

Clinical Trials in Kenya

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Colophon

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By:

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Acronyms

ACCT	African Centre for Clinical Trials
AKH	Aga Khan Hospital
AMREF	African Medical Research Foundation
AZ	Astra Zeneca
CDC	Centre for Disease Control
CHAK	Christian Health Association of Kenya
CIN	Consumer's Information Network
CRO	Contract Research Organization
CSC	Centre Scientific Committee
CSO	Civil Society Organization
DFID	Department for International Development
DNDi	Development of Neglected Drugs Initiative
EPN	Ecuminical Pharmaceutical Network
ERC	Ethical Review Committee
FDA	Food and Drug Authority, USA
FHI	Family Health International
FWA	Federal Wide Assurance
GAP	Global AIDS Program
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GSK	Glaxo SmithKline
HAI	Health Actional International
HIV / AIDS	Human Immunodeficiency virus/Acquired immunodeficiency disease syndrome
IAVI	International AIDS Vaccine Initiative
ICH	International Conference on Harmonization
IMLU	International Medico-Legal Unit
JICA	Japan International Corporation Agency
KAVI	Kenya AIDS Vaccine Initiative
KEC	Kenya Episcopal Conference, Catholic Churches Secretariat
KECOFATUMA	Kenya Consortium To Fight AIDS, TB and Malaria
KEMRI	Kenya Medical Research Institute
KENWA	Kenya Network of Women with AIDS
KETRI	Kenya Trypanosomiasis Research Institute
KHRC	Kenya Human Rights Commission
KNH	Kenyatta National Hospital
MOEST	Ministry of Education, Science and Technology
MoH	Ministry of Health
MSF	Medecins sans Frontieres
MVI	Malaria Vaccine Initiative
NACC	National AIDS Control Council
NARESA	Network of AIDS Researcher's of Eastern & Southern Africa
NCST	National Council for Science and Technology
NEPHAC	Network of People Living with AIDS
NGO	Non Governmental Organization
OHRP	Office for Human Research Protections
PEPFAR	President's EmergencyPlan for AIDS Relief
PPB	Pharmacy and Poisons Board
SPC	Scientific Programme Committee
SPRR	Strategic Public Relations & Research Ltd.
SSC	Scientific Steering Committee
UoN	University of Nairobi
USAID	United States Agency for International Development
USAMRU	US Army Medical Research Unit
WHO	World Health Organization
WRP	Walter Reed Project

Abstract

The report describes relevant regulations, procedures, and actors in Kenya with regard to ethical standards in clinical trials involving human beings. It is based on the review of official documents and secondary information and on interviews with representatives from research institutes, pharmaceutical companies, civil society and others. Currently tens of trials are conducted in Kenya, the majority by public research institutes with donor funding and a smaller number by multinational pharmaceutical corporations with local counterparts. Due to limited transparency a complete overview of trials in Kenya could not be established.

As main ethical issues, respondents emphasized fair benefits for participants, post-trial treatment access and informed consent. Ethical aspects of all research protocols must be approved by the National Council of Science and Technology (NCST) or one of the three national research institutes with a standing NCST clearance and institutional Ethics Review Committee (ERC). The NCST and individual institutions have different guidelines for ethical review, based on international standards including GCP, ICH Guidelines, and sometimes WHA Declaration of Helsinki. Special guidelines exist for HIV/AIDS vaccine research.

Although in theory the application and clearance process is clear, limited coordination and communication among the NCST, individual research institutes, and different Ministries might cause substantial variation in review procedures. Furthermore, various respondents raised doubts about institutional capacity for ethical reviews. Some ERC members are also responsible for research programmes and may therefore experience conflicts of interest. Monitoring of ongoing research projects was not studied in detail and may be an issue for further research.

Introduction

About the report

The aim of this report is to try and give a detailed understanding of the research system in Kenya by looking at a broad spectrum of institutions and the regulatory procedures and guidelines used for the conduct of clinical trials. The study also identifies the existence of Civil Society Organizations (CSOs) that may be directly or indirectly involved with research programs. In this introduction, a brief country profile and findings from previous related studies are presented as background information. The approach of this study is further explained in chapter 1.

Country Profile

Kenya lies on the east coast of Africa along the equator. The climate and topography are characterized by diverse geographical conditions ranging from glaciated mountain peaks to cool plateau, the humid coastal region and vast expanses of arid and semi-arid land. It has a population of approximately 31 million people with more than 70 ethnic groups and the languages of Kenya's ethnic groups fall into three linguistic groups – Bantu, Nilote and Cushite. English is the official language. Urban-rural distinction is 33% of Kenya's population live in cities while 67% live in rural areas. Age Structure 43% of Kenya's population are aged 0-14, 54% aged 15- 64 and 2.7% over 65.¹ Some or all of these diverse demographic factors contribute to making Kenya a favourable location for conduct of biomedical research.

Kenya has a wide range of disease conditions and patterns among them the world top three pandemics of Malaria, Tuberculosis and HIV / AIDS (7% prevalence). Other tropical diseases include all types of bacterial, viral and parasitic infections. Some examples are Schistosomiasis, Leishmaniasis, Rift valley fever, Sleeping sickness just to name a few. Malaria is an important public health and socioeconomic problem affecting more than 4 million people in Kenya. In Africa, more than 1 million children die of severe malaria each year, the majority being less than five years old.²

Tuberculosis is now considered a re-emerging infection (one of the reasons being the compromised immune status of HIV / AIDS Patients). In Kenya, figures have risen to 106,000 cases in 2005 compared to just 10,000 cases a decade ago.³ As there is well known and effective treatment available for Tuberculosis, there have been no known clinical trials conducted in Kenya in the last few years.⁴ Official estimates show that currently 2.2 million people have been infected with HIV, while 1.5 million have already died from AIDS, leaving behind 140 000 infants and children living with the virus.

The recent developments of drug resistance have only added to the challenge of innovative interventions for prevention and treatment of these life threatening diseases. Biomedical Research is therefore an integral part of the health system in Kenya and there are many well established research institutes which undertake research directly relevant to people's health, such as KEMRI, AMREF, Teaching University and some of the major hospitals.

¹ "Distance based learning for Global Health in Africa".01.03.2006

² Wellcome Trust – KEMRI Kenya Brochure

³ "Kenya pledges to aid TB war", Saturday Nation, January 28th 2006, pg 7

⁴ Brief interview with Dr. Chakaya, Head of National Tuberculosis Programme, Kenya. January 26th 2006

Findings from related research articles

Before this report goes further into the details of the structures and procedures of research of clinical trials in Kenya, it is important to highlight that an internet search has resulted in three articles conducted in the recent past which give a brief indication of similar work done in the field of clinical trials in Kenya. These are summarised below:

The first one is called “current status of clinical trials in Kenya”⁵, article in Drug Information Association Jan-Mar 2002. The study is done by Prof. Ebi KIMANANI, PHD. The paper is an appeal to those in the international drug development arena to include some of the poorest countries in their drug development programs. It is also a challenge to health professionals and regulatory authorities in those countries to upgrade clinical trial procedures in order to meet international standards and to provide other incentives that attract clinical trials from international drug companies. There were three objectives to the survey, these were:

To find out who the clinical trial investigators in Kenya are, including their training, therapeutic areas and research experiences.

To find out what the regulatory procedures are for conducting clinical research in general, and pharmaceutical clinical trials, in particular

To get a profile of pharmaceutical industry activities in Kenya.

Forty-four clinical researchers and potential researchers were surveyed. Findings indicated that Thirty-one researchers were based in Nairobi, five in Kilifi, and the remaining eight were based in Kisumu and Kakamega, in Western Kenya. Twenty-three researchers were affiliated with KEMRI; 10 with government provincial, district, or institutional hospitals; 7 were in private practice; 3 were affiliated with the University of Nairobi; and 1 was affiliated with an international organization.

11% of the investigators had a medical degree with no further graduate training and 78% had graduate training. Of the remaining 11%, two had a higher diploma in medical laboratory, one had a diploma in clinical medicine and surgery, one had a diploma from the Kenya Polytechnic, and one investigator's education was unknown. Twenty-six investigators (59%) had both local and international training while 18 (41%) had local training. All were academically active.

Thirty-two investigators (73%) had postgraduate training, including in epidemiology and biostatistics, clinical pharmacokinetics, clinical research methodology, the World Health Organization clinical monitors certification course, management methods in international health, use of computers in clinical research, and principles of good clinical research.⁶

Further findings can be found in the article but the basic regulatory procedures are identical to those outlined in chapter 3 of this report.

The second article is titled “A golden chance for medical ethics in Kenya”, written by Pamela Andanda, dated 15th June 2004. Source: SciDev.Net

Pamela Andanda is an advocate of the High court of Kenya and a member of the Institute of Certified Public Secretaries of Kenya (ICPSK). She is currently carrying out research on the regulation of clinical research in Kenya and other countries. The article makes reference to several incidences of legal issues arising from disputes between the various parties conducting clinical trials in Kenya. Another legal issue was raised due to the slow speed of the NCST to process approval for protocol for HIV /AIDS Vaccine Trial. “The fact that these disputes were actually brought into legal actions

⁵ http://www.findarticles.com/p/articles/mi_qa3899/is_200201/ai_n9064218/print - “Current status of clinical trials in Kenya, article in Drug Information Association Jan-Mar 2002. By Prof. Ebi KIMANANI, PHD.

⁶ http://www.findarticles.com/p/articles/mi_qa3899/is_200201/ai_n9064218/print - “Current status of clinical trials in Kenya, article in Drug Information Association Jan-Mar 2002. By Prof. Ebi KIMANANI, PHD.

demonstrate that Kenyans are now sufficiently sensitised to bring research disputes to court. Kenya therefore needs to revise and seal loopholes that may lead to the exploitation of Kenyan researchers, scientists and research participants”.⁷

The third article is titled “Understanding of informed consent in a low-income setting: three case studies from the Kenyan coast” by C.S.Molyneux, N.Peshu and K.Marsh.

The paper focuses on participant understanding of one field based and two hospital based studies, all of which involve blood sampling. The findings highlight a range of interrelated issues for consideration in the study setting and beyond, including conceptual and linguistic barriers to communicate effectively about research, the critical and complex role of communicators in consent procedures, features on research unit community relations which impact on these processes, and the special sensitivity of certain issues such as blood sampling.⁸

The researchers concluded that the perception of the participants is that the institute’s main aim is health service provision or assistance as opposed to research. This understanding is the result of a number of inter-related factors, including conceptual and terminology complications; the relative wealth of the institution and it’s staff; the very real benefits that do accrue to study participants and community members as a result of the Unit’s activities in the area; and a lack of prioritization by investigators and communicators and even many community members in getting research information across.⁹

Several changes were recommended at aiming to improve the communication to participants among which a change to ethical review procedure was also suggested.

The main reason for highlighting these three articles is to show that some work has been done in the past to look at the existing systems and regulations for conducting clinical trials. The above paragraphs are merely quotes from the articles and are in no way conclusive statements for this report.

⁷ Pamela Andanda, dated 15th June 2004. Source: SciDev.Net
<http://www.scidev.net/gateways/index.cfm?fuseaction=readitem&rgwid=4&item=Opi>.

⁸ “Understanding of informed consent in a low-income setting: three case studies from the Kenyan Coast” by C.S.Molyneux, N.Peshu and K.Marsh. Social Science & Medicine Journal, Volume 59, Issue 12, December 2004, Pages 2547 – 2559.

⁹ “Understanding of informed consent in a low-income setting: three case studies from the Kenyan Coast” by C.S.Molyneux, N.Peshu and K.Marsh. Social Science & Medicine Journal, Volume 59, Issue 12, December 2004, Pages 2547 – 2559.

1. The Study

1.1. The Goal:

Description of existing regulations and procedures in Kenya related to clinical trials, description of relevant actors, and an overview of ongoing and recently concluded trials.

1.2. Specific Objectives:

- An overview of existing legal regulations in Kenya regarding clinical trials, including for example requirements for trial registration and approval and for patient care.
- A detailed description of existing procedures in Kenya for the approval of clinical trials, describing the various organizations involved in this process such as Research Ethics Committees.
- A description of existing standards, codes or procedures for clinical trials from national (Kenya) or regional (African) industry organizations.
- An general analysis of whether and how international standards for the conduct of clinical trials are incorporated in applicable legal regulation and industry regulations in Kenya.
- An overview of main actors in Kenya working on or interested in the conduct of clinical trials in Kenya, such as civil society organizations, consumer or patient organizations, academics or consultants, government agencies, influential doctors/specialists/pharmacists or activists, health organizations or of foreign aid organizations working in Kenya.
- An inventory of clinical trials that are currently being conducted in Kenya or were concluded/ended during the past three years, based on available information.
- An overview of unethical trials conducted in Kenya when applicable (source i.e. local press).
- Concluding, a recommendation of follow up field research on the conduct of clinical trials in Kenya.

1.3. Methodology

For the purpose of this study, the definition of clinical trials was limited to research on drugs and vaccines. The methodology to conduct the research is planned as highlighted below:

Step 1:

Identify the various organizations and institutions involved in Research and Clinical Trials in Kenya.

