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African AIDS Vaccine Programme

Defining and strengthening priority areas in terms of ethics, law, human rights and HIV vaccine research.

THE ETHICAL-LEGAL REGULATION OF HIV VACCINE RESEARCH IN AFRICA:
A study of the regulation of health research in Botswana, Ethiopia, Kenya, Tanzania & Uganda to determine their capacity to protect and promote the rights of persons participating in HIV vaccine research

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1 SUMMARY

1.1 Health research, including HIV-related research such as HIV vaccine research, has been prioritised in several African countries. There are a number of recent legislative and policy developments to build the capacity of these countries to conduct lawful and ethical research. This report will, however, focus on the following five countries; Botswana, Ethiopia, Kenya, Tanzania and Uganda.

1.2 In each of the five African countries under study, there are various legal and ethical structures that have the capacity to regulate HIV vaccine research.

1.3 However, in many cases the statutory bodies responsible for regulating clinical trials of drugs and/or regulating scientific and technological research and development have not developed detailed regulations for the ethical review and approval of research. Where ethical structures, processes and procedures have been developed, they are not yet legally binding.

1.4 Laws, regulations, policies, guidelines and codes of ethics in the countries under study combine to provide strong protection of the rights of all people, which would include trial participants taking part in HIV vaccine research.

1.5 However, of the countries under study, only Kenya has national guidelines specifically dealing with HIV research and development. This means that some of the more complex ethical and legal issues raised by HIV vaccine research remain unanswered.

1.6 Ongoing monitoring of research on human participants is provided for in some instances by law, in others in terms of ethical guidelines. However, in many cases, monitoring mechanisms are inadequate.

1.7 Likewise, enforcement mechanisms are provided for by the civil, criminal and constitutional courts, as well as by professional councils that regulate the activities of medical practitioners. However, more accessible enforcement mechanisms (such as the Human Rights Commissions in Uganda) are lacking in most countries.

1.8 In conclusion, it would seem that the ethical-legal framework in the 5 African countries studied, although not ideal, would be able to support HIV vaccine development and research. In principle, basic laws and ethical guidelines would protect the fundamental rights of all people, including trial participants.

1.9 However, key concerns are the following:

- Many of the ethical review processes and structures are still in the process of development, and are in most cases not legally binding, which may lead to research taking place without certain accepted procedural safeguards;
- Many of the more complex ethical issues raised by HIV vaccine research are not specifically dealt with by the general laws and/or ethical guidelines in the country, which may lead to participants' rights being abused;
- Monitoring and enforcement mechanisms are inadequate, and would in all likelihood be inaccessible to most trial participants and deprive them of legal remedies; and finally
- As a result, many persons may be unwilling to volunteer to participate in HIV vaccine research.

2 INTRODUCTION

2.1 Background

Africa and the developing world are increasingly being used as a site for clinical trials, with funds dedicated to pharmaceutical research outside of the United States of America increasing from 1.6 billion dollars in 1991 to 3.7 billion dollars in 1999[1]. According to the International AIDS Vaccine Initiative (IAVI), the number of HIV vaccine trials in humans has doubled since 2000, and developing countries are now helping to lead the field. In 2000, only one African country (Uganda) was conducting an HIV vaccine trial. At the time of this study, four African countries had small-scale trials underway and another five African countries are preparing for trials.[2]

Considering the nature and the volume of research being conducted in Africa, it is generally understood that African countries need to develop strong legal and ethical capacity to regulate local research on new drugs and research in general.

This is particularly important in the context of the research and development of an affordable, effective and locally-relevant African HIV preventive vaccine. HIV vaccine research, while regarded as a research priority in a number of African countries, nevertheless poses many complex ethical-legal challenges, which may be difficult to resolve in the absence of a sound regulatory framework.

Recent African AIDS Vaccine Programme (AAVP)-sponsored research on the capacity of research ethics committees (RECs) in Africa revealed that members of RECs had limited knowledge of the legal rights of trial participants or the local laws pertaining to health research. [3] Additionally, it appears that very little research has been undertaken into the nature and extent of ethical-legal frameworks in African countries[4].

In this context, it is imperative that research is undertaken into the nature and extent of health legislation and laws regulating research in Africa, and the extent to which these laws protect the rights of HIV vaccine research participants. An understanding of the ethical-legal framework for research in Africa will assist in identifying the strengths and weaknesses of existing processes, and in developing plans to build strong local ethical-legal capacity throughout Africa.

[1] Washington Post, 18 December 2000.
[2] IAVI, 2004.
[3] Milford et al., 2003
[4] See Bartlett, 2005

2.2 HIV/AIDS epidemic

According to the UNAIDS *2004 Report on the Global AIDS Epidemic*, it is estimated that around 38 million people are living with HIV globally. Of this number, an estimated 25 million are from Sub-Saharan Africa. In 2003, more people became infected with HIV in any year since the beginning of the epidemic. Of the 5 million new infections, about 3 million took place in Sub-Saharan Africa. In the same year, global deaths due to AIDS amounted to almost 3 million people, of which 2.2 million (75%) were from Sub-Saharan Africa.

UNAIDS also reports that rates of infection are still on the rise in many sub-Saharan African countries, such as Madagascar and Swaziland. In Southern Africa, all seven countries have HIV prevalence rates over 17%, with Botswana and Swaziland having prevalence above 35%.

While preventive measures such as condom use and treatment of sexually transmitted infections (STIs) have had some success, given the scale of the epidemic, the development of a safe, effective and accessible HIV vaccine is viewed by many as a priority intervention.

2.3 HIV Vaccine Research in Africa

HIV vaccine research is being undertaken in a number of African countries. At the time of the study, two Phase I HIV vaccine trials had taken place in Kenya and Uganda.[5] HIV vaccine trials in humans are currently taking place in Kenya, Uganda Tanzania, Rwanda, Zambia, Botswana and South Africa.[6]

Furthermore, a trial is being planned in Cote d'Ivoire[7]; while different levels of vaccine preparedness are also under way in Burkina Faso, Cameroon, Ethiopia, Gabon, the Gambia, Malawi, Nigeria, Senegal and Zimbabwe.[8].

