UNDERSTANDING THE MULTIPLE ROLES FOR THE STATE IN HIV VACCINE RESEARCH IN KENYA.

ELIZABETH AKOTH ODUWO
FACULTY OF LAW AND BIOMEDICAL ETHICS UNIT

MCGILL UNIVERSITY, MONTREAL
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Abstract

Kenya has a rich and controversial history of HIV vaccine-related research and incidents between researchers, participants and authorities have highlighted pertinent and endemic ethical, legal, social and political issues. The role of the state during these events and in wider vaccine research is unexamined and misunderstood; yet, the state is a deeply involved and dominant party.

My thesis provides a coherent explanation of the role of the state in vaccine research and links recurrent ethical issues to the multiple and competing interests the state has in this activity. I develop multiple roles for the state as a *Facilitator, Guardian, Participant, Regulator, Researcher* and *Sponsor* based on a common understanding of the key parties in biomedical ethics. These roles explain the complex state participation and are developed and shaped by crucial influential factors in the environment surrounding HIV vaccine research.

Abstrait

Le Kenya a une histoire riche et controversée **à** l'**é**gard de la recherche relative au vaccin contre le VIH. En effet, plusieurs incident et conflits entre les chercheurs, les participants et les autorités mettent en évidence les difficultés éthiques, légales, sociales et politiques de la recherche d'un vaccin. Le rôle de l'Etat au cours de ces évènements et en ce qui a trait a la recherche de vaccin en général est non examine et mal compris, et pourtant, l'Etat est une partie profondément impliquée et dominante.

Ma thèse propose une explication cohérente du rôle de l'E tat dans la recherche d'un vaccin et relie les difficultés éthiques récurrentes aux multiplies intérêts concurrents que l'Etat détient a l'egard de cette activité. En se basant sur une compréhension commune des principales parties impliquées en éthique biomédicale, je développe de multiples rôles pour l'Etat en tant que facilitateur, gardien, participant, régulateur, chercheur et mémé commanditaire de l'activité. Ces rôles, expliquant la participant complexe de l'Etat sont façonnes par des facteurs cruciaux et influents provenant de l'environnement qui entoure la recherche d'un vaccin contre le VIH. En effet, l'implémentation de ces rôles créé un environnement propice aux conflits et aux difficultés éthiques.

INTRODUCTION

In this thesis, I analyse the role of the state in HIV vaccine research and provide a more sophisticated understanding of the ethical and legal challenges in HIV vaccine research in Kenya.

Background and Problem

HIV/AIDS is a major health issue in Kenya and a wide variety of prevention and treatment approaches have been put forward to address HIV/AIDS, including HIV vaccine development as a long-term preventative measure.

HIV vaccine research in Kenya began in 1985, with a study that investigated the immune response of commercial sex-workers who were resistant to HIV infection despite high exposure to the virus (the *Majengo study*).[1] This study was controversial and raised numerous ethical and legal concerns. The participants were very poor women, who had little formal education and lived under poor conditions in an informal urban settlement known as *Majengo*. Some of these women were reported to be undocumented economic migrants unable or unwilling to return home. They suffered high incidences of sexually transmitted diseases and had little access basic healthcare services.[2] As a cohort, they were identified and recruited into the study when they attended a government-supported clinic that treated sexually transmitted illness that offered free or heavily subsidized services and support.[3]

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[1] See especially Ruth M. Greenblatt et al., "Genital Ulceration as a Risk Factor for Human Immunodeficiency Virus Infection" (1988) 2 *AIDS* 47 at 47-50 [Greenblatt] (publications of scientific findings from Majengo study).

[2] See Judith Rowbotham. "Migration, Aids and International Relations," (2001) 2 Asian Journal of International Studies 173 at 189 (description of poor living conditions at *Majengo*, *Majengo* sex workers being renowned for their lifestyles, rejection of women by surrounding communities, reports of economic migrants from the East-African region working as sexworkers).

[3] See especially Ambrose D, Rachier. "Ethical and Legal Issues in Hiv Vaccine Research and Development in Kenya the Case of the Kenya Aids Vaccine Initiative (Kavi) and University of Oxford Collaborative Research in Nairobi" (Paper presented to the 15th International Conference on AIDS Bangkok Thailand, 2004), online: National Library of medicine, National Institute of Health). <http://gateway.nlm.nih.gov/MeetingAbstracts/ma?f=102280489.html> [Rachier] (identification and discussion of lego-ethical concern about participants in *Majengo*).

The study enrolled women who had frequent and multiple unprotected sexual encounters. The trial investigated the effect their risky lifestyle had on transmission of HIV virus and on the apparent delay in the onset of AIDS. These women were not informed that barrier methods such as condoms could prevent transmission of HIV during sex, and in any case, they would not have been able to afford or access these interventions without assistance.[4] Under these circumstances, it was questionable whether they gave valid informed consent, whether the study was designed to minimize risks to the participants, or indeed, if any authority had carried out a benefit versus risk assessment before enrolling these women.[5]

In 2000, the media reported that Kenyan researchers working on a candidate vaccine (developed from the *Majengo study*) in a joint venture with the Kenya AIDS Vaccine Initiative (KAVI), Oxford University and the Medical Research Council had boycotted the study because their international partners had applied for a patent in the U.K. without informing or including them in the process.[6] MRC researchers counterpointed that the Kenyan team had no ownership rights as MRC researchers had come up with the concept of the gene used in the candidate vaccine using public information and with limited contribution from the Kenyan team. However, they were willing to share any revenues with the Kenyans, if a vaccine was developed from this information.[7] This incident highlighted the difficult relationship between local and international parties involved in HIV

[4] See especially Pamela Andanda. "Vulnerability: Sex Workers in Nairobi's Majengo Slum." (2009) 18 *Cambridge Quarterly of Healthcare Ethics* 138-46 (review of legal, ethical and social concerns about the *Majengo* study focus on vulnerability of the women and informed consent) [Andanda].
[5] See Rachier *supra* note 3.
[6] See BBC Health Team, "Row over AIDS Vaccine" *BBC* (19 October 2000), online: BBC <http://news.bbc.co.uk/2/hi/health/980187.stm>, (media report and description of an intellectual property dispute).
[7] *Ibid.*

vaccine research. Although this dispute was resolved[8] with government involvement, the terms of the agreement were never publicised.

A few years later, a new scandal on HIV vaccine associated research captured public attention. A local researcher, Dr. Moses Otsyula, accused an Oxford University research team of illegally exporting blood samples taken from children living in Nyumbani Children's Home in Nairobi with the collusion of the home director, Father D'Agostino and of running an unauthorised study. *Nyumbani's* Children's Home cares for children who are either orphaned by HIV/AIDS or abandoned by their parents and relatives due to their HIV status and is funded mainly by international donors. The children investigated had tested HIV positive early in their lives but had resisted succumbing to AIDS for many years without treatment and in some cases tested HIV negative.

