INAUGURAL BIOETHICS SOCIETY OF KENYA CONFERENCE

SCIENTIFIC REPORT

DECEMBER 16TH -17TH 2015

KENYATTA UNIVERSITY CONFERENCE CENTRE
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<td>BSK</td>
<td>Bioethics Society of Kenya</td>
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<tr>
<td>CAB</td>
<td>Community Advisory Board</td>
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<td>CE</td>
<td>Community Engagement</td>
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<td>CFR</td>
<td>Code of Federal Regulations</td>
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<td>CLG</td>
<td>Community Liaison Group</td>
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<td>CPD</td>
<td>Continuing Professional Development</td>
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<td>DNA</td>
<td>Deoxyribonucleic Acid</td>
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<td>ERC</td>
<td>Ethical Review Committee</td>
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<td>EVD</td>
<td>Ebola Virus Disease</td>
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<td>GE</td>
<td>Genetic Engineering</td>
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<td>GMOs</td>
<td>Genetically Modified Organisms</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>KCR</td>
<td>KEMRI Community Representatives</td>
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<td>KEMRI</td>
<td>Kenya Medical Research Institute</td>
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<td>KWTRP</td>
<td>KEMRI Wellcome-Trust Research Programme</td>
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<td>MTRH</td>
<td>Moi Teaching and Referral Hospital</td>
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<td>NACOSTI</td>
<td>National Council for Science, Technology &amp; Innovation</td>
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<td>PI</td>
<td>Principal Investigator</td>
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<td>PPB</td>
<td>Pharmacy and Poisons Board</td>
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<td>RAs</td>
<td>Research Assistants</td>
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<td>RCTs</td>
<td>Randomized Controlled Trials</td>
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<td>RECs</td>
<td>Research Ethics Committees</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<td>TM</td>
<td>Therapeutic Misconception</td>
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<td>WHO</td>
<td>World Health Organization</td>
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ACKNOWLEDGEMENTS

This scientific report has been made possible by the efforts and contributions of various stakeholders, researchers and partners who supported the Inaugural Bioethics Society of Kenya Conference and the related document. We take this opportunity to express our sincere gratitude to all those who participated and supported the conference as well as the documentation process. We especially wish to thank:

- The Bioethics Society of Kenya Committee
- The Chief Rapporteur and all the rapporteurs of the conference
- All the researchers who presented their research work at the Conference
- Conference Secretariat
- All participants of the Conference.

We are also very grateful to the Chief Guest, Dr George Ombakho, Director for Research and Development at the Ministry of Education, Science and Technology for taking time out of his busy schedule to come and grace the occasion.

We further wish to express our sincere gratitude to the following institutions that provided invaluable support: Kenya Medical Research Institute, Moi University, Indiana University, and the National Council for Science and Technology.
FOREWARD

The Bioethics Society of Kenya successfully organized and hosted the inaugural Bioethics Society of Kenya Conference on 16th and 17th December, 2015. The conference theme was "Fostering Development of Bioethics in Kenya in the 21st Century". The conference provided a platform to share and disseminate information in the field of ethics. It was also provided a great opportunity for networking as this was the first time a conference specially dedicated to the field of research, clinical and bioethics was being held in Kenya.

The scientific report is an overview of the conference proceedings and has attempted to extract some of the scientific and technical aspects from the conference presentations.

The report has been structured based on the Scientific Programme of the Conference which was based on the following sub-themes:

- Bioethics and Culture
- Clinical Health
- Bioethics and Public Health/ Community Engagement
- Media and Ethics

The purpose of this report is to disseminate evidence and information from the conference proceedings with each section ending with recommendations that can be implemented at different levels and settings.

Prof. Elizabeth Bukusi,
Chair,
Bioethics Society of Kenya
EXECUTIVE SUMMARY

This conference was a culmination of the steady growth of this very young organization- BSK. It is a journey that began in 2012, when together, a group of professionals came up with the concept of Bioethics Society in Kenya. The journey has had its fair challenges but with the commitment and hard work of the founders, the Bioethics Society of Kenya is firmly on its feet.

The theme of the inaugural conference was “Fostering Development of Bioethics in Kenya in the 21st Century”. It was an opportunity for Kenyan professionals, passionate and interested in ethics, to come together and share and discuss work being done in this area. Bioethics is a growing field in Kenya, and this conference was a great first step towards accelerating its growth.

There was a rich array of presentations with the need for community engagement standing out as one of the key issues during this conference. Community research is a highly interactive process and proper structured community engagements will go a long way in ensuring that research is conducted in an ethical manner.

This conference also brought together members of various ethics review committees for the first time in Kenya. Of note, is a presentation from a survey conducted among members of ethics committees which highlighted some of the challenges being faced by ERCs in the country as well as recommendations for the way forward. The key note presentations also touched on a wide array of topics including genetic engineering as well as law and ethics.

This scientific report will serve as a way to ensure that the society will continue on the path of growth and establish itself as a force to reckon with, in matters of bioethics in Kenya and beyond.
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1. BACKGROUND/CONTEXT OF THE CONFERENCE

Kenya, being a developing country is facing the double burden of diseases; infectious diseases continue to impact the health of the population negatively, and non-communicable disease cases are on the rise. This situation means that more medical research will continue to be conducted within Kenya to help address these health problems. The double burden of disease also implies that the healthcare system will also be overburdened. More medical research and a strained health system are fertile breeding grounds for ethical challenges and dilemmas for both researchers and health providers. The Country is now in an era where in theory, there are mechanisms in place to regulate research, but implementing these practically has proven to be a challenge mainly due to the scarcity of resources. While more and more organs have begun to actively engage in research, the language of research ethics and bioethics remains a relatively foreign one to many researchers.

It has taken time for Kenya and indeed a large part of the African Continent to wrap its head around the concept of bioethics. This has been evident by the dearth of information on ethics and expertise to teach bioethics related curricula. Indeed, it is not surprising to find that many of the ethical guidelines in Kenya and Africa have been heavily borrowed from the developed countries that through history learnt the importance of conducting research ethically. However, with advances in technology and increase in knowledge, expertise as well as exposure, Kenya as a country is slowly realizing the need for proper systems for regulating research to ensure that it is conducted ethically. The establishment of a bioethics society is timely as it will provide the leadership needed at this budding stage of the field of bioethics in Kenya and help address the various ethical issues that keep cropping up across different fields.

