

# Research for Health: Dissemination of the landscape analysis on regulatory and ethical oversight of clinical research in Kenya

## A report of the meeting proceedings

December 6, 2010

Sarova Panafric Hotel, Nairobi



NCST LOGO HERE



*Expanding HIV prevention options, especially for women*  
[www.global-campaign.org](http://www.global-campaign.org)



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL



|  |           |
|--|-----------|
| List of Abbreviations and Acronyms .....   | 4         |
| Acknowledgements .....   | 5         |
| <b>1. Background.....</b>  | <b>6</b>  |
| Official Opening Session .....   | 7         |
| a. Role of the Global Campaign for Microbicides in HIV prevention research .....   | 7         |
| b. Opening Remarks .....   | 8         |
| c. Vote of Thanks .....  | 8         |
| <b>2. Regulation and Oversight of Health Research in Kenya .....</b>   | <b>9</b>  |
| a. The Role and mandate of the National Council for Science and Technology .....   | 9         |
| b. Role of the National Bioethics Committee .....  | 9         |
| c. Regulatory Framework for research in health.....  | 10        |
| Plenary discussion session .....   | 10        |
| <b>3. The landscape analysis of the actors and processes of clinical research review in Kenya.....</b>   | <b>12</b> |
| Background and overview .....  | 12        |
| Strengthening Structures for HIV Prevention Research in Kenya: Landscape Analysis of the Actors and Processes of Clinical Research Review..... | 12        |
| <b>4. Group Discussions: Strengthening Structures for Research Ethics in Kenya.....</b>  | <b>14</b> |
| Group 1 .....  | 14        |
| <i>Topic: Strengthening Structures for Research Ethics in Kenya: NCST Authority</i> .....  | 14        |
| Group 2 .....  | 17        |
| <i>Topic: Strengthening Structures for Research Ethics in Kenya: Ethical Review Harmonization</i> .....  | 17        |
| Group 3 .....  | 19        |

*Topic: Strengthening Structures for Research Ethics in Kenya: Capacity Building*..... 19

Group 4 .....21

*Topic: Strengthening Structures for Research Ethics in Kenya: Clinical Research Documentation* .....21

**5. Recommendations and next steps .....23**

## **List of Abbreviations and Acronyms**

|       |  |
|-------|--|
| AMREF | African Medical and Research Foundation    |
| CNHR  | Consortium for National Health Research    |
| ERC   | Ethical Review Committees                  |
| ESCR  | Ethical and Scientific Review Committee    |
| GCP   | Good Clinical Practice                     |
| GCM   | Global Campaign for Microbicides           |
| ICT   | Information and Communication Technology   |
| IRB   | Institutional Review Boards                |
| KEMRI | Kenya Medical Research Institute           |
| M&E   | Monitoring and Evaluation                  |
| NBC   | National Bioethics Committee               |
| NCST  | National Council of Science and Technology |
| REC   | Research and Ethics Committee              |
| SOP   | Standard operating procedures              |

## **Acknowledgements**

The National Council for Science and Technology (NCST) would like to thank the co-conveners of this national meeting for the dissemination of the landscape analysis on regulatory and ethical oversight of clinical research in Kenya namely: the Global Campaign for Microbicides (GCM), the Kenya Medical Research Institute (KEMRI) and the Consortium for National Health Research (CNHR) for their commitment to improving health research in Kenya.

The co-conveners particularly acknowledge the financial contributions of: USAID who supported the Landscape Analysis process and the Bill and Melinda Gates Foundation who supported the national dissemination meeting. In addition, CNHR provided support to its partners to participate in the meeting thus facilitating engagement of a wider group of health research stakeholders.

## 1. Background

Internationally sponsored research is moving toward a model where studies will only be conducted in countries where there are clear regulatory and ethical frameworks. In order to reinforce Kenya's position as a leading site for collaborative international research, the National Council for Science and Technology (NCST) is seeking to develop national guidelines for the oversight of clinical research in Kenya. The NCST is collaborating with different partners in various stages of this process.

