Scientific and Ethics Review.





**Anne Wang'ombe** is an Assistant Director (Human Resources) in KEMRI. She joined the Institute in February, 2011. She is currently pursuing a PhD in Human Resources Management at Jomo Kenyatta University of Agriculture & Technology and a holder of a Master Degree in Education Administration and Planning (University of Nairobi), Bachelor's Degree in Education (Kenyatta University) and a Diploma in Human Resource Management (Kenya Institute of Management).

She is also a part-time lecturer at Kenya Methodist University.

She is member of the ADILI task force and has a keen interest in Health Research Ethics. She is also a member of the Staff Housing Committee and Top Management Team. She is planning to undertake a post graduate degree in Bioethics.

## Members of the Task Force Visits UCSF

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Building on the long-standing research collaboration between the University of California, San Francisco (UCSF) and KEMRI, two members of the Task Force, Dr. Gerald Mkoji and Dr. Christine Wasunna, visited UCSF's Human Research Protections Program (HRPP) office between 1st and 2nd December 2010, before the official start of the ADILI project. The purpose of the visit was to:

- a) Identify common themes between the KEMRI ERC and UCSF CHR review process;
- b) Identify differences in the review processes;
- c) If appropriate, propose ways of adopting practices identified at the UCSF CHR that would ensure that research participants are continually protected from the potential risks but to enhance efficiency, consistency, dependability and the quality of the review process.

The two Task Force members met with the following key people at UCSF: John Heldens (Director Human Research Protection Program [HRPP]), Richard Wagner (HRPP Associate Director), Lisa Denney (HRPP Assistant Director – Quality Improvement Unit), Karen Chao (Coordinator – Laurel Heights IRB), Elizabeth Mendelsohn (Coordinator – SFGH IRB), and Melanie Mace (Education Coordinator).

From the visit it was clear that the KEMRI could

significantly reduce the administrative burdens of scientific and ethical review by:

- a. Expanding the number of the ethics review committees to match the scope and types of research undertaken in the Institute;
- b. Reorganizing the SSC and ERC secretariat
- c. Investing in an electronic information management and tracking system
- d. Training and supporting ERC and SSC members
- e. Identifying areas of improvement at the earliest opportunity and taking whatever corrective action may be warranted.

After this visit, the two Task Force members attended a joint grantees meeting of the program to enhance NIH-supported global health research involving human subjects and international research ethics curriculum and career development. All grantees for the NIH/FI grant gave an overview of the activities in their proposed projects. There were presentations from Latin America, Asia, Eastern Europe, Africa, and the NIH/FIC. The KEMRI-UCSF project was presented by Dr. Gerald Mkoji. The title of the presentation was “Restructuring and Building Capacity for Ethics Review at KEMRI”



# John Heldens Visits KEMRI



*Everlyne Ombati, Elizabeth Bukusi, with John Heldens and Abdi Mohamed*

John Heldens, the Director of the Human Research Protection Program at the UCSF recently visited KEMRI between June 26th and June 30th for the first time to familiarize himself with the ethical review process at the Institute. John has a background of more than 20 years in human subjects' protection and review. He is a certified clinical research professional. During this visit John met with the KEMRI Director, Dr. Solomon Mpoke; the Deputy Director Research & Training Dr. Elizabeth Bukusi; Deputy Director Finance and Administration Ms. Linah Boit. He also held discussions with the KEMRI Center Directors within Nairobi, who included Dr. Festus Tolo representing the Director Center for Traditional Medicine and Drug Research (CTMDR), Dr. Kimani Gichuhi of the Center for Biotechnology Research and Development (CBRD), Dr. Manduku of the Center for Clinical Research (CCR), Dr. Fred Okoth of the Center for Virus Research (CVR), Dr. Benjamin Ngugi representing the Director Center for Microbiology Research (CMR), Dr. Yeri Kombe of the Center for Public Health Research (CPHR), Dr. Evan Amukoye of the Center for Respiratory Disease Research (CRDR), and Mr Mohammed Abdi the Head Information Technology Department (ICT).