Dr. Otsyula sued the research team, for using his data developed from years of samples taken from these children without his permission.[9] Although the authorities announced that they would look into the *Nyumbani* incident and quickly organised a tour of inspection of the home,[10] the results of their investigation were never released and it is not known whether government authorities took any further steps. The *Nyumbani* incident raised concerns about the exploitation of orphans or abandoned children who were also in some cases HIV positive, and about unauthorised research and under-regulated research.[11] To date, the civil suit regarding *Nyumbani* is unresolved.[12]

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[8]See Cathy Jenkins, "Truce over AIDS Vaccine Row" News Report BBC (20 October 2000), online: BBC http://news.bbc.co.uk/2/hi/africa/982323.stm > (resolution of dispute over patent rights).

[9] See Samuel Siringi. "British Scientists Face Law Suit" (2004) 4 The Lancet Infectious diseases 389 (Report of events surrounding *Nyumbani incident)*[Siringi] and See also *Children Of God Relief Institute v. Nation Media Group Ltd* [2004] H.C.C. 318[2004][*Nyumbani*] (civil dispute between MRC and Dr. Otsyula).

[10] See Sunday Nation "The Shame of Children Used in Experiments in AIDS" *Sunday Nation [of Kenya]* (23 May 2004) (Nation Investigative report) (media reports of government action on Nyumbani incident).

[11] *Ibid* Nation investigative report (ethical, and legal concerns raised).

[12] See Jared, Ogutu. "Dispute over Blood Samples to go to Full trial" *The Standard* (5 march 2009) (In March 2009, a Nairobi high court fixed a date for the hearing of Dr. Otsyula suit).

HIV vaccine research has attracted a lot of negative publicity in Kenya. The events referred to above and discussed further below are disturbing because they highlight a prevalence of social, ethical and legal issues in vaccine research and point to underlying inherent problem.

The role of the state in HIV Vaccine research, particularly during these events, is confused. The general summary of duties one would expect from the state includes the regulation of vaccine research, the protection of the parties involved including the participants and researchers in clinical trials. According to the government, the problem in HIV vaccine research has been a regulatory vacuum, which the government addressed by preparing and updating regulations for HIV vaccine research in 2005.[13]

The question is how the state defines and interprets its' role, and whether there are responsibilities and duties explicit and implicit for the state in HIV vaccine research. In the incidents briefly examined above, the involvement of the Kenyan Government was significant and diverse. All the domestic researchers involved in the clinical trials were public researchers and either worked with, or had associations with public research institutions such as the University of Nairobi (UoN) and the Institute of Primate Research.[14] The MRC study had been authorised and cleared by the requisite public authorities, such as the National Council of Science and Technology (the Council), the Ministry of Health and various ethical review boards at public institutions.[15] Moreover, the state hosts several clinical trials, including the above-mentioned KAVI trial, and other trials

[13] Ministry of Health, *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines 2005* at vi. [*Vaccine Guidelines*]. (Other regulations prepared in this time period include the HIV/AIDS Act, 2006 and the NCST guidelines 2004 and are discussed below in chapter one, and three, below).

[14] In the *Majengo study*, researchers were from the teaching hospital at University of Nairobi and were working in a Ministry of Health clinic for sexually transmitted infections. In the KAVI trial, the researchers were from the teaching hospital at a public university, University of Nairobi See *Supra note 4*. In Nyumbani Dr. Moses Otysula worked as a researcher at the Institute of Primate research, a government research institute. See generally Siringi *supra* note 9.

[15] Although in the case of *Nyumbani* the issue of whether there was research authorisation and clearance was in dispute-See Nation investigative report s*upra* note 10.

located at the UoN,[16]Kenya Medical Research Institute (KEMRI) and at the Moi University Teaching Hospital.[17]

This brief description of government affairs in HIV vaccine research in Kenya shows that state involvement in HIV vaccine research is complicated and may be linked to the prevalent conflicts and disputes. In addition, vaccine research in Kenya is carried out in an environment rich with issues, and there are noted diverse "political, economic, socio-cultural and policy issues"[18] surrounding vaccine research.

The most apparent factor affecting vaccine research is the lack of indigenous sources of funding to carry out vaccine research[19] as highlighted by the *Majengo and Nyumbani* incidents. These issues require an in-depth examination and analysis because they may shape the legal and regulatory framework for vaccine research and dictate the extent and nature of state participation in vaccine research.

Although a large amount of policy, law, regulation and programs for HIV vaccine research have been developed over the past decade, their singular and sum effect on HIV vaccine research has not been evaluated, nor have the linkages between the different forms of state participation within this environment been investigated.[20] Few studies look at HIV vaccine research in an overarching way that cuts across dominant socio-economic, ethical-legal, political and global issues in the environment surrounding vaccine research, nor are there any

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[16] See University of Nairobi "Ongoing Research Activities at the University of Nairobi" (22 February 2009), online: University of Nairobi <http://www.uonbi.ac.ke/activities/?thispage=research> [UoN Research Activities].
[17] This study is carried out in partnership with the Walter Reed Army Institute. See chart I & chapter 3 below.
[18] *Vaccine Guidelines supra* note 13 at 13 (background on the non scientific difficulties and issues in vaccine research).
[19] See generally *Vaccine Guidelines supra* note 13, c. 1 & 2 (background on the non-scientific difficulties and issues in vaccine research) and participation chart 3 in the Appendix below).
[20] Law, policy, regulation and programs for vaccine research are described below in chapter 3 & chart. See also *Vaccine Guidelines supra* note 13.

analyses of the complicated involvement of the state in vaccine research, despite pressing evidence of state involvement.

The government has stated that the main goal for Kenya is to conduct "[r]esearch and development for an HIV vaccine in an effective, safe, affordable, accessible and acceptable manner."[21] Given that little is understood about how the state participates in vaccine research: it is important to analyse the government's performance against this goal.

In my study, I describe state participation in HIV vaccine research to account for the issues surrounding HIV/AIDS in Kenya. My thesis provides a clear insight into the diversity of state participation by neatly dividing and packaging a general state participation into specific thematic roles, which are easy to understand, and where the outcomes of the governance model adopted by the state for involvement in HIV vaccine research can be evaluated. I put forward an understanding of multiple roles for the state in vaccine research by defining and developing six different roles adopted by the state in this context, thus explaining the multifaceted and sometimes contradictory government model of participation in HIV vaccine research.

Thesis

The state participates in HIV vaccine research through the thematic and multiple roles of *Facilitator, Sponsor, Guardian, Regulator, Participant* and *Researcher*. These roles are based on a conventional understanding of biomedical research with participants, are intuitive of government practices, and are characteristic of the six main interests the state has in HIV vaccine research. The development and implementation of these roles are influenced by political, social, cultural, religious and economic factors in the environment surrounding vaccine research.

[21] *Vaccine Guidelines supra* note 13 at 1.

By examining: (1) the practices, law, policy and institutions associated with each role, and (2) their formative influences and interdependencies, I unpack, and describe an otherwise complicated state participation and outline the strengths and shortcomings of each role.