Additionally, the existing research regulatory structures and teaching curriculum for bioethics in medical and public health schools may not adequately address every concern, through this and subsequent conferences, the hope is that there will be snippets of information and updates on the status of bioethics in Kenya, so that we can work together with concerned regulatory authorities and institutions to strengthening the role of bioethics in ensuring responsible conduct of research, quality healthcare provision and adequate ethics training of staff in the health sector. This conference was thus structured to provide a platform for healthy and enriching discussions among academicians, researchers and health practitioners for the benefit of bioethics growth in Kenya.
2. SUMMARY OF SCIENTIFIC PRESENTATIONS

2.1 KEYNOTE PRESENTATIONS:

A total of three (3) keynote presentations were made on community engagement, genetic engineering and ethical considerations for research on experimental products in an outbreak situation. A number of key messages and recommendations arose from the keynote presentations:

1. **How should Research Ethics Committees review the ethical merit of community engagement?**
   
   By Jim Lavery, PhD - Human Evidence Lab, St. Michael’s Hospital, Dalla Lana School of Public Health, University of Toronto

   **Key Messages:**
   
   - Community engagement (CE) has had an uncertain status in global health and public health research and is important in helping researchers establish a relationship with stakeholders but little work has been done to explore this area even though it has something to do with ethics.
   - Traditional research ethics are effectively at odds with clarifying and mainstreaming better thinking about CE.
   - Community engagement raises complex ethical questions that are not adequately addressed in existing research ethics guidance and addressing them will require a new set of concepts and ideas and interactions among funders, investigators and host communities.
   - The harm of disregard involves failing to acknowledge stakeholders as people, to recognize and acknowledge that people have interests, assuming that certain people/interests are less worthy of acknowledgement and engagement and failing to engage with individuals or groups that have relevant interests.
   - The growing attention to CE offers an important opportunity to extend our understanding of the ethics of research with human beings beyond the concerns of individual research participants.

   **Recommendations:**
   
   1. There is need for a coherent way to assess the contribution and implications of community engagement strategies to the ethics of research with human beings.
   2. Research Ethics Committees can play a significant role in this process, but need to be willing and able to embrace new ways of thinking about the ethics of research.

2. **Ethical Issues in Genetic Engineering**
   
   By ZulPremji, Aga Khan University Hospital

   **Key Messages:**
- Genetic engineering (GE) is on the brink of handing us the key to our own creation, of giving us the power to redesign ourselves. Though it is beneficial in many aspects like new products to improve health, potential to increase food production, GE can non-intentionally be intentionally hazardous and can be misused by overzealous scientists.

- Although genetic tests for certain diseases have been available for two decades, the completion of the Human Genome Project has certainly lead to an exponential increase in the number of genetic tests available and this renewed concern on genetic test controversies. Main questions at the heart of the controversy include:
  - When should genetic testing be used?
  - Who should have access to the results of genetic tests?
  - Should genetic tests be used only for treatable diseases?
  - Should individuals have the freedom to decide who has access to their test results?

- There are concerns that we have consciously interfered with evolution through breeding and though nothing bad has happened so far, there is a fear that scrambling genomes will lead to total chaos in evolution.

- GE exposes people to the increased dangers of horizontal gene transfer and does involve some risk taking but all procedures are subject to strict risk analysis and monitoring. GE is potentially dangerous and therefore involves taking risks. The consequences of which may occur slowly could be devastating and irreversible.

- Though GE is a scientific and technological process, and its evaluation and governmental regulation should be based on purely scientific and objective criteria; however, purely scientific assessment of aspects like GMOs ignores the fact that, for many people, food has cultural, ethical and religious dimensions that must also be considered.

- The unpredictable disruptions in normal DNA functioning can produce unanticipated and unknown side effects for human health like allergies, antibiotic resistance and production of new toxins. There are also concerns about the effects of genetic engineering on the environment and its threat to biodiversity. It can only be definitively assessed through human testing.

**Recommendations:**

1. In debating the ethics of genetic engineering it is essential to develop an appropriate ethical framework for this new and powerful technology which can literally transform not just human life but life itself. This will demand a major shift away from the almost exclusively human or homocentric focus which has been so pervasive in the past.

2. **Question: How do we handle bioethics in relation to mental health/disorders?**
   **Response:** Mental health participants should have an assessment done on them to determine their cognitive capability for their inclusion in a study. The science of mental health is difficult and is developing hence in time there will be evidence to stand the robust of scientific evidence. The consenting on mental health issues should be documented since there are ways in which people/researchers do it out there that needs to be captured in the consenting process.

3. There is need for policies on genetic engineering that are consumer centred and take religious and cultural concerns into considerations.
3. Ethical Considerations in Use of Experimental Products during Outbreaks

By Prof. Edwin Were, Moi University

Key Messages:

- REC’s need to consider the use of experimental or unregistered productions within clinical trials and in the context of emergency situations like the Ebola Virus Disease (EVD) outbreak in terms of post-trial access before registration of products of proven efficacy and safety.
- “Emergency use” of unregistered products is allowable alongside properly designed trials to generate more generalizable data and is also referred to as “Compassionate Use” or “Expanded Access”.
- Properly designed Randomized Controlled Trials (RCTs) are premised on equipoise, equal chances of being randomized to the intervention product or comparator and clear stoppage rules.
- Some of the challenges of doing research during outbreaks include:
  - Outbreaks usually time limited and other related conditions rare.
  - Timeliness of review process
  - The condition may be associated with high mortality and have no proven therapeutic intervention
  - Research may divert resources from critical clinical care – worse in resource constrained settings
  - The choice between disease with high mortality and product with unproven efficacy and uncertain safety
    - Threat to clinical equipoise
    - Compromised consent process
  - Study design that does not engender therapeutic misconception
- Even though RCTs are usually the gold standard, it may be unethical not to use experimental products if animal studies show safety and potential efficacy and use of controls may not be acceptable since it denies some participants access to a potentially effective product.

Recommendations

1. Trials should be designed and conducted with the active participation of local scientists and researchers, and with proper consultation with communities and local ethics committees.
2. Community engagement prior to and during the conduct of a trial is an ethical requirement.
3. Some of the ethical considerations during outbreaks include:
   a. Community engagement
   b. Access to experimental product
   c. Ensuring scarce care resources are not diverted to research without adequate attention to treatment
   d. Consenting process
      i. The power differentials and valid informed consent
      ii. The concept of play-the-winner
   e. Participant safety amidst inadequate preliminary data
   f. Assessing efficacy in adaptive designs
4. Law and Ethics as applicable to Research with human participants in Kenya

By Mr. Ambrose Rachier, Lawyer & Chair, KEMRI Ethics Review Committee

The presentation is about regulation of research involving human participants by law or ethics and necessitates a look at the law and ethics regulating research generally and in Kenya. It also sought to define, distinguish and draw nexus between Law and Ethics.

Key Messages:

- It is important to distinguish between law and ethics where ethics is concerned with morals and the breach of ethical rules generally attract disciplinary action prescribed in a code, while the law does not concern morals and the breach of the law invites either civil or penal sanctions.
- Laws represent the minimum standards of human behavior, are universally accepted within its jurisdiction and are enforceable while ethical behavior goes much beyond the legal expectations.
- However, there are areas where the line between ethics and law is blurred; where the law enforces immorality/ unethical conducts for instance legalization of commercial sex work, homosexuality, euthanasia and abortion in some countries.
- Law and ethics has evolved over the years in relation to regulating research with human participants out of research scandals in the 19th and 20th centuries.
- The research scandals underscored the need to develop ethical standards to regulate the conduct of scientific research. Consequently ethical codes have emerged and these have been incorporated in the laws and/or regulations of many countries.
- International bioethics guidance instruments derive validity in Kenya through recognition and enforcement of rights arising under treaties or common law, incorporation in the constitution bill of rights, ordinary legislation and subsidiary guidelines.

Questions from participants

1. How do one view legitimacy of the use of common rule in other countries?
   Answer: Importation of CFR Part 45 and CFR Part 46 is used because of the existing vacuum in African countries and that the USA conducts a lot of research in other countries.