Table 1: Country Profiles (IAVI, 2002, 2003)

Conducted HIV vaccine trials	Trials currently being conducted or being planned	Different levels of vaccine preparedness activities		
A	B	C	D	E
Uganda	Botswana	Ethiopia	Zambia	Zimbabwe
Kenya	Kenya	Senegal	Nigeria	Malawi
	South Africa			Cameroon
	Uganda			Burkina Faso
	Tanzania			Gambia

[5] IAVI, 2002.
[6] Thior, 2005
[7] IAVI, 2002.
[8] Kaleebu, 2002.

2.4 Role of the Ethical-Legal Framework

When the goals of science and medical research are so important and urgent, as they are argued to be in the case of HIV vaccine research, there is always a danger that the well-being of human beings participating in the research may be compromised. The ethical-legal framework operating in a country helps to balance the goals of science and the rights and welfare of human beings, by providing for legally binding structures and processes to oversee, regulate and monitor research on human participants according to accepted norms and standards.

Promoting and protecting the rights and welfare of human trial participants is important for a number of reasons:

- Medical research is not just about science and the advancement of scientific knowledge, but is also about human development. For this reason, protecting the rights of human beings is just as important as advancing science;
- Protecting and promoting the rights of trial participants may help to promote good science, since it encourages trial participants to participate in, and remain in clinical trials; and
- Ethical and lawful research can promote public confidence in the research and its findings.

A lack of knowledge about ethical legal frameworks was identified in an AAVP report as a key challenge facing research ethics committees (RECs) in Africa.[9]

Ideally, an ethical-legal framework should include:
- A national ethical-legal structure to regulate research, development and approval of new medical products;
- ethical review of research by independent research ethics committees at a national or local level;
- national ethical standards or guidelines to assist RECs in their deliberations;
- laws protecting trial participants and researchers; and
- mechanisms to monitor and enforce legal rights and ethical obligations.[10]
- Specific guidelines for HIV vaccine trials[11]

2.5 Purpose and Objectives of the Research

In 2003, the UNAIDS AAVP initiated research to establish the extent to which legislation in 5 African countries protected and promoted the rights of HIV vaccine trial participants.

The research project had the following primary objectives:

[9] Milford et al., 2003.
[10] Strode, Slack, Tangwa et al., 2001.
[11] Cf. e.g.,, Kenya Ministry of Health, 2005; MRC, 2005; UNAIDS, 2000.

2.5.1 To establish the content of all laws and policies in Botswana, Kenya, Uganda, Ethiopia and Tanzania relating to the ethical-legal structures and processes for review, approval and monitoring of health research and registration of new drugs, as well as to the rights of trial participants and mechanisms to enforce those rights.

2.5.2 To establish whether the ethical-legal framework identified in the countries is able to support and guide HIV vaccine development and research, either in terms of general legal and ethical principles or in terms of HIV vaccine specific policies and guidelines.

2.5.3 To establish whether the framework protects and promotes the rights of HIV vaccine trial participants (including minors) from the major ethical concerns raised by HIV vaccine research.[12]

2.5.4 To compare and contrast the various models of ethical-legal frameworks in the countries studied, in order to develop recommendations on a required ethical-legal framework for African countries.

2.5.5 The intended purpose of the study was to assist in the development of an advocacy and training plan on ethics, law and human rights, for developing the capacity of the researched countries to strengthen their ethical-legal systems.

2.6 Methodology of the Research

2.6.1 Due to budgetary constraints, five African countries, namely Botswana, Ethiopia, Kenya, Tanzania and Uganda were selected[13], based on the following criteria:

- *Countries where HIV vaccine trials are currently taking place*
- *Countries where HIV vaccine trials are planned for the near future*
- *Countries in which legislation and policy is available in English*

2.6.2 A questionnaire (Appendix A) was developed and sent to local contact persons involved in ethical or legal aspects of health research in each of the 5 African countries. The questionnaire was designed to elicit

[12] Such as whether trial participants will have access to a candidate HIV vaccine after development, whether participants who become infected with HIV during the trial will have access to anti-retroviral treatment provided by the sponsors or by the state, whether minors will be protected from being enrolled in trials with an unacceptable level of risk etc.

[13] At the time of study, HIV vaccine development is planned in Senegal, Zambia, Nigeria, Zimbabwe, Malawi, Cameroon, Burkina Faso and the Gambia. If further funding becomes available these countries will be studied in phase two of the research project once the methodology has been tested and the accessibility of information has been established, to ensure accurate budgetary planning. South Africa was excluded on the basis that an audit of South African legislation and policy relating to HIV vaccine research was undertaken in 2001 (Barrett Grant and Strode, 2001) on behalf of the AIDS Legal Network.

information and documentation relating to relevant health, health research and/or HIV vaccine research legislation, policy or guidelines in the country;

2.6.3 A desk review, including internet search, was conducted on relevant health, health research and/or HIV vaccine research legislation, policy and guidelines in the 5 African countries;

2.6.4 Based on the results of the questionnaire and follow-up correspondence with local contacts, as well as the desk review, 5 Country Reports (Appendix B) were developed;

2.6.5 A final report was developed, based on the findings of the individual Country Reports.

2.7 Limitations of the research

2.7.1 This study has been limited by a number of factors including:

- An inability to fully verify the information received with state authorities within each country
- A reliance on volunteers, not all of who were lawyers, within each country who assisted with collecting information
- Limited availability of, and access to central data bases containing copies of legislation and policies
- The informal, developing nature of many of the ethical-legal systems which makes establishing procedures difficult
- Limited resources for the research which excluded the possibility of country visits.

3 ETHICAL-LEGAL REGULATION OF HIV VACCINE RESEARCH

3.1 Introduction

None of the five African countries studied, namely Botswana, Ethiopia, Kenya[14], Tanzania and Uganda, had developed guidelines specifically to regulate the ethical review of HIV vaccine trials. However, each country had in place:

- Existing legal and ethical structures and processes able to play a role in regulating HIV vaccine research and development in the country;
- Existing or draft laws, policies, guidelines and ethical codes able to play a role in protecting and promoting the rights of trial participants; and
- Existing statutory bodies or administrative bodies able to play a role in monitoring and enforcing the rights of trial participants.