Research question

My research question has two parts:
1. What are the roles for the state in Kenya in vaccine research and how are these roles developed?
2. What are the factors that affect the implementation and fulfilment of the multiple roles for the state in HIV vaccine research?

Justification

My interest in HIV vaccine research comes from my shared experiences and close contact with friends and relatives living with HIV/AIDS in Kenya and with the struggle to access treatment and care, deal with HIV/AIDS and remain hopeful for a cure. Over the years, HIV vaccine research in Kenya and around the world has grown into a globally significant industry: candidate vaccines have been developed and important scientific discoveries made in Kenya. Yet, vaccine research has been controversial. A discussion of HIV vaccine research is crucial for Kenya and for Sub-Saharan Africa. Few other health issues have received as much government attention and HIV/AIDS vaccine research is one of the largest research programs for human health issues in Kenya.[22] Only five other countries in Africa have HIV vaccine research programs. Many African countries including Kenya use scarce resources and rely on research to address health problems in Kenya and in Africa such as maternal health, infant mortality and malaria.

[22] See generally UoN Research Initiatives *supra* note 13. The University of Nairobi vaccine research program has the largest recorded research grant ever in the University and the implications are wide considering this is the largest university in East and central Africa.

The Pfizer trial in Nigeria where children enrolled in a clinical trial testing a new therapy during a meningitis outbreak died, and the HIV012 NET study in Uganda where researchers used placebos in a study to find suitable therapy to prevent transmission of HIV from mother to child during childbirth,[23] show that sub-Saharan Africa is facing serious challenges in biomedical research that may be similar to the problems facing Kenya. Both studies were done at public institutions and the role of the state in those countries has not been clarified. My research questions and thesis have wider implications in sub-Saharan Africa and my approach can be used to successfully synthesize comparable issues in biomedical research with participants in countries in sub Saharan Africa.

Theoretical framework

From my literature survey below, it emerges that part of the problem of understanding the role of the state in HIV vaccine research is the lack of a complete and readily available theoretical framework, with which to synthesis and look into vaccine research in Kenya. This maybe due to the relative novelty of HIV vaccine research, the relative youth of the field of biomedical ethics, and scarcity of investigations carried out into the role of government in HIV vaccine research or in general biomedical research in Kenya, East Africa or even sub-Saharan Africa. Another important aspect revealed in my literature survey is an over abundance of international perspectives and a scarcity of Kenyan theories, or indigenous application of other theoretical tools on issues about vaccine research.

The challenge for my thesis is to create a robust yet flexible theoretical framework and synthesize state participation in vaccine research in an overarching manner without losing the depth of issues in the environment or the diversity of state participation. My theoretical framework is developed using theoretical tools from two fields: (1) established principles in research and medical ethics and a common understanding of the key parties in biomedical

[23] Discussed in detail in chapter 1& 2 below.

research with participants, and (2) instrument-choice perspectives and tools theory from governance theories.

I rely on the principle approach from research ethics to identify and discuss issues in HIV Biomedical Vaccine research. For instance, in the *Nyumbani* and *Majengo* incidents the principle of justice and beneficence[24] outlines the main issues arising from enrolment and treatment of HIV orphans and commercial sex workers as participants.

A key part of my theoretical framework for inquiry is built on a common understanding of the categories of parties involved in biomedical research to be the *Sponsor, Facilitator, Guardian, Regulator, Participant* (Research subject), *Physician* and *Researcher,* which is rooted in the history and development of research with participants, and is common and intuitive in the field of medical ethics and research ethics.

The common understanding of the main parties involved in biomedical research with participants was incrementally developed throughout history. As early as the 18th century, scientists had begun experimenting using participants, and these studies usually involved only two categories of parties; the *Researcher* who was often referred to as the scientist or physician, and the *Participant* sometimes also a patient, and referred to as the research subject or human subject.[25] This understanding was prevalent for the main part of two centuries and only begun to change in the early 20th century when scientists such as Claude Bernard questioned the moral basis of research with participants, and looked into rules for research thus developing duties and responsibilities for parties involved in

[24] See Beauchamp, L & Childress, JF, *Principles of Biomedical Ethics* (Oxford: Oxford University Press, 2001) c.1. [Beauchamp and Childress].

[25] For example, in experiments to develop a smallpox vaccine, the two distinct categories involved were the scientists, and several persons acting as participants who were inoculated with the cowpox virus to stimulate an immune response to smallpox. See generally N.J. Willis, "Edward Jenner and the Eradication of Smallpox" (1997) 42 Scott. Med. J. 118 at 118-121 (early acknowledgement of the researcher and the participant in smallpox vaccine studies).

research and in the process identified key parties involved in research.[26] Levine contributes to this understanding by defining the parties in biomedical research with participants as the investigator, who may or may not be a physician, and the *Participant*, sometimes called volunteer or subject and in some cases, patient-subject.[27]

The Nuremberg war trials, held after the Second World War to try Nazi scientists for carrying out cruel and inhuman experiments on Jewish prisoners and other prisoners interred at camps, are key to the development of this present day understanding. Nuremberg trials set out the duties and rights of parties in research with participants and established a set of principles for research with humans in the *Nuremberg Code*.[28] In the process, the Nuremberg war trials acknowledged and codified the presence of the "*physician-scientist,"*[29] the *"human subject,"*[30] and the *"experimental subject"*[31] as they laid out the rights and responsibilities for the aforementioned parties.[32]

During the latter half of the 20th century, clinical research became more sophisticated as was signified by an increase in the learning institutions, army research centres and hospitals, and research centres that carried out research with participants. The amount spent on research increased leading to the development and increased presence of sponsors who would provide the funds for research.[33] Beecher, a key author in research ethics and bioethics, is credited with

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[26] Claude Bernard, *An Introduction to the Study of Experimental Medicine*, (Dover Publications, 1957) (acknowledgment and reference to the *Researcher*, *Participant* and *Physician*).
[27] Robert Levine, *Ethics and Regulations of Clinical Research*, 2d ed. (New Haven and London: Yale University Press, 1988) at 9 (outline of the investigator, investigator-physician, research subject as actors in biomedical research).
[28] See *The Nuremberg Code, Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2*, (1949), Washington, D.C.: U.S. Government Printing Office, at 181-2 [*Nuremberg code*].
[29] *Nuremberg Code ibid* para. 5, 8 &10 (Reference to experimental physician, "scientifically qualified persons" and scientists)
[30] *Nuremberg Code supra* note 28 para. 1 & 9 (Reference to human subject in research).
[31] *Nuremberg Code supra* note 28 para. 1 & 10 (Reference to experimental subject).
[32] See generally *Nuremberg Code supra* note 27.
[33] Henry K. Beecher, "Ethics and Clinical Research: From the Anaesthesia Laboratory of the Harvard Medical School at the Massachusetts General Hospital" (2007) 45 International Anesthesiology at 65 (increase in research funding and development of the *Sponsor* in research).