2. In your opinion, is it easier to have an Act of parliament for ethics regulation?
   Answer: An Act of parliament should give a framework for enforcement of ethics as a complement so as not to kill ethics.

3. What ethics arise where magistrates dismiss medical reports during court proceedings?
   Answer: Magistrates rely on the need for prosecutors to prove beyond reasonable doubt the legitimacy of the reports and their relation with the matter at hand.
4. **In regards to some section of constitution (Sec 4) to what extent can a patient have right as far as freedom of patients is concerned and what is the safety of medical practitioners?**

   Answer: Patients rights have been stated in ethics and medical practitioners are expected to comply with them.

5. **If a drug like the controversial Pearl-Omega was to turn out to be the cure for HIV, could the discoverer have been penalized?**

   Answer: It would be ethically acceptable because there will be no justification of how one got there and there is no compliance and ethical clearance.

6. **What is the intersection between law and ethics and is there a mechanism to prosecute rogue Principal Investigators (PIs) under the law?**

   Answer: There is no legal framework guiding the prosecution due to violation of ethical guidelines by PIs apart from stopping the research unless criminal case is filed.

**Recommendations**

1. There is need for an appropriate ethico-legal framework to ensure no investigator carries out research on human participants without scientific and ethical approval.
2. There is also need for institutional framework for monitoring and evaluation of already approved studies.
3. There is need to mesh ethics and law to make them work in a complementary manner.

**2.2 OTHER PRESENTATIONS**

There were several other presentations made, mostly under the conference sub themes.

**2.2.1 ENHANCING ETHICS REVIEW CAPACITY IN KENYAN ETHICS REVIEW COMMITTEES**

*Presented by Prof. Elizabeth Bukusi, Chair, Bioethics Society of Kenya*

This presentation highlighted the challenges facing HIV research in Kenya and presented the findings from a survey which was a key component of an exciting project on ethics review practices in Kenya that was being undertaken by a group of collaborators. The survey was consistent with the ethical concerns noted by the Kenyan National AIDS Control Council, Kenya HIV and AIDS Research Agenda in the National AIDS Strategic Framework and was distributed to the different Research Ethics Committees in the Country. The overall goal of the project was to respond to Kenyan-identified needs for enhancing efforts to respond to the ethical challenges that arise from the dramatic growth in HIV research. Some of the specific aims included identification and describing key structural, policy, and training impediments to ethics review in Kenya, with a focus on HIV studies, building a network of Kenyan ERCs to enable sharing of best practices, strategies, and research opportunities for improving ethics review in HIV research and other areas of health and piloting selected approaches for improving quality and efficiency of ethics review of multi-centre HIV studies in Kenya using an online collaborative environment, and to make recommendations for further refinement of these approaches.

IRB approval sought by Indiana University and Moi University and a total of 25 respondents from 17 IRBs participated in the survey.
Key Findings:

- There was a lack of expertise in administration or ethics/research ethics and the main areas of expertise were seen in basic science, health professional research and profession health services.
- Amongst the 17 ERCs, the average number of committee members was between 11 and 15.
- Out of 17 ERCs, 2 ERCs stated that they have more than one ERC that reviews research involving human participants.
- Out of the 17 ERCs that responded, 7 contain subcommittees and within those 7 ERC subcommittees there are an average of 2-3 subcommittees and an average of 1-5 members per subcommittee.
- All ERCs reported having access to a regular meeting room, a computer and printer, lockable cabinets and a reliable internet connection.
- Amongst all 17 ERCs, many have been conducting reviews on research involving Electronic medical records, participant surveys and biological specimens
- The majority of the ERCs have policies that involve issues such as reviewing multi-center protocols, expedited review, conflict of interest and ERC review with other institutions.
- Amongst the 17 ERCs, they typically completed the review process within 6-8 weeks.
- Challenges faced by many of the respondents related to organization, training/expertise, funding, and institutional support and a common issue amongst all the respondents was the lack of training and commitment from the ERC members.

Questions

1. What is the average amount of time taken for review?
   Response: The feedback from the RECs indicated 3 months, KEMRI for example had monitored the timeline and found out that on average a new protocol takes 5 to 6 months, however, this was dependent on how fast the PI responds. Currently, review at KEMRI takes approximately 8 weeks.

2. Is there a model that ensures committee reviewing science and ethics takes different times?
   Response: Using KEMRI as an example, the review of science before ethics took a long time but the Institute has managed to strengthen center level reviews, and combined scientific and ethical reviews. However, some universities may prefer different models.

3. Did you categorize the various proposals such as expedited and take into consideration the outcome of review?
   Response: The designers of the survey considered the responses but the questions centered around policies that guide different categories. KEMRI for instance, has specific policies for expedited where they benchmark at 5 days but this has to be appropriately justified.

Recommendations:

1. Improving the training protocol amongst ERC members
2. Other improvements related to enhancing organization of the ERC and providing compensation or token of appreciation to reviewers
3. A few respondents suggested an online review system and a network that enabled networking.

Feedback from small group discussions
Following the presentation, conference participants were divided into several groups and were requested to discuss some questions on the above mentioned topic. The following were some of the outcomes from the discussions:

1. **What challenges do ERC’s face in Kenya?**
   a. **Human Resource:**
      1. Training – Many ERC/IRB members lack the requisite technical capacity due to lack of formal training in research ethics with most having on the job training. There are also relatively few local institutions that offer formal training in research ethics. Locally and internationally, quite a number of training opportunities are short term and this might not be adequate to build capacity.
      2. Membership – There is lack of adequate numbers of people to serve on these IRBs since membership is voluntary. The variety of expertise in the ERCs is also not expansive and this presents a challenge where specific expertise for instance in health economics is needed from time to time.
      3. Incentives for review – There is little or no compensation (either monetary or otherwise) for review of applications even though the workload is quite high in many of the IRBs. Lack of recognition for time and effort given by reviewers especially those from within the institutions housing the ERCs is also a challenge as it leads to lack of motivation and low levels of commitment from reviewers.
      4. Lacks of staff – Many ERCs lack a supportive, well-resourced secretariat.
   b. **Infrastructure and technology:**
      1. Many ERCs lack proper offices with many having offices lacking office equipment including data cabinets and furniture.
      2. Lack of a proper standardized recording system for applications received.
      3. Many ERCs still lack the technology to handle online submissions with quite a number still doing manual reviews.
   c. **Financial:**
      1. Low budgetary allocations for ERCs both institutionally as well as at government level and this consequently affects operations.
   d. **Process:**
      1. Requirement for dual and sometimes multiple reviews by accredited ERCs locally and globally.
      2. Lack of standard quality of reviews across members within the ERCs and across the accredited ERCs. This leads to researchers shopping for ERCs where they can get easy approvals to avoid rigorous review.
      3. Long turn-around-time for protocol review brought about the constant back and forth as PIs try to address the concerns raised by the ERCs. This makes the review process tedious and has particularly proposals with set deadlines.
      4. Poor monitoring and evaluation of research studies.
      5. Instances of conflict of interest arising from the review process.
   e. **Legal:**
      1. Lack of legislation for what requires approval and what does not as well as what constitutes research and vice versa.
      2. Lack of a platform for common policy at government level.
3. Accreditation - The permit to conduct research in Kenya given by the National Council for Science, Technology & Innovation (NACOSTI) is often confused with ethical approval by the general public.