Step 2:

Meet key informants to understand who does what, and how, and to obtain further and more appropriate contacts.

Step.3:

To obtain the legal regulations, procedures, protocols and codes of conducts for medical professionals.

Step 4:

Conduct literature review of articles and information gathered by internet search and reports obtained from the various institutions.

Step 5:

To establish a list of all studies conducted in the last three years as well as all currently approved trials ongoing.

Step 6:

Analyse information gathered and compare the procedures in clinical trials being conducted in Kenya in relation to international standards and requirements.

1.4. Tools used:

- A questionnaire for information gathering, to be used during the meetings or by e-mail communication. The questionnaire was to be designed to accommodate the different type of organization
- Laws of Kenya and professional code of conduct
- Other regulatory documents and guidelines
- Internet websites as recommended by contact persons or for organizations met

1.5. Process:

A selection of institutes and organizations was identified to conduct a situation analysis on research and clinical trials. These have been categorized into the following categories:

- National Regulatory Authorities (NRA)
- Research Institutes (RI)
- Teaching Institutions (U)
- Donor Agencies such as Bilateral Aid Organizations (DA)
- Local and Multinational Pharmaceutical Companies (PC)
- Civil Society Organizations (CSO's)
- Non- Governmental Organizations (NGO's)
- Community Based Organizations (CBO's)
- National Hospitals (HOSP)
- Private companies (Private)

The following table indicates the organizations met as per the above named categories.¹⁰

NRA	RI	U	DA	PC	CSO	NGO / CBO	HOSP	Private
NCST	KEMRI	UoN	DFID	Cosmos	IMLU	MSF	KNH	SPRR
MoH	KETRI	Jomo Kenyatta University	USAID	Regal	KES	NARESA	AKH	PharmaQ Limited
NACC	Wellcome Trust	Maseno University	JICA	Universal Corporation	CIN	KADA	Mater Hospital	Campus research and Training Consultants Ltd.
PPB	CDC	Egerton University		Dawa Pharmaceuticals	HAI	KECOFAT UMA		
PSK	WRP	Moi University Referral Teaching Hospital		Beta Healthcare	EPN	KENWA		
Division of Malaria Control programme	FHI				CHAK	NEPHAC		
National Tuberculosis Programme	KAVI / IAVI			Glaxo Smithkline	KHRC			
KEBS	ACCT (it is a CRO)			Astra Zeneca	FIDA			
				Pfizer				
				Sanofi Pasteur				

1.6. Constraints

The following constraints were met which led to the non-conformation of the initial methodology planned:

The questionnaire did not really materialise as the institutions met were of wide diversity and their operational modalities of research were too varied to be confined to a set of questions. However where a meeting was not possible (in one case) a set of questions were sent out by e-mail and response received. In the case of a private hospital (Aga Khan Hospital Nairobi) a doctor was approached to provide assistance in trying to meet the appropriate person in authority, but did not respond to the e-mail.

No donor agencies were met mainly due to time constraint.

Unavailability of key informants meant meeting assistants who were unable to provide full information as per the requirement.

¹⁰ See contact list for details of the organizations and all people met during the research.

Inventorization of clinical trials (both completed and ongoing)

This was the most challenging task and it was not possible to gather this detailed information from the key informants. The researchers are not obliged to publish their findings in a fixed manner and well established institutions publish all research conducted in their annual report (eg. KEMRI). Records are maintained at the institutional level but not in the format as was required for the purpose of this study, as it was quite a specific request on drug clinical trials, while the institutions conduct research on various subjects. One possibility to obtain this information would be to make a formal request to the director of the institute to commission the provision of such information. This should be done during the second phase of the project by SOMO / partner organization. A second option is to search the findings in publications in scientific journals and on websites of the institutions. However this is a tedious process and therefore it was concluded that it was impossible to trace an inventory on clinical trials exhaustively.

2. National Regulatory Authorities

The research system in Kenya is elaborate comprising of regulatory and executing institutions. The research system is spearheaded by the National Council for Science and Technology (NCST); the Ministry of Education, Science and Technology and has several active key players such as public research institutes; commodity-based research institutes; institutions of higher learning; and semi-private non-governmental organizations. The legal framework of science and technology is provided by the Science and Technology Act of 1979. Any research planned to be undertaken in the country requires clearance and authorization.¹¹

2.1. The National Council for Science and Technology (NCST)

2.1.1. Historical Context

In 1977 the Science and technology Act (Cap 250) was enacted as a result of the need at that time to institutionalise mechanisms for coordinating and promoting science and technology in the country. Through the act, the National Council for Science and Technology (NCST) was established as an advisory body to government. Amendments to the act in 1979 saw the creation of research institutes such as Kenya Medical research Institute (KEMRI) and Kenya Trypanosomiasis Research Institute (KETRI).¹²

Over the years different ministries have been created and mandated to oversee the evolution of national science and technology base. The ministries have been charged with the responsibility of upgrading the country's science and technology, marshal the requisite human, financial, infrastructural and other resources for S&T and boost the country's efforts to generate, select, adopt and apply appropriate science and technology for sustainable development.

The ministry of Research, Science and Technology that oversaw these, was disbanded and its functions integrated, in 1999, into the present Ministry of Education, Science and Technology (MOEST). The various research institutions are currently under relevant parent ministries (e.g. KEMRI is under the Ministry of Health – MoH).¹³

2.1.2. Institutional Background

The NCST receives both local and external funding mainly from ministries which are directly related to research activities, Financing institutions like Development Banks (e.g. ADB); NGOs, UN Agencies (UNEP, UNICEF, UNDP, UNHCR, etc); International Development Agencies (e.g. USAID, CIDA, SIDA, DFID, DANIDA, etc); Foundations (e.g. Ford, Rockefeller) and Trusts.¹⁴

The institutions currently engaged in active research and technology development are Universities (Kenya has 6 public universities and several private universities); Specialised (sector-based) government or donor sponsored institutions (like KEMRI and KETRI); International research and technology development institutes (eg. ICIPE and ILRI). Individual companies (especially private commercial companies) also have research units that engage in research by employees or external consultants. Individuals and professional bodies like the Kenya National Academy of Sciences (KNAS)

¹¹ Guidelines for ethical conduct of biomedical research involving human subjects in Kenya. By the National Council for Science and Technology (NCST No.45, 2004)

¹² Scenarios for Research on Technological Development (RTD) Cooperation with Europe (SCOPE): Kenya Country Report- Author: Joseph O. Malo SCOPE coordinators for Africa: Luke Georghiou & Jennifer Harper

¹³ The Science and Technology Act, Chapter 250. Revised Edition 1980

¹⁴ Scenarios for Research on Technological Development (RTD) Cooperation with Europe (SCOPE): Kenya Country Report- Author: Joseph O. Malo SCOPE coordinators for Africa: Luke Georghiou & Jennifer Harper

as well as regional bodies like IGAD, EAC and other professional and academic networks also carry out specialised research.

The overall Research and Technology Development system in the country is made up of structures and subsystems, which perform the following functions:

- Coordination of S&T activities (NCST)
- Scientific and technological education and training (public and private universities, national polytechnics, technical institutions, etc)

“The MoEST is charged with the overall responsibility of managing science and technology in Kenya. The ministry formulates the national policy on S&T while NCST undertakes advisory and coordination functions. At sector level, however, the management of respective RTD lies with parent ministries.”¹⁵ With focus on clinical trials in Kenya, only two national research institutes will be detailed for this study.

2.1.3. Legal Provision

The NCST is empowered under the Science and Technology Act (1979) to coordinate all research work in Kenya and advise the government on all matters of science and technology. This also entails authorising and documenting all research work in Kenya. The Council is responsible for assessing technical and ethical aspects of proposals submitted for clearance and authorisation. It is illegal to conduct research in Kenya without clearance. The offence is punishable as provided for in the Science and Technology Repeal Act Cap.250 of the Laws of Kenya.¹⁶

2.1.4. Clearance for research:

Some of the main objectives of the research clearance are to: Facilitate coordination of research; Encourage quality research for the direct benefit of Kenya and to ensure appropriate storage / security of data records of research work undertaken in Kenya.¹⁷

2.1.5. Issuance of Research Permit

An application for a research permit, must be submitted in two (2) copies to reach the Permanent Secretary, Ministry of education, Science and Technology. This application must be made at least one month before the date the applicant intends to start conducting the research. The NCST will issue a permit to the project leader or the expedition leader who will be undertaking research. The Permit may be issued to the leader of an institute if there is a standing research clearance eg. KEMRI.¹⁸

2.1.6. Ethical conduct of biomedical research involving human subjects

For research of a biomedical nature to be conducted on humans in Kenya, ethical clearance is mandatory. Institutional ethical clearance committees do the ethics clearance. KEMRI, Moi Referral Hospital, KNH and Aga Khan Hospital have ethics clearance committees. However, only KEMRI has formal research guidelines including formal review guidelines for the ethics committee. Most researchers who do not belong to these institutions but wish to conduct clinical research are often advised to be affiliated to any one of these institutions and have their proposals reviewed by the appropriate ethics committee.¹⁹

¹⁵ Scenarios for Research on Technological Development (RTD) Cooperation with Europe (SCOPE): Kenya Country Report- Author: Joseph O. Malo SCOPE coordinators for Africa: Luke Georghiou & Jennifer Harper

¹⁶ Kenya National Guidelines for Research and development of HIV / AIDS Vaccines. March 2005

¹⁷ Kenya National Guidelines for Research and development of HIV / AIDS Vaccines. March 2005

¹⁸ Kenya National Guidelines for Research and development of HIV / AIDS Vaccines. March 2005

¹⁹ Guidelines for ethical conduct of biomedical research involving human subjects in Kenya. By the National Council for Science and Technology (NCST No.45, 2004)

With the emergence of pandemics such as HIV/AIDS, Malaria and Tuberculosis as the top three killer infectious diseases globally, the advent of biomedical research involving human subjects is rapidly expanding in Kenya. As the number of non-governmental organizations increasingly getting involved in biomedical research in Kenya, the NCST developed the “Guidelines for ethical conduct of biomedical research involving human subjects in Kenya” to set standards to be complied with by those institutions wanting to conduct research involving human experimentation. These standards must be scientific and ethical in nature and universally acceptable. In the making of these guidelines internationally recognised reference materials were used.

2.2. The Kenya Medical Research Institute (KEMRI)

2.2.1. Historical background

The Kenya Medical Research Institute (KEMRI) was established in 1979 under the Science and Technology (Amendment) Act, Cap. 250 of the Laws of Kenya, as the national body responsible for carrying out health research in Kenya. Prior to the establishment of KEMRI, health research in Kenya was done under the umbrella of the East African Medical Research Council. The Council was established in 1957. However, following the collapse of the East African Community in 1977, the Kenyan Parliament passed the Science and Technology Act (1977) which was amended in 1979 to, among other issues, provide for establishment of research institutes.²⁰

KEMRI is a leading health research institute in Africa. The institute cooperates with other relevant organizations within and outside Kenya in the furtherance of its mission “In Search of Better Health”. KEMRI has been provided with a standing mandate by the NCST to conduct, coordinate and manage all medical research in Kenya. Within Kenya, the Institute works closely with several government ministries especially the Ministry of Health. The Institute also collaborates with the national universities and locally based research institutions. In addition, KEMRI collaborates with and receives support from a number of international organizations. These include the World Health Organization (WHO), Japan International Cooperation Agency (JICA), the International Development Research Centre of Canada, the United States Agency for International Development (USAID), the Wellcome Trust (UK), the Walter Reed Army Institute of Research (USA), the Centres for Disease Control (USA), the British Medical Research Council and the Royal Tropical Institute of Amsterdam, Netherlands, and the Institute of Virological Research, Germany.²¹

KEMRI is also affiliated with a global project called DNDi (Development of Neglected Drugs initiative), which is coordinated at KEMRI by the director of the Centre for Clinical Research (Dr. Monique Wasuna). She is the Liason officer and coordinated the DNDi project for Ethiopia, Kenya and Sudan.

2.2.2. Research Centres

Currently, KEMRI has ten specialized research centres. Each centre conducts research on specific mandated programmes and all of them may conduct clinical trials depending on the areas of specialization of each centre but all the proposals must go through the CCR. These are:

1. Centre for Clinical Research (CCR) - Nairobi
2. Centre for Vector Biology and Control Research (CVBCR) - Kisumu
3. Centre for Public Health Research (CPHR) - Nairobi
4. Centre for Virus Research (CVR) – Nairobi
5. Centre for Infectious and Parasitic Diseases Control Research (CIPDCR) – Busia
6. Centre for Geographic Medicine and Research (CGMR) – Coast Province

²⁰ About Kemri - Summary of Activities (Staff and Research Growth) at the KENYA MEDICAL RESEARCH INSTITUTE (KEMRI) for Sustainable National Development by David Koech, Monday 31st May, 2004, pg 3.

²¹ About Kemri - Summary of Activities (Staff and Research Growth) at the KENYA MEDICAL RESEARCH INSTITUTE (KEMRI) for Sustainable National Development by David Koech, Monday 31st May, 2004, pg 3.