In March 2010, the Global Campaign for Microbicides (GCM), with the Kenya Medical Research Institute (KEMRI) carried out a landscape analysis on regulatory and ethical oversight of clinical research with a special emphasis on HIV prevention research in Kenya. The analysis was a first step in the process of developing these national guidelines and its objectives were to:

- Identify the existing governance structure that regulates clinical research in Kenya, for HIV/AIDS prevention;
- Identify issues of concern to those overseeing research in Kenya, with a special emphasis on issues related to HIV prevention trials;
- Make recommendations for improving research governance and for sharing information on the ethics and regulation of clinical research with a special emphasis on HIV prevention trials.

The analysis employed process tracing methodology to examine the actors and processes involved in the review of clinical research. The specific steps of this method involved:

- Identification of key actors involved in the review or regulation of clinical research in Kenya
- Gathering information from identified individuals through semi-structured interviews conducted at the host sites
- Collection of corresponding documentation. Including legislation and regulation, scope of practice guidelines and other correspondence

A report was compiled which outlined the stated official roles of these organizations in the review of research proposals and highlighted gaps in current understandings of the regulatory process. This report highlights the proceedings of the national meeting on 'Research for Health: Regulatory framework and dissemination of the landscape analysis on regulatory and ethical oversight of clinical research.' that was hosted by the NCST which brought together various stakeholders involved in health research in Kenya. It documents their feedback on the findings of the landscape analysis and the recommendations made on the way forward.

## Official Opening Session

The dissemination meeting was officially opened by Prof. Shaukat Abdulrazak, the Secretary and Chief Executive Officer of the National Council for Science and Technology (NCST), who welcomed all the participants to the meeting and gave an overview of the roles of the NCST. Prof. Abdulrazak explained that NCST was responsible for all research in Kenya and it derives its authority from the 1977 Science and Technology Act, which gives it the mandate to advise the government on issues of science and technology and to review and approve all scientific research in the country. He further explained that the NCST is housed under the Ministry of Higher Education Science and Technology and it is responsible for setting standards for ethical compliance, approval of research permits, reviewing applications for research grants and advises the government on how to implement the results of the research.

He emphasized on the need for all institutions involved in research to identify an institutional contact person who will facilitate sharing of information and challenges facing all diverse research initiatives.

### a. Role of the Global Campaign for Microbicides in HIV prevention research

Dr. Samukeliso Dube, the Africa Program Leader, Global Campaign for Microbicides (GCM), followed on and described GCM as a civil society organization that works to ensure the ethical and accelerated development and widespread access to new and existing HIV-prevention options — especially for women. She emphasised that GCM works to ensure that as research proceeds, the rights and interests of women, potential end-users, trial participants and communities are represented and respected. GCM collaborates with civil society, researchers, policy makers and industry to develop and share resources, inform and develop policy, identify and promote better practices, and build and strengthen the capacity of the HIV-prevention field — with a special focus on Microbicides and pre-exposure prophylaxis (PrEP).

The goals of GCM are to:

- *Mobilize and sustain political will:* Build citizen demand and governmental support for the timely development, introduction and use of new HIV prevention technologies, particularly for women.
- *Promote stronger civil society involvement:* Strengthen capacity and expand opportunities for advocates and communities to engage with research and clinical trials productively.
- *Enable trials:* Identify ethical challenges and policy obstacles to the timely implementation of HIV prevention trials and broker the open, well-informed discussion and cross-sectoral consensus building needed to resolve them.

### **b. Opening Remarks**

Prof. Kirana Bhatt, the Chairperson of the National Bioethics Committee (NBC), thanked the participants for availing time to attend the dissemination meeting and also for participating in the interviews as the landscape analysis was being conducted. She acknowledged the time and effort in collecting data and presenting the report and thanked all those who participated in the interviews for their views and insights that would go a long way in improving clinical research in Kenya. She added that the NCST is looking at improving research and has in the past (2004) issued guidelines specifically looking into the ethical treatment of human subjects.

She added that NCST has over the years revived science and technology in the country and aims to do even more to popularize itself and develop more innovations in line with Kenya's Vision 2030.

### **c. Vote of Thanks**

Dr. Solomon Mpoke, Director, KEMRI, explained the role of KEMRI in health research. He outlined KEMRI's mandate as having the responsibility to carry out health research through its various research sites country wide, strengthening research partnerships with domestic and international research organizations, and, disseminating and translating research findings for policy formulation and implementation.