highlighting the poor application of regulations in research, unethical practices in clinical experiments and the tensions between the parties involved in research. He was on the forefront of discussions about the ambiguity surrounding the responsibilities of physician and the researcher.[34] Later literature, guidelines and regulations for research with participants have incrementally built on the original outline of the parties in research with participants by defining key parties further, developing new key parties and drawing out distinctions among parties.[35]

Governance theories explain the complex state participation in HIV vaccine research and the development of multiple roles. Some of the early work with governance theories was by Trebilcock et al. who investigated the pressure on governments to regulate economic activities and the interaction between government policy and regulations.[36] Their study put forward the concept that governments use different tools to take action on problems, policy and regulations being some of these tools. They pioneered the 'Tools of government theory,'[37] which argued that; (1) regulation is one of the many tools that governments use to take action, (2) the choice of governing tools is motivated by governments' self interest, and (3) the choice of tools deployed by governments will depend on their decision-making process, which is in turn, politically influenced.[38]

Trebilcock's concept describes the development of multiple roles of the state in vaccine research and accounts for the interests that shape each of the roles. Although Trebilcock focused regulation as the main tool, and on the political

[34] *Ibid* at 69.
[35] See generally Jay Katz, "The Education of the Physician-Investigator" (1969) Daedalus 489 at 489-501 (early discussion of ambiguities in the physician-investigator role that led to the eventual separation in understanding of these two parties). See also World Medical Association, World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects, [2000] para. 2 & 6 [*Helsinki*] (Development of *Researcher* and *Sponsor* role).
[36] See generally Micheal J. Trebilcock, Canada Economic Council, *The Choice of Governing Instrument* (Toronto:University of Toronto, Faculty of Law, Law and Economics Programme, 1980) [Treblicock] and Pearl Eliadis & Micheal Howlett, eds., *Designing Government; From Instruments to Governance* (London: McGill Queen's University Press, 2005) at c.1 [Designing governments].
[37] See Trebilcock *ibid* at c.1 (early development of tools of government theory).
[38] Designing Governments *supra note* 36 at 3-4.

influences on government choices, I postulate that there may be a variety of influences behind state participation in HIV vaccine research, such as the philanthropic interests of international sponsors, and examine the environment for these interests.

My investigation draws from Salamon's definition of a government tool: "[A] tool or instrument of public action is an identifiable method through which collective action is structured to address a public problem."[39] This definition has been used successfully to investigate the "nature of government action,"[40] especially with regard to economic policy development and implementation.

My study investigates all the identifiable methods through which the state participates in HIV vaccine research including policy, regulation, law and institutions. This aspect is crucial to understanding the multiple roles the state has in HIV vaccine research as it makes sense of state participation; it allows my synthesis to collate the choices of tools, to the implementation of each role, and to the thematic interests vested in that role.

Salamon acknowledges that "[t]ools choices are fundamentally political choices"[41] and factors in external influences on government into his analysis of decision-making and implementation choices. Similarly, strong environmental influences bear on state participation in vaccine research in Kenya. I analyse the socio economic, political, global, cultural and scientific factors that have shaped state participation in vaccine research, carved out, and developed the above roles.

Salamon described a "[n**]**ew governance paradigm"[42] where the focus of analysis is the underlying tools and their interdependencies.[43] In addition, instrument-

[39] See Lester, Salamon. ed., *The Tools of Government: A Guide to the New Governance* (New York: Oxford University Press, 2002) [Tools of Government].
[40] Designing Government *supra* note 36 c. 1.
[41] Tools of Government *supra* note 39 at 11.
[42] Tools of Government *supra* note 39 at 601.
[43] Tools of Government *supra* note 39 at 10 -11.

choice-perspectives have approached "[g]overnment and policy processes not as monolithic entity but as panoply of actors, instruments and motivations."[44] These ideas are useful to describe state participation in vaccine research in Kenya, which is hardly direct or monolithic but is modelled into a complex web of law, regulation, and policy, processes.

This framework achieves two aims: it enables the description of the problem and provides a theoretical tool for my synthesis.

Chapter Summary

Chapter one discusses the impact of HIV/AIDS in Kenya and introduces HIV vaccine research as one of the multiple approaches taken to tackle HIV/AIDS. I list and outline vaccine trials conducted in Kenya highlighting the dominant and complex state involvement. In the latter part of chapter one, I review the literature on biomedical research in sub-Saharan Africa, HIV and vaccine research, biomedical ethics and research ethics principles, and on governance in order to situate my study. Chapter one develops a theoretical framework to explain my understanding of the multiple roles for the state in HIV vaccine research.

Chapter two examines the environment surrounding HIV vaccine research and identifies factors and issues such as resource disparity, the north-south separation, globalisation, religion and culture, that have shaped HIV vaccine research and generate, support and explain the multiple roles for the state in vaccine research.

Chapter three synthesizes the development and fulfilment of each of these roles. I outline the goals and interests of each role and analyse the law, practices, institutions employed by the state to fulfil and implement each role. Chapter three also highlights the shortcomings and limitations of the roles and suggests areas for improvement.

[44] Designing Government *supra* note 36 at 27.

In my conclusion, I summarize the challenges of this understanding of multiple roles for the state in HIV vaccine research. In particular, I outline the focus in literature and within the Kenyan vaccine framework on the role of Guardian, the confusion and amalgamation of the role of guardian and regulator, the emergence of a strongly implemented Facilitator and Sponsor and the lack of acknowledgement of the role of Researcher.

Chapter One

Finding a Theoretical Framework to Investigate State Participation in HIV Vaccine Research in Kenya.

1. HIV/AIDS

The Human Immuno deficiency Virus (HIV) is a retrovirus transmitted through contaminated blood products, unprotected sexual encounters and from mother to child. Once the virus is in the body, it replicates and progressively destroys the immune system until the patient develops Acquired Immuno Deficiency Syndrome (AIDS).[45] At this point, the human body has no defence against illness, and the patient succumbs to any number of opportunistic infections. There is no cure for HIV/AIDS, but there are treatments known as Antiretroviral Therapy (ART) that will slow down the replication of the HIV virus and may delay the progression of HIV to AIDS for more than 20 years.