7. Centre for Microbiology Research (CMR) – Nairobi
8. Centre for Respiratory Diseases Research (CRDR) – Nairobi
9. Centre for Biotechnology Research and Development (CBRD) – Nairobi
10. Centre for Traditional Medicine and Drug Research (CTMDR) – Nairobi

Each Research Centre is managed by a Director who coordinates a team of research officers and support staff.

Any external organization or individual wishing to apply for a research project, has to submit a proposal to the Centre for Clinical Research. The CCR does play a central role in evaluating research proposal and collaborates internally with the KEMRI Research Centres as well and the Kenyatta National Hospital and other international research institutes.

2.2.3. Ethics and Professionalism

At KEMRI, all the research protocols undergo intensive review by various committees before it is granted approval and clearance. KEMRI has various scientific and technical committees among other management committees. The main ones related to biomedical research involving humans will be discussed in this report. These are:

- The Centre Scientific Committee (CSC)²²
- The Scientific Steering Committee (SSC)²³
- Ethical Review Committee (ERC)

If the proposal is being generated within KEMRI, it will be reviewed by the Centre Scientific Committee first. Otherwise if the research protocol is generated from independent research organizations outside of KEMRI, then it will be reviewed by the CSC for the Clinical Centre for Research, where the application has to be made.

The Centre Scientific Committee:

This is a committee at every centre composed of the staff of the Centre, such as research officers, technologists, technicians and other personnel. The duties of the CSC include:

- Review of all research project proposals generated at the Centre, ensuring that the proposal is within the mandate of the Centre. If the proposal is not from a permanent KEMRI staff, then the investigators curriculum vitae has to be attached to the proposal. This ensures that the investigator is of appropriate qualification to be able conduct biomedical research.
- Review of all manuscripts intended for publication by staff of the Centre to ensure that the authorship of a manuscript is consistent with the research findings which it emanates and the appropriate authors and co-authors are qualified.

A project proposal approved by the CSC should be submitted through the Director of the Centre with a forwarding form certifying that the proposal has been duly reviewed and approved for submission to the SSC.

The Scientific Steering Committee (SSC):

This Committee is composed essentially of all the Directors of the KEMRI Research Centres. The Chairperson of the SSC can be invited to the meetings when relevant programmes are under consideration by the SSC every six months (May and December meetings). The duties of the SSC include:²⁴

²² http://www.kemri.org/kemri_scitec.asp

²³ http://www.kemri.org/kemri_scitec.asp

²⁴ http://www.kemri.org/kemri_scitec.asp

- Review and approval of all research project proposals. No research should start without the written approval of the SSC (plus approval from the Ethical Review Committee). The approval is forwarded to the Scientific Programmes Committee (SPC) for ratification.
- Reviewing the minutes of the meetings with various CSC's whose role is also to monitor the progress of all research activities at the Centres.
- Presenting regular reports and updates to the SPC's on matters affecting scientific performance of the various research centres.
- Developing and promoting continuing education for all the Institute staff

The Scientific Programme Committee (SPC):²⁵

This committee is responsible for scrutinising, evaluating and approving research programmes, performance and output of research projects.

The Ethical Review Committee (ERC):

There is an ERC at KEMRI which reviews all research proposals involving biomedical research on human beings. The committee is multi-sectorial and has multi-disciplinary representation from outside the institute with the Director of the Centre for Clinical Research as the Secretary to the Committee. The multi-disciplinary team is comprised of laymen, nurses, medical practitioners, lawyers, engineers etc.²⁶ The presence of representatives from external professions enables the committee to maintain its independence of the institutional influence in terms of ethical issues during research (The exact size of the committee is not known, maybe KEMRI can elaborate). Any project proposal which requires an ethical approval can only be cleared by the SSC when it has been approved by the Ethical Review Committee.

Based on the guidelines for writing project proposals, it can be assumed that the ERC would review issues such as study site, patient selection, inclusion and exclusion criteria, summary of procedures to be used etc. Also the Informed consent forms and explanations must be attached to the application as appendices.

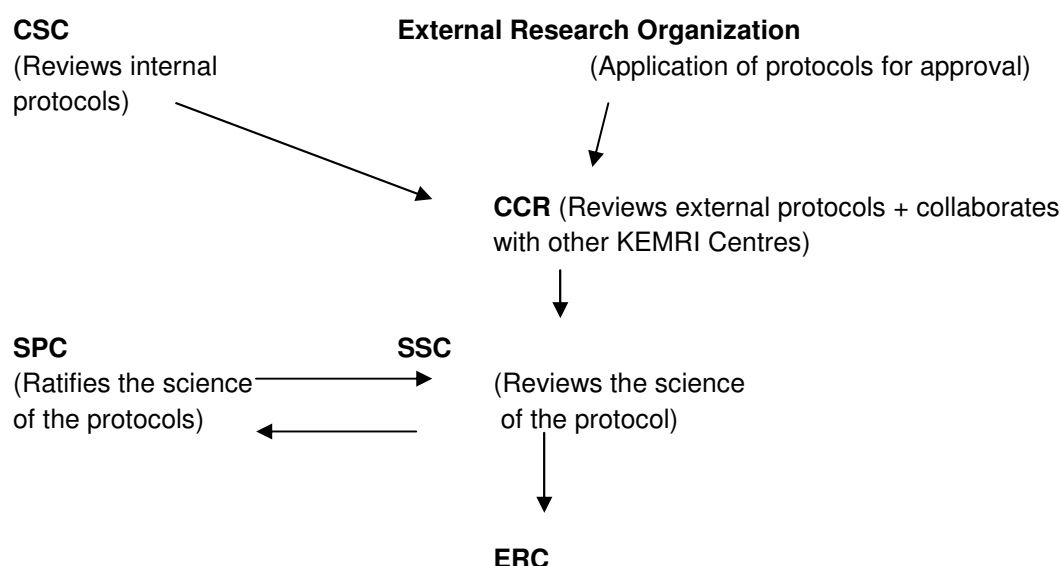
An inter-institutional collaboration is shown by the presence of a KEMRI member (the Director of the Centre for Clinical Research) on the Ethical Review Committee of Kenyatta National Hospital and vice versa. The Ethical guidelines at KEMRI are compiled using international standards using WHO, FDA and ICH as references.²⁷

All KEMRI staff are trained on Good Clinical Practices (GCP) and Good Laboratory Practices (GLP). At the time of the study there was a training session ongoing in South Africa on "Design of conduct of clinical trials".

²⁵ http://www.kemri.org/kemri_management.asp

²⁶ Interview with Dr. J.Rashid, "Acting Director for Centre for Clinical Research", KEMRI on 25th January 2006.

²⁷ Interview with Dr. J.Rashid, "Acting Director for Centre for Clinical Research", KEMRI on 25th January 2006



2.3. Kenya Trypanosomiasis Research Institute (KETRI)

KETRI is only working on research on trypanosomiasis of animals and humans. Trypanosomiasis (also known as sleeping sickness in humans and nagana in animals) is caused by the bite of a Tsetse fly. It is known that the tsetse fly infests 37 of Africa's sub-Saharan countries. It is estimated that each year Africa loses about 3 million cattle and other domestic livestock through deaths caused by trypanosomiasis. In addition, more than 60 million people are at risk of getting infected and the number of new infections in a year is estimated to be over 40,000.²⁸

Existing and current treatment for human trypanosomiasis is limited to injectable form of Melarsoprol and Pentamidine. They are known to be highly toxic. They also require systemic injections which demand that sleeping sickness patients be hospitalized for appropriate medical management of the illness. This also means that highly qualified medical expertise is required due to the high number of side effects of the medicines. It is also known that about 30% of the parasites are resistant to Melarsoprol in certain parts of Africa and a mortality rate of about 5% is reported from toxic effects at therapeutic doses.

KETRI is currently testing a new synthetic novel prodrug, DB289 and studies have shown that the drug exhibits curative properties for early T.b. rhodesiense infection in monkeys. This may be the future progression of developing a user-friendly oral drug for the treatment of sleeping sickness compared to existing ones which are relatively toxic. The investigators believe that an oral drug for treatment of sleeping sickness would be favourable to patients for self administration without being confined in a hospital. The new drug is also known not to have toxic side effects. This is a four year project funded by Bill and Melinda Gates Foundation.²⁹

²⁸ KETRI HIGHLIGHTS; Published by the Kenya Trypanosomiasis Research institute, Muguga; Vol.6, No.1, April,2002, <http://www.ketri.org> ; <http://www.ketri.org/research.htm>

²⁹ KETRI HIGHLIGHTS; Published by the Kenya Trypanosomiasis Research institute, Muguga; Vol.6, No.1, April 2002, <http://www.ketri.org> ; <http://www.ketri.org/research.htm>

2.4. Ministry of Health

The Ministry of Health is mandated to look after the health and wellbeing of Kenyan citizens and in order to safeguard the ethical issues and dilemma's raised during biomedical research, the ministry has established a Committee that controls, regulates and monitors research activities in Kenya.

The ministry has been structured into four departments, namely, Promotive and Preventive Health Services, Curative and Rehabilitative Health Services, Standards and Regulatory Services, and Health Sector Reform Secretariat. The Director of Medical Services (DMS) heads all these departments. Of interest on the context of clinical trials and research activities are the two departments of:

- Department of Curative and Rehabilitative Health Services
- Department of Standards and Regulatory Services.

The Pharmacy Division (also known as the Pharmacy and Poisons Board, PPB) is under the Department of Curative and Rehabilitative Health Services. The main roles of the Department of Standards and Regulatory Services are to coordinate medical research among others such as health policy and traditional medicine; review, update and harmonize health-related laws in Kenya; and coordinate and strengthen regulatory bodies.

The MoH being the parent ministry for research institutes on human health, i.e. KEMRI, the ministry sets the scene for requirement of medical research and prioritises on medical research areas. The MoH therefore must be informed of all health projects being undertaken in Kenya via the office of the Director of Medical Services. In Certain cases research protocols may be presented directly to the ministry instead of the research institution and hence the committee reviews the protocols. More specifically for clinical trials the following special requirements need to be adhered to:

- A concept paper must be submitted to the Director of Medical Services and the Department of Standards and Regulatory Services. The concept paper should give a broad outline of the type of trial proposed including the qualifications of the investigators and mainly the subject groups to be used in the trial.
- The concept paper is then reviewed by ten members of the Committee. Sometimes external reviewers may be brought in from relevant institutions such as teaching universities.
- After the concept paper has been approved, the paper must be sent to the PPB. (often this process can take place simultaneously).³⁰

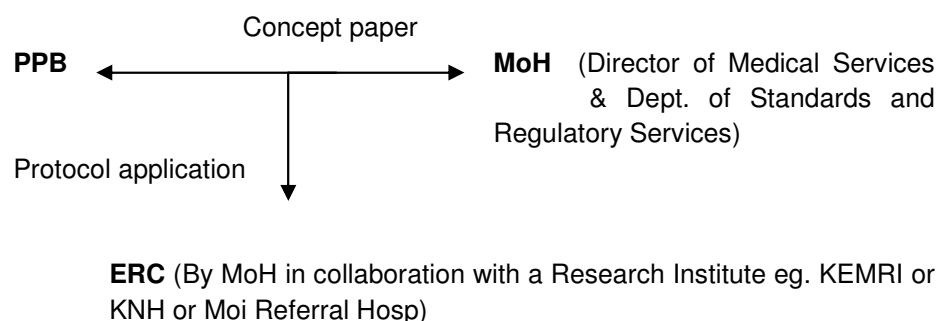
Once approval from the Ministry of Health Committee and PPB are obtained, then a protocol application must be made for an ethical clearance. The MoH Committee works in collaboration with Ethical Review Committees of approved institutions. Currently these are KEMRI, KNH and Moi Referral University Hospital. The process of ethical review applies to any type of biomedical research to be conducted in Kenya.

The Committee meets on the first Tuesday of every month. The Committee consists of 20 members from various organizations and institutions, some of which are:

- Representatives from various departments of the ministry eg, Pharmacy and Poisons Board and Department of Standards and Regulatory Services
- Teaching universities
- Medical professionals / specialists
- Stakeholders such as external research institutes eg. CDC, Wellcome Trust, Walter Reed

³⁰ 30, Interview with Mr. Kepha Ombacho "Assistant Chief Public Health Officer" on 28th February 2006. (Due to restricted time for the interview details on what types of protocols for clinical trials were not dwelled on during the interview)

- NGO Consortium
- Lawyers



2.5. Pharmacy and Poisons Board, Ministry of Health (PPB)

The Pharmacy and Poisons Board is empowered, under the Pharmacy and Poisons ACT Cap.244 (2002) to regulate the manufacture, importation, exportation, registration, distribution and sale of all pharmaceutical and medical devices including vaccines and vaccine products. When a new pharmaceutical product is brought into Kenya, it must be registered by the PPB, drug registration department. As part of the registration procedure, a complete dossier must be presented which includes details of all types of studies conducted, including clinical trials done during the development of the product.

In practice, the PPB has not really been involved in the field of Clinical Trials in Kenya. However, in 2005, the guidelines for Research and Development of HIV/AIDS Vaccines were being formulated whereby the role of the PPB was defined in these guidelines. In late 2005, a subcommittee of the practice committee has been identified to represent the PPB and to establish working protocols for all clinical research work on drugs and vaccines being conducted in Kenya. The sub-committee is composed of members from various scientific backgrounds. The sub-committee is yet to meet and define a plan of action.