The key areas which KEMRI is involved in research are: infectious diseases such as, HIV, STIs, TB, Polio and measles; parasitic diseases such as malaria Public Health epidemiology on diseases including H1N1; as well as lifestyle diseases such as diabetes, malnutrition and nutritional disorders.

He added that KEMRI has been conducting meetings with herbalists to discuss alternative treatments in Kenya because this is a potential area of development but requires research. In his concluding remarks, he thanked the Chief Guest Prof Bhatt for opening the meeting, the conveners of the meeting NCST, all who contributed in the development of the report, the participants and the organisations that provided financial support especially USAID and the Bill and Melinda Gates Foundation through the Global Campaign for Microbicides.



## 2. Regulation and Oversight of Health Research in Kenya

### a. The Role and mandate of the National Council for Science and Technology

Dr. Simon Langat, Chief Science Secretary, NCST, explained that the NCST derives its authority from the 1977 Science and technology Act and the 1979 amendment, which gives it the mandate to advise the government on issues of science and technology and to review and approve all scientific research in the country. NCST is housed in the Ministry of Higher Education, Science and Technology.

- The NCST sets standards for ethical compliance, approves research, reviews applications for research grants and advises the government on how to implement the results of research. The NCST is structured as follows:
- Has a secretariat headed by the Secretary [who is the Chief Executive Officer]
- Has 4 specialist committees
- The NBC is one of the Council's committees established under section 6 of the Act

The NCST is responsible for accrediting ethics review committees (ERCs)/institutional review boards (IRBs) in Kenya. It gives them mandate to review research emanating within their institutions including collaborative research. Since its inception, the NCST has delegated its research review powers through accrediting five ERCs namely:

- University of Nairobi/Kenyatta National Hospital
- Kenya Medical Research Institute (KEMRI)
- Africa Medical Research Foundation (AMREF)
- AGA Khan University
- Moi University School of Medicine/Moi Teaching and Referral Hospital

NCST reserves the right to summarily decommission any ERC or terminate any research taking place in Kenya.

### b. Role of the National Bioethics Committee

- Development of national ethics review policy and guidelines, accreditation of ERCs, arbitration and dispute resolution, monitoring and evaluation
- Give advice to the government and other public authorities on ethical issues in research, new technologies, nature and other issues affecting life
- Provide information on research and innovation to the public to generate debates regarding Science, technology and innovation
- Report on general and fundamental ethical issues to the NCST

### **Gaps**

Dr. Langat noted the following gaps:

- There was need to raise awareness of the research community and other stakeholders on the role of the NCST.
- NCST has limited resources for evaluation of research activities and enforcement of guidelines
- Currently, there is no nationwide clinical research documentation database

A draft Bill that is in parliament will re-establish the NCST as a state corporation so that it can carry out its mandate more effectively.

### c. Regulatory Framework for research in health

Prof. Gilbert Kokwaro, Director, National Consortium for Health Research (CNHR) started by stating that the role of the regulatory frame is not to control; rather, it is to define the boundaries for “Research for Health” and to guard the public/study participants against harm. Research should be seen as an arena for cooperation and not exploitation. He noted that in clinical trials, one of the trickiest situations is the issue of compensation.

Prof. Kokwaro emphasized that various stakeholders should be involved in transforming the regulatory environment in Kenya. There is need to develop guidelines and update them regularly to keep up with the developments in research. Such guidelines should also be disseminated widely to ensure those involved in research at various levels adhere to the set standards. Regular monitoring and evaluation should be carried out and this should not be confused with fault finding. Once a proposal is approved, relevant bodies such as the NCST and ERCs need to be vigilant. Researchers also have ethical responsibility to protect participants and communities involved in research.

CNHR is a local funding agency that seeks to find ways of working with the Ministries of Health and the NCST. It is a consortium of various national and private universities, the two national referral hospitals and key health research organizations. CNHR aims to improve the quality of health in the country through promotion of quality research. It encourages practice of evidence-based health policy formulation to improve healthcare and its delivery. It also coordinates research funding efforts while avoiding duplication. CNHR is committed to supporting development of a robust regulatory framework for research for health in Kenya and building necessary capacities among ERCs and relevant ministries.