Sub-Saharan Africa is particularly hard hit by the HIV/AIDS pandemic. Over 60 million people in the world are living with the HIV, and about 60 per cent of people living with HIV/AIDS (PLWHA) are in sub-Saharan Africa,[46] a region where there is little or no access to treatment. In Kenya, government surveys reveal, "[7.4] (percent) of Kenyans aged 15-64 are infected with HIV."[47] The health system is overburdened by HIV/AIDS and related illnesses and 50-70% of all hospital admissions are HIV-related.[48] Infection rates are highest in the age

[45] See Marc Girard et al., "A review of Vaccine Research and Development: The Human Immunodeficiency Virus" (2006) 24 Vaccine at 4063 (description and definition of HIV virus and the AIDS disease) [Girard].
[46] National AIDS and STI Control Programme, Ministry of Health, Kenya. July 2008. *Kenya AIDS Indicator Survey 2007: Preliminary Report.* Nairobi, Kenya. online: Republic of Kenya, National AIDS Control Council <http://www.nacc.or.ke/2007/default2.php?active_page_id=307&aid=6&newsid=280> [KAIS 2007].
[47] KAIS 2007 *supra* note 46 at 11.
[48] *Vaccine Guidelines* supra note 13 at vi.

group of 15-49 year, thus HIV/AIDS pandemic severely curtails the productivity of the Kenyan workforce.[49]

The impact of HIV/AIDS on Kenya is complex. Over 250,000 children are orphaned by HIV/AIDS, and in some villages, children as young as 13 years of age are acting as the head of household after their parents and the adult relatives have either died from or are living with HIV/AIDS.[50] An unfortunate 250,000 children are infected with HIV and recent reports indicate they are receiving inadequate care and have very limited access to treatment.[51] A demographic health survey, the Kenya AIDS indicator Survey (*KAIS*) conducted in 2007, shows that there are 1.4 million people living with HIV/AIDS (PLWHA) in Kenya.[52] KAIS 2007 developed demographic data and estimates about 390,000 PLWHA need antiretroviral therapy, and only 35 % of PLWHA who need treatment have access to treatment.[53] The effect of HIV/AIDS, the urgency surrounding approaches to tackle HIV/AIDS, and the resources being used in vaccine research and in other preventative approaches compel my study.

1.2 Origin of the General Role for the State in HIV/AIDS Vaccine Research.

The general role for the state to provide healthcare services is drawn from the Kenyan *Constitution*.

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[49] KAIS 2007 *supra* note 46 at 13 (peak of prevalence for both men and women is in the age group 30-34).

[50] Otieno et. al examine in detail the social phenomena of "AIDS orphans" whereby, culture, economics and HIV/AIDS has led to new social practices with "aids orphans" and a different, harsher social life for this category of orphans; Erick Otieno et al., "Changing Patterns of Orphan Care due to the HIV Epidemic in Western Kenya " (2003) 57 Social Science & Medicine 301 at 301-311.

[51] Kenya Human Rights Watch. "A Question of Life or Death Treatment Access for Children Living with Hiv in Kenya " Investigative Report (2008) New York: Human Rights Watch [Human Rights Watch Report].

[52] *KAIS 2007 supra* note 46 at 16.

[53] *KAIS 2007 supra* note 46 at 23-24, 189,000 PLWHA have a CD4 count of less than 200 and 71,000 PLWHA have a CD4 count of between 200 and 250. Government treatment policy recommend all PLWHA with a CD4 count of less than 250 should receive anti retrovirals therapy and PLWHA with a CD4 count of between 250 and 350 may need ART bases on their clinical status. Based on government treatment guidelines, which are comparable to World Health Organisation treatment guidelines, about 250,000 should be receiving ART.

Every individual is entitled to:

> […] Life, liberty, and security of the person...and the protection of the law.[54]

The general right to healthcare, including prevention and treatment services, is implied in the above rights: providing healthcare is a means through which the government can guarantee the fundamental right to life and liberty of each individual. As a signatory to the *Convention on Economic, Social and Cultural Rights*, Kenya recognizes the right of individuals to "[t]he highest attainable standard of physical and mental health,"[55] which requires "the prevention, treatment and control of epidemic, endemic, occupational and other diseases."[56] HIV/AIDS is an epidemic and that was declared a national emergency,[57] the state has an obligation to address HIV/AIDS.

The *HIV and AIDS Prevention and Control Act [HIV/AIDS Act*] reinforces the duty to act against HIV/AIDS by providing that the state should "[p]ositively address and seek to eradicate conditions that aggravate the spread of HIV infection."[58] Although there isn't an explicit legal duty for the state to conduct or support HIV vaccine research, under the *Science and Technology Act*, [*S & T Act*], Kenya has a duty to use research to aid national development in the area of health.[59] The Science and Technology Act incorporates research into Kenyan healthcare programs and establishes the Kenya Medical Research Institute (KEMRI) and the Kenya Trypanosomiasis Research Institute (KETRI) to carry out research into human health.[60]

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[54] *Constitution of Kenya Act*, s. 70(a), 71 &72 [*The Constitution*].
[55] Article 12 *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, 993 U.N.T.S. (ratified by Kenya on 1st may 1972).
[56] *Ibid,* article 12(c).
[57] See *Vaccine Guidelines supra* note 13, executive summary.
[58] *HIV and AIDS Prevention and Control Act*, No 14 of 2006, s.3, part (d). [*HIV/AIDS Act*]
[59] *Science and Technology Act, cap 250, s. 4* [*S & T Act*] (Government to use research to improve social and environmental conditions).
[60] *S & T Act, fourth & fifth schedule* (legal provisions for government institutes to carry out research into human health).

The legal obligation for governments to take preventive measures was established in South Africa by the case the *Minister of Health and Others v. Treatment Action Campaign and Others*. A local AIDS activist group successfully sued the South African government to compel the provision of Nevirapine to HIV positive expectant women within the national antenatal care program.[61] The court disregarded the South African government's argument that Nevirapine was too expensive to provide within the national antenatal care program as a credible reason for refusing to provide a preventive treatment for HIV-positive expectant women that would reduce the incidence of HIV in their children. This judgement is morally persuasive to Kenya and provides compelling grounds for the argument that governments hard hit by HIV/AIDS have a duty to initiate and pursue preventative methods even when they have restricted resources.

For sub-Saharan Africa, there is a persuasive argument for vaccine development as a viable strategy, which may provide a fail-proof method to prevent new infections and eradicate HIV/AIDS.[62] A vaccine overcomes many of the structural problems in treating and preventing HIV/AIDS in countries such as Kenya. Vaccines are easy to use in low resource settings in comparison to other prevention methods. They are administered once to each person and are relatively compatible with many cultures and traditions in Kenya.[63] A recent study applied empirical models to estimate the impact of an HIV vaccine in Kenya and found that even a partially successful vaccine if integrated into Kenya's HIV approaches could significantly impact the HIV/AIDS pandemic. A vaccine with 30% efficacy given to 30% of the population would prevent 1.4 million infections, 409, 000

[61] This case is discussed in detail in chapter 2 below. See generally Abdool Karim, "HIV treatment in South Africa: Overcoming Impediments to Get Started " (2004) 363 Lancet 1394 (south African government obliged to take initiative in HIV treatment issues). See generally *Minister of Health and Others v. Treatment Action Campaign and Others* (No 2) (CCT8/02) [2002] ZACC 15; 2002 (5) SA 721; 2002 (10) BCLR 1033 (5 July 2002) [2002].