Sub committee reports to Practice Committee of PPB, which reports to the Full Board (comprising of 9 – 10 members; the chairman is the DMS and the secretary is the registrar)

The following regulations were found in the Kenya National Drug Policy related to research and clinical trials. These clearly indicate that the PPB has a role to play in the research of drugs and vaccines as well as in the regulation and control of registration, importation and exportation of new investigational drugs. However, for now it can be concluded that this role exists only in theory, but is not practiced.

2.5.1. The Kenya National Drug Policy:

Chapter 5: Regulatory Control

Section 5.2: Drug Registration

“New investigational drugs will be considered for exemption from normal registration requirements in order to facilitate their availability for clinical studies”.³¹

³¹ The Kenya National Drug Policy, July 1994, Section5, 5.2 Drug Registration, pg.11

Section 5.5: Clinical Trials

“Clinical trials are an essential part of drug development. The Pharmacy and Poisons Board will approve protocols for clinical trials for new drugs and established guidelines for clinical trials involving drugs already registered in Kenya”.³²

Chapter 10: Local Production

Section 10.3: Research and Development

“Pharmaceutical research and development will be encouraged to support local production. The priority areas for drug research and development will be developed jointly with the Ministry of Health Division of Research and Development, the Division of Pharmacy, the department of Veterinary Services (for veterinary drugs) and other concerned parties in universities, research institutions and the private sector. A current inventory of research in the field of drugs will be established”.³³

2.6. Kenyatta National Hospital

Kenyatta National Hospital (KNH) in Nairobi is a state corporation under the Ministry of Health. It is the national referral hospital for Kenya but also serves the regional neighbouring countries. KNH was established in 1901 and currently comprises of 50 wards, 20 out-patient clinics, 24 operation theatres (16 specialized) and an Accident & Emergency Department. KNH has a capacity of 1800 beds. It offers a comprehensive array of preventive, promotive and curative services, with specialist consultants in charge of the different departments.

KNH is strongly attached to the medical faculties of the University of Nairobi and most of the teaching takes place on the premises of the hospital. KNH also works in collaboration with the University for all types of research activities. KHN conducts research in the areas of Preventive Mother to Child Transmission (PMTCT), HIV/AIDS and behaviour change, surgery, internal medicine, radiology, pathology, obstetrics and gynaecology and paediatrics.³⁴

The KNH is an internationally recognised institution for conducting research on human subjects. It is a registered Institutional Review Board (IRB) by the Office for Human Research Protections (OHRP) in the USA. The OHRP provides an OHRP-approved assurance of compliance with the Health and Human Services regulations for the protection of human subjects. This approval is granted in the form of an International (non U.S.A) Federal-wide Assurance (FWA)³⁵ number. The KNH has been granted an FWA number. Other institutes in Kenya with an approved FWA number, are KEMRI, Ministry of Health, Coast Province and Moi University in Eldoret.³⁶

The FWA number is granted to an institution and is updated on a regular basis.

The hospital ERC reviews limited study areas and both the scientific and ethical aspects are reviewed by the same body. The major difference in comparison to KNH is that KEMRI works on a wider scope of studies and has two independent committees for the scientific and the ethical review. The hospital collaborates with both local and international health and research institutes, as well as collaborates with multinational pharmaceutical companies eg. GlaxoSmithkline, Novartis and Astra Zeneca.

³² The Kenya National Drug Policy, July 1994, Section5, 5.2 Drug Registration, pg.11

³³ Footnote no.31, 32, 33, The Kenya National Drug Policy, July 1994, Section5, 5.2 Drug Registration, pg.11

³⁴ “The Standard, Friday March 3rd 2006”, pg 20- 21.

³⁵ <http://ohrp.cit.nih.gov/search/iorglstn.asp?LOCATIONID=134&otype=n&ILST=Sub...>

³⁶ http://hhs.gov/ohrp/assurances/assurances_index.html

2.6.1. Ethics and Research Committee of the KNH

The members for this committee are selected and appointed jointly by the hospital and the University of Nairobi, College of Health Sciences. There are a total of 20 members, represented by Medical specialists, the hospital legal advisor, persons from the community and the Secretary the ERC of KEMRI. An equal gender balance is maintained. The mandate of the ERC is to review all proposals that involve research on human beings for biomedical research. An ethical clearance is mandatory for all proposals.

The ERC observes the following issues on the proposal:³⁷

- 1) Researchers – The balance between local and external participants and their roles must be clearly identified. The investigator's CV has to be attached to evaluate the medical capacity of the investigator. It is the policy of the hospital to ensure that for every proposal an investigator from the hospital is assigned to the project or the project has to be conducted at the hospital facilities.
- 2) The science of the research is reviewed
- 3) The Ethical aspects are reviewed – including autonomy of the subjects, informed consent in writing. The consent forms have to be signed by the investigator as well as the subject in front of a witness. The subject must have a copy of the consent form.
- 4) The budget must be considered whereby each component of the budget is evaluated to ensure that finance is accorded in balance to the resources required for the project
- 5) Records of previous studies are reviewed in order to avoid duplication
- 6) Post trial benefits and risks are required to be clearly stated in the protocol which are critically reviewed by the ERC

The ERC conducts reviews for the hospital as well as the Ministry of Health and external collaborators. The ERC members are all trained on GCP and bioethical issues. The University of Washington has collaborated with the hospital institute to provide GCP training to a wider group of professionals. The trials are monitored regularly and sometimes independent monitors are used. The independent monitors visit the project sites and review all documentation of the project. A software database is created for each research by a safety monitoring body and these are used by trial monitors.

The hospital has a guideline indicating the format in which the proposal has to be presented. An application must be made using the Ethics and Research Application Form. It is reviewed by two principal reviewers on the Committee. The Committee meets on the 2nd Wednesday of every month for a minimum of three hours. An additional special meeting can be convened if necessary. The Committee has set standard operating procedures (SOP's) for reviewing the proposals and conducting the meetings in an orderly manner.³⁸ The attendance and deliberations of the meetings are documented, signed by the chairperson and secretary and then are filed appropriately.

Approval for research is granted for one year only but is renewable. Regular update needs to be provided to the ERC (hence the monthly meetings) in the form of bi-annual and annual report for renewal of the proposal. If there are changes in the protocol during the research, request for approval of amendments must be sought.

Adverse drug reactions MUST be reported within 72 hours of occurrence. If there is a failure to do so then a valid reason must be provided to the ERC otherwise disciplinary action can be taken.³⁹

³⁷ Guidelines for Protocol development" by KNH obtained from Prof. Guantai (secretary of ethical review committee)

³⁸ Interview with Prof. Bhatt at KNH (Chairperson of the ERC) on 10.02.2006 based at Kenyatta National Hospital

³⁹ Interview with Prof. Guantai(secretary of ethical review committee) on 16.02.2006 based at Kenyatta National Hospital

2.6.2. Teaching Institutes

University of Nairobi (UoN)

The medical departments of the University of Nairobi are located within the compound of the Kenyatta National Hospital. The medical departments involved in biomedical research are those in the schools of Pharmacy, Medicine, Nursing and Kenya Medical Training Centre (KMTTC). Research in the Social sciences (anthropology) and Nutritional Sciences are also picking up. The University collaborates with the Kenyatta National Hospital for most of its biomedical research programmes.

Other teaching institutes include Moi University and it is affiliated to a Referral Teaching hospital. As it is located in Eldoret it was not possible to meet them but the university was mentioned in several interviews. Maseno University in Kisumu and Eldoret University.

2.7. International Research Institutes

There several international research institutions based in Kenya and working on various research projects in collaboration with the national research institutions. Most of them work in research areas of Malaria, HIV and other life threatening diseases. Each research institute has its own mandate to conduct research in Kenya and the following paragraphs attempt to highlight the main features of these institutes.

Wellcome Trust Research Institute is an independent medical research funding charity based in the UK. KEMRI-WELLCOME TRUST collaborative research programme was initiated in 1989 largely dealing with the clinical epidemiology of malaria in Kilifi and pharmacology in Nairobi. KEMRI-Wellcome Trust research Centre has recently been rated as the third most important facility conducting malaria research in the world.

Research studies in Kilifi focus on clinical, basic and epidemiological aspects of malaria and other diseases of childhood, while work in Nairobi targets the pharmacology and therapeutics of anti-malarial drugs, as well as malaria epidemiology, control and healthy policy.⁴⁰ Currently there a number of studies ongoing, one of them being “Role of hypovolaemia in the acidosis of severe malaria”.

The Centre for Disease Control and Prevention (CDC) is one of the 13 major operating components of the Department of Health and Human Services in USA. The CDC Research Station has been operational in Kenya since 1979 and was established by the Division of parasitic diseases as part of KEMRI.⁴¹ CDC is based in Western Kenya, Kisumu under the umbrella of the KEMRI Centre for Vector Biology and Control Research (CVBCR). CDC conducts research projects on malaria and HIV/AIDS. The latter is supported by the Division of HIV/AIDS Prevention (DHAP/NCHSTP) and HIV prevention and care program activities supported by the Global AIDS Program (GAP / NCHSTP). The KEMRI/CDC Research Station has well developed malaria and HIV laboratories and the former is actively engaged in research on the immunology of malaria in children under five and pregnant women. Other research areas include microbial investigations such primary isolation and identification of enteric organisms (*Vibrio cholerae*, *Shigella*) and immunology of schistosomiasis.

The proposals of CDC require a clearance from CVBCR in Kisumu first before it is forwarded to KEMRI in Nairobi. This is due to the fact that each Centre has its own SSC which approves the proposal at Centre level. Main study areas are Malaria and HIV / AIDS. A recent study on bed nets was done in 2001 to see if insecticide treated bed nets can reduce malaria related mortality in children. All CDC protocols need to be approved by the FDA in USA, as well as collaboratively with KEMRI.

⁴⁰ http://www.wellcome.ac.uk/doc_WTD003487.html

⁴¹ <http://www.cdc.gov/about/default.htm>

CDC is also collaborating with other international institutions such as the “Global AIDS Programme (GAP)”, the President’s Emergency Plan for AIDS Relief (PEPFAR) programme. At the same time CDC also sponsor’s non-governmental organizations in the form of funding and technical support.

It is mandatory for CDC to have a FWA number approved by OHRP. KEMRI also has the FWA number. As CDC is responsible to report to the FDA, it must receive an annual renewal from KEMRI. For all research work conducted by CDC, every project is monitored by an independent monitor. All CDC staff is e trained on GCP and for every project the subjects undergo a thorough consent process. The subjects sign the consent forms in the presence of a witness. The independent monitors also audit the consent forms.

The US Army Medical Research Unit Kenya is also known as the Walter Reed Project (WRP) and has been operational in Kenya in since 1969. There are two centres in Kenya, Kisumu and Kericho. The mission of USAMRU-K is to develop and test improved means for predicting, detecting, preventing and treating infectious disease threats to military and civilians in East Africa.⁴² The Walter Reed Project conducts research in the following areas: Malaria Immunology, Leishmaniasis, HIV / AIDS, Entomology, Viral diseases, Malaria drug discovery and surveillance and Enterics.

A successful example of the result of research by USAMRU is the development of the Hepatitis A vaccine.⁴³ A recent announcement was made in one of Kenya’s national newspaper “THE DAILY NATION”⁴⁴ states that KEMRI jointly with the WRP is launching a clinical trial for an AIDS vaccine. Currently trials are conducted in Phase I and Phase II. There are plans to conduct trials in Phase III and IV in the future. WRP has international donors such as Bill & Melinda Gates Foundation (MVI – Malaria Vaccine Initiative) and PEPFAR among others.

All protocols are approved by the US Army and its regulatory authorities in the USA. WRP has its own scientific and ethical review committee. WRP follows international standards (ICH) as well as FDA regulations. WRP projects often collaborate with multinational companies like GSK, Novartis and Pfizer. This collaboration is mainly at the international level. The companies usually send independent monitors who sometimes come from South Africa. These monitors are from the Private Product Development (PPD’s) institutions. WRP also collaborates with other partners like KEMRI, CDC, USAID and the US based National Institution of Health (NIH).

Some current trials ongoing or planned are:

- Malaria vaccine based on merozoite surface protein –1 or the apicalmerozoite antigen 1 (AMA-1)⁴⁵
- Diagnostic development and evaluation of five different types of testing kits for Leishmaniasis⁴⁶
- AIDS vaccine trials in Kericho⁴⁷
- Phase III trials on the new malaria drug, Tafenoquine are ongoing in partnership with Glaxo Smithkline⁴⁸
- Research on dengue and typhus infections

Kenya AIDS Vaccine Initiative (KAVI) AND International AIDS Vaccine Initiative (IAVI)

IAVI is a global not for profit organization working to speed the search for a vaccine to prevent HIV infections and AIDS; was founded in 1996 and operational in 23 countries. IAVI has partnerships in 12

⁴² <http://www.cdc.gov/malaria/cdcactivities/kenya.htm>

⁴³ <http://www.usamrukenya.org/>

⁴⁴ Article “Aids Vaccine trials set to start” Daily NATION, Monday February 27, 2006.