### Plenary discussion session

| Plenary Discussions/Question/Comment                    | Response from the Presenters   |
|---|--|
| How do researchers access funds for research from CNHR? | There have been calls for applications in the local media for the setting up of a centre for research excellence and a knowledge base. However, there has been reluctance to fund individual applications because they do not cover the national constituency. |

|   |  |
|---|--|
| <p>What is Kenya's position in provision of compensation for trial subjects?<br/>It is very difficult when the issues of compensation arise. There are too many loopholes. How do we share the benefits coming out of research?</p> | <p>This should be distilled by the ethical committee. IRBs have policies on compensation. There is always a statement on compensation and when the need for this arises, it is when ERCs look at the fine print of the informed consent form. Normally, the research sponsor will look at what the law of the land says and they will comply with it.</p>  |
| <p>On the issue of Intellectual Property rights, who would own the IP rights that accrue from collaborative research with international research organizations?</p>   | <p>Every international proposal must get authority and Intellectual Property rights respected, enforced and recognized as stipulated by the law. During review, IP issues need to be looked into.</p>  |
| <p>There are many advertisements in the media for herbal remedies to diverse diseases. Are there existing guidelines on traditional medicine? Are these regulated?</p>  | <p>Guidelines for clinical trials on herbal products are still under development. The Pharmacy and Poisons Board (PPB) is working closely with the Ministry of Culture and Social Services and the guidelines will cover conduct of clinical trials using herbal products. In the absence of guidelines, quacks will find ways to infiltrate the system and make claims that they have found cures and remedies to diseases.</p> |

### **3. The landscape analysis of the actors and processes of clinical research review in Kenya**

#### **Background and overview**

Dr. Elizabeth Bukusi, the Deputy Director, (Research and Training) KEMRI, gave a brief overview of the landscape analysis process explaining the objectives of the landscape analysis. She emphasized that there is need for all health research stakeholders to be on the same page in understanding the regulatory requirements and process. The landscape analysis was carried out to identify the gaps were and make recommendations.

#### **Strengthening Structures for HIV Prevention Research in Kenya: Landscape Analysis of the Actors and Processes of Clinical Research Review**

The landscape analysis was presented by Dr. Benjamin Mason Meier, Assistant Professor of Global Health Policy, University of North Carolina at Chapel Hill. He summarised the findings of the landscape analysis, highlighting the gaps and recommendations made by those who were interviewed.

All biomedical and health research projects are required to receive approval from an authorized ERC, with clinical trials subsequently requiring scientific and ethical approval from the Pharmacy and Poisons Board (PPB) in order to import an investigational product or pharmaceutical. Subsequent to this two-step approval process, these institutions are required to keep the NCST apprised of the investigators and the current status of all research projects in Kenya. With periodic reporting to these organizations required throughout the course of the study—culminating in yearly renewals—each study concludes with a final study report and a close-out letter to both the ethical review committee and the Pharmacy and Poisons Board.

Dr. Meier described the ethical review process employed by each of the accredited ERCs, highlighting the gaps. Some of the key gaps included:

- Currently there is no standardisation of the review process across the ERCs, although those interviewed indicated that they follow international principles.
- Different ERCs face the challenge of inadequate resources, including human and infrastructural resource such as limited office space and computers to facilitate their work.
- There is not standardised training of ERC members across the accredited ERCs. The ERCs rely on periodic grants from foreign institutions.
- There is no formal communication between the ERCs and the PPB despite the fact that each study requires approval from both.
- The Ministry of Medical Services (MoMS) bears responsibility for medical service policy formulation and implementation, providing preventive, promotive, curative and rehabilitative health services, creating standards and regulations, and

monitoring and evaluating health care service provisions. However its formal role in the ethical review process is unclear.

There is no central repository of up to date information on current health research in Kenya, as institutions often overlook the NCST requirement to submit annual reports on the outcomes and progress of research that have been approved. The requirement is also not enforced.

To assure the future of Kenyan research systems—for the benefit of the health of the Kenyan people—it is necessary to consider the process and the need for the development of national guidelines for health research.