[14] Kenya has subsequently published dedicated HIV vaccine trial guidelines. Republic of Kenya (2005)

The study examined these structures, processes, laws and guidelines in the context of HIV vaccine research and development, in order to determine the extent to which the various countries were able to regulate HIV vaccine trials, and possible recommendations for strengthening and improving the ethical-legal framework in the various countries.

3.2 Ethical-Legal Framework

All of the 5 African countries studied have statutory and administrative bodies that are, or have the capacity to be, involved in various aspects of the ethical-legal regulation of research. Some of these are research-related bodies whilst others are not directly involved in regulating research but could play a broader role of protecting and promoting the rights of trial participants within the ethical-legal framework.

3.2.1 Models for regulating health research

The study identified three different models for regulating research within the respective countries. These are:

- A non-statutory administrative body reviews and approves research, such as the Health Research and Development Committee in Botswana.
- A statutory science and technology council reviews and approves research, for example, the Kenyan Science and Technology Council and the Ugandan National Council for Science and Technology. This council acts in conjunction with ethical review bodies and the national drug regulatory authority.
- A national drug regulatory authority reviews and approves research in conjunction with ethical review bodies. For example, the Tanzanian Food and Drugs Authority and the Ethiopian National Drug Advisory Commission.

All of the models appear to be effective mechanisms for reviewing and approving research. However the regulation of research by non-statutory bodies is limited by the fact that the independence of such bodies is not guaranteed and their powers and obligations are not clearly defined by law.

3.2.2 Institutions and bodies able to participate in regulating health research

The study revealed that statutory or administrative bodies, national law making bodies, bodies to regulate medical practitioners, courts and commissions are all able to play a role in the ethical-legal regulation of research.

(i) *Statutory or administrative bodies dealing with research*
Most of the countries have a *statutory (or administrative) body tasked with regulating clinical trials on drugs*,[15] and/or *a statutory body tasked with guiding*

[15] Such as Ethiopia, Tanzania and Uganda. These bodies are set up by national laws dealing with drugs and related substances. See Table 2 and Appendix B: Country Reports for more detail.

science and technology programmes and policies[16] in the country (see Table 2 below).

Table 2: Statutory and Administrative Bodies set up to regulate clinical trials / science & technology

	BOTSWANA	ETHIOPIA	KENYA	TANZANIA	UGANDA
Statutory body		The National Drug Advisory Committee is responsible for regulating clinical trials of drugs. The Ethiopian Science and Technology Council (ESTC) is responsible for guiding scientific and technological research and development. It has created a system of Ethics Review Committees (ERCs) to regulate research on human subjects.	The National Council for Science and Technology (Medical Sciences Advisory Research Committee) is responsible for regulating clinical research on drugs. This body works with the Pharmacy and Poisons Board. Approval must be obtained from both bodies.	The Tanzania Food and Drugs Authority is responsible for regulating clinical trials of drugs. In addition, the National Health Research Ethics Review Sub-Committee, established by the National Policy on HIV/AIDS, is responsible for approval and review of research, including HIV/AIDS research on humans.	The National Drug Authority is responsible for regulating clinical trials on drugs. The Uganda National Council for Science & Technology (UNCST) is responsible for guiding and co-ordinating research and development.
Administrative body	The Ministry of Health is responsible for regulating clinical trials of drugs through the Health Research and Development Committee.		*Kenya HIV/AIDS Vaccines Sub-Committee* of the Ministry of Health reviews concept papers relating to proposed HIV vaccine trials. It is an advisory committee and not a regulatory body.		
Development of research guidelines including ethics	Ministry of Health has issued the *Drugs & Related Substances Regulations*.	National Drug Advisory Committee has not yet finalised any regulations. ESTC has developed *National Health Research Ethics Guidelines and Procedures*, 2003	Ministry of Health has issued *Kenya National Guidelines for Research and Development of HIV Vaccines.*	Minimal guidance is set by the enabling legislation, the Tanzania Foods, Drugs and Cosmetics Act.	The National Drug Authority has not yet finalised any regulations. The UNCST has developed the *Guidelines for the Conduct of Research involving Human Subjects in Uganda,* 1997.
Monitoring of research	The Director of Health Services in the Ministry of Health is responsible for monitoring a trial.	The ERCs set up by the ESTC are responsible for monitoring trials.	The National Council (Advisory Research Committees) are responsible for reviewing the progress in research	The Tanzania Food and Drugs Authority and the National Institute for Medical Research are responsible for monitoring trials.	The UNCST monitors research through reporting requirements.

(ii) *National law making bodies*

[16] Such as Ethiopia, Kenya and Uganda. These councils are set up by national laws dealing with science and technology broadly. See Table 2 and Appendix B: Country Reports for more detail.

Each country has a *democratically elected, national law making body* ('Parliament' or 'National Assembly') that has the power to make national laws for the country. Uganda has the added benefit of a Law Reform Commission[17] established in terms of the Constitution, whose function is to modernise the laws of the country by repealing obsolete laws, giving effect to international instruments and improving the methods of administration of the law. These bodies are in a position to enact national laws to govern the process of research (including HIV vaccine research) and the rights of trial participants, where necessary.

(iii) *Bodies to regulate medical practitioners*
Almost all of the countries have a *statutory (or administrative) body to regulate medical practitioners*. These bodies generally have statutory authority to develop ethical guidelines for the medical profession[18], and would therefore be in a position to develop, monitor and enforce ethical guidelines to govern the conduct of medical practitioners as researchers.

(iv) *Courts*
All of the countries have a system of *courts to enforce breaches of civil, criminal and constitutional law*. Kenya has proposed the establishment of an *Equity Tribunal*[19] to resolve HIV-related disputes, which could include dealing with disputes arising from HIV vaccine research.

(v) *Commissions*
Some of the countries have commissions which could assist trial participants to enforce their rights, for example, Uganda has a *Human Rights Commission*[20] that could potentially become involved in the monitoring and enforcement of the rights of trial participants in HIV vaccine research.