⁴⁵ <http://www.usamrukenya.org/malaria/m/body.htm>

⁴⁶ <http://www.usamrukenya.org/leishmania/body.htm>

⁴⁷ The Daily Nation, Monday February 27th 2006 – Aids vaccine trials set to start

⁴⁸ <http://www.usamrukenya.org/malariasen/body.htm>

countries (Kenya being one of them) to conduct trials, and a core laboratory oversees the vaccine testing procedures at each site so that the results on different candidates can be compared. IAVI is researching new concepts for the design of a vaccine. Its advocacy programme promotes awareness among political and scientific leaders, community groups and others worldwide about the urgent need for a vaccine. In areas where vaccine trials are taking place, IAVI works to educate community members about the research process, and Community Advisory Boards provide input into the setup and conduct IAVI sponsored trials.⁴⁹

The Kenya AIDS Vaccine Initiative is a collaboration between the University of Nairobi, the Medical Research Council in Oxford, UK and IAVI. KAVI is currently in the process of developing a preventive vaccine. This vaccine has been specifically designed to be used in Kenya because it is based on the most common type of HIV circulating in Kenya.⁵⁰ Vaccine trials are conducted in three sequential phases (unlike clinical trials of drugs where there are four phases). So far three, Phase I studies have been completed in Kenya between Feb. 2001 and March 2003. A Phase II study is ongoing since April 2003.⁵¹

There are a number of international universities that also conduct clinical research in Kenya in collaboration with National and International research institutes. Some of the known universities are: University of California-USA, University of Washington-USA, University of Manitoba-USA, University of Illinois –USA, University of Maryland-USA; London School of Hygiene and Tropical Medicine-UK, University of Liverpool-UK; Nagasaki University Institute of Tropical Medicine-Japan; University of Ghent, Belgium just to name a few.

2.8. Pharmaceutical Companies

2.8.1. Multinational

Kenya hosts a number of multinational pharmaceutical companies namely GSK, Astra Zeneca, Pfizer Sanofi Pasteur, Ely Lilly, Novartis, Bayer and Boehringer Ingelheim. GSK is the largest pharmaceutical company in Kenya in terms of manufacturing and marketing. The other pharmaceutical companies are mainly service oriented marketing and sales offices, with their regional headquarters in South Africa or West Africa. In Kenya they are managed by an Agent called “High Chem” which coordinates all the activities of importation and logistics for a group of the multinationals, such as Sanofi / Aventis, Boehringer, Pfizer and Astra Zeneca to name a few.

Normally a new product is imported into Kenya after the product has been in the market in originating country for 3 – 4 years. Prior to the importation process, the product is introduced to the medical experts in Kenya of the relevant therapeutic field. The experts are provided information by way of lectures, meetings and dissemination of information. The product is later registered with the Pharmacy and Poisons Board before it is released to the team of medical experts already sensitized who actually start the use of the products in small groups of known patients. The product is then launched and is available for wider use in the country.

GSK, Pfizer, Novartis and Sanofi / Aventis and Astra Zeneca (AZ) conduct clinical trials in Kenya.⁵²

⁴⁹ <http://www.iavi.org/viewpage.cfm?aid=24>

⁵⁰ <http://www.kaviuon.org/About%20KAVI.htm>

⁵¹ Details of these studies can be found in the ref: <http://www.kaviuon.org/Ab%20Trials.htm>

⁵² GSK – Interview with Dr. Mwatu; Pfizer – Interview with Dr. Rashid of ACCT; Sanofi Aventis – Interview with Dr. Mercy Njuguna; Astra Zeneca – Interview with Mr. Willy Soriney; Novartis – <http://www.npicentre.com/anm/anmviewer.asp?a=12640&print=yes>

Ely Lilly does not conduct any clinical trial in Africa as there is only a liaison office with mainly marketing and sales activities.⁵³

AZ has four therapy areas: Heart, Infections, Respiratory diseases and gastro intestinal diseases and cancer. AZ has a well organized marketing team with hierarchical division of therapy areas and tasks. AZ conducts mainly Phase IV clinical trials in Kenya composed of comparative studies. Three studies have been done (one mentioned to be completed in 1997). They were investigator initiated and AZ was the funder for the studies. If the studies require ethical clearance, it is sought at a major hospital in Nairobi such as KNH, The Aga Khan Hospital or the Nairobi Hospital. The Ethical Review of these hospitals would provide the clearance. AZ will only agree to fund the study once the study has been given the approval and an ethical clearance. These studies have been independent studies by post graduate students or specialists conducting specific disease oriented studies. AZ would generally provide assistance in terms of funding (100%), relevant drug donations or support with analysis of the data. (Sometimes the investigators would process the raw data themselves).⁵⁴

GSK conducts Phase II and III clinical trials in the region of East Africa (including Ethiopia, Malawi, Zambia and the Great Lake Region of Rwanda and Burundi). They conduct research on drugs and vaccines in various therapeutic classes. GSK collaborates with other research institutions such as KEMRI, KNH, WRP, Wellcome Trust and CDC. Collaboration could take the form of funding (100% of which about 15 – 20% is for the institutions overheads and administration costs) or drug donations as per the requirements. GSK submits the protocols to the Ministry of Health and the Pharmacy and Poisons Board for approval. According to GSK, all GSK sponsored clinical trials conducted according to Good Clinical Practice (GCP) guidelines developed by the International Conferences on Harmonization (ICH) and has its own standard operating procedures (SOP's) and procedures. GSK always seeks an Ethical clearance from KEMRI or KNH and follows all processes necessary for the consent which is informed. Compensations are also clearly indicated defined in the protocol. An independent international Ethics Review Committee (from UK) monitors the trials. GSK's main research areas are antimalarials, helminths and asthma.⁵⁵ GSK quotes an approximate cost of £80,000 - £100,000 for a small scale trial of 400 to 500 patients and a trial / study can take an average of 3 – 4 years minimum time for completion. GSK has several trials ongoing which are listed in the inventory. It is GSK's position that tested drugs should be registered in country where the testing was done.

Sanofi Pasteur is the vaccine group of Sanofi Aventis separate from the general pharmaceutical group. In Kenya Sanofi Pasteur conducts Phase IV clinical trials, as vaccines clinical trials are generally conducted in the originating company due to complex nature of vaccine development, transportation and storage. Sanofi obtains ethical clearance from the national institutes KEMRI and KNH but have their own internal SOP's and procedures which are in line with GCP. When Sanofi works in collaboration with national institutes, they fund the trial 100%. Some trials have been conducted with the University of Nairobi whereby the Regional office in South Africa sponsor the trial and local investigators are used. Sometimes a CRO is contracted in South Africa and local monitors in Kenya are appointed to follow the trials.⁵⁶ Current studies include:

- A sero-prevalence study on Hepatitis B – This study is under publication
- An epidemiological study for Hepatitis A – This study is under publication
- Cost effectiveness studies of typhoid vaccines – Ongoing

⁵³ Phone conversation with Dr. Nyalita of Ely Lilly

⁵⁴ Astra Zeneca; Interview with Mr. Willy Soriney, "Therapy support manager" on Monday 30th January 2006

⁵⁵ Detailed information on products currently undergoing trials are found on: <http://ctr.gsk.co.uk/medicineslist.asp>. It was difficult to obtain individual trials information as it involves looking at each drug individually and time did not allow this exercise.

⁵⁶ Interview at Sanofi Pasteur with Dr. Mercy Njuguna, "Medical Manager" on 23.02.2006

■ Surveillance for influenza in collaboration with KEMRI – Ongoing

The contact person for Pfizer was rather busy during the study period hence it was agreed that he would respond to a short questionnaire by e-mail. Pfizer's statement was that they do not conduct clinical trials in Kenya. However, this information was found contrary to information about a clinical trial being conducted in Kenya by a CRO (ACCT) and in Uganda. The study is researching a combination of Azithromycin Plus Chloroquine Versus Mefloquine for the Treatment of Uncomplicated Malaria in Africa. Pfizer was re-contacted to confirm about this study but no reply was received by the time the report was being finalized.

Most of the multinational companies indicate that they have very well defined protocols on how to conduct clinical trials. According to the companies, they follow the international standards and guidelines of ICH and GCP in combination with their own SOP's. The websites of each of these companies were visited and each company elaborated on the company policies on clinical trials, how they are conducted and a joint declaration made to committing registration of trials and disclosure of results at an international level. A joint position has been taken up by the major pharmaceutical manufacturers at an international level to disclose clinical trial information via Clinical Trial Registries and Databases. The Joint position as taken on by the innovative pharmaceutical industry (Represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA), The International Federation of Pharmaceutical Manufacturers and Association (IFPMA), the Japanese Pharmaceutical Manufacturers Association (JPMA), and the Pharmaceutical Research and Manufacturers of America (PhRMA) have committed to registering information about all new and ongoing clinical trials, other than exploratory trials, in a free, publicly accessible clinical trial registry.⁵⁷ During the research two sites for registration of clinical trials (ClinicalTrials.gov & <http://129.35.73.130/wps/portal>) were found and one site for posting the results of the trials (Clinicaltrialresults.org).

2.8.2. Local Manufacturers

There are 34 pharmaceutical manufacturing companies in Kenya.⁵⁸ A range of pharmaceutical products are manufactured including oral medicines, medicines for external use, infusion solutions, injectables and disinfectants. The local pharmaceutical industry serves largely the Kenyan market as well the region of East Africa including the Great Lake Region of Burundi and Rwanda.

In general most of the local manufacturers do not conduct clinical trials as they are not innovating new molecules but only manufacturing known molecules. The companies do conduct production trials such as bioavailability studies and stability testing in house. There is a lack of system which should authenticate and regulate the local manufacturers for registering in house trials such as pre-formulation studies. The companies conduct in house experiments but it is common knowledge that they are not very willing to share the findings, one reason for this could be because there is no regulation requiring the same. Another situation is that there are numerous combination of drug molecules which are manufactured locally but do not undergo clinical trials. The justification provided for this is that the molecules are usually well known and widely researched by the innovator companies, so the local industries are not required to conduct the trials. However, during several interviews, concerns were raised about this lack of regulatory requirement on the local manufacturers. The local industry is occasionally approached to collaborate in a clinical trial whereby they are mainly donating the drugs required for the comparative studies.

⁵⁷ Joint Position on the Disclosure of Sensitive Information via Clinical Trial Registries, IFPMA, 5th September 2005

⁵⁸ "Assessment of Pharmaceutical Situation in Kenya" A Baseline Survey by HAI, 2003,pg.4

A new development in Kenya occurred in 2004 whereby GSK allowed Cosmos pharmaceuticals a voluntary license to manufacture two of GSK's patented medicines. This allows Cosmos to supply the much needed HIV drugs, but in order to be able to compete in the international market, Cosmos will have to ensure prequalification by WHO. Therefore it will be obligatory to conduct clinical trials and bioequivalence studies. The company is currently in the process of applying for clinical trials in the areas of malaria and TB and HIV / AIDS. These trials are planned to be sub-contracted to CRO's in India mainly due to the cost factor.⁵⁹

Clinical trials in Kenya cost anything USD\$ 70,000 per trial (this a minimum figure) to about £100,000 depending on the type of trial, size of the trial group and therapeutic study area. This kind of cost is not feasible for a local manufacturing company. Some figures were mentioned during one of the interviews which may be used here for comparison only and are not to be quoted precisely.

country	Cost in USD \$ for Clinical Trials and / or Bioequivalence studies
Kenya	42,000 – 70,000 (£80,000 - £100,000)
South Africa	50,000 (another quote was 120,000 Euros)
India	30,000

Based on the above figures (quoted as approximate figures during various interviews), it only makes sense to conduct clinical trials in India or other countries where costs may be lower.

Until recently, the requirements of providing drug supplies at a national and international level were not very stringent. However due to the pandemics of HIV / AIDS, Malaria and Tuberculosis, the World Health Organization has implemented a prequalification project whereby any manufacturing company wanting to provide these drug categories must have their products pre-qualified according to the WHO standards in order for them to be registered and available internationally for use in relevant programmes. One of the pre-qualification requirements is that the products have undergone a minimum level of trials and bioequivalence studies to assure the quality of these products. This is forcing manufacturers to look at issues of thorough testing of the pharmaceutical products. And one pharmaceutical company stated that they would be interested in investigating the possibilities of conducting clinical trials in the future.

2.9. Civil Society Organizations:

Several CSO's were contacted but none had any direct experience in terms of clinical trials. Some of the CSO's contacted were:

- Health Action International (HAI)
- Ecuminical Pharmaceutical Network (EPN)
- Christian Health Action Kenya (CHAK)
- Consumer Information Network (CIN)
- Kenya Human Rights Commission (KHRC)
- International Medico-Legal Unit (IMLU)
- Kenya Episcopal Conference, Catholic Churches Secretariat, health unit
- Kenya Consortium to Fight AIDS, TB and Malaria (KECOFATUMA)

⁵⁹ Interview with Quality Assurance Pharmacist of Cosmos pharmaceuticals Ltd

- Strategic Public Relations and Research Ltd (SPRR)
- Family Health International
- African Centre for Clinical Trials (ACCT)

Family Health International is the only CSO found to be involved in the area of clinical trials in Africa. The team interviewed, work as monitors for preparation phase for clinical trials. FHI is currently working on a multi-centre clinical trial on malaria combination drug in Uganda, Senegal and Gambia, in Africa. Other studies ongoing are trials on microbicides in collaboration with International Partnership for microbicides. They are also in the process of preparing ground work for a clinical trial on HIV vaccines. The monitors are currently working on information gathering for HIV incidence in four regions in Kenya.