Following the presentation of the landscape analysis, participants made various recommendations for revision of the document. These recommendations form part of the Landscape Analysis Report, which is a separate document from this report of the meeting proceedings.

#### 4. Group Discussions: Strengthening Structures for Research Ethics in Kenya

This was a group discussion session. The participants had been divided into four groups prior to the meeting based on their expertise and experience to discuss and make recommendations to the team that developed the landscape analysis. Discussion documents had been prepared prior to the meeting which included descriptive scenarios and questions to guide the group discussions. These are highlighted below followed by recommendations from the participants.

##### Group 1

###### **Topic: Strengthening Structures for Research Ethics in Kenya: NCST Authority**

*The NCST role in the current landscape for ethical review of clinical trials is not clearly defined. While NCST is legally responsible for granting permission to other institutions to form and operate ethical review committees and has de jure oversight over all research in Kenya, the NCST has not taken an active and consistent role in review processes, creating ambiguities in its de facto authority and lessening predictability in the research approval process. Where NCST has exercised its authority in the regulation of clinical research, it has often done so arbitrarily and in a way that implies that national procedures are not fully standardized. With uncertainties in the research review process and a lack of coordination across review authorities, there are concerns among informants that Kenya could become a comparatively less attractive location for the international research community.*

*Establishing a clear and transparent mechanism for approval and accountability will reassure that community that the very expensive undertaking of clinical trials can be efficiently and effectively undertaken in Kenya. In addition to authority for approval, NCST requires transparent abilities to sanction those who run afoul of research ethics. While the NCST has authority to inspect research sites at any time or even raise any queries, it has been denied adequate resources to discharge its research oversight function; and while the NCST has terminated many studies consistent with its authority, this legal authority should be clarified. To begin to alleviate the ambiguities stemming from NCST's semi-autonomous status, NCST is currently advancing a draft bill through Parliament to provide it with financial, human, and technical resources independent of the Ministry of Education, Science and Technology, allowing NCST to formalize its mandate to streamline the structures of application, review, and approval of research proposals. Should these additional authorities be granted, these new powers will need to be clarified nationally and applied consistently.*

##### Discussion Questions

- How can NCST make its authority clear to all stakeholders?
  - Standards and processes for approval of ethics review committees
  - Clarity of communication with researchers/ ethics committees
  - Transparency of communication of decision-making
  - Oversight authorities (evaluation of approved committees, research sanctions for ethical violations)
  - Coordination across review institutions (e.g., ethics review committees, Pharmacy and Poisons Board, National ministries)
  
- What resources would be necessary to carry out these authorities?

### **Discussions and recommendations**

The group noted that currently, the NBC is in the process of finalizing standards for Ethics Review Committees. In addition, the participants made the following recommendations:

- There is need to improve communication with researchers and Ethics Review committees/Institutional Review Boards
- For special cases, the National Bioethics Committee may look into a protocol and handle any controversies and appeals
- Periodic reports from the Ethics Review Committees to the NBC
- Transparency of communication of decision making, clear SOPs and clear channel of communication between NBC and IRBs, and also between IRBs and Investigators
- Individual stakeholders should also be involved in the development of guidelines
- As an oversight authority the NBC:
  - Will accredit IRBs/ERCs
  - Should conduct monitoring and evaluation of IRBs/ERCs, including visiting the ERCs/IRBs. In turn, ERCs/IRBs should monitor and evaluate investigators
  - Should encourage formation of more ERCs/IRBs
  - Should put in place research sanctions to check violations
  - Can stop studies, however, this needs legal backing. Local IRBs can also stop studies that violate expectations

- Should create awareness on its activities and mandate and promote bioethics in the country
- To improve coordination across review institutions,
  - Communication between all stakeholders involved should be enhanced
  - A database of all approved research protocols should be developed and maintained
  - NCST should conduct an annual national research forum to share ongoing research activities

***Resources required:***

- Support for continuous capacity building
- Support for infrastructure development
- Financial Support