John's visit is in line with the Institute's vision of building capacity in research ethics for both members of the ethics review committees and for investigators

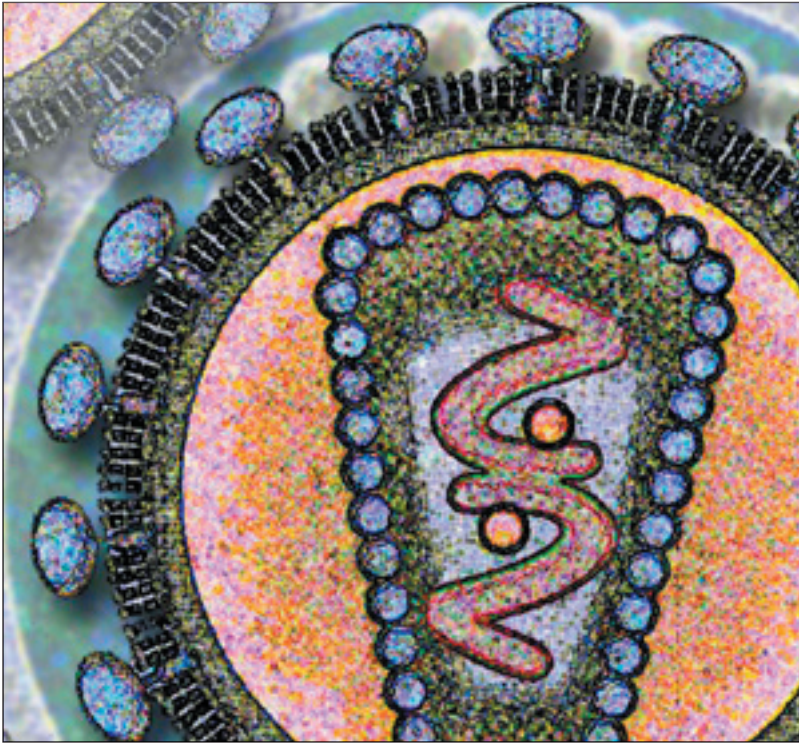
at the Institute with the aim of establishing an independent bioethics unit at KEMRI. As the Institute is in the process of overhauling, restructuring and developing an electronic system that is database-driven to improve timelines in submission of protocols, reporting and communication the ethics review process, it seeks to partner with collaborating institutions with experience in such systems, e.g. the Committee for HRPP at the UCSF and the recently

launched integrated Research Information System (iRIS) system (<http://cbe.ucsf.edu/announcements/projects/imedris.html>). During his visit John briefed the Institute about the ethical review system in UCSF, which uses the iMedRIS system, a Web-based system that enables online application submission, real-time submission tracking, review, post-approval compliance activities, and data management. The system also functions as a document repository, providing investigators with easy access to submission records and study documents.

Similarly, the electronic submission and review system that the Institute is in the process of developing, will have a user-friendly electronic interface that guides users directly to the relevant information and documents (templates for reports or forms), thus providing a timely, easily updated and easily accessible resource for investigators. The system will enable the uploading of protocols and key documents including CVs of key personnel. Security systems will ensure that only appropriate staff at the bioethics unit can download and print the documents for distribution for review. The system will also allow for electronic sending of letters to the principal and key investigators in a timely manner. It will also enable the bioethics unit to keep accurate records of dates of submissions, responses and of submissions of amendments or other relevant reports and communication with the ERC.

The ADILI project team would like to acknowledge the UCSF for invaluable support during John's visit, and the KEMRI Center Heads who hosted him during his visit to the Institute. In addition all the other KEMRI staff that made John's visit worthwhile are recognized and greatly appreciated.

# Guatemala STD Research



experiments there—these doctors also were morally culpable: they knew there was a moral requirement to obtain informed consent. But they chose not to ask for it in Guatemala. And they went to great lengths to keep their experiments as secret as possible while still obtaining funding from higher-level authorities who should have disapproved the experiments.

The original plan for the Guatemala experiments—what Dr. Cutler argued brought them to Guatemala initially—was to test the orvus-mapharsen prophylaxis wash as a prophylaxis for syphilis in prisoners exposed to infected commercial sex workers. The purpose was to develop more effective preventative tools for U.S. military personnel. This experiment never happened. Instead, the researchers faced difficulties in diagnosing syphilis, reliably

inducing infection (through the use of commercial sex workers), and procuring a compliant subject population. The experiments, upon review, appear to lack logical progression: baseline experiments for background infection rates were conducted after prophylaxis experiments began and new experiments were started before the results for

pilot experiments were known. Intentional exposure experiments began in the Guatemalan Army and focused almost equally on efforts to infect as efforts to test a prophylaxis for gonorrhea. As in Terre Haute, the researchers never mastered a technique with which to infect subjects.