ACCT is an international NGO, registered in Kenya. It is a Contract Research Organization (CRO) and has offices in Nairobi and Uganda. ACCT facilitates, promotes and conducts high quality trials and research in partnership with institutions and organizations. ACCT provides clinical trial services, Training and capacity building, Source Documents, Clinical Pharmacology and Molecular Parasitology, Clinical trial analysis and Clinical data management. More details can be found on the ACCT profile.⁶⁰

KECOFATUMA works in collaboration with the international AIDS vaccine initiative to create Community Based Organizations (CBO's) who are appropriately sensitized on all aspects of clinical trials, and these CBO's then sensitize the population groups who may be involved in clinical trials as subjects. This programme ensures that people are made aware of what entails in clinical trials of vaccines. They work closely with other groups such as NEPHAC (Network of People living with HIV/AIDS) and KENWA (Kenya Network of women living with HIV / AIDS).

Other CSO's will not be detailed here as the team of Francis Weyzig and Annelies den Boer from Amsterdam were to follow up meetings in the week of February 27th 2006.

⁶⁰ Organization Profile provided by Dr. Rashid of ACCT on 27.02.2006

3. The Scientific Basis of Research in Kenya

3.1. Analysis of International requirements

The following international guidelines were reviewed to make a comparative analysis of standards used for research protocols in Kenya:

1. International Ethical Guidelines for Biomedical Research Involving Human Subjects by, The Council for International Organizations of Medical Sciences (CIOMS) 2002.
2. ICH Harmonized Tripartite Guideline, 1996
3. World Health Organization, Guidelines of Good Clinical Practice for Trials on Pharmaceutical Products, World Technical Series, No.850, 1995 Annex 3
4. PhRMA, Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.
5. World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.
6. Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products. World Health Organization, Technical Report, Series No. 850, 1995. pp 97-137

Most of the organizations met during the study referred to three main international standards, these were ICH Guidelines, WHO GCP Guidelines and GLP Guidelines. The Declaration of Helsinki was also mentioned. The Research institutes have based their guidelines for protocols on the same international standards. For example NCST based their guidelines on the international standards of WHO, ICH, FDA, CIOMS etc while KNH base their guidelines on ICH, WHO and Declaration of Helsinki.

All the people interviewed mentioned the use of Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) as absolutely essential for research and clinical trials.

The Guidelines for ethical conduct of biomedical research involving human subjects in Kenya by the National Council for Science and Technology give a background on the progress of some of the main international guidelines and have been based on all the above references as well as other regional guidelines.

The KNH and KEMRI Ethical Review Committee's use a standard format using the points highlighted in Appendix A titled "Critical Analysis of a Protocol". Some vital points considered are the inclusion and exclusion criteria, the study area and population of subjects to be recruited for the trial. Other considerations are the scientific hypothesis and data management. Investigators qualifications must be verified by supporting curriculum vitae.

Ethical considerations are given prime importance during the analysis of protocols in Kenya.

Some of the main ethical considerations are informed consent, explanation provided to the participants as part of the system for obtaining informed consent, after trial treatment, provision of incentives to trial participants etc. The analysis reviews whether the protocol has taken into consideration the ethical value of human or animal research and it is also ensured that the ethical considerations are in respect of the Declaration of Helsinki. Informed consent and the way in which consent will be conducted is reviewed thoroughly.⁶¹

⁶¹ Statement derived as emphasised by most interviewee's

This ethical review is theoretical and it was not possible to determine how realistically the ethics are maintained in practice. However, for example, the reporting of an adverse event is given high importance and the research institute requires for such an adverse event to be reported to the institute within 72 hours. If this is not done there the researchers must have a very good reason to explain why the report was not made in time.

KEMRI guidelines also ensure that the benefits and risks are mentioned in the protocol. In the case of a drug trial, any potentially known side effects (as observed in previous animal studies) should be indicated. While in the case of use of animals for study, methods to minimize pain and distress must be included in the protocol.

3.2. The Process for Conducting Research in Kenya

3.2.1. Research Protocols

Every research institute involved in bio-medical research has set out its own guidelines on “Protocol development”. That is the protocol should have a defined set of criteria as indicated in the relevant guidelines of the institution. This also means that in order to make an application for a proposal to conduct bio-medical research in collaboration with the particular institute, the proposal should have the minimum of information as outlined above. Each Institute has its own format of protocol development. This report will broadly outline guidelines for two institutes KEMRI and KNH. A third guideline is given for the protocol development for Vaccine research.

KEMRI - Guidelines for writing project proposals

- Title of the Project
- Investigators and Institutional Affiliations
- Abstract
- Introduction / Background
- Justification of the study
- State the Null Hypothesis
- General Objectives
- Specific Objectives
- Design and Methodology
- Data Management
- Time Frame / Duration of the Project
- Ethical Considerations
- Expected Application of the Results
- References
- Budget
- Justification of the Budget
- Appendices

Once a proposal has been received by a research institute, the different institutions have varying procedures for approving a proposal simply due to the diverse nature of the medical institutes. For example KEMRI has individual Centre Scientific Committees which review the proposal while at KNH, two members from the ERC are selected to review the proposal.

KNH – Guidelines for Protocol Development⁶²

Title
 Investigators and supervisors where applicable
 Any Collaborative Institute
 Summary
 Introduction / Background / Rationale
 Hypothesis / Hypotheses
 Methodology
 Study area
 Study population
 Study design
 Sample size
 Sampling method
 Inclusion / exclusion method
 Definition of cases / controls
 Materials – equipment, supplies, personnel
 Procedures – Field, Laboratory, quality control
 Variables- dependent, independent, confounders
 Data collection instruments
 Study limitations
 References
 Budget

Ministry of Health – Kenya National Guidelines for Research and Development of HIV / AIDS Vaccines CONCEPT PLAN OUTLINE⁶³

Study title and research team contact list
 Description of product or intervention
 Study Capsule
 Study Objectives
 Design
 Study populations and eligibility criteria
 Specific end points
 Statistical considerations and analyses plan
 Participation requirements
 Participating sites and institutions
 Ethical considerations
 Product – related considerations
 Time Frame
 Special consideration
 Budget considerations
 Appendix includes:
 2. Informed Consent Checklist
 3. Sample consent information guidelines
 4. Enrolment consent form signature
 5. Participant's Right
 6. Biological Material Transfer Agreement

⁶² Guidelines for protocol development" by KNH

⁶³ Kenya National Guidelines for Research & Development of HIV/AIDS Vaccines.Mar 2005 pg 50-51

3.2.2. Application procedure

At the National level

Although The NCST is empowered under the Science and Technology Act to coordinate all research work in Kenya and advice the Government on all matters on Science and Technology, it's role has however been largely advisory. The NCST has developed the following guidelines to explain the application procedure for research work in Kenya, "Procedures and Guidelines for research authorization in Kenya". The Application for clearance to receive a research permit must be submitted to the Ministry of Education and Science and Technology. The Application constitutes of the following forms:

- Application for authority to conduct research in Kenya by Non- Kenyans
- Application for authority to conduct research in Kenya by Kenyans
- Affiliation Form
- Application for Renewal of research permit

Details of the application can be obtained in the guidelines. The research permits are issued by the Ministry of Education, Science and Technology.

Two types of applications are possible, an institutional application and an individual researcher application. The institutional application can apply for a standing clearance which if authorised is valid for five years. The individual researcher can apply for a clearance which is valid for three years. However these authorizations are reviewed annually and the research permit holders must submit annual reports and progress status of the studies. The Ministry of Health, Kenyatta National Hospital and KEMRI have a standing research clearance.

A concept paper must be submitted to the Ministry of Health (the Director of Medical Services) for approval of the proposal concept. Simultaneously the concept paper can also be submitted to the Pharmacy and Poisons Board for approval / registration of the investigative molecule. The researcher may then affiliate themselves with the appropriate research institute as guided by the Ministry of Health or the NCST.

At the Institute Level

Each research institute has developed it's own guidelines for the application of protocols which are described in detail in section 3.2.1 above.

The Application procedure at Kenyatta National Hospital is described in detail in the Ethics and Research Application Form.⁶⁴ However the title of the form indicates that this form is used for the application to the following research institutes, Kenyatta National Hospital, University of Nairobi and KEMRI Centres. The following documents need to be submitted as indicated below:

- Three copies of the "Ethics and Research Application form", of which at least one copy should have original inked signatures.
- Three copies of all relevant documentation (consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statements, advertisements etc)
- Three copies of research protocol and grant or contract
- One copy of the Protocol and Investigator's brochure for clinical trials
- Students should attach three copies thesis or dissertation proposals.

⁶⁴ See "Ethics and Research Application Form"

The application form is a seven page document which needs to be filled in and where necessary specific guidelines have been provided to allow for only relevant information placement on the form.

Ethics and Research Application Form⁶⁵

Principal Investigator
Project Title
Research Personnel
Funding Information
Description of research project
Research Methodology and Procedures
Research Methodology and Procedures Guidelines
Human Subjects in the Project
Risk Benefits and Adverse Events
Confidentiality of Research Data
Additional Information
Consent / Assent Forms and Waiver

The Principal investigator is bound by three clauses on the application form. These are:

- Any change to this protocol and/or procedure shall be notified to the Scientific Steering Committee and effected only after approval by the Ethical Review Committee.
- The results of this study shall not be published, presented in any journal and/or conference without the written approval of the Director of the Institute.
- Other members of the research team are bound by the clause 1 and 2 as above.

3.2.3. Review and Approval Procedure for Proposals

Once an application has been received by the institute, it is given to two reviewer's (who are identified by the Ethical Review Committee). Once the reviewer's have reviewed the proposal it is presented to the ERC and if there is no discordant result in the review then it is given an approval. In case if there is no consensus and sometimes if there are controversial issues. Then more than two members of the ERC will review the proposal. If a proposal is approved, permission is granted in written form for a validity period of 2months. During these 12 months, the project progress is discussed during the ERC meetings. The project leader needs to receive a renewal of the approval every 12months in order for the research to continue. If the project is found to have changed any part of the research from the original proposal, then a new application has to be made for the acceptance of this change and the same process is undertaken.

The following is a summary of the review and approval process from one of the research centres of KEMRI who can be considered as a sub committee level as they would be the people directly in contact with the research project and hence the review and approval procedure vary slightly.

KEMRI Centre for Public Health Research (CPHR) - Nairobi

The Ethical requirements are indicated in the proposal. The subjects give a written consent signed by both the subject and the investigator. Each has a copy of the consent form. The patient has the right to autonomy (that is the option to withdraw from the study at his/ her own will). Any invasive procedure involved in the study will require strict clearing from both the Scientific Steering Committee's and Ethical Review Committee's. If there is any change in process during the research process, then new clearances are required.

Once a proposal is approved, the date of implementation is known and one method of in process monitoring is conducted by receiving monthly reports. The reports are first presented to the Centre that

⁶⁵ See "Ethics and Research Application Form"

is responsible for the project. From there it is forwarded to the CSC and then on to the relevant funding agencies and participants where appropriate.⁶⁶

3.2.4. *Renewal of Approval for Research Protocol*

The projects are monitored regularly. The investigators have to provide monthly reports. And for example at the KNH they have a regular monthly meeting of the ERC. The approval of a project proposal is only valid for a year. Upon submission of an annual report, then the approval has to be renewed. In this case the ERC has to ensure that the investigators are following the project proposal as it was approved and no changes are being made in the process.

3.3. Qualification and levels of Training of Professionals involved in the conduct of research

For any type of biomedical research (especially that involving trials in human subjects) to be conducted in Kenya, the qualification of the researchers should be provided at the time of the application of the protocol. This information is required to be provided in the form of curriculum vitae (especially if these are non Kenyan investigators). This is to ensure that the Investigators and project teams are appropriately qualified in the medical field and capable of handling the human subjects medically. The investigator(s) must be aware of the international standards and guidelines on ethical conduct during the trials. These are mainly the ICH and WHO guidelines of GCP and GLP.

The Project Leaders and all supporting personnel of the research should be well trained on the GCP and GLP guidelines. These are the gold standard guidelines and standards followed internationally for any type of research work at all the research institutes.