In general, effective regulation of research requires:

- research ethics guidelines,
- competent research ethics committees,
- clear procedures,
- a process for approving research protocols, and
- ongoing monitoring of research.

While most of the countries have developed some form of regulation of research on human participants applicable to HIV vaccine research, many processes are inadequate for the following reasons:

[17] Ugandan Law Reform Commission Statute, 1990

[18] Evidence of such guidelines was found in Kenya and Tanzania. The Kenyan Medical Practitioner's Board has developed the *Code of Professional Conduct and Discipline* (5th Edition) to govern the conduct of medical practitioners; the Medical Association of Tanzania has developed the *Guiding Principles on Medical Ethics and Human Rights in Tanzania*. See Appendix B: Country Reports for more detail.

[19] Created by the Kenyan HIV and AIDS Prevention and Control Bill, 2003. This subordinate court has the power to summons witnesses, take oral evidence and to request any relevant documentation. The Tribunal does not have criminal jurisdiction but can award damages or make an appropriate order relating to any complaints arising out of the a breach of the provision of the Bill or an appeal provided for in the Bill.

[20] Chapter 4, section 52 of the Constitution of the Republic of Uganda, 1995.

- It appears that the statutory bodies set up to regulate *drugs*, including clinical trials of drugs, are often given the power to enact legally binding regulations. However, in most cases (e.g., in Botswana and Tanzania) these laws and regulations are minimal, and fail to provide for a thorough process of scientific and ethical review of research on human participants. Likewise most national parliaments have failed to pass dedicated legislation setting out the rights of trial participants.

- The statutory bodies set up to oversee *science and technology* (i.e. the various Science and Technology Councils) tend to be the bodies that develop detailed guidelines providing for the scientific and ethical review of research on human participants; however, these guidelines do not have the status of law. (e.g., in Uganda and Ethiopia).

- In Botswana there is no statutory body to approve clinical trials; the Drugs and Related Substances Act delegates this authority to an official within the Ministry of Health, the Director of Health Services. The Director has in turn set up a body within the Ministry, the Health Research and Development Committee, which approves clinical trials. This body, however, has no statutory powers. This is problematic as the independence of the committee is not protected by law and it has no defined powers.

3.3 The legal rights of trial participants

The study found that each of the 5 African countries have existing *human rights and other laws* that would protect the rights of all people, including HIV vaccine trial participants.

- Each country has a Constitution, which is supreme, and which protects basic human rights and freedoms, such as the right to life, the right to liberty, and the right to equality and non-discrimination.[21]
- The study found that almost all of the countries[22] have acceded to a number of international human rights instruments protecting the rights of persons[23], including the rights of vulnerable persons such as women and children.
- Some of the countries had statutory laws dealing specifically with the rights of trial participants[24], and rights in the context of HIV and AIDS[25], such as the right to participate in research only with voluntary and informed consent (see Table 3 below).

[21] See Appendix B: Country Reports for more information in this regard.

[22] The Tanzania Country report did not provide details regarding international law.

[23] Such as The African Charter on Human and Peoples' Rights, 1981; The International Covenant on Civil and Political Rights, 1966; The International Covenant on Economic, Social and Cultural Rights, 1966; The Convention on the Elimination of all Forms of Discrimination Against Women, 1979; and The Convention on the Rights of the Child, 1989. See Appendix B: Country Reports for more detail in this regard.

[24] For example, in Ethiopia Proclamation 60/1999[24] contains provisions relating to clinical trials, including provision for participation only with written consent; confidentiality; and a prohibition of including vulnerable groups such as nursing and pregnant women and children under the age of 18 in research. The Tanzania Food, Drugs and Cosmetics Act, 2003 provides safeguards for trial participants such as provision for participation only with voluntary consent and full information.

[25] In Kenya, the proposed HIV and AIDS Prevention and Control Bill, 2003 protects various rights in the context of HIV and AIDS. It also states that no person may undertake HIV or AIDS related biomedical research on another person unless such research complies with the requirements set out in the Science and Technology Act. Furthermore all such research must be with the written informed consent of each participant, unless such person is a child, then with the written consent of his or her parent or guardian. During the consent process the trial participant must be adequately informed of the aims, methods, anticipated benefits and the potential hazards and discomforts of research.

Table 3: Example: Sources of the right to informed consent in the 5 African countries

Rights	Botswana	Ethiopia	Kenya	Tanzania	Uganda
The right to take part in a trial only with voluntary, informed consent	The Constitution protects the right of all people to security of the person. The common law protects the right of all people to bodily and psychological integrity	The Constitution gives every person the right to security of the person. Proclamation 60/1999 provides for participation in clinical trials only with written consent and prohibits children less than 18 years from participating in research. The Ethiopian Civil Code provides for treatment only with consent, and for the right to refuse consent. The *National Health Research Ethics Guidelines and Procedures*, 2003 provide for written informed consent for research. The *HIV/AIDS Policy* provides for informed consent for research	The Constitution gives every person the right to security of the person. The HIV and AIDS Prevention and Control Bill, 2003 provides for HIV testing only with written and informed consent of the person, or parent/guardian in the case of a child, unless the child is at high risk of HIV infection. It also provides for written informed consent of the person, or the parent/guardian in the case of a child, for all HIV-related research. The *Code of Professional Conduct* for medical practitioners provides that a person must give informed consent for medical treatment.	The *Guidelines on Medical Ethics and Human Rights in Tanzania* state that medical interventions on patients may only take place with informed consent. The Tanzania Food, Drugs and Cosmetics Act, 2003 protects trial participants from participation without free, informed consent. The *Guidelines on Health Research* in Tanzania provide guidance on consent and protect. participants	The Constitution gives every person the right to security of the person. In terms of the common law, every person has the right to security of the person, which includes the right to medical treatment only with informed consent.

Some of the countries studied had various *policies, guidelines and codes of ethics that would protect the rights of trial participants*. While these policies and guidelines are not legally binding, they nevertheless provide valuable norms and standards that could be used to monitor the conduct of HIV vaccine trial site staff:

- The study found that both Ethiopia and Uganda have detailed ethical guidelines[26] governing the rights of trial participants.
- The findings show that Kenya and Tanzania have codes of ethics for medical practitioners[27], detailing the rights of patients to issues such as consent for treatment and confidentiality.
- The study shows that Ethiopia and Tanzania have national HIV/AIDS policies[28] protecting the rights of people living with HIV/AIDS, and containing provisions with regard to HIV-related research and development.