## Group 2

### **Topic: Strengthening Structures for Research Ethics in Kenya: Ethical Review Harmonization**

*Among the six institutions that have authorized ethical review boards, there is no formal mechanism to standardize processes, procedures and substantive standards of ethical review. Having processes and standards uniform across different organizations is important for the research landscape in Kenya for a number of reasons. Most importantly, an unscrupulous investigator could engage in 'forum shopping' – applying to the review board that is perceived to be the weakest or applying to more than one at a time. Secondly, in the absence of any concrete ethical guidance in decision-making, many ethical review committees focus on the scientific basis of the proposal and the content of the informed consent forms (where the forms are scrutinized largely to assure that consent is in the local language). And finally, international investigators are more likely seek partnerships with local institutions if they are assured that research they are engaging in will follow the letter and spirit of the local law.*

*As the oldest and largest research institution in Kenya, KEMRI has relationships with most of the other ethics boards and has conducted informal training and capacity building activities with them. (To alleviate forum shopping, KEMRI has an MOU with UoN/KNH, which spells out a non-compete arrangement in the event that proposals are simultaneously submitted to both organizations.) Beyond these informal mechanisms, there is no national-level body coordinating the harmonization of processes in the various ethics review committees. At the national level, NCST has held several meetings in the past to bring ethical review committee members together in a forum to share experiences and raise the issue of harmonization; at the international level, ethical review committee members in the East African region interact and exchange experiences, mostly through regional bioethics training workshops or ethics meetings. Nevertheless, informants remained concerned that there are no standard practices enforced across ethical review committees, and NCST does not have the ethical expertise to establish or standardize best practices for these committees. For example, the ethical review committees examined in this report all take their standards and operating procedures from recognized international guidelines (CIOMS, Belmont Report, Declaration of Helsinki), but there is no mechanism to measure the application of these standards by the ethical review committees. Although NCST issued guidelines on ethical conduct of human research in 2004, these have not been routinely incorporated in the policies of ethical review boards, and there is no mechanism in place for NCST to verify that ethical review boards meet these standards.*

### **Discussion Questions**

- What structural reforms need to be institutionalized to assure:
  - Translation of international ethics standards into ethical review committee evaluation?

- Comparable standards for ethics review and expectations of equivalent outcomes of review?
- Formal meeting forums for exchange of information across committees?
- What resources would be necessary to carry out these authorities?

### **Discussions and recommendations**

The participants recommended that:

- In order to have translation of international ethics standards, the NCST needs to provide a template to IRBs on:
  - Composition of ERCs/IRBs
  - Standard operating procedures
  - Annual Reporting format
  - Data Management
- There should be on going capacity building for IRBs through continuous education (workshop, meetings etc)
- With regards to information exchange across committees, the structural reforms needed are:
  - Annual meetings with all IRBs (Joint evaluation)
  - NCST to build capacity to monitor IRB activities
  - IRBs to monitor research activities
  - IRBs to have capacity to electronically monitor research activities

### ***Resources needed include:***

- Financial resources
- ICT equipment
- Human Resources

### Group 3

#### **Topic: Strengthening Structures for Research Ethics in Kenya: Capacity Building**

*Although there is widespread agreement that ethical review boards need “initial and continued education regarding the ethics and science of biomedical research”—a WHO consensus copied verbatim into the NCST’s Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya—this recognized importance of ethics education is not reflected in the policies and practices of ethical review boards.*

*While the scopes of practice for ethical review boards all specify the qualifications and makeup of their respective boards none require any previous knowledge or training on ethical matters. Where membership in these boards is usually based on clinical experience and expertise, a prospective member’s training in ethics is often not considered. As a result, several informants noted that members make decisions based largely upon their own intuitions, rather than on a framework grounded in international ethical standards.*

*With current regulations prescribing no level of training in ethics for ethical review board membership, informants often found that standards for the capacity of members are vague and unenforceable. Some ethical review boards have conducted training sessions for their members, largely through work with international research institutions, but there has been nothing more than ad hoc, piecemeal efforts at ethical capacity building over the years. It is necessary that Kenya develop mechanisms to train members on bioethics if they are to undertake ethical review.*

#### **Discussion Questions**

- What steps are necessary to assure that ethics review committee members:
  - Have backgrounds and training appropriate for ethical review?
  - Have an understanding of the ethical review committee’s standards of review?
  - Have training opportunities (local and otherwise) to assure ongoing capacity and continuing education?
- What resources would be necessary to carry out these authorities?