4. Lack of indemnity for decisions made by ERCs.

**f. Coordination and Networking:**

1. Weak linkage between the accredited ERCs hence there is no cross-sharing of information.

2. Different bodies still request information/data from ERCs despite these Committees providing NACOSTI with information/data – indicates lack of coordination.

2. What support do ERCs in Kenya need to do a good job of reviewing protocols?

a. *Training:* Training of ERC members and researchers
   i. Quarterly training fully funded by the host Institutes/organizations
   ii. Research ethics/bioethics should be integrated into university education in public universities so that individuals do not have to leave the country to study ethics.
   iii. A curriculum for short courses/certificate/diploma and degree programs/accreditation of certificates should be initiated

b. *Human Resource:*
   i. Provision of a well-resourced and functional secretariat.
   ii. Create a pool or hub of reviewers that includes reviewers from across all the accredited committees.
   iii. Increasing motivation and commitment from reviewers through proper reward system.

c. *Institutional commitment:* Ethics review committees could be put into the organogram of the institute and be included in the policies of the institute

d. *Legal:*
   i. There is need to have legal frameworks developed by the host institutes/organizations to defend decisions made by the committee.
   ii. There is need for improved oversight by NACOSTI on implementation of reviews according to their guidelines.
   iii. NACOSTI needs to support the independence of ERCs.

e. *Process:*
   i. There is need for a functional Standard Operating Procedure to guide and support ERC functions.
   ii. There should be standardization and harmonization of quality of review across the Ethics Review Committees.

f. *Financial:*
   i. The Regulatory Unit in each organization should be given a budget line to cover compensation for reviewers. Clinical/pharmaceutical studies could pay a fee for review.
   ii. Provision of financial support to supervise or monitor studies in the field.

g. *Networking and coordination:*
   i. Development of reliance agreements to minimize the dual review or replication of review.
Development of a central database for all research projects for ERCs.

**Infrastructure:** Improvement of infrastructure through provision of adequate office space, computers, data cabinets etc.

**Technology:** Digitalization of IRB systems.

3. **Is there a need for a monitoring system for approved protocols?**

   Yes, especially because most ERCs currently rely on reports from the investigators which may not be accurate. Additionally it is important to:

   a. To determine if studies actually begin.
   b. To determine if studies are in compliance and being conducted as per the protocol.
   c. To minimize plagiarism and duplication of research.
   d. To prevent data piracy.

4. **Is networking of ERCs necessary?**

   Yes, so as:

   - To make use of reliance agreements or central review.
   - To share information related to protocols under review and approved studies and minimize ERC shopping.
   - To provide a forum or platform for harmonization.
   - To provide opportunities for mentorship of the younger ERCs.

5. **What additional ethics concerns/issues would ERCs (or any other person) would like to have addressed at the policy/legal level**

   a. There should be a national policy that has the mandate to coordinate multi-agency approvals for e.g. A study that involves bats in the National park, animal and human subjects
   b. There is need for additional funding from the government for training and opportunities to work in bioethics.
   c. NACOSTI permit should require research ethics review and approval where applicable before studies are conducted.
   d. There is need look into research regulation at the county level and ways of coordinating research approval and permission in the devolved system of government.
   e. The current/existing structures of the ERCs need to be reviewed.

2.3 **SUB-THEME 1: BIOETHICS AND CULTURE**

   There were two presentations under the session for this sub-theme during the conference. One focused on gender negotiations for research participation for a researcher and the other one on the challenges of research regulation in Kenya from a university Professor.

   **1. Gendered Negotiations For Research Participation In Community Based Studies: Implications For Ethics And Health Research In Kenya**

      *By Dr. Dorcas Kamuya, KEMRI-Wellcome Trust Research Programme*

   **Key Messages**
1. There is an excessive reliance placed on international declarations and guidelines to explain and inform decision making during recruitment of research participants.
2. Where researchers target households, the stakeholders who make decisions in these households should be factored in during the consenting processes.
3. The male household members still have pronounced roles as they determine the risks/benefits of joining studies. However, the women/youth/minors do find ways to influence/subvert decisions made by their male(adult) counterparts(silent refusals).
4. In the informed consent process, the decision making process is influenced by, agency power, significant shifts in gender roles, migration, incoming technology, level of education, authority holders and cultural norms.

Recommendation

1. There is need for more time, clarification and information parity amongst the stakeholders during the consenting process mostly at the household level.

Questions

1. How should one handle Community vs Individual consenting?

Consenting is done on an individual basis. But the community leaders ought to be informed about the research before the research takes place, although the information should be filtered and given to different levels of the community from the leader to the individual, hence avoid crowding out.

2. What roles do IRB play in consenting process?

They approve the study if the language, is simple and understandable by the study participants.

2. Challenges in the Regulation of Biomedical Research: The Case of Kenya

By Prof. Moni Wekesa, Mount Kenya University

Key Messages

1. Inadequate and lack of proper oversight and regulation of research can lead to violation of human rights, abuse of local resources and lack of standardization of research protocols. This is evidenced by some of the historical events in research ethics.
2. In Kenya, The National Commission for Science, Technology & Innovation is mandated with general co-ordination of research and setting the research agenda. In this regard, they also accredit research institutes and approve all scientific research in Kenya.
3. There is an overlap in functions across the government agencies(KWS,KEMRI, NEMA etc) as there is no specific legal framework laid down to govern research in the country and this has led to the different bodies of government have the same roles eg. Incase of material transfer, one needs permission from NACOSTI, biosafety Authority, and NEMA etc.
4. There is a dearth of monitoring and evaluation resources to oversee sound research studies. NACOSTI mostly relies on self-reporting of accredited institutions.
5. The ever-evolving nature of science/research is such that there is insufficient information about the ever evolving technologies and this poses a challenge in accepting biomedical research in the country.

6. There is a higher likelihood for intellectual property theft/"poaching" especially for studies that have foreign investigators because the intellectual property rights are not well understood and a framework to manage this as stated in Article 11 of the constitution is missing.

**Recommendations**

1. There is need to harmonize various legislations to address the question of overlap
2. The issue of Monitoring and Evaluation of research studies needs to be addressed.
3. The Industrial Property Act, 2000, needs to be revised to accommodate matters of communal rights.

**2.4 SUB-THEME 2: CLINICAL HEALTH**

There were a total of five presentations under this sub-theme. These presentations revolved around clinical ethics and conducting clinical research in the community. The presenters included researchers, students and university professors.

1. **What they say and what they do—views of those who are taught and those who teach medical/clinical ethics in Kenya.**
   *By Prof. Elizabeth Bukusi, Kenya Medical Research Institute*

This was a qualitative study aimed at understanding issues around ethics and documenting the views of those who teach and those who are taught clinical ethics. 10 lecturers, 14 post graduate students and 35 medical students from Moi University and University of Nairobi participated in the study.