Based on the various constitutions, laws, policies and ethical guidelines it could be argued that the following *key rights are available to trial participants* in all 5 African countries:

[26] See Appendix B: Country Reports for more information.
[27] See Appendix B: Country Reports for more information.
[28] See Appendix B: Country Reports for more information.

- The right to life
- The right to respect for dignity
- The right to protection from cruel, inhuman or degrading treatment
- The right to liberty and the right to security of the person, which includes the right to participate in research only on the basis of voluntary and informed consent
- The right to equality and to be protected from unfair discrimination on a number of grounds
- The right to privacy, which includes the right to medical confidentiality
- The rights of vulnerable groups such as children and women.

Additional rights available to trial participants in some of the countries include the following:

- The right to the highest attainable standard of physical and mental health[29]
- The right to be compensated for unlawful acts that cause harm[30]
- The right to be protected from injury or risk.[31]

As a result, there is fairly extensive protection of the rights of all people, including trial participants, in the 5 African countries. However, protection of rights is limited by the following facts:

- Many of the rights are broad-based, and are not specific to research in general, or HIV vaccine research in particular. The rights of trial participants are drawn largely from laws and policies conferring broad rights, such as the right to security of the person and the right to privacy. None of the countries in question have guidelines specific to the rights of trial participants in HIV vaccine research (although in Ethiopia, the *National Health Research Ethics Guidelines and Procedures* (2003) commit to compliance with international ethical guidelines). The Kenyan national guidelines on HIV vaccine development do not detail the rights of trial participants (Kenya Ministry of Health, 2005).

- Using general legal principles and applying them to research may result in some of the more complex issues raised by HIV vaccine research remaining unanswered – for example, in most of the countries studied it is unclear if,

[29] Those countries that have ratified the International Covenant on Economic, Social and Cultural Rights, 1966, namely Ethiopia, Kenya and Uganda, are bound to take steps to provide for this right. The Tanzania Country Report fails to deal with international law ratified by Tanzania, and the position in Tanzania is thus unclear.

[30] The civil law of delict, or *tort* in Botswana and Uganda, provides for compensation for unlawful acts that cause harm. Further information with regard to civil law was not obtained in terms of the Ethiopia, Kenya and Tanzania country reports; however, from the information available it is assumed that these or similar basic principles would also apply in their countries. See Appendix B: Country Reports for more details in this regard.

[31] In Ethiopia, the *National Health Research Ethics Guidelines and Procedures*, 2003 state that trial participants should be protected from the risks and participate in the benefits of research. The *Guidelines on Medical Ethics and Human Rights in Tanzania* state that medical practitioners must protect patients from unnecessary risks, while the Tanzania Food, Drugs and Cosmetics Act, 2003 states that researchers must ensure that dosages in a clinical trial minimize risk of injury to trial participants.

when and how children may participate in HIV vaccine trials[32]; whether trial participants are entitled to treatment if they become infected with HIV as a result of participating in a trial[33], or whether trial participants would have access to a successful vaccine after a trial has been completed.

- Not all of the rights are protected by constitutional or other forms of national law, which generally provides the strongest protection for the rights of trial participants. Some of the rights are those found in international law conventions ratified by the countries; however such provisions are not enforceable until they are incorporated into domestic law. Others are found in policies and guidelines. These rights are, in many cases, not legally binding although they may have strong persuasive value.

- There appeared to be no legislative protection for the participation of children in research, except in Ethiopia where children are prohibited from participating in research.[34] This overly protective approach denies children the opportunity of benefiting from research.

3.4 Determining research priorities

All of the countries studied had mechanisms for establishing research priorities. Not all, however, had national policy documents setting out research priorities or had developed HIV vaccine plans.

3.5 Procedures for ethical-legal review of trials

All of the 5 African countries have a *process set down by law for reviewing and approving clinical trials on drugs*. This process would therefore be followed for clinical trials of an HIV vaccine. However, the legislated processes for review of

[32] The Botswana Country Report does not deal with the issue, although in terms of the common law it appears that a minor may not consent to medical treatment; in Ethiopia statutory law states that children under 18 years may not participate in research – although the ethical guidelines suggest a cautionary approach when involving children in research; draft legislation in Kenya allows for the participation of children in (unspecified) HIV-related research but only with the consent of a parent or guardian; in terms of the Tanzanian Country Report, the Tanzanian Food, Drugs and Cosmetics Act, 2003 does not appear to deal with the issue of child participation in research; likewise it is unclear from the Uganda Country report whether children are able to participate in research, and the law does not deal with the issue. See Table 2 and Appendix B: Country Reports for more detail.

[33] Although many of the countries studied have, or are presumed to have, civil laws that provide for compensation for harm, whether these laws would apply to compensation, in the form of medical treatment, for trial participants who become infected with HIV is a more complex question. In Kenya, there are a number of coercive legal provisions that compel persons with HIV to submit to treatment. For example, s 43 of the Public Health Act places a duty on any person who knows or who has reason to believe that they are suffering from a venereal disease to come forward for treatment and to remain in treatment until they are cured or free from such disease. Any person who fails to comply with s 44(1) shall be guilty of an offence. This may have serious consequences for researchers in HIV vaccine trials who will in many instances be testing persons for a range of sexually transmitted infections (STIs) at each contact visit.

[34] Proclamation 60/1999, s 21(3), Federal Negarit Gazeta, No. 60, 29th June 1999

clinical trials on drugs by drug authorities generally do not necessarily provide for detailed *ethical review* of the clinical trials.

Broadly speaking, each country follows a 4-step process:

- The initial step for all clinical trials in each of the 5 countries is to submit a signed application to the relevant authority.
- This authorising body evaluates the application and if convinced of its safety, permission will be granted for the clinical trial to proceed. In most instances an approval certificate is issued.
- The clinical trials are monitored by the relevant authority, and if the guidelines that are in place are not adhered to or the clinical trial is found to be unsafe, the trial may be stopped or suspended.
- If however the trial is evaluated as being safe, effective and in the public interest, approval will be granted for the registration of the drug.