It is clear that that Guatemala experiments were morally wrong, and although some individuals are more blameworthy than others, the blame for this episode cannot be said to fall solely on the shoulders of one or two individuals. The unconscionable events that unfolded in Guatemala in the years 1946 to 1948 also represented an institutional failure of the sort that modern requirements of transparency and accountability are designed to prevent. Institutions are comprised of individuals who, however flawed, are expected to exercise sound judgment in the pursuit of their institutional mission. This is all the more true and important when those individuals hold privileged and powerful roles as professionals and public officials. One lesson of the Guatemala experiments, never to take ethics for granted, let alone confuse ethical principles with burdensome obstacles to be overcome or evaded, is a sobering one for our own and all subsequent generations. We should be ever vigilant

From 1946-1948, a team of medical researchers, headed by Dr. John Cutler, in the United States Public Health Service intentionally infected more than 1,300 Guatemalan prison inmates, psychiatric patients, commercial sex workers and soldiers with sexually transmitted diseases. The team also used children in diagnostic testing. Done completely without consent, their experiments resulted in a living hell for many of their subjects.

The Guatemalan project was co-sponsored by the U.S. Public Health Service, the NIH, the Pan American Health Sanitary Bureau (now the Pan American Health Organization) and the Guatemalan government.

The researchers apparently were trying to see if penicillin, then relatively new, could prevent infections in the 1,300 people exposed to syphilis, gonorrhea or chancroid. Those infected included soldiers, prostitutes, prisoners and mental patients with syphilis. The ages of subjects involved in the exposure experiments ranged from 10 to 72 years, with the average subject being in his/her 20s. Only about 700 of those infected received some sort of treatment. Eighty-three people died, although it's not clear if the deaths were directly due to the experiments.

The researchers were unusually unethical, even when placed into the historical context of a different. They violated the ethical standards not only of our time but also of theirs. As is evident by the fact that just a few years earlier they obtained the informed consent of prisoners in Terre Haute, Indiana before conducting



to ensure that such reprehensible exploitation of our fellow human beings is never repeated.

### References:

1. **The Guardian:** Shocking new details of US STD experiments in Guatemala Fresh revelations about 1940s medical tests come to light, including deliberately exposing people to sexually transmitted diseases: <http://www.guardian.co.uk/world/2011/aug/30/guatemala-experiments>. Accessed on 12th October 2011
2. **Amy Gutmann (2011).** Ethically Impossible. <http://blog.bioethics.gov/2011/09/13/ethically-impossible/> Accessed on 12th October 2011
3. “Ethically Impossible” STD Research in Guatemala 1946 to 1948: Presidential Commission for the Study of Bioethical Issues, September 2011

### WIT CORNER!

*Members of the Task Force and SSC/ ERC secretariat are not eligible to answer*

**A prize is offered to the first 3 correct answers sent to the email [DDRT@kemri.org](mailto:DDRT@kemri.org)**

1. What is the first point of submission for a protocol
2. What does SSC stand for? Name at least five members of SSC (Give names)
3. What does ACUC mean?
4. Who is the Chair of ERC
5. How many members are there in ERC

### Acknowledgement

ADILI-The KEMRI Bioethics Center is a Project funded by the following partners:

- A Capacity Building Grant for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards from the European and Developing Country Clinical Partnership (EDCTP), Project Code: CB.2010.41302.016
- International Research Ethics Networks for Southern Africa (IRENSA), a Fogarty International center supplementary grant through the University of Cape Town (UCT), Contract No 3R25TW006057-08S2 and;
- NIH stimulus grant via the University of California, San Francisco (UCSF), Grant No. 1S07TW008843-01

We would like to express our sincere gratitude to all of our collaborators and donors. Your support will enable help in the training and capacity building for Bioethics within KEMRI



### 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. (The editorial staff reserves the right to edit submitted items).