[62] *Vaccine Guidelines supra* note 13 at x, p 2, See also Jon Cohen, "The first shot in a Highly Targeted Strategy" (2004) 306 Science 1276 at 1276-7. See also Richard Klausner et. al, "Medicine: Enhanced: The Need for a Global Hiv Vaccine Enterprise" (2003) 300 Science at 2036

[63] An HIV vaccine circumvents most of the culturally based opposition faced by other prevention and treatment methods such as male circumcision, counselling and testing and condoms which have faced cultural oppositions or may introduce new traditions to some populations.

deaths and reduce new infection by 25 percent. [64] The Kenya government has outlined a research imperative for HIV/AIDS, made HIV vaccine development a vital part of the multisectoral government strategy against HIV/AIDS, and acknowledged the central role of the government in HIV vaccine research.[65]

In summary, the Kenyan state has a role in HIV vaccine trials because: (1) a preventative vaccine may be the best chance to stop the spread on HIV in Kenya, (2) there is a moral duty to act against HIV/AIDS, (3) the state has acknowledged this moral duty and created a legal duty to act for itself, (4) the state has a history in vaccine research and is already deeply involved, and (5) the state is able and best-placed to marshal the resources needed for vaccine research, as there are limited domestic private resources to carry out vaccine trials.

1.3 HIV Vaccine Research.

If developed, a preventive HIV vaccine will teach the human immune system to resist infection by the HIV virus: vaccinated individuals who are exposed to HIV would not acquire the HIV virus.[66] The first candidate vaccine trial was conducted in the USA around 1986 and by 2006, over 35 candidate vaccines have been tested, and two Phase III trials involving 7500 volunteers are complete.[67] In various research programs executed around the world, multiple vaccine concepts and vaccination strategies have been tested; "including DNA vaccines, subunit vaccines, live vectored recombinant vaccines and various prime-boost vaccine combinations."[68] In late 2009, researchers testing a candidate vaccine in Thailand announced their phase III study was a success. They had developed a viable

[64] International AIDS Vaccine Initiative, Policy Brief, "Kenya: Estimating the Potential Impact of an AIDS Vaccine" (December 2009), online: IAVI <http://www.iavi.org/Pages/home.aspx>.
[65] *Vaccine Guidelines supra* note 13 at vi.
[66] National Institute of Allergy and Infectious Diseases "Challenges in designing an HIV/AIDS Vaccines" (2009) online: National Institute of Allergy and Infectious Diseases <http://www3.niaid.nih.gov/topics/HIVAIDS/Understanding/Vaccines/>.
[67] Phase III trials test the efficacy of the candidate vaccine. See Girard *supra* note 45.
[68] See Girard *supra* note 48.

candidate vaccine that had a 31% percent efficacy over a placebo.[69] However, questions are being asked about the methods and analysis of the trial data. In spite of the high hopes and significant efforts, vaccine research faces serious scientific difficulties.[70]

Girard et al. have noted this impasse, and in their review of the global search for an HIV vaccine, they discuss the efforts by scientists to regroup and develop a joint plan to move forward.[71] The lack of scientific progress in vaccine research is an opportunity to review other aspects of vaccine research such as ethical, legal, political, social challenges of vaccine research.

Vaccine research in Kenya began with the *Majengo study,* which led to a candidate vaccine that was tested in trials conducted by the Kenya AIDS initiative and the MRC, UK in 2001. Since then, several trials have been conducted. IAVI Trial 004, IAVI Trial 008 and IAVI Trial 010, are trials where a candidate vaccine based on a recombinant viral vector was tested in studies sponsored mainly by the IAVI and involving Kenya AIDS Vaccine Initiative (KAVI) and hosted at the University of Nairobi (UoN). The US Army Military Agency, the Walter Reed Army Medical Research Centre, is conducting a phase I/II trial in partnership with the Kenya Medical Research Institute (KEMRI) and evaluating potential cohorts for Phase III clinical studies. Below, Chart 1 lists HIV Vaccine trials in Kenya.

[69] See generally Rerks-Ngarm et. al. "Vaccination with Alvac and Aidsvax to Prevent Hiv-1 Infection in Thailand" (2009) 361 *N Engl J Med*. at 2209.
[70] See generally Girard *supra* note 45. See also *Vaccine Guidelines supra* note 13 at 5-7. Girard lists and discuss the main scientific difficulties in HIV vaccine research including the lack of a suitable animal models to develop the vaccine, little knowledge about how to stimulate the immune response, unidentified correlates of immunity, a diversity of strains of HIV and mutation of the HIV Virus.
[71] See Girard *supra* note 45. See also Richard Klausner et al, "Medicine: Enhanced: The Need for a Global Hiv Vaccine Enterprise" (2003) 300 Science at 2036 (the need for novel approaches in HIV vaccine research).

Chart 1
List of Vaccine Trials conducted in Kenya

Sponsor	Name and type of vaccine	Initiation Date	Investigator /Research site	Status
International AIDS Vaccine Initiative (IAVI)	IAVI Trial 008 Recombinant viral vector approach[72]	January 2003 Phase I study	Sponsored jointly with KAVI	Complete
	IAVI Trial 004[73]	June 2002 Phase I study	Department of Medical Microbiology, University of Nairobi, 18 volunteers,	Complete
	IAVI Trial 010[74]	April 2003 Phase IIa Trial	Department of Medical Microbiology, University of Nairobi & St Thomas' Hospital in London, 111 volunteers.[75]	Complete
U.S. Army Medical Research Unit–Kenya (USAMRU-K)	RV 172 Phase I/II[76] First HIV vaccine study in Kenya outside of Nairobi.	April 2006	Kenyan Medical Research Institute (KEMRI) Walter Reed project & U.S. Army Medical Research Unit–Kenya (USAMRU-K) - Walter Reed project at Eldoret.	Ongoing

Vaccine research in Kenya is conducted in partnership with public institutions. This list may not be exhaustive of vaccine research in Kenya: the lists only those research programs were available in public records maintained by international parties such as IAVI and the US Army Medical research Unit and involved participants or a candidate vaccine for trial. This information is limited in scope to reported HIV vaccine research.[77]

Nevertheless, Kenyan HIV vaccine research is significant on a global scale, about 150-200 clinical trials have been initiated globally, and only 23 trials are ongoing

[72] International AIDS Vaccine Initiative, "*Iavi Database of Aids Vaccines in Human Trials*", online: IAVI Database of Aids Vaccines in Human Trials <http://www.iavireport.org/trials-db/Pages/default.aspx> accessed December 21, 2008 [IAVI Database].
[73] IAVI Database ibid..
[74] IAVI Database *supra* note 72.
[75] IAVI Database *supra* note 72.
[76] United States Military HIV Research Program, "*HIV Vaccine study"* online: US Army Medical Research Unit–Kenya: Walter Reed Project <http://www.usamrukenya.org/hivvaccine.htm>.
[77] Although there is no register of vaccine research in Kenya available in the public domain, this information may be available upon request from research authorization authorities such as the Council and MoH.

with only 3 of these trials in phase II or III. Most of these studies are safety and immunogenicity studies and some of these clinical trials involve multiple concepts or the same candidate vaccine tested in multiple clinical trials in different sites.[78] Two candidate vaccine concepts have been developed and tested in Kenya,[79] and a phase III clinical trial is imminent, where the efficacy of a candidate vaccine will be tested in a large group of participants. This represents a significant portion of global HIV vaccine research. Moreover, only five countries in sub-Saharan Africa are reported to be involved in HIV vaccine research.[80] Government practices in HIV vaccine research in Kenya are setting precedents for sub-Saharan Africa and as such should be analysed. My research questions are located against this backdrop.