In addition to the process described above, some of the countries have begun to develop *structures and processes for the ethical review of all research* (which would include HIV vaccine research)[35].
There has been considerable investment in the past 5 years by various funders in developing the capacity of ethics review committees in Africa. These include ethics committee training initiatives by the UNAIDS AAVP (Lagos, Kampala & Dakar), HAVEG, AMANET, PABIN, NIH Dept of Clinical Bioethics, NIH/Fogarty (SARETI, IRENSA, Malawi, Nigeria, Egypt), FHI, PRIM&R, WHO and a new EU Bioethics Initiative for Francophone African countries called NEBRA.

Case study 1 below illustrates the process of ethical review in Ethiopia.

Case Study 1: Ethiopian System of Ethical Review developed by *National Health Research Ethics Guidelines*, 2003

The *National Health Research Ethics Guidelines and Procedures* (2003) contain national operational guidelines providing for the ethical review of all research proposals. Although these guidelines have been approved by the Council of Ministers, they have not yet been enforced by law.

The *Guidelines* establish 3 levels of Ethics Review Committees (ERC) in Ethiopia: National, Regional and Institutional Ethics Review Committees.

The **National Ethics Review Committee (NERC)**, based at the Health Department of the ESTC, is tasked with giving final ethical approval for, amongst other things:

- all clinical trials involving new drugs, vaccines, new therapeutic regimens and other biological products as well as invasive diagnostic procedures[36];
- research which addresses very sensitive issues such as HIV/AIDS[37];
- research, which is fully or partially initiated, financed and some times wholly or partly carried out by external donors and international agencies[38].

The **Regional Ethics Review Committees (RERCs)** are tasked with giving ethical approval for:

- projects involving more than one institution in the regional state;

[35] See Case Study 1 and Appendix B: Country Reports for more detail. The Ugandan Council for Science and Technology has also developed ethical guidelines detailing the process and content of ethical review of research on human subjects, including the establishment of institutional ethics review committees. Tanzania has created a National Research and Ethics Committee that is also tasked with reviewing and approving all HIV-related research.

[36] Section 4.2.1(i) *National Health Research Ethics: Guidelines and Procedures*, 2003, page 8.

[37] Section 4.2.1(ii), page 9.

[38] Section 4.2.1(iii), page 9.

- projects where there is no Institutional Ethics Review Committee; and
- all projects that do not fall to be reviewed by the NERC[39].

Institutional Ethics Review Committees (IERCs) serve as an entry point for all research applications. They are responsible for reviewing health research projects, which do not fall under the mandate of the **NERC** or the **RERC**[40]. According to the *Guidelines*, the ERC's, in their review of the proposals, must emphasise the principles of Beneficence, Justice and Respect for persons, and must give particular attention to issues such as:

- The justification of predictable risks and anticipated benefits;
- The adequacy of provisions made for monitoring and auditing the conduct of the research;
- Safety procedures in the administration of drugs, vaccines and other biological products;
- The manner in which the study participants are selected, without discrimination;
- The informed consent process; and
- Measures taken to ensure confidentiality.

Problems with the process of ethical-legal review of trials include:

- In many instances there is no formal relationship between the various bodies within the ethical-legal framework. This means that the bodies do not act collectively to protect and promote the rights of trial participants. Furthermore it is unclear which body is ultimately required to provide approval for a trial or what process would be followed in the event of a dispute between the various bodies; and
- In some cases these structures and processes are not prescribed by statute and are therefore not legally binding.

3.6 Monitoring mechanisms

All the countries had mechanisms to monitor trials, although this was regarded as one of the weakest areas of the ethical-legal framework.[41] Many of the statutory bodies established to approve clinical trials are also tasked with monitoring. In many cases, the law simply provides for reviewing of reports provided by the researchers. In Ethiopia, the Ethiopian Science and Technology Council has delegated this function to Ethics Review Committees (ERCs) set up in terms of its research ethics guidelines.
The study identified the following problems with the ethical-legal framework for the monitoring of clinical trials:

- Monitoring by way of reviewing written reports is arguably inadequate, although it is unlikely that the bodies in question would have the capacity to conduct any more detailed form of monitoring, as they are known to be under-resourced[42].
- Although the Ethiopian model is perhaps a more realistic mechanism for monitoring, the function is not prescribed by law and is therefore not legally binding.

3.7 Enforcing the rights of trial participants

[39] Section 4.2.2, page 9.
[40] Section 4.2.3, page 9.
[41] Workshop Report, WHO/AAVP Programme meeting to establish a National Regulatory Structures Taskforce, Addis Abba, 28 – 29 January 2005
[42] Milford et al., 2003.

The study found that almost all of the countries[43] had principles of the civil law of delict (tort) as well as constitutional law (including human rights and freedoms) that protect the rights of all people from harm. It is submitted that these principles would also protect trial participants from harmful acts, such as an unlawful invasion of the right to privacy that caused harm, or a negligent act of a researcher that caused injury to a trial participant. Accordingly, the courts could be used to enforce the rights of trial participants.

Furthermore the study established that there were various bodies (other than courts) that could be used to enforce or assist with the enforcement of trial participant's rights. These included:

- Almost all of the countries have a *statutory (or administrative) body to regulate medical practitioners*. These bodies generally have statutory authority to develop ethical guidelines for the medical profession[44], and would therefore be in a position to develop, monitor and enforce ethical guidelines to govern the conduct of medical practitioners as researchers.

- Uganda has a *Human Rights Commission*[45], that could potentially become involved in the monitoring and enforcement of the rights of trial participants in HIV vaccine research.

However problems with enforcing the rights of trial participants include:

- In most cases statutory rights were limited, and did not deal with the various issues raised by complex trials such as HIV vaccine trials.

- No precedents exist on how to apply these rights within the context of research and particularly to HIV vaccine trials.

- Access to legal services is generally limited due to a lack of resources and limited state legal aid funds.