**Key Findings:**

1. Both universities had approved curricula for training medical doctors
2. Teaching of medical ethics was mainly theoretical
3. At both universities ethics is examined within the other core disciplines.
4. Teaching of medical ethics was unsystematic and inconsistent throughout academic years
5. Lecturers and students cited the curriculum contents as inadequate
6. There was a consensus that insufficient emphasis or attention was given to the teaching of clinical or medical ethics across the board
7. There was concern about the students not getting enough information on consequences or expectations in the medical profession as not enough was taught on the legal aspects of medicine.

**Recommendations:**

1. Teaching of medical ethics should incorporate sufficient theoretical and practical training
2. Ethics should be taught continuously from 1st year to the final year.
3. Universities need to identify and train lecturers dedicated to teaching medical ethics to advance ethics courses such as master or PhD in ethics.
4. Universities should consider evaluating medical ethics independently to enable the students put more effort towards understanding ethics.
5. Medical ethics should be part of Continuing Professional Development (CPD) points to facilitate training in ethics build and capacity in this area.

2. Therapeutic Misconception (TM) And Inappropriate Inducement Among Patients Participating In Clinical Trials At Moi University Clinical Research Center (MUCRC), Eldoret

*Presented by Mr. Alfred Koskei, Kabianga University*

This was a descriptive cross-sectional study conducted at the Moi University Clinical Research Center at Chandaria Chronic Disease center, MTRH Eldoret. The study targeted all active HIV/AIDS patients participating in trials and consented within the last one year and managed to recruit a total of 113 participants. Data was collected using interviewer administered questionnaires. An audit of the recruitment process of research was done focusing on previous history, methods to relay information and frequency of visits.

**Key Findings**

1. No internationally recognized method for determining TM and undue coercion. Data is also mostly qualitative
2. Medical research is confused to be equivalent to medical care
3. There is little or no knowledge on therapeutic misconception.
4. Patients assume that doctors have the best interest at heart.
5. Most patients consider a placebo as standard care of treatment.
6. Patients participate in studies for financial gain, to enjoy the free meals, to please the doctor and to receive free treatment which they can’t afford
7. Participants don’t know about the concept of randomization.

**Questions**

1. **What is the root cause of therapeutic misconceptions?**
Therapeutic misconception happens mostly in desperate situations exemplified by limited treatment options and in cases of inadequate recruitment procedures.
2. **At what stage of the study was there a mention of the placebo concept to the participants?**
The study involved already completed studies so I did not need to mention placebo to participants.

**Recommendations**

1. Recruitment procedures and rules need to be reviewed to minimize TM and undue coercion

3. **Ethical Issues raised by the 2014-2015 Ebola Outbreak in West Africa**

*Presented by Prof. Karori Mbugua, University of Nairobi*
The presentation focused on some of the ethical issues raised by the Ebola outbreak in West Africa including the ethics of quarantine, the use of unproven therapies during medical emergencies, prioritization of issuance of experimental drugs in an emergency setting, conflict between public health ethics and clinical ethics and the question of global justice in health.

Key Messages
1. Quarantine is an ethically controversial strategy to control the spread of epidemics as it undermines individual freedoms.
2. During the Ebola outbreak, the principle of distributive justice requires fair distribution of risks and burdens was not upheld as quarantine was only imposed in the poorer sections of Liberia.
3. The quarantine was imposed without the community’s consent.
4. The principle of reciprocity was not upheld as those confined were not provided with the basic necessities such as food and water.
5. The principle of least restrictive means was also not upheld as the police and army used unnecessary force to impose the quarantine.
6. It was difficult to tell whether the experimental drug used during the Ebola outbreak was effective because of lack of controls.
7. In Aug 14, 2014, WHO panel endorsed the use of unproven therapies on compassionate grounds. There are several grey areas in this endorsement inducing:
   a. Who will give consent for use of these therapies?
   b. Who has the responsibility of weighing risks and benefits?
   c. Who is to pay for the unapproved drugs?
   d. How will pharmaceutical companies indemnify themselves?
8. During epidemics, prioritization of health care workers in the provision of experimental drugs would exacerbate existing inequalities hence priority should be given to frontline care-givers i.e. those providing informal care at home e.g. relatives-who are at the most vulnerable.
9. The Ebola epidemic has brought to the fore the conflict between clinical ethics and public health ethics where the initial response to the crisis was largely individualistic and yet the epidemic was a public health tragedy.
10. Public health measures should have been given priority since in the face of an epidemic; issues of public safety outweigh individual rights.
11. Non-pharmaceutical public health measures should have been given priority during the outbreak.
12. The profit making nature of pharmaceutical companies makes Ebola an unattractive disease since it has fewer deaths than malaria, TB and diarrheal diseases. It therefore represents a small and unrewarding market.

Recommendations
1. Separate clinical ethics issues from public health ethics issues.
2. Focus more on prevention and containment but ensure that it is done in an ethical manner.
3. Address the problem of global health inequalities.
4. Focus on strengthening of health systems and basic infrastructure rather than experimental treatments.
5. Stem the tide of medical brain drain from resource poor countries to rich countries.
6. Governments should give incentives to companies doing vaccine research.
7. With globalization, infectious diseases have shown no respect for international boundaries.
8. Developed nations have a moral obligation and self-interest (i.e. self-preservation) in helping to fight infectious disease emergencies.

4. **What we have learnt with over a decade of engaging communities in Health Research: Experiences from a long term multi-disciplinary research institute based on the Kenyan coast.**
   
   Presented by Noni Mumba, KEMRI-Wellcome Trust Research Programme

The presentation was based on the experiences in a Kilifi based on a study conducted in 2001-2004 on community perceptions on KEMRI. Many positives arose especially on improvement of health of their children but the negatives are that there is little understanding on research.

**Key Messages:**
1. There has been increased emphasis on the importance of engaging communities participating in research due its intrinsic and instrumental value.
2. The KWTRP developed a communication strategy in 2005 through a consultative process and established a community liaison group to coordinate and implement community engagement.
3. Some of the challenges faced in the programme include having ethically “inappropriate” suggestions from community members, confusion between research and treatment and determining what aspects of their CE, consent activities and guidelines are relevant elsewhere.

**Lessons Learnt:**
1. Community engagement should be considered and planned as a long term process.
2. Views and voices of the community is a central facet of the entire engagement work.
3. CE requires buy-in by researchers, dedicated funding, and personnel.
4. Research ethics an integral part of CE.
5. CE implemented as an action plan with built in empirical research.

**Questions**
1. *How do you deal with post trial benefits?*
   Researchers typically share benefits with participants/community
2. *How do you deal with the issue of conflict of interest between community and researchers/research?*
   Community views are normally collected through community representatives or leaders and this helps to minimize instances where conflict of interest arises.

5. **Building Community Partnerships: Understanding Community Engagement as a Pillar for Ethical Conduct of HIV Vaccine Research in Selected Countries in Africa.**
   
   Presented by Otieno Omutoko Lillian (PhD), University of Nairobi, Kenya
The presentation reported finding from a study which conducted a desk review of literature from HIV related studies carried out in Kenya, Uganda and South Africa from 2000 to 2014. There has been much debate on controversies surrounding HIV research and the fact that there is not much literature on community development of HIV vaccine. The studies aimed at improving community health and reduction of inequalities and addresses community needs and provide solutions.