All the Members of Ethical Review Committee's are also trained in GCP and GLP practices. The NCST makes a provision in the guidelines of the requirement for ERC members to be appropriately educated for their roles as ERC members. EC members have a need for initial and continued education regarding the ethics and science of biomedical research. The conditions of appointment should state the provisions available for EC members to receive introductory training in the work of an EC as well as ongoing opportunities for enhancing their capacity for ethical review.⁶⁷

Training of staff members and committee members is integral to the research centres. These trainings are provided by the institutes often in collaboration with external institutions. Some practical examples of training conducted in Kenya are as below:

- WRP train all their staff and the subjects on GCP and GLP for every trial.
- CDC also train all their staff on GCP and GLP regularly. These trainings may be outsourced or conducted by CDC itself.
- KNH conducts GCP / GLP training in collaboration with the University of Washington. They are conducted on a regular basis. All the members of the ERC are also provided with the training.
- All KEMRI staff are trained on GCP / GLP trainings regularly. Other trainings are outsourced such as training on how to conduct clinical trials.

⁶⁶ Interview with Dr. Mohamed KAMARA at Centre for Research on Public Health.

⁶⁷ Guidelines for ethical conduct of biomedical research involving human subjects in Kenya. By the National Council for Science and Technology (NCST No.45, 2004)

3.4. Subjects or Participants in research programs

In Kenya, medical personnel at the university and medical facilities can be used as subjects for clinical trials. These medical personnel may be clinical officers, nurses, medical students and other health care workers. The reason for this is that the medical personnel understand the nature of the trials and studies to be undertaken and would be making conscious decisions of participating in the research. In some cases, the researchers provide the GCP / GLP training to the subjects of the trial for example the medical students.

Where other non medical subjects are used, they must be explained in full detail, the nature of the project and what will be happening to them in the trial.. The subjects must be allowed autonomy (ie. Be allowed to withdraw from the study at any time that they wish), their confidentiality must be maintained, and any benefits or risks must be clearly explained before they sign the consent form. The subjects then have to sign a consent form, which is known as informed consent in the presence of a witness

3.5. Publication procedure

According to the Kenyan regulations as defined by the National Council for Science and Technology, the research findings are not allowed to be published without the approval of the appropriate review committees and should be provided to the relevant institutions as described below:

“Final research reports will be deposited in the Council Library with copies to affiliating institutions, the National Archives and the relevant Ministry. Every researcher will be expected to submit at least four bound copies of the report to the Ministry for distribution to the various bodies. If the report is in the form of a large document, which is expensive to reproduce, a special case can be made for depositing two copies with the Ministry”.⁶⁸

The individual research institutes also have their own methods of submission of research findings. There is a Publications Committee at KEMRI, who is responsible for evaluating all manuscripts intended for publication in scientific journals and other publications. The Committee provides a certification which indicates that the manuscript has been evaluated and is considered approved for publication. At the KNH also, the findings have to be reported the ERC and an approval will be given. However, actual method of publication is not systematic and the reports are published in various types of scientific journals. Some articles are published in local journals, depending on the subject areas. The main publisher being the, “East African Medical Journal” (EMJ). The EMJ has pre-requisition that the researchers have to present the original ethical approval by the ERC before the manuscript can be published. International publications include:

- Medical journals for example The Lancet / British Medical Journal / Science Journal / American Journal of Medicine)
- Electronic medical databases such as Medline and Pubmed

On an international level, the innovative pharmaceutical industry has agreed jointly to publicly make available information on ongoing and completed clinical trials. The ongoing clinical trials will be registered on a database called Clinical Trial Registry⁶⁹ while the completed clinical trials will be submitted to the database called “Clinical Study Results”.⁷⁰

⁶⁸ “Monitoring and Evaluation of authorised projects”, (Procedures and Guidelines for Research Authorization in Kenya) by NCST NCST No. 15 Revised 2002

⁶⁹ <http://www.clinicaltrials.gov/ct/info/resources>

⁷⁰ <http://www.clinicalstudyresults.org/>

The Multinational Companies have integrated these sites into their websites, and hence detailed information is provided on clinical trials. Most have agreed to post all clinical trials in the databased dating from 1st July 2005 onwards. So far only Multinationals have mentioned this international Registry. And data for GSK, PFIZER and Novartis have already been identified during the search for an inventory.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) launched a new initiative called the “Clinical Trials Portal” in September 2005. This search engine has been programmed to access relevant on-line sources of clinical trial information. It also complements the above stated databases.

4. Other Issues on Clinical Trials

4.1. Controversial Cases of Clinical Trials in Kenya:

As the search for a preventive or treatment measure for the world pandemic HIV/AIDS intensified over the last 20 years, the nature of scientific studies have increased dramatically worldwide. At an institutional level this kind of research is done in a regulated manner, but when done by individuals it raises the issues of how ethical are these experiments. That does not exclude the fact that there are issues of benefit sharing with developing countries such as Kenya which experiences disease patterns that attracts funding and collaborative research arrangements with developed countries.

Kenya has had a fair number of controversial issues over drug development for AIDS, some concerning the ethical conduct of trials and some concerning other issues such as ownership of intellectual property rights. A number of recent incidences have been exposed via the media in the last few years. Many cases have also gone unnoticed as disputes have been taken through the legal system. Below are brief accounts of these cases:

The case of “KEMRON”, (a low dose oral interferon) was developed in Kenya as a multi – collaborative effort between KEMRI, Amarillo Cell Culture Company (ACC) of Texas, USA and Heyashibara Biomeclinical Laboratories of Japan.⁷¹ The drug was approved in 1989, but unfortunately a controversy was raised that the drug had undergone uncontrolled clinical trials and further testing would be required to claim its findings. At the same time that Kemron was under controversial discussions, a new drug called “Immunex” was being imported into Kenya for the management of AIDS. It was believed that Immunex was the same molecule as Kemron, and unconfirmed reports said that a former worker of ACC was behind the production of Immunex by an Australian firm, Encarich Development limited who was also part of the team for the development of Kemron. The Government was obliged to ban the use of Immunex until disputing information was clarified. While the three collaborative institutes were in dispute over the ownership and distribution rights for Kemron. In 1992, The National Institution of Health (NIH) in the USA decided to conduct trials on Kemron⁷².

Another controversial case of AIDS cure came in 1996 whereby Scientists and Researchers in Kenya demanded proof of authenticity of claims by Prof. Obel (a chief government scientist) over his new wonder drug, “Pearl Omega” which was hailed as being the cure for AIDS.⁷³ Once again the government of Kenya announced that extensive testing needed to be done to prove the theories of this drug.

Still in 1996, another controversial case was being given the official approval by the Ministry of Health to a Dr. Wainright, alias “Dr. Stone”, who presented a proposal for setting up a “Polyatomic Apheresis Centre” as an AIDS therapy was granted permission by the Ministry of Health in July 1996. Dr. Stone claimed that his ozone therapy was effective against AIDS and he presented a 46-page document on research conducted in conjunction with the University of Nairobi which he said contained data on the efficacy of the polyatomic apheresis therapy. The govt. at the time denied having any knowledge of

⁷¹ <http://qrd.org/qrd/aids/1991/kemron-12.04.91>

⁷² <http://www.aegis.com/news/ads/1992/AD922307.html>

⁷³ <http://www.aegis.com/news/ips/1996/IP960302.html>

this research and later outlawed this type of treatment.⁷⁴ It was due to intense pressure from the medical practitioners and dentists board that made the govt. take action on Dr. Stone. Dr. Stone who was later investigated was found to have criminal records in the UK and the USA. Dr. Stone who was not a registered medical practitioner (he claimed that he was a scientist).

Yet a third case emerged in 2001, when a dispute between the Department of Microbiology at the University of Nairobi, Kenya, and the Human Immunology unit of Oxford University, United Kingdom, arose concerning research of a vaccine development for AIDS.⁷⁵ This development was based on the findings of that some Kenyan sex workers from Majengo slum in Nairobi have an immune response to HIV that protects them from the disease.⁷⁶ Extensive studies were carried out genetic material obtained from the sex workers to see if it could become the basis of an effective vaccine. Disagreements arose when the University of Nairobi scientists protested that their partners at Oxford had patented the HIV vaccine development process without giving them sufficient acknowledgment. The dispute was resolved by drawing up a new memorandum of understanding and Trials of the vaccine were started in 2001.⁷⁷

A most recent case in 2004 involved the illegal and unethical export of blood samples without proper approvals. The parties involved were the Oxford University and an orphanage run in Nairobi and a leading Kenyan Scientist conducting research at the orphanage. At the orphanage, children infected with HIV are rescued from the city slums and brought to the orphanage for care. Studies have shown that some HIV-infected children seem to have a natural immunity to HIV that has intrigued scientist's around the world. The researcher at the orphanage who has been working officially on the study claims that scientists from Oxford University came to Kenya and illegally took away samples of his patients. After investigations were carried by the NCST, it was discovered that a proposal had been made by the University in the proper manner, but the protocol had not indicated that they would be exporting blood samples to the UK. This oversight was brought to notice and an application was made in 2001 for which the ethical clearance was only given in 2002. In the meantime samples had been exported. However, the defending researcher from Oxford admits that samples had been taken but it was her understanding that this had happened with appropriate permissions by way of a verbal approval and that the university had no intentions of conducting unethical practices during trials.

These are just a few cases described in detail based on information gathered from news articles and media networks. These cases raise two very important questions about the ethical conduct of clinical trials:

- Although in theory when applications for protocols are being presented for approval by the ethical review committees, are the ethical issues respected and followed throughout the trial?
- Are there appropriate legal regulations in place to deal with such controversial cases in Kenya?

It is important to note that in a few of the above controversial cases, the medical practitioners and dentist's board intervened to regulate the controversial activities conducted during the trial, example Dr.Stone's case. (Ref: The code of conduct Clause 16, chapter 1, is titled Protection of the Public).⁷⁸ The code of conduct also highlights how medical practitioners must conduct clinical trials combined with professional care and non therapeutic clinical research. The code also states that a doctor must be registered and licensed if he / she wish to practice in Kenya. Other chapters include Ethical issues of consent, confidentiality, conflict of interest, Human rights. Appendixes on The Geneva declaration,

⁷⁴ <http://www.nationaudio.com/News/EastAfrican/2707/Regional/Regional110.html>;
<http://www.nationaudio.com/News/DailyNation/1998/090798/News/News999.html>

⁷⁵ <http://www.nationaudio.com/News/EastAfrican/2707/Regional/Regional110.html>;

⁷⁶ Kaiser Daily HIV/AIDS Report, 11 May 2001; http://www.kaisernetwork.org/Daily_reports.cfm?DR_ID=4553&dr_cat=1

⁷⁷ http://observer.guardian.co.uk/uk_news/story/0,6903,1227883,00.html

⁷⁸ The code of professional conduct and discipline, 5th Edition, revised in May 2003

The International code of medical ethics – 1949 and The Declaration of Helsinki on human experimentation – 1964, all comprise the code of professional conduct and discipline.

4.2. Inventory of clinical Trials in Kenya

As expressed earlier due to the diverse nature of scientific research ongoing, there is no standard format in which such data is gathered. The relevant institutions will have databases on all types of research done, so it was very difficult to obtain specific research done on clinical trials of drugs and vaccines. The following is an attempt to try and compile an inventory of clinical trials conducted in Kenya. The list comprises of some ongoing trials and very few completed trials.

Findings on clinical trial research can be found in various publications such as medical journals, Institutional annual reports which list all publication by that institute during the year. Some information was obtained from the people interviewed.

GSK

Conduct clinical trials in Phase II and Phase III.

The therapeutic areas of study are: Tropical diseases, antimalarials, anti-helminths and Treatment for Asthma.

WALTER REED PROJECT

Their work is mainly involved in product development and clinical trials are done in Phases I and II. Study areas are:

Malaria research, drugs and vaccine trials.

A partnership between Walter Reed, KEMRI, USAID and MVI (Malaria vaccine initiative) is testing Walter Reeds MSP 1 vaccine candidate in Kenya. The vaccine was previously tested for safety in U.S civilian and military volunteers. Following favourable results in a Phase I trial in Kenyan adults, the vaccine is expected to be tested in Kenyan children.⁷⁹

- HIV projects in Kericho – Vaccine development and treatment for HIV / AIDS.
- Surveillance system in Nairobi for other projects.
- Collaboration with Maseno University - To find attack rates of malaria in freshers (1st year students). The trials involve testing of new drugs in Phase I and Phase II.
- Most recently the WRP has evaluated tafenoquine (antimalarial) which has shown great promise to be a safe, efficacious and preventive. It acts against the liver stages of the parasite and is long-acting. Currently, it is being tested in partnership with Glaxo Smithkline; Phase III trials are underway in western Kenya as well as in Asia and Latin America.⁸⁰

CDC

The effect of folic acid supplementation on efficacy of sulfadoxine-pyremethamine in pregnant women in western Kenya

Efficacy and Safety of Intermittent preventive treatment for infants (IPTi) with antimalarial drugs in decreasing anemia and malaria morbidity in Rarieda Division, Western Kenya

In vivo response to Plasmodium falciparum to antimalarial treatment in HIV-infected and HIV-uninfected individuals – a 28 day efficacy trial in adults

⁷⁹ <http://www.malariavaccine.org>

⁸⁰ <http://www.usamrukenya.org/malariasen/body.htm> pg 2

KAVI

Currently a vaccine is being tested has been specifically designed to be used in Kenya because it is based on the most common type of HIV circulating in Kenya.

Protocol / Vaccine	Date of enrolment	No. of volunteers	Status
002/DNA.HIVA	Feb.2001	18	Study completed
004/MVA.HIVA	Feb.2002	18	Study completed
008/MVA.HIVA	March 2003	10	Study completed
010/DNA.HIVAMVA.HIVA	April 2003	70	Study in Progress

KETRI

There is possibility of developing a user friendly oral drug for the treatment of sleeping sickness. This is a four year study funded by Bill and Melinda Gates foundation. The novel drug is called DB289, a diamidine. The drug has shown curative properties for early T. b.rhodesiense infections in monkeys. Reports further show 60% cure rate with no toxic effects when administered at 10mg/kg x 10 days from day 14 after infection.⁸¹

KNH

1. Collaboration with KAVI. HIV vaccine trials.
2. Clinical trials ongoing for drugs used in the management of malaria. The trials include new drugs as well as drug combinations of known molecules. These trials are ongoing as well as some proposals in the process if review for approval.
3. Many trials ongoing for anti-cancer drugs including trials of combination therapies. These are collaborations between KNH, UoN and Multinational Drug Companies.
4. Trials for anti-asthmatic drugs especially use of steroids in special formulations and delivery systems. Trials also include studies on paediatric formulations. These initiatives are in collaboration between KNH and GSK
5. Other types of research involve studies on family planning agents such as female diaphragms, spermicidal agents and female condoms.
6. Studies are ongoing for diagnostic agents namely rapid diagnostic tests for testing for HIV.

NARESA

NARESA is currently conducting a randomised trial on breast feeding formula among HIV infected infants. Other studies include topics such as PMTCT (Prevention of mother to child transmission of HIV).

SANOFI PASTEUR

Mostly conducts Phase IV studies (post-marketing surveillance) as the vaccines are usually tested extensively in the parent company in South Africa.

- Sero prevalence study on Hepatitis B – Currently under publication
- Epidemiological study on Hepatitis A – Under publication
- Cost-effectiveness of typhoid vaccine
- Surveillance of Influenza, a collaboration with KEMRI.

WELLCOME TRUST FOUNDATION (Malaria research centre)

- Malaria – clinical trials of new drugs for treatment of malaria. Recent development of a new drug called LapDap
- Development of vaccines for malaria and pneumococcal disease

⁸¹ <http://www.kaviuon.org/About%20KAVI.htm>

- Research on role of invasive bacterial pathogens – providing better ways of assessing and treating sick children
- Research on preventive measures for malaria – Insecticide treated bed nets
- Role of hypovolaemia in the acidosis of severe malaria

EDCTP

Understanding the mechanism of piperacine resistance, by Dr. Alexis Nzila, KEMRI / Wellcome Trust Laboratories, in 2004.

OTHERS

Samaritan Pharmaceuticals Inc., its philanthropic arm, the Samaritan Innovative Science Foundation (Sisf) and a Harvest Biotech Foundation International Africa (AHBFI) launched a clinical trial of an AIDS drug in 2003. This drug is manufactured in Kenya. The drug was not named in the article.⁸²

In vitro assays and In vivo studies of drugs eg. Antimalarials. Effectiveness of antimalarial herbs. Chelimo K, Ofulla AV, Narum DL, Kazura JW, Lanar DE, John CC. Antibodies to Plasmodium falciparum antigens vary by age and antigen in children in a malaria-holoendemic area of Kenya. Paediatric Infect Dis J. 2005 Aug;24(8):680-4.

About 44 trials were highlighted in the Clinical Portal of IFPMA (International Federation of Pharmaceutical Manufacturers and Association). The hyperlink is:

HYPERLINK "<http://129.35.73.130/wps/portal>"

<http://129.35.73.130/wps/portal>, ongoing trials, search on 'Kenya

⁸² <http://www.afrika.no/Detailed4062.html>

Conclusion

A brief overview of the research activities in Kenya can be identified as an elaborate structure headed by the National Council of Science and technology, supported by the implementing Ministry of Education and Science and Technology and the relevant ministry is responsible for coordinating the individual research institutes. All research protocols presented by external researchers must be submitted to the Ministry of Education and Science and Technology for clearance and authorisation. The theoretical application and clearance process is clear, but in practical terms the flow of protocol between MoEST, MoH and Research Institute (KEMRI, KNH or Moi University) is not very clear. As Pamela Andanda pointed out about how previously a case of speed of approval has been raised.⁸³ A vertical procedure down from the MoEST may take long to process the application.

For clinical trials involving human subjects, the Ministry of Health is responsible for coordinating the individual research institutes and protocols. The Ministry therefore should be informed of any research activities to be undertaken in the Health Sector. Certain institutes are provided a standing clearance by NCST for these institutes to conduct research without seeking clearance for each and every protocol. These institutions are KEMRI, KNH and Moi Referral University Teaching Hospital. Individual research institutions may also receive protocols directly due to the standing clearance. Guidelines on presenting protocols and conduct of clinical trials are available at research institution level and at the NCST.

Due to the global demand of increased research for HIV / AIDS Vaccines, Specific guidelines have been developed by the Ministry of Health for the research and development of HIV / AIDS Vaccines. From the interviews conducted it was established that research protocols are reviewed in detail by Institutional Ethical Review Committees.

Other research institutions include higher learning institutions, international research organizations, non-governmental organizations, external universities and pharmaceutical companies. It was established that local pharmaceutical companies do not conduct clinical trials in Kenya as they are very costly. One company is in the process of contracting CRO's in India. These institutions must mandatorily collaborate with a national research institute in Kenya for transparency purposes and benefit sharing.

Funding during the collaboration can either be shared by the collaborative institutes or there may be external funding agencies, for example The Bill and Melinda Gates Foundation may fund KEMRI or Wellcome-Trust Foundation to conduct a trial on malaria drugs. Other funding organizations may be bilateral agencies such as DFID, USAID and the European Union among others.

From the information obtained it may be conclude that majority of the research is conducted by various research institutes and the proportion of clinical trials conducted by multinational pharmaceutical companies is a small proportion of all research conducted in Kenya. The main areas of research are HIV / AIDS, malaria and other infectious diseases. Some other trials are being conducted on respiratory conditions such as asthma, cardiac conditions and oncology. Very few trials of chronic conditions were mentioned which does not necessarily mean that they are not being conducted. The reason for this is that information on previous clinical trials from multinational companies was limited or not possible to obtain at the time of the study. Many multi-centre research projects are ongoing at international, regional and local levels. Given that the Multinationals must maintain credible standards, they do go through the legal channels to conduct clinical trials in Kenya. However, contradicting information obtained about whether Pfizer conducts clinical trials in Kenya (whereby Pfizer denied of

⁸³ "A golden chance for medical ethics in Kenya", written by Pamela Andanda, dated 15th June 2004. Source: SciDev.Net <http://www.scidev.net/gateways/index.cfm?fuseaction=readitem&rgwid=4&item=Opi>.

any clinical trials in Kenya while the international clinical trial register indicate that Pfizer is conducting a clinical trials in Kenya) raises the question of transparency on information sharing on ongoing clinical trials. (See clause 16 of the Declaration of Helsinki).

It would also be impossible for any organization to by pass the official channels for them to operate in Kenya, however it may be possible that certain elements of trial procedures may be omitted from reporting to the authorities and this can be one possibility that unethical trials are conducted without the knowledge of the relevant authorities. This is only a hypothesis and needs to be proved with evidence, which can be an almost impossible task.

Payment of incentives is an issue that may require further researching. The type of reimbursement or other recompense offered to participate in a clinical trial should be appropriate to the local economy and submitted to independent review committees for consideration.⁸⁴ This is being done in Kenya and details are required to be outlined in the protocol application. At the individual level, reimbursement for costs incurred by the participant are reasonable, as it is particularly important in resource poor setting that individuals do not suffer loss by involvement in a trial. In Kenya, theoretically the ERC's are involved at the level of protocol review, whereby all budgetary details need to be clearly indicated. Again, what actually may be happening in practice would require a field survey of subjects recruited for trials.

Another important issue of benefit sharing and post trial access to medicine requires further investigations. According to GSK, two categories result from clinical trials:

- Investigational (non-approved) medicines (phase I and II)
- Marketed medicines (phase III)

In the case of non-approved medicines, it is not correct to assume that the specific intervention has been proven successful. After the trial, the product undergoes multiple studies and review of the data before the benefits of the medicine can be confirmed and the investigators may continue research on the product for a while. The final Government approval may take many years before the product can be made available and in some cases it may be for restricted use to a narrower population than the population it was trialled on, therefore it would be inappropriate to provide a research intervention to a trial participant after the trial is over. To overcome this situation, an intense explanation must be provided for the consent procedure and all details of post trial access and costs must be discussed with the subject in order for them to make the appropriate decision to participate in the trial. Other questions raised are who takes care of patients post trial study period and for how long should the treatment be provided for.

For marketed medicines, GSK believes that it should be the government's responsibility as part of the national healthcare system, to provide registered medicines to it's population. As the drug under trial does not automatically get registered in the country it is being trialled.⁸⁵

Based on these points, looking at the situation in Kenya, one of the major discussions ongoing is that of the benefit sharing of the outcomes of clinical trials. The above issues need to be seriously considered at the application level and post trial benefits must be clearly agreed upon by the investigators, the ERC's and the patients. This is one point that does come out very clearly so far in the guidelines that were provided. Unless the research institutions have separate procedures for addressing this, there seem to be many controversial cases resulting from the lack of proper understanding between the collaborating institutions.

⁸⁴ Global Policy Issues, Clinical Trials in Developing Countries. GlaxoSmithkline's Position. GSK website

⁸⁵ Global Policy Issues, Clinical Trials in Developing Countries. GlaxoSmithkline's Position. GSK website

Finally, as result of all the interviews, the following points were highlighted and to be seen as areas requiring improvements in the areas of clinical trials and related issues:

- Standardization of Review Process at National Level is much needed as private institutes conduct research independently. There could be serious variation in the ethical review process which is currently not known. The private institutions are also not obliged to divulge internal information and hence there may be potential for biased decision making during the review process.
- Involvement of appropriate professionals in the element of clinical trials. Pharmacists need to enhance their role in the regulation of clinical trials. Pharmacists have so far been inactive in the field of research. Hence it is important to establish criteria on research investigators and the roles of various medical professional in clinical trials.
- Appropriate regulating mechanisms to control medical practitioners and pharmacists from conducting unregistered trials need to be put in place. Although these professionals are regulated by the respective boards, in reality the relationship between pharmaceutical companies and medical practitioners is quite inter-linked (daily / regular visits of medical representatives to doctors and pharmacists, meaning there could be some sort of unregistered trial of marketed products on going).
- Regulatory procedures require strengthening especially registration of combination drugs and quality of drugs. Continued post marketing surveillance needs to be implemented. Although not directly related to the subject of this study, these points were raised by several researchers interviewed.
- Similarly, not directly related to the ethics of clinical trials but interesting to note, new research findings on pharmaco-genetics due to the diversity in ethnicity are being lost as the data are not being collated in a proper way. This is an area lacking in information collation and the interviewee felt that a lot of the research conducted in Kenya was actually providing this type of information. This lack of information collation may also hinder future research efforts.

Recommendation for the second phase of this study is to try and establish a consortium of organizations, both interested in clinical trials and wishing to conduct further research on the same. A combination of organizations would be one to conduct the research and the other organization for the advocacy part. My recommendations would be either HAI or ACCT for the research part and probably CIN or IMLU for the advocacy part. The project must proceed through all official channels via NCST, MoH, and a research institute therefore it is vital to have partners who understand the system and are known in the system as well.

As a concluding statement, it is important to bring to notice that Kenya, being a frontline African country in the field of research has made an excellent initiative to dialogue with the 59th World Health Assembly on the crucial subject of Research and development of Biomedicines for people living in resource poor settings. Below is a brief outline of issues raised, however the outcome is not yet known.

A proposal has been presented to the 59th World Health Assembly (meeting on 23rd January 2006). It is called the Kenyan Resolution on “Global Framework on Essential Health Research and Development” Proposal to the World Health Assembly, and was presented to the WHO on November 16th 2005. The resolution is a really strategic and important opportunity to get support for a new global framework for health R&D which addresses the priority health needs of people living with HIV / AIDS and other diseases, especially those in poor countries, and to develop improved safe and affordable health products such as HIV vaccines. Although it does not directly address ethical issues

in clinical trials, it calls for the right priorities regarding the type of medicines that are being tested and refers to availability of medicines to people living in poverty after approval.

The resolution brought out three main points as detailed below:⁸⁶

- “To make global health and medicines a strategic sector and to take determined action to direct R&D priorities according to the needs of the patients, especially those in resource-poor settings.
- Requesting member states to actively participate in the development and establishment of a global framework for defining global health priorities, supporting essential medical research and development predicated upon the principle of equitable sharing of the costs of research and development, and incentives to invest in useful research and development in areas of patients’ needs and public interest.
- To ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products – drugs, vaccines and diagnostics – to respond to all patients’ needs especially those living in poverty and that essential medicines are rapidly delivered to people”.

⁸⁶ E-drug group email: Support needed for Kenyan Resolution WHO EB, dated 16.01.2006