1.4 Parties involved in HIV Vaccine Research in Kenya.

The University of Nairobi (UoN), KEMRI and the Ministry of Health (MoH) are local public institutions involved in HIV vaccine research, and are conducting scientific research. International researchers involved in vaccine research include the Centre for Disease Control, National Institutes of Health (NIH) from the US and the Medical Research Centre and Oxford University in the UK.[81] Government departments involved in vaccine research in a non-researcher capacity are the National AIDS Control Council (NACC) which coordinates and initiates HIV/AIDS program on a national basis, the National Council for Science and Technology (the Council) which regulates all biomedical research with participants, and the National AIDS/STDs Control Programme (NASCOP),[82] which runs the national health program for sexually transmitted diseases. Other government offices involved include the HIV Vaccine Subcommittee (VSC), the

[78] See also National Institute of Health, "Clinical Trials", online: Clinical trials <http://clinicaltrials.gov/> accessed December 26, 2009 (Registry of HIV vaccine clinical trial supported or funded by the US).
[79] *Vaccine Guidelines supra* note 14.
[80] See generally IAVI Database *supra* note 72.
[81] See participation chart, above page 27.
[82] Ministry of Health, National AIDS/STD Control Program (NASCOP), online: National AIDS/STD Control Program <http://www.aidskenya.org/>.

Pharmacy and Poisons Board (PPB) who authorise and clear HIV vaccine research and the Data and Safety Monitoring Board who review data from clinical trials.

The Kenya AIDS Initiative (KAVI), International AIDS Initiative (IAVI), and the global fund to fight HIV/AIDS, TB and Malaria are local and international non-governmental organisations that sponsor HIV vaccine research in Kenya. KAVI also conducts research. Other groups interested in HIV vaccine research are the local and international pharmaceutical industry that have on occasion sponsored vaccine research and may be required to manufacture and distribute the vaccine if, developed. The medical fraternity is keenly interested in HIV vaccine research and participates through offices the Director of Medical Services (DMS) at the Ministry of Health, which represents all medical practitioners employed by the government, and the Medical and Dentist Practitioners Board of Kenya.[83] International organisations such as the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organisation (WHO) are deeply concerned with HIV/AIDS and monitor and evaluate the progress of vaccine research.[84]

State participation in vaccine research includes legislation and policy for HIV/AIDS and HIV vaccine research. Legal provisions for HIV vaccine research are spread out in sections of parliamentary legislation. *HIV/AIDS Act* [85] creates a general duty for the state to act on HIV/AIDS, outlines informed consent as the guiding legal principle for involvement of participants, and mandates the Council

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[83] See Zachary A. Kwena, "Politics, Etiquette and the Fight Against HIV/AIDS in Kenya: Negotiating for a common front" (Paper presented to the Codesria General Assembly, Kampala, Uganda, 8 December 2002), Council for the Development of Social Science Research in Africa, online: CODESRIA <http://www.codesria.org/Links/conferences/gen_assembly10/panels.htm#>, [Kwena].

[84] See the Joint United Nations Programme on HIV/AIDS, "Policy and Practice", online: Joint United Nations Programme on HIV/AIDS (UNAIDS) <http://www.unaids.org/en/PolicyAndPractice/default.asp> (UNAIDS developing policy and providing technical guidance on HIV issues). See also World Health Organisation, "WHO and HIV/AIDS", online: World Health Organisation, WHO and HIV/AIDS <http://www.who.int/hiv/en/ > (Activities of WHO on HIV/AIDS).

[85] *HIV/AIDS Act supra* note 58 s.39 & s.40.

to regulate vaccine research according to practices set out in *Science and Technology Act* (*S & T Act*). The *S & T Act* sets up KEMRI as a state institution for research with participants and mandates the Council to make regulations for all biomedical research.[86]

Two regulations provide for HIV vaccine research; the general *Guidelines for Ethical conduct of Biomedical Research Involving Human Subjects in Kenya* (*NCST Guidelines*),[87] which regulate all biomedical research with participants, and the more specific *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccine*s (*Vaccine guidelines*),[88] which regulate only vaccine research but are subject to "[p]revailing Kenyan laws."[89] HIV/AIDS is the only health issue and HIV vaccine research only human health research sector to be separately regulated in Kenya.[90] In addition, there are policy provisions for HIV vaccine research in Kenya, are included in the HIV /AIDS vaccine regulations.[91]

The law surrounding HIV vaccine research is fragmented, located in different parliamentary and delegated legislations, and its' precise effect has yet to be studied or interpreted.

Understanding the multiple roles for the state in HIV vaccine research

Vaccine development is a long-term activity; the time taken from preclinical studies through to phase III studies, which is when a vaccine may become available for the public, will take over a decade as each phase spans several years.[92] A synthesis of the role of the state in HIV vaccine research will enable the evaluation of past performance and improve future performance of the state in this

[86] *S & T Act supra* note *59 S.4 & fourth schedule.*
[87] National Council for Science and Technology, *Guidelines for Ethical conduct of Biomedical Research Involving Human Subjects in Kenya*, No. *45*, of 2004 [*NCST Guidelines*].
[88] See *Vaccine Guidelines supra* note 13.
[89] *Vaccine Guidelines supra* note 13 at 20.
[90] All other health research involving participants is covered by the *NCST guidelines*.
[91] *Vaccine Guidelines supra* note 13 c.1.
[92] *Vaccine Guidelines supra* note 13 at 7-9 (process and timeline for vaccine research and development).

sector. Below, I review the other approaches and discussions to HIV vaccine research and related issues.

1.5 Literature Review

My literature review looks at a wide variety of literature from the field of research ethics with participants, research in developing countries and sub Saharan Africa, and on governance theories, to pull together ideas that can help investigate the role of the state in HIV vaccine research. Several issues arise from my literature review and support my choice of theoretical tools.

Approaches in Medical Ethics and Research Ethics.

Ethical, legal and moral approaches to research with participants are often situated in the field of biomedical research ethics and medical ethics where there are a large variety of theoretical tools. A brief literature survey of research ethics shows most discussions focus on well-established concepts and principles as well as on frameworks that elucidate standards and guidelines.