- The regulation of the conduct on non-medical members of a research team is not clear. Kenya and Ethiopia have regulations requiring the registration of all scientists participating in clinical trials. However despite the requirement that scientists must register with an appropriate authority, it was unclear whether any powers exist to discipline scientists who breach ethical codes.

[43] The Tanzania Country Report did not provide details regarding civil law.

[44] Evidence of such guidelines was found in Kenya and Tanzania. The Kenyan Medical Practitioner's Board has developed the *Code of Professional Conduct and Discipline* (5th Edition) to govern the conduct of medical practitioners; the Medical Association of Tanzania has developed the *Guiding Principles on Medical Ethics and Human Rights in Tanzania*. See Appendix B: Country Reports for more detail.

[45] Chapter 4, section 52 of the Constitution of the Republic of Uganda, 1995.

3.8 Conclusions

3.8.1 Health research, including HIV-related research such as HIV vaccine research, has been prioritised in a number of African countries such as Ethiopia, Kenya, Tanzania and Uganda. As a result, there have been a number of recent legislative and policy developments in these countries to build the capacity of the countries to conduct ethical research. In Ethiopia there has been explicit recognition of the need to develop guidelines specifically to deal with HIV vaccine research, and such guidelines have been published in Kenya.

3.8.2 In each of the five African countries under study, there are various legal and ethical structures that have the capacity to regulate HIV vaccine research, including:

- Bodies (e.g., Parliament) to create national laws to regulate research in general, or HIV vaccine research in particular;
- Bodies (e.g., drug authorities) to regulate, review, approve and monitor clinical trials on drugs;
- Bodies (e.g., ethical review committees) to regulate and conduct scientific and ethical review of research and development, including research on human participants;
- Bodies (e.g., professional councils) to regulate and monitor the medical profession; and
- Bodies (e.g., courts, professional councils) to enforce laws and professional codes of ethics.

However, in many cases the statutory bodies responsible for regulating clinical trials of drugs had not yet developed detailed regulations for the ethical review and approval of a clinical trial, including an HIV vaccine trial. In countries where more detailed ethical review structures and processes have been developed for research on human participants (e.g., Uganda, Ethiopia), these guidelines and structures are not legally binding, and are still in the process of development.

So, where African countries have structures and processes to conduct scientific and ethical review and approval of HIV vaccine research, there would be numerous limitations to this review:

- The ethical review process is not legally binding
- The ethical review process contains broad principles, and does not contain guidelines specific to HIV vaccine research[46]
- Many of the review structures (such as ethics review committees) are still in the process of being developed.

[46] Except Kenya.

3.8.3 Laws, regulations, policies, guidelines and codes of ethics in the countries under study combine to provide strong protection of the rights of trial participants taking part in HIV vaccine research, so that in all of the countries, trial participants would have the right:

- To take part in an HIV vaccine trial only with voluntary, informed consent
- To refuse to take part in an HIV vaccine trial
- To privacy, including medical confidentiality with regard to their participation in an HIV vaccine trial and their medical information relating to the trial
- To be treated with dignity and respect, and to be protected from cruel and inhuman treatment
- To equality and to be protected from unfair discrimination on the basis of participation in an HIV vaccine trial, or on the basis of real or perceived HIV status
- To special protection of the rights of women and children.

Additionally, in a number of the countries, trial participants would also have the right:

- To the highest attainable standard of physical and mental health at all times (during and after the HIV vaccine trial)
- To be protected from harm caused by the HIV vaccine trial; and
- To be compensated for any unlawful harm that comes to them as a result of the trial.

3.8.4 The countries studied have few, if any, laws, guidelines and policies that deal specifically with the rights of research participants. Most of the rights of trial participants are drawn from laws and policies conferring broad rights, such as the right to security of the person and the right to privacy. It is unclear whether such laws will be able to be applied directly to HIV vaccine research; and if they are, whether they will be able to deal with some of the complex issues such as adolescent participation in HIV vaccine trials.

3.8.5 Ongoing monitoring of research on human participants is provided for in some instances by law, in others in terms of ethical guidelines. However, in many cases, monitoring of research simply consists of setting down reporting requirements for researchers. This may be inadequate for monitoring the rights of trial participants in HIV vaccine research.

3.8.6 Likewise, enforcement mechanisms are provided for by the civil, criminal and constitutional courts. Additionally, most of the countries studied have a council to regulate the activities of medical practitioners. These councils generally have disciplinary powers over medical practitioners. This means that trial participants in HIV vaccine research would be in a position to bring complaints of abuses of their rights to the courts, or to the

professional councils. The regulation of non-medical personnel is not so clear and it is uncertain what remedies participants would have against such members of the research team in Botswana, Tanzania and Uganda. However, other more accessible forms of enforcement of rights (such as the Human Rights Commissions in Uganda, ombudspersons set up specifically to deal with the rights of trial participants, or community based organisations with the capacity to deal with HIV vaccine research-related complaints) are lacking in most countries.

3.8.7 In conclusion, it would seem that the ethical-legal framework in the 5 African countries studied, although not ideal, would be able to support HIV vaccine development and research. In principle, basic laws and ethical guidelines would protect the fundamental rights of all people, including trial participants. However, in the countries under study, where many trial participants come from a position of socio-economic disadvantage, an inadequate regulatory framework places a double burden on trial participants and researchers[47]:

- Many of the ethical review processes and structures are still in the process of development, and are in most cases not legally binding, which may lead to research taking place without certain accepted procedural safeguards;

- Many of the more complex ethical issues raised by HIV vaccine research are not specifically dealt with by the general laws and/or ethical guidelines, which may lead to participants' rights being abused;

- The ethical-legal frameworks do not adequately provide for the protection and promotion of the rights of child research participants;

- Monitoring and enforcement mechanisms are inadequate, and would in all likelihood be inaccessible to most trial participants and deprive them of legal remedies; and finally

- As a result, many persons may be unwilling to volunteer to participate in HIV vaccine research.

[47] Milford et al., 2003.