**Key Messages**

1. HIV is a great health concern with many effective but not sufficient measures to curb its spread. The development of HIV vaccines makes community engagement worthwhile for assessing needs and significance.
2. Communities, advocacy groups and funders require researchers to address health needs and apply community approaches that promote respect, beneficence and equity.
3. There is a gap in the availability of empirical research on CE in HIV vaccine trials.
4. Low education levels of community members leads to therapeutic misconceptions, affects relationships and communication between CABs and researchers and this hinders CE.
5. Selection of participants is sometimes viewed as unfair.
6. The Ugandan HIV vaccine 1 and 2 trials are a good illustration of need for education, capacity building, communication and dissemination of HIV information.

**Recommendations**

1. Messages on vaccine trials need to be precise and realistic to avoid raising expectations of community members that the end result of a trial is availability of a vaccine.
2. Development of a systematic communication plan and continuous education and training of community members will help in keeping abreast with developments in research and vaccine development.
3. There is need to conduct empirical assessment of CE to examine extent, relevance, effectiveness, weaknesses and relationships between variables and facilitate development of indicators of CE.

### 2.5 SUB-THEME 3: BIOETHICS AND PUBLIC HEALTH/COMMUNITY ENGAGEMENT

There were a total of four presentations under this sub-theme. The presentations revolved around community engagement, which has stood out under most sub-themes, exploring the principle of justice, involvement of research stakeholders in data sharing policies and challenges in application of global HIV research ethics locally. The presenters were students, researchers and academia.

1. **Challenges of application of Global HIV research ethics in Western Kenya**  
   *Presented by Catherine Wahome, Moi University*

   A case presentation on a hypothetical situation involving a pharmaceutical company that is testing a product that has not been approved. According to the company, the product is for the prevention of HIV transmission. The dealings of the company are shoddy because the company does not get approval for the research to be initiated; no IRB is involved in the review of the proposal but the company goes on to implement the research i.e to enrol participants into the
study and to give the trial product out to the participants. The company involves a single nurse as the PI and the nurse is the one who is given the mandate of managing the entire process of the research. The company is a culprit of undue coercion as the study PI and the participants of the study are all given money to participate in the research. The participants are poorly educated on the product that is being tested on them. The product is an anti HIV drug and the participants are encouraged to involve in sexual activity without protection. The product being tested doesn’t prove to have the efficacy or the product definitions that had been given to the participants prior to the inception of the research.

Key Messages

1. Many research organs usually fail to educate the various study participants on the drug being tested and regularly misinform the participants about the usefulness of the drug being tested.
2. Targeted populations in HIV/AIDS research are the low income earners, owing to the fact that they are easily available.
3. A number of research participants are driven by inducements.

Recommendations

1. Principal investigators should ensure that research assistants are well educated on the various aspects of research and the processes that are involved.

2. Involving research stakeholders in developing policy in sharing public health research data in Kenya: Views on fair process for informed consent, access oversight and community engagement.
   Presented by Irene Jao, KEMRI-Wellcome Trust Research Programme

This presentation highlighted findings from a qualitative study that used modified IDIs, FGDs and follow-ups to collect views from approximately 60 stakeholders in the KWTRP and its partners.

Key Findings

1. Data sharing is a novel concept hence there are risks of misunderstanding its implications. Though data sharing can negatively or positively influence the process and outcome of research, it is however necessary among stakeholders.
2. The key areas of concern in data sharing include the researchers’ and primary communities’ interests, participants’ autonomy and choice as well fair governance and accountability mechanisms.
3. Institutional trust-building policies are essential in data sharing.
4. Data sharing can be beneficial to primary communities by promoting near and long term translational health benefits.
5. There is potentially high value of sharing within scientific collaborations as it will help in building local scientific capacity building and enhancing scientific validity. In the long it might contribute to the reduction of global gaps in access to resources.
6. Archived information sharing became a challenge when the consent of the participants was to be given. Participant data sharing has the potential to jeopardize the entire process of research. Additionally, participants lack of trust on the researchers and the investigators, and this can interfere with the formulation of policy and regulations.
Recommendations

1. There should be individual prior awareness and agreement (broad consent) prior to data sharing.
2. Governance processes need to be strengthened in the following aspects:
   a. Independence and accountability, including community engagement
   b. Feedback
   c. Promotion of interests
   d. National framework for international data sharing
3. Promotion of scientific collaborations should be enhanced.

   Presented by Juma Albert, Moi University

Key Messages

1. There exists a neo-colonialism mentality among research participants that research scientists will offer solutions to their research health needs.
2. Most PI’s delegate their Research Assistants (RAs) to conduct data collection and recruitment of participants
3. Targeted populations in HIV/AIDS research are the low income earners, owing to the fact that they are easily available.
4. A number of research participants are driven by inducements.
5. While the PI and other study investigators are knowledgeable about the various aspects in the research, the junior staff, the study participants and other stakeholders, usually don't have information or education on the matters of research

Recommendations

1. There is need for cooperation and collaboration between researchers is required to alleviate the gaps that are observed in research.
2. There is need to ease the research fatigue that is put on some of the research/study participants in low income settings.
3. There should be proper training of RAs in various research aspects especially research ethics as well as in universal ethics principles
4. Research ethics should be popularized across the community
5. All groups in the community should be involved in the research.
6. There is need to exercise the principle of justice in HIV/AIDS research in the community especially at the output levels of the research to ensure equity in distribution of the research benefits.

4. Evolving community engagement in Health research: perceptions on the process of regularly replacing members of a network of community representatives
   Presented by Joyline Jepkosgei, KEMRI-Wellcome Trust Research Programme
This presentation highlighted findings from a mixed methods but largely qualitative study that sought to determine stakeholders’ (KCR and Community Liaison Group (CLG) members) perceptions on the system of regularly electing new KCR members, and whether and how the previous KEMRI Community Representatives should be involved in KWTRP activities. Data was collected through review of records, in-depth interviews and focus group discussions.

**Key messages**

1. There were a number of expectations among members of KCR, some of which included employment.
2. Retired KCRs reported interacting with KWTRP staff in activities such as KCR elections, census, participating in studies.
3. Some of the KCR members were not keen to step down after serving their terms and some felt that KWTRP had forgotten about them since they ‘retired’.
4. Interaction of KWTRP with retired KCR members was perceived as a potential threat in undermining current KCR members.
5. The system of regularly replacing KCRs was perceived to be good; it provides an opportunity for many community members to interact closely with KWTRP staff, build good relations and learn about KWTRP.

**Recommendations**

1. The system of regularly replacing KCR members be retained.
2. While engaging retired KCR members is desirable, need for careful considerations of the dynamics between the retired and current KCR members.
3. Periodic involvement of the entire network after a reasonable amount of time is necessary (e.g. once in 5 years), given the evolving nature of CE programme.

**2.6 SUB-THEME 4: MEDIA AND ETHICS**

There were a total of three presentations under this sub-theme. These included the role of the media in bioethics, benefits and payments and bioethical issues in gender research. The presenters were from the research community and academia.

**1. The Role of Media in Promoting Public Debate on Bioethical Issues**

*Presented by Dr. Jacinta Mwende Waweru, Dept. of Philosophy, University of Nairobi, Kenya*

This presentation highlighted preliminary findings from a paper that examined the role of mainstream media in promoting informed public debate on key bioethical issues such as Genetically Modified foods so as to raise public scientific awareness on those issues. A qualitative content analysis of how the Daily Nation and The Standard newspapers have covered the GMO debate between 2012 and 2015 was conducted and a total of 25 articles from both papers was analysed.

**Key Messages:**

1. The way that the media reports on issues including bioethical issues can have a strong influence on how the general public perceives, interprets and understands those issues.
2. The media are the public informers/people’s watchdog/fourth estate/public educators and therefore can have a significant influence on public opinion.

3. Whether the public will approve or disapprove a particular biotechnological breakthrough will depend on their level of understanding and awareness on that issue.

4. The issue of whether or not to adopt and allow the use of GM food in Kenya has been a hotly contested one.

5. Due to lack of understanding and sufficient information on what GMOs are there is a general fear, suspicion and misconception among majority of Kenyans on the health risks associated with GMOs.

6. Using the theory of the media as a Public sphere and the agenda setter, the paper argued that media has the responsibility to facilitate public dialogue on this complex controversial issue.

7. All of the 10 articles analyzed so far lacked depth of reporting and analysis focusing mainly on quoting the government, researchers and activists on their positions on the GMOs.

8. There was a sort of detached superficial presentation of information that cannot help the common person to make informed decision on whether or not to adopt GMO technology.

9. The story behind the story is largely missing- there was no definition of what GMO is other than giving the meaning of the abbreviation.

10. There was also no mention of the various forms it takes to enhance public understanding.

11. The print media in has not acted as genuine public spheres by setting the agenda to foster informed public debate on GMOs.

12. Most coverage has just ‘scratched’ on the surface of this complex and controversial bioethical issue creating a “false consciousness” on the matter.

**Recommendations**

1. There is need for capacity building in terms of training of journalists on biotechnological issues to sharpen their depth and understanding of the issue.

2. The lack of depth of reporting points to lack of proper understanding on the part of journalists.

3. The media has a core responsibility to with the aim of both informing the citizens and giving them opportunities to deliberate, voice their concerns and to exchange viewpoints and arguments on those issues.

2. **Benefits and Payments: Consulting Community Members in Kilifi, Kenya**

   *Presented by Francis Kombe, KEMRI-Wellcome Trust Research Programme*

This presentation highlighted findings from a qualitative study involving 90 purposively selected local residents. There was a two-stage consultation process involving a workshop and small group discussions.

**Key Messages:**

1. The level of benefits and compensation in research affects people’s thinking about research where they think less of study and more about the benefits.
2. Benefits and compensation can in some instances negatively impact on relations between husband and wives as well as the community at large.
3. Risk of inadequate compensating indirect costs (too little) may be greater than those of undermining voluntariness (too much).
4. Researchers have the responsibility for humanitarian response in communities affected by poverty.

Recommendations:

1. Ensuring indirect costs are adequately compensated and considering potential for community wide benefits in addition to individual participants benefits is critical

3. Bioethical Issues in Gender Research in International Health Research Programme in the Department of Behavioural Sciences, School of Medicine, Moi University, Eldoret Kenya
   Presented by Dr J.B.Baliddawa, Department of Behavioural Sciences, Moi University

This presentation highlighted the gender situation at Moi University’s College of Health Sciences. It examined the aspect of Gender as a dimension in research process in particular how research is conceptualised and carried out.

Key Messages:

1. Good research must take into account biological (sex) and social (gender) differences between men and women.
2. Gender is a dimension in research ethics
3. To rectify ethical issues, it is important to address the experiences of equal opportunity for each gender and deep seated sex and gender inequities.
4. It is important to ensure that no particular gender is underrepresented in research.
5. Gender based analysis should be conducted to better understand the gender dimensions and assist in finding the best strategies and solutions to address the different needs and dynamics of men and women in research.

Recommendations:

1. There is need for strategies of incorporating gender dimensions in the review process.
2. Gender balance does not really mean equal numbers but should be an equal representation of experiences among both the female and male representation in research.
## ANNEX 1: LIST OF BSK COMMITTEE MEMBERS

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<thead>
<tr>
<th>NO</th>
<th>NAME</th>
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<tr>
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<td>Prof. Elizabeth Bukusi</td>
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<td>2</td>
<td>Dr. Simon Langat</td>
<td>NACOSTI</td>
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<td>3</td>
<td>Prof. Karori Mbugua</td>
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<td>4</td>
<td>Dr. Wambeti Njiru</td>
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<td>5</td>
<td>Prof. David Ayuku</td>
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## ANNEX 2: LIST OF CONFERENCE PARTICIPANTS

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<td>Aga Khan University</td>
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<td><a href="mailto:Wahomecatherine89@gmail.com">Wahomecatherine89@gmail.com</a></td>
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<td>Karani Anne Kagure</td>
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<td>37</td>
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<td>Gideon Cornel Msee</td>
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<td>Muoki Benedict Killu</td>
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<td>Were Vincent</td>
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<td>Gitome Serah W.</td>
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<td>Njoroge Betty</td>
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<td>46</td>
<td>Obonyo Charles</td>
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<td>49</td>
<td>Mudegu Daisy Kadenyi</td>
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<td>50</td>
<td>Emily Too</td>
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<td>Elizabeth Njenga</td>
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<td>Amina Salim</td>
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<td>Miranda Barasa</td>
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<td>Salome Ngamau</td>
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<td>Anne Moochi</td>
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<td>Moni Wekesa</td>
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<td>Amolo Okero</td>
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<td>62</td>
<td>Rachel Mwakisha</td>
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ANNEX 3: CONFERENCE PROGRAMME

WEDNESDAY 16, DECEMBER, 2015

7AM-8AM
REGISTRATION

<table>
<thead>
<tr>
<th>TIME</th>
<th>SPEAKER/ACTIVITY</th>
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<tr>
<td>8:00AM</td>
<td>REGISTRATION</td>
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<tr>
<td>8:30AM</td>
<td><strong>Opening Remarks</strong>: Chair Conference organizer, Prof. David Ayuku</td>
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<tr>
<td>8:45AM</td>
<td><strong>Opening Prayer</strong>: Rev Joseph Katwa</td>
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<tr>
<td>9:00AM</td>
<td><strong>Keynote Presentation</strong></td>
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<tr>
<td>9:15AM</td>
<td>Dr. Jim Lavery, Ph.D.: How should Research Ethics Committees judge the ethical merit of community</td>
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**Session Chair**: Prof David Ayuku