#### **Discussions and recommendations**

The participants recommended that:

- Training course for the ethics review committee members should entail:
  - NCST and its role in current developments in research in Kenya
  - Human subject protection

- Non-human subject protection
- Have an understanding of ethical review standards
- Good Clinical Practice (GCP)
- There is need to provide training opportunities to ensure ongoing capacity building for ERC members
- Have assistance from NCST in development and training on Kenyan specific guidelines for ethical conduct of biomedical research
- An annual meeting for ERCs/IRBs should be planned that offers general updates and networking opportunities

***Resources Needed***

- Standardised training programs to be availed for the ethical review committee members
- Same online courses which could be at no cost
- National review meeting to share with the Key stakeholders

## Group 4

### **Topic: Strengthening Structures for Research Ethics in Kenya: Clinical Research Documentation**

*One of the conditions under which organizations are allowed to grant ethical clearance is that they must submit annual reports on the outcomes and progress of research that was approved. However, this requirement is largely overlooked and unenforced.*

*Aside from depriving the NCST of important information for oversight, this also means in practice that there is no central repository of up to date information on current research in Kenya. Several informants stated that they were unable to easily find out who else was doing similar research in Kenya and thereby to benefit from their experiences. This is especially important for the ethical review process, as issues or problems that had come up in the past could be used to inform current decision-making.*

*In August 2009, the CNHR held a conference to solicit ideas about the establishment of a resource database of approved studies in the country and the results of the studies (similar to the United States database [clinicaltrials.gov](http://clinicaltrials.gov)). If the NCST could enforce the current requirements that the investigators provide current information on a ongoing studies, it would be possible for an organization like CNHR to assist NCST with the technical support necessary to create such a database.*

### **Discussion Questions**

- How can national institutions be developed to:
  - Centralize information on the conduct of health research?
  - Compile and aggregate information from ethical review committees?
  - Make this information available to relevant stakeholders
- What resources would be necessary to carry out these authorities?

### **Discussions and recommendations**

The participants made the following recommendations:

- Centralising information:
  - Mapping of currently existing information, storing, archiving and sharing mechanisms should be put in place
  - A standardised format for storing information should be developed for use by the various institutions

- Levels of access of information should be clearly defined to avoid information breach
- To ensure that institutions share information amongst themselves and other stakeholders:
  - A mechanism for inter-institutional information sharing should be in place
  - A national documentation centre under the NCST should be developed so that information is availed through a central point
  - Clear guidelines on access and use of data with stipulated penalties for deviation and misuse should be developed

***Resources Needed***

- At the Institutional Level:
  - Physical Infrastructure such as: Computers and office space
  - Human resources
- The National Documentation Centre will require the following:
  - Physical infrastructure
  - Database servers
  - Broadband connectivity
  - Well trained Human resource

## **5. Recommendations and next steps**

At the close of the dissemination meeting, the facilitators and participants discussed the following as the next steps in improving structures for review and oversight of health research in Kenya:

- There is need to look into the bill of rights and what it mentions about ethics in research. Issues particularly looking at compensation need to be addressed clearly
- There is need for proper documentation of all research that is undertaken in the country to avoid duplication and wastage of resources.
- There is urgent need to set up a knowledge sharing platform in the country to keep abreast with current technological innovations to reinforce Kenya's position as a leading site for international research
- There is need for the NCST to work with other relevant bodies to harmonise and update guidelines on the following:
  - Clinical research;
  - Research on animals
- There is need for the NCST to work with relevant bodies to strengthen the capacity of ethical review boards

### **Final Comments from convening agencies**

In their concluding remarks, the co-conveners of the meeting namely: NCST, GCM, KEMRI and CNHR made commitments to follow up on the meeting recommendations. The landscape analysis report would be revised and disseminated to the key stakeholders. In addition the NCST informed all participants that it would be hosting a Science week in May 2011 which would involve conferences and exhibitions at the Kenyatta International Conference Centre, Nairobi as a platform to promote research, science and technology.