4 RECOMMENDATIONS: ADVOCACY & CAPACITY BUILDING PLAN

4.1 Advocacy Plan

It is recommended that the 5 African countries under study develop an Advocacy Plan, with the goal of advocating for a legal and ethical framework that protects and promotes the rights of trial participants in HIV vaccine research. Detailed objectives for such a plan are set out below:

4.1.1 Advocating for laws and ethical guidelines to provide for:

- Structures (e.g., research ethics committees) to review and approve research on human participants (including HIV vaccine research), overseen by an independent national statutory body;
- Legally binding processes to ensure ethical review, approval and ongoing monitoring of research, including HIV vaccine research;
- Legislation to establish research-specific rights for trial participants;
- National ethical norms and standards, including detailed provisions for the rights of trial participants, in terms of which ethical review takes place;
- Codes of ethics for medical and non-medical practitioners, including those involved in research;
- General guidelines on the ethics of health research; and
- Specific ethical guidelines for HIV vaccine trials.

Further country-specific actions are suggested in Table 4 below.

Table 4: Country specific recommendations.

COUNTRY	EXISTING LAWS AND REGULATIONS	RECOMMENDATIONS	RESPONSIBILITIES
Botswana	The Drugs and Related Substances Regulations	1. Develop guidelines to provide for structures & processes for ethical review of research on human subjects as well as national ethical norms & standards. 2. Enact guidelines as law 3. Amend Drugs and Related Substances where necessary, to concur with above. 4. Develop statutory body & code of ethics to guide medical practitioners 5. Develop ethical guidelines for HIV vaccine research 6. Develop legislation to protect trial participants rights 7. Train REC members	Ministry of Health National Drug Authority Any existing RECs National AIDS Co-ordinating Agency
Ethiopia	Proclamation 60/1999 National Health Research Ethics Guidelines and Procedures, 2003 National HIV/AIDS Policy	1. Enact National Health Research Ethics Guidelines and Procedures, 2003 as law. 2. Amend Proclamation 60/1999 where necessary, to concur with above. 3. Amend Drugs and Related Substances where necessary 4. Develop code of ethics to guide medical practitioners 5. Develop ethical guidelines for HIV vaccine research 6. Train REC members	ECST National, Regional and Institutional RECs Ministry of Health
Kenya	Public Health Act Science and Technology Act Food, Drugs and Chemical Substances Act Code of Professional Conduct & Discipline (5th Edition) HIV and AIDS Prevention and Control Bill, 2004	1. Develop guidelines to provide for structures & processes for ethical review of research on human subjects as well as national ethical norms & standards. 2. Enact guidelines as law 3. Amend Public Health Act, Science and Technology Act and Food, Drugs and Chemical Substances Act, where necessary, to concur with above. 4. Review Code of Professional Conduct & Discipline (5th Edition) to include ethics in research 5. Consider inclusion of rights of trial participants in HIV research, including HIV vaccine research in HIV and AIDS Prevention and Control Bill, 2004. 6. Train REC members	Central Board of Health National Council for Science and Technology Medical Science Advisory Research Committee Other Advisory Research Committees Medical Practitioners Board National AIDS Control Council

Tanzania	Foods, Drugs and Cosmetics Act Guiding Principles on Medical Ethics and Human Rights in Tanzania National HIV/AIDS Policy	1. Enact guidelines as law 2. Amend Foods, Drugs and Cosmetics Act and National HIV/AIDS Policy, where necessary, to concur with above. 3. Regularise the review of Guiding Principles on Medical Ethics and Human Rights to include research-related issues. 4. Develop ethical guidelines for HIV vaccine research. 5. Regularly train REC members.	Tanzania Food and Drugs Authority National Research and Ethics Committee Medical Council of Tanzania Tanzania Commission for AIDS
Uganda	National Drug Policy and Authority Act Guidelines for Conduct of Health Research on Human Subjects, 1997	1. Review Guidelines for Research on Human Subjects to ensure adequate provision for structures & processes for ethical review of research on human subjects as well as national ethical norms & standards. 2. Enact guidelines as law. 3. Amend National Drug Policy and Authority Act where necessary, to concur with above. 4. Develop code of ethics to guide medical practitioners, including research-related issues. 5. Develop ethical guidelines for HIV vaccine research. 6. Train REC members	National Drug Authority UNCST Existing RECs Uganda Medical and Dental Practitioners Council Ugandan AIDS Commission Uganda Law Reform Commission

4.1.2 To date most capacity building has focused on the ability of African RECs to undertake the ethical review of HIV vaccine research. Advocacy is needed for broader based capacity building and development of the range of bodies who are able to assist in regulating, monitoring and enforcing the *rights of trial participants* in HIV vaccine research and development including:

- Research Ethics Committees
- Community Advisory Boards
- Non-governmental and community based organisations
- Courts, commissions and tribunals.

4.2 Capacity Building Plan

Furthermore, it is recommended that the 5 African countries under study develop a capacity building and training plan to build the capacity of various bodies to regulate, monitor and enforce the rights of trial participants in HIV vaccine research. In particular, capacity building is recommended for:

4.2.1 Research Ethics Committees and Community Advisory Boards, on the ethical norms and standards for the conduct of HIV vaccine research.

4.2.2 Community Advisory Boards, non-governmental and community based organisations, on the rights of trial participants in HIV vaccine research, and skills to assist in monitoring abuses of rights.

4.2.3 Courts, commissions (e.g., Ugandan Human Rights Commission), tribunals (e.g., the proposed Kenyan Equity Tribunal) and professional bodies (e.g., medical practitioners' councils) on ethical norms and standards for HIV vaccine research, and the rights of trial participants in HIV vaccine research, and enforcement of rights.

4.3 Research Plan

4.3.1 The development of indicators of an effective ethical-legal structure to enable countries to continually review their framework against international best practice.

4.3.2 Research into the extent to which current ethical-legal frameworks are able to both facilitate child participation in research and protect their welfare.

4.3.3 Research into the most effective mechanisms for monitoring clinical trials.

4.3.4 Further research into the most effective mechanisms for enforcing the rights of trial participants. In particular, research into institutional protections such as a trial ombudsperson and into the most effective laws to protect trial participants such as whether the criminal or civil law would be the most appropriate enforcement mechanism.

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