**Rapporteur**: Victoria Soi

**Austine Odiwour**
<table>
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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>9:15AM – 9:30AM</td>
<td>Mr. Ambrose Rachier: Law and Ethics</td>
</tr>
<tr>
<td>9:30AM – 9:45AM</td>
<td>Prof. Edwin Were: Clinical Ethics</td>
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<tr>
<td>9:45AM – 10:00AM</td>
<td>&quot;Ethical considerations for research on experimental products in an outbreak situation&quot;</td>
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<tr>
<td>10:30AM – 11AM</td>
<td>TEA BREAK</td>
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<tr>
<td>11:00AM – 11:45AM</td>
<td>OPENING CEREMONY: Guest of Honor</td>
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<tr>
<td>11:45AM – 12:15PM</td>
<td>KEY NOTE ADDRESS: Dr. M.K. Rugutt, Director General/CEO NACSOSTI</td>
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<tr>
<td>12:15PM – 12:30PM</td>
<td>Vote of Thanks: Vice Chair Dr. Simon K. Langat</td>
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<td>12:30PM – 2:00PM</td>
<td>LUNCH BREAK</td>
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<tr>
<td>2:00PM – 2:15PM</td>
<td>David Nderitu (002): Implication of the Implicit Consent in Teaching Public Hospitals in Kenya</td>
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<tr>
<td>2:15PM – 2:30PM</td>
<td>Prof. Elizabeth Bukusi for Dr. Meslin Challenges In HIV Research in Kenya</td>
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<td>2:30PM – 3:00PM</td>
<td>Break Into Small Discussions Groups</td>
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### Thursday 17, DECEMBER, 2015

<table>
<thead>
<tr>
<th>TIME</th>
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<tr>
<td><strong>BIOETHICS AND CULTURE:</strong></td>
<td><strong>Session Chair:</strong> Dr. Lucy Maina</td>
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</table>
| 8:15AM-8:30AM | Dorcas M. Kamuya (003)  
Gendered negotiations for research participation in community based studies: Implications for ethics and health research in Kenya | **Rapporteur** Benedict Kiilu  
Maryanne Metto |
| 8:30AM-8:45AM | W Wekesa (001)  
Challenges in regulation of biomedical research: The case of Kenya  
M Wekesa     |
| 8:45AM-9:00AM | **CLINICAL HEALTH:**  
Prof. Elizabeth Anne Bukusi (004)  
What they say and what they do - views of those who are taught and those who teach medical / clinical ethics in Kenya |
| 9:00AM-9:15AM | Mr. Alfred Koskei (013)  
Therapeutic Misconception And Inappropriate Inducement Among Patients Participating In Clinical Trials At Moi University Clinical Research Center (Mucrc), Eldoret |
| 9:15AM-9:30AM | Prof. KaroriMbugua (012)  
Ethical Issues Raised By The 2014-2015 Ebola Outbreak In West Africa |

**10:AM — 10:30AM TEA BREAK**
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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>10:30AM-10:45AM</td>
<td>Everlyne Wambai (006)</td>
<td>Knowledge, attitude and practices towards family planning methods among women of reproductive age in South Teso Sub-County, Busia County.</td>
</tr>
<tr>
<td>10:45AM-11:00AM</td>
<td>Eunice Kamaara (005)</td>
<td>Challenges of Application of Global HIV Research Ethics in Western Kenya</td>
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<tr>
<td>11:45AM-12:00PM</td>
<td>Joyline Jepkoskei (010)</td>
<td>Evolving Community Engagement in Health Research: Perceptions on the process of regularly replacing members of a network of Community Representatives</td>
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**MEDIA AND ETHICS:**

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<tr>
<td>12:00PM-12:15PM</td>
<td>Dr. Jacinta Mwende Waweru (008)</td>
<td>The Role of the Media in promoting Public Debate on Bioethical Issues</td>
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<tr>
<td>12:30PM-12:45AM</td>
<td>Maureen Njue (015)</td>
<td>Benefits And Payments: Consulting Community Members In Kilifi, Kenya</td>
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<td>12:45AM-</td>
<td>Prof Ayuku and J.B Baliddawa (009)</td>
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<tr>
<td>1:00PM</td>
<td>Bioethical issues in gender research in international health research Programme in the Department of Behavioural Sciences, School of Medicine, Moi University, Eldoret, Kenya</td>
<td></td>
</tr>
<tr>
<td>1:00PM-1:15PM</td>
<td>CLOSING SESSION: Prof. Adiel Magana Recap Vote of thanks LUNCH AND DEPARTURE</td>
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**ANNEX 4: SPEECH FROM THE REPRESENTATIVE MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY BY DR. GEORGE OMBAKHO**

Officials of the BSK,

Members of the BSK

Distinguished presenters,

Ladies and Gentlemen

It gives me great pleasure to join you here today for this important conference. From the science, technology and innovation sector, we welcome this conference as a distinct activity in our calendar. This is because we recognize that it is an enabler in our effort to connect our thinking with the society we serve.

I am informed that the BSK is a young institution; I thank the organisers of this conference and the supporters like the University of Indiana, the National Institutes of Health (NIH) of the United States of America and all our local collaborators which include the Kenya Medical Research Institute, Moi University and our own NACOSTI. The conference provides a rare forum for persons looking at ethics to come together and share in an orderly manner the goings-on in our public engagements and thought. It is my hope that the conference will develop into a respected annual function that contributes to the promotion of ethics in Kenya.

The science and technology sector needs a strong vibrant professional society like the BSK to assist in providing an analytical assessment of both our policies and decisions. I am glad you made the decision to create the BSK. Such a body will have the capacity and flexibility to interact with all stakeholders and drive dialogue in bioethical issues. You will engage the media, the three arms of government, the public, academia and students in their own language so that you get the real meaning of things that matter most to them and to all of us. We look forward to a time when public engagements in ethics are informed by actual knowledge and founded on solid
reasoning. Your intervention is mostly required in the arena of research using human subjects. Today, there is tremendous progress in the life sciences making it necessary for all of us to reconsider the meaning of some basic activities. We need guidelines that help us decide how to embrace the new technologies. Have humans crossed the red line regarding the use of stem cells? Is biotechnology an answer to our nutrition problems? Is it time to consider what the impact of the sciences will be on human life in the future? This and other questions are not in any way easy to answer but we must attempt. The BSK can engage these and other questions in order to be relevant to the community in which we live. It is true such questions are facing the whole of humanity, but the response to them will determine how every country makes progress and improves the quality of life.

Ladies and gentlemen,

It is our values that make us who we are. We must develop our systems in relation to what we hold dear as Kenyans. Today we have a constitution that has underlined the need to be people-centred in our thinking. It is not only lawyers and economists who will interpret it for our prosperity rather ethicists have an equally important role. I challenge you to look at our policies at every stage and provide input with a view to improving them. First let us look at the current practice in science, technology and innovation, my ministry has created three institutions to address specific needs like regulation, promotion and financing. NACOSTI, according to the Science, Technology and Innovation Act of 2013 be the regulator. It will enforce quality rules, register research institutions and license individual research projects. The National Research Fund has the mandate of channelling public funds for research and sourcing for more such funds to be availed for research. The Kenya National Innovation Agency is the body mandated to promote innovative activity and outline priorities for national attention. Under my watch, these institutions will perform to the expectation of Kenyans and as required by quality standards. This is the most basic ethical expectation we have regarding public institutions.

Dear participants,

As I conclude, I wish to thank you for your interest in the activities of the BSK. I expect the outcome of this conference to be important for the development of bioethics in Kenya and a positive influence on the development of our beloved motherland. None of you should live this place as you came but should be reinvigorated and challenged to think more clearly about the matters of ethics. Indeed virtue is developed by constant practice.

I wish you all the best as you deliberate. And with these few remarks I declare the Inaugural BSK Annual Conference officially open.

Thank you