Beauchamp and Childress articulated the four ethical principles of respect for autonomy, nonmaleficence, beneficence and justice,[93] which are foundational theoretical tools in bioethical theory and are widely and substantively discussed. Supporters argue, " '[t]he four principles of medical ethics can explain and justify, alone or in combination, all the substantive and universalisable claims of medical ethics and probably of ethics more generally"[94] positing that the principles can be a basis for creating a global moral standard. Beauchamp reflected on 'the four principle approach' years after it was first developed and found they have had

[93] See Beauchamp and Childress *supra* note 23 at 12.
[94] Raanan Gillon, "Ethics Need Principles - Four Can Encompass the Rest- Respect for Autonomy Should be the First Among Equals" (2003) 29 JME at 307.

practical application in the healthcare environment as "[r]ules for healthcare ethics can be formulated by reference to these four principles."[95]

In a similar approach, Emannuel Kass et. al have outlined seven ethical requirements for biomedical research with participants.[96] Other authors have used the principle approach to develop and apply core ideas that are normative in discussions, analyses or critiques of healthcare and research with participants.[97] The principle approach is advantageous because it provides theoretical tools that have helped to define issues in research involving participants. The principle of justice and beneficence are particularly attractive for an investigation of HIV vaccine research with participants and have in fact been used to discuss challenges in biomedical research with participants in international research, developing nations and in underdeveloped communities.[98]

Kimmelman investigates the issue of benefit and justice to participants from developing world in research where innovations being tested will be primarily available in the developed world. Furthermore, he questions the moral basis of placing a research burden for such innovations on vulnerable or marginalised populations who may have limited access to the products and benefits of research.[99] This is a crucial issue for HIV/AIDS research, vulnerable groups are consistently exposed to harm and there is little evidence to show there are strong structures to deliver benefits of research in Kenya. There are limitations of the principle of beneficence in the analysis of the role of the state in HIV vaccine research. This principle defines the problem in HIV vaccine research as a question of benefit, and will focus on the role of the state in ensuring HIV/AIDS vaccine

[95] See Beauchamp and Childress *supra* note 22.
[96] See Emmanuel Kass et al., "What Makes Clinical Research Ethical?" (2000) 283:20 JAMA 2701-2710.
[97] See e.g. R. M. Veatch, "The Place of Care in Ethical Theory" (1998) 23 Journal of Medicine & Philosophy 210 (Veatch discusses Carol Gilligans' development and use of the principle of care to achieve a balance in healthcare setting).
[98] See e.g Jonathan, Kimmelman. "Clinical Trials and Scid Row: The Ethics of Phase 1 Trials in the Developing World" (2007) 3 Developing World Bioethics 128 [*Kimmelman*].
[99] See generally Kimmelman *ibid.*

research is beneficial to Kenya and leave other dimensions of state participation unexamined.

Norman Daniels looked at justice and health care at a macroeconomic level, which he argues is a level that has a much greater impact on health than approaches that look at issues at the personal or individual level. This inclination towards the macroeconomic level is fitting for my inquiry as it can accommodate an analysis of all the actors, practices, law and policy surrounding HIV vaccine research. Daniels suggests there has been a preoccupation with issues on the micro or individual level because they are dramatic.[100] This is characteristic of HIV/AIDS vaccine research in Kenya, whereby dramatic incidents and conflicts such as *Nyumbani* and *Pearl omega* raised disturbing ethical, moral and legal issues and drew attention to the individuals involved.[101]

These dramatic incidents are useful to illustrate features of the problem in vaccine research but are symptomatic and should direct us to focus on finding an overarching analysis that has a high impact on HIV vaccine research in Kenya and in sub-Saharan Africa. Addressing individual incidents or singular issues arising from these incidents may legitimise harmful approaches and structures and thus perpetuate endemic problems in HIV/AIDS vaccine research on the micro and macro level. For instance, government mediation efforts in disputes between international researchers and local researchers without an established framework and standards for balanced partnerships may perpetuate harmful patterns. My analysis uses principles to highlight issues but goes beyond incidents to focus on the activities of the state, the vaccine research framework and the environment, which is the formative realm for issues in HIV vaccine research.

[100] Norman Daniels, "Justice, Health, and Healthcare" (2001)16 American Journal of Bioethics 290 at 290.
[101] Also a characteristic of discussions of health issues in Africa, refer to discussion in chapter two of the South African landscape where AIDS denialism fuelled by the individual personalities (Mbeki) detoured and distracted the fight against AIDS for a decade.

HIV/AIDS has developed as a multi-faceted pandemic and most principles are too narrow to examine all the issues at play. For example, an over-emphasis on informed consent and benefit may lead to an assumption that the state has a limited role in vaccine research: to either protect participants or regulate research.

Moreover, moral and ethical principles are unwieldy because they are developed outside sub-Saharan Africa for a foreign environment to respond to concerns in that (foreign) environment and require adaption in other contexts. The four principles were developed in an environment wealthy with public and private resources for biomedical research with participants, a proliferation of pharmaceutical companies doing research in a capital economy and a thriving research and teaching sector in learning institutions as well as a number of public research institutions. This scenario is unlikely in most of sub-Saharan Africa where negligible private research is done, the domestic pharmaceutical industry is small and few can afford to pay market prices for health innovations.

Petryna discusses the difficulties in drug development by international researchers in developing countries. She notes that "[e]thical variability refers to how international ethical guidelines are being recast as trials for global research subjects are organised,"[102] arguing that the differences in context between developing countries and developed countries leads to a negative interpretation of principles that is harmful to participants from the developing world. Although Petryna concentrates on the globalisation of participants, she identifies certain aspects in the environment in developing countries such as "[e]conomic instability" and "[u]nprecedented health crises"[103] which are crucial aspects of the HIV/AIDS pandemic in Kenya, as contributing to ethical variability.

Domestic approaches in literature discussed below are wary of the use of global principles and regulations and focus on their interpretation for Sub-Saharan

[102] Adrianna Petryna, "Ethical variability: Drug Development and Globalizing Clinical Trials" (2005) 32 American Ethnologist 183-197 at 184 [Petryna].
[103] Petryna *ibid* at 183.

Africa. My thesis applies principles from biomedical ethics and medical ethics sparingly because they require interpretation and ranking: it is difficult to select a single principle for use from among a list of suitable principles.

Legal theories, legislative and regulatory approaches.

Legislative approaches to HIV Vaccine research are often rooted and linked to the principles approach in medical ethics and research ethics literature. Various authorities have developed regulations and guidelines to provide for the ethical conduct of vaccine research including the World Medical Association that developed the Declaration of Helsinki[104] and the Nuremberg military tribunal, which developed the *Nuremberg Code*[105] using principles from research and medical ethics.

The concept of voluntary informed consent developed from the *Nuremberg Code* has become a legal standard in research with participants.[106] Informed consent appears in most discussions about research in developing nations, research with restricted resources, vulnerable communities and in international HIV vaccine research.[107] The notion of informed consent is described as

> […]Falling into the area of preventive ethics, which is concerned with advance identification of potential areas of ethical concern or conflict and preventing these from arising (and as an) essential concern in optimizing HIV vaccine trials in South Africa, and ensuring their efficacy for both this country and the world."[108]

[104] *Helsinki supra* note 35.
[105] *Nuremberg supra* note 28 at 181-182.
[106] *Nuremberg supra* note 28 at 181-182.
[107] See especially Adnan Hyder & Salman Wali " Informed Consent and Collaborