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Challenges in regulation of biomedical research: The case of Kenya

M Wekesa

Department of Public Law, School of Law, Mount Kenya University, Nairobi, Kenya

Abstract

Unregulated biomedical research has previously caused untold suffering to humankind. History is full of examples of abuse of animal and human subjects for research. Several codes and instruments have been formulated to regulate biomedical research. In Kenya, the Science, Technology and Innovation Act, 2014, together with the Constitution of Kenya, 2010, provide a fairly robust legal framework. Possible challenges include capacity building, overlap of functions of institutions, monitoring and evaluation, scientific/technological advances, intellectual property rights, funding for research, and dispute resolution. It is hoped that the new legislation will adequately address these challenges.

Key words: Biomedical research regulation, Kenya, law

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Introduction

Regulation of biomedical research in Kenya has been uncoordinated for many years. The Ministries in charge of Wildlife of Science/Technology and that in charge of Health were involved. Several institutions had their own “clearing houses” that worked independently. Their roles were never clearly defined between the ministries, Ethical Review Committees (ERCs), and other bodies in charge of Clinical Research.^[1] Commenting on the presence of many ERCs at institutions that carry out research, it was once said that it was not clear if the ERCs use the same standard operating procedures. This apparent ambiguity of roles contributed to the lack of strong leadership, accountability, and also to duplication of effort. This situation has been described as:

...fragmented, overly competitive and duplicative, lacking health systems-related research or skills, having weak governance and ethical oversight, and marked by official bodies seen as cumbersome and unable to offer incentives for collaboration and innovation.^[2]


In a study on informed consent in Kenya,^[3] it was found that many doctors do not seek informed consent from their patients or when they do so, the quality of the consent cannot meet the standard of “free and informed” consent, based on knowledge.

In Kenya, it has been shown that informed consent is either not obtained from patients in public hospitals during normal clinical operations or that the consent so obtained does not fit the bill. With respect to research involving human subjects, the line between physician and researcher or treatment and research is very thin and confusing to many participants. There is a need to have a coordinated approach

Address for correspondence:

Prof. M Wekesa,
School of Law, Mount Kenya University, Nairobi Campus,
Moi Avenue, P. O. Box 4701-00100, Nairobi, Kenya.
E-mail: moniwekesa08@gmail.com

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to biomedical research. Kenya has responded to this through the enactment of the Science, Technology and Innovation Act, 2014. This new law describes itself in the preamble as:

An Act of Parliament to facilitate the promotion, coordination and regulation of the progress of science, technology and innovation of the country; to assign priority to the development of science, technology and innovation; to entrench science, technology and innovation into the national production system and for connected purposes.

This law is a more serious attempt at regulating biomedical research. It also creates offenses for noncompliance.

A Brief History of Suffering of Research Subjects

The abuse of human subjects in biomedical research appears to be as old as humankind. History teaches that people with power have used human subjects as guinea pigs. For example, when the French King Louis XIV was sick, the royal surgeon was allowed to operate on as many patients with similar symptoms until he gained sufficient experience to operate on the King, successfully.^[4]

In 1906, a doctor injected 24 Filipino prisoners with cholera bacteria. He did not tell them what he was doing. Over half of them died.^[5] In 1931, an American doctor carried out the experiments in Puerto Rico during which he infected his subjects with cancer cells.^[6] From 1932 to 1972, over 400 black men in Tuskegee, Alabama, were recruited in a study of the natural progression of syphilis. Scientists neither sought consent from their subjects nor did they inform them of the available cure. It went on for over 30 years.^[6]

During the Nuremberg trials, it came out clearly that human subjects were used in horrendous experiments without their permission.^[7,8] Doctors and scientists inflicted a lot of pain and suffering on their human subjects during experiments which resulted in mutilation, disability, and in many cases, untimely death. In some experiments, victims were submerged in icy water either naked or in aviator suits for five or more hours. Experiments were done on 1000 twins with the aim of understanding how to quickly multiply the German race. After the experiments, such twins were injected with chloroform directly into the heart. Only 200 survived probably because the Russian army invaded the concentration camp and freed them. A total of 200 hundred people died because of the experiments on tuberculosis bacteria. The doctors wanted to establish the development of immunity with a view to developing a vaccine. The subjects were directly injected in the lungs with tuberculosis bacteria. Furthermore, many prisoners

in the concentration camps were subjected to transplant experiments, from which many died. In yet another experiment, 90 subjects were starved and forced to drink seawater. In another concentration camp, Russian prisoners were injected with various poisons in an attempt to find out new methods of execution. In yet another experiment, over 300 women were artificially inseminated with sperms from different animals.^[9]

The Tuskegee syphilis study (1932–1972) was continued despite the existence of the Nuremberg Code and the Declaration of Helsinki.^[10,11] The Milgram Obedience examined how in a shock study subjects would give to others following the order of a researcher. In reality, no shock was actually given although participants were not told of this. Participants were not fully informed.^[10,11]

The US set out to study the efficacy of penicillin on syphilis and other sexually transmitted diseases (STIs). This Guatemala Inoculation study (1946–1948) was exposed on 2082 subjects. Sex workers who had STI's were paid to infect prisoners, patients in mental hospitals, and soldiers. There was no informed consent. About 83 persons died. Such a study would not have been approved in the US.^[6]

In the period 1957–1964, the US government paid a doctor in Canada to carry out the experiments on how to influence the mind. This was dubbed Project MKULTRA. The doctor used electroconvulsive therapy that was 30–40 times higher than the normal power. The subjects forgot how to talk, forgot about their parents, and suffered amnesia.^[6]

In the 1970's and 1980's, in an attempt to eliminate homosexuality in the army, the South African government subjected over 900 lesbian and gay soldiers to a variety of forced experiments including sex change. Some of the soldiers were sent to psychiatric units; mainly ward 22 of 1 Military Hospital at Voortrekkerhoogte around Pretoria. Others were subjected to drugs, aversion shock therapy, hormone treatment, or chemical castration.^[6]

A Japanese doctor is reported to have done vivisection on his subjects without anesthesia during the second Sino-Japanese war and the Second World War. He forced pregnant women to abort their babies and induced strokes, heart attacks, frost bite, and hypothermia in other subjects.^[9]

Indeed, several years after the Nuremberg code and other instruments, examples abound of exploitation of human subjects in biomedical research.^[4]

In Kenya, there is hardly any reporting of malpractices connected to the lack of or poor regulation of biomedical research. Nevertheless, anecdotal evidence points a grim picture.

Evolution of a Regulatory Framework for Biomedical Research

Nonregulation or poor regulation of biomedical research on human beings has led to untold suffering. Hitherto, there were no written principles anywhere to guide research on human beings.^[12] A major selling point of the code was the emphasis on informed consent. However, this document was deemed to be too legalistic. The World Medical Council came up with a “softer” version called the Helsinki Declaration in 1964. The Declaration softened the rigid requirement for the respect of persons, and at the same time, differentiated the concept of informed consent into several categories, retaining the “paternalistic” value of the doctor-patient relationship.^[13] The Declaration of Helsinki in 1964 has been revised several times.^[14] This Declaration introduced the concept of independent Ethics Committees.

The Council for International Organizations of Medical Sciences has also issued some guidelines.^[15] Another document, the Belmont Report^[16] distinguishes research and clinical practice, and how the ethical principles can be applied. The contents of this report appear to have been accommodated in the latter revisions to the Helsinki Declaration.^[14]

Another vital document in this regard is the Universal Declaration on Bioethics and Human Rights.^[17] As a part of the preamble this document provides thus:

Considering that all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research.

Paragraph 1 of Article 3 of this Declaration is on human rights, and it speaks to the need to fully respect the dignity, human rights, and fundamental freedoms. Finally, this provision accords well with chapter four of the Constitution of Kenya as well as all modern human rights instruments. Paragraph 2 comments that the interests and welfare of the individual should be placed above those of science and society. Article 6 is on consent. In particular, for both medical intervention and scientific research, it provides that consent must be prior, free, and informed, based on adequate information. Article 19 proposes that Ethical Review Committees must be independent, multidisciplinary, and pluralist. These are the ones to handle all matters related to biomedical activities. Article 23 foresees the need to promote bioethics education, training, and information. On the whole, this Declaration has borrowed a lot from other instruments. Based on article 2(6) of the Constitution of Kenya, 2010,^[18] this Declaration is a part of Kenyan law. More specifically, the guidelines prepared by the National Commission for Science, Technology

and Innovation incorporate all recent developments in biomedical ethics.

Informed consent is particularly at the core of these endeavors. In developing countries, it is made difficult by lower levels of literacy, religious, and societal/cultural values, such as women being seen as the property of men, the deep scientific language, and a deliberate move by researchers to conceal material information from the subjects.^[19] In certain circumstances, subjects may suspect that the police could use the forms to get at them. Another major concern is payment. It has been suggested that this should not be too high.^[4] Another aspect of concern relates to Research Ethics Committees. These are supposed to be independent, multidisciplinary, multisectoral, and pluralistic. However, then, these committees could be absent, ineffective, or under-resourced in many countries.^[20]

It is clear that although no country or medical association adopted the Nuremberg code, nevertheless, it influenced all subsequent codes and guidelines on biomedical research.^[12]

For a very long time, attempts to standardize ethical review procedures and guidelines in Kenya were unsuccessful. This situation was exploited by scientists, especially foreign ones, to carry out experiments which do not meet the international ethical standards and which they could obviously not carry out in their own countries. Biological materials/specimens were exported without controls. Instances of some scientists purporting to seek research permission while the studies were already going on were not uncommon. Most critically, there was no mechanism for monitoring whether the scientists were following their approved protocols. In certain instances, some study participants complained in the press of not being given information regarding the studies they were involved in.

Regulation of Biomedical Research in Kenya

All the above examples point to the need for a robust regulatory regime. Kenya has the Science, Technology and Innovation Act, 2013, which came into force in 2014.^[21]

The Act established three institutions. These are the National Commission for Science, Technology and Innovation, the Innovation Board, and the Research Fund Board.

The National Commission for Science, Technology and Innovation is established under section 3(1). Its functions as enumerated under section 6 include accreditation of research institutions and approval of all scientific research in Kenya; coordination, monitoring, and evaluation of activities relating to scientific research, and development of technology; development and enforcement of codes, guidelines, and

regulations; and undertaking regular inspections, monitoring, and evaluation of research institutions.

Licensing

The commission must license a research project involving human subjects, including social science research before it is commenced. University research is exempted from this provision. It is an offense to violate this provision, which attracts a fine of up to USD 60,000 or 5 years in jail.

Accreditation of research institutes

This is provided for under section 17. Accordingly, any institution that desires to carry out biomedical research must be accredited by the commission. Such an institute must by necessity form an Institutional Review Committee (IRC) in line with standard operating procedures established by the commission. It is the duty of such an IRC to approve protocols on behalf of the commission, to monitor adherence of researchers to their protocols, and to submit an annual report of its activities to the commission.

Guidelines by the commission

The commission has prepared several guidelines that touch on the formation of an IRC, material transfer, animal care, and standard operating procedures. The latter document concerns itself with formation of an IRC, processes for approval of research protocols, and monitoring and evaluation. The guidelines, for approval of research protocols on their part, are quite detailed, and they require an applicant researcher to indicate institutional affiliation and co-researchers (if any); to provide a scientifically sound protocol providing for informed consent, withdrawal from the study, lack of inducements, and sources of funding; to provide for aspects of benefits sharing with the community; and mitigation of adverse effects (if any).

In addition, the guidelines produced by the Commission to a very large extent incorporate all the requirements of the UNESCO Declaration on Bioethics as well as the latest version of the Helsinki Declaration.

Previously, it was very difficult to monitor research, especially from and or by foreigners. As a result, many foreigners exploited the legal lacuna and did research sometimes in the most unethical way. Under the current law, unethical research practices have been criminalized.

What Challenges, if any, Still Remain in the Regulation of Biomedical Research in Kenya?

The fact of a legal and institutional framework shows a serious desire by the country to regulate biomedical research. However, the success of such efforts will depend largely on human and financial capital. Capacity, as it relates to human resources, is a major challenge. This is made worse by the

exportation of highly qualified doctors and scientists under the rubric of “brain drain” to other countries. For example, it has been estimated that there are more Kenyan doctors working outside of the country than those in the public service. There is, therefore, a need to train and retain those persons, who should play the role of gatekeepers through the ERCs, and to cascade such training to students to be part of their course work. Another challenge relates to an overlap of functions with other institutions. For example, the Pharmacy and Poisons Board is responsible for drug trials. The Biosafety Authority controls the transfer of materials for biotechnology. The National Environment and Management Authority is the designated authority for implementing the 1992 UN Convention on Biological Diversity. As such, it controls research using genetic materials and elements of materials transfer. The Kenya Wildlife Services administers the International Convention in Trade of Endangered Species. As such, experiments involving certain endangered materials including certain algae, bacteria, and plants will need their approval. This means, there is a need to harmonize the approval process so that a researcher does not spend a lot of time knocking on several doors in search of approval.

Monitoring and evaluation pose another challenge. The need to monitor whether researchers are actually following the approved protocols cannot be overstated. However, such monitoring and evaluation relies on self-reporting of accredited institutions. At these institutions, those who can and should monitor are themselves engaged full time elsewhere. There are no specific “police officers” foreseen by the Act for such purposes. There is, therefore, a risk of researchers going “wild”. Participants may not be able to give reliable feedback as most confuse treatment with research. The aspect of monitoring and evaluation needs to be enhanced and to ensure that researchers operate within the approved proposals. Whereas the requirement of Institutional Review Boards (IRBs) to report annually to the commission is a good measure, IRBs need to be more involved in monitoring ongoing projects. So far, it has been left to IRBs to monitor and identify or intervene where unethical practices are detected.

Another challenge is posed by the ever-evolving nature of science. There are several biotechnologies at the moment. For example, questions are being asked whether the process used to move such products from the laboratory to the dining tables does not infringe on bioethical considerations, such as informed consent. Another area of technological advancement is nanotechnology. This technology is still evolving, is little understood, but it involves the use of products of science in human body. Is it possible to regulate what one does not clearly understand? With respect to information and communication technologies, it is murmured that radiation from mobile phones and computers could be carcinogenic. The whole area of stem

cells research is ethically challenging—whether the cells are to be harvested from embryos (and in the process destroying such embryos) or from the placenta. For example, in case some useful innovation is discovered—how should the aspect of “benefit sharing” be dealt with? Furthermore, should researchers always be on standby to seek consent from expectant mothers on the possible use of their discarded placentas for research? The Supreme Court in California has held that a donor has no proprietary right in excised or discarded tissue. For how long will such a holding remain good law? Since science thrives on discoveries, some planned, others accidental, it is not possible to set up regulations before such a discovery. Law will always, therefore, lag behind science. Nevertheless, the age old principles including beneficence and nonmaleficence should help scientists and IRBs to ensure all scientific endeavors are done within the rules.

The aspect of intellectual property rights is slowly becoming alive in Kenyan research institutions. There is a risk that foreign co-researchers may take advantage of the ignorance of locals in matters of proprietary rights over innovations emerging from research. In particular, it may be quite easy to abuse the rights of communities. Community rights to property are provided for by the Constitution of Kenya, 2010.^[18] What is missing to date is an institution to manage community claims to intellectual property. The current Kenyan laws on intellectual property rights are modeled along the lines of the Trade Related Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization.^[22] A recognition of community rights is not captured under TRIPS. This is, however, provided for in the Swakopmund protocol of 2010,^[23] concluded by the African governments. Its implementations, as well implementation of the constitutional provisions on community intellectual property rights, are affected by the lack of enabling legislation. Legislation in this direction will help communities benefit better from research activities.

One other challenge relates to the lack of a mechanism for dispute resolution. The act is silent on this. This leaves the council in charge of resolving disputes with appeals going to the superior courts. Cases in courts can take many years, a prospect sponsor of research dislike. A better view would be to have an independent tribunal to resolve all matters relating to regulation.

Another challenge relates to funding for research. In Kenya, most of this appears to come from foreign countries. It has been said that pharmaceutical companies like to do clinical studies in developing countries because of the poor regulatory regime for biomedical research. A contrary view holds that these companies do so for diseases whose required subjects can only be found in such countries.^[24] In *Abdullahi v Pfizer, Inc.*, the US Supreme Court allowed

Nigerian families to sue Pfizer on the use of a new antibiotic on their children, in which consent was not sought.^[25]

An investigation by the British Union Against Vivisection in Kenya that lasted 18 months revealed how baboons are subjected to harmful experiments that violate international research guidelines. These experiments are normally done by scientists from the USA and Europe whose laws cannot allow them such latitude. Such activities are blamed on lax laws on animal protection in Kenya.^[26]

It is hoped that the new law will be effective.

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There are no conflicts of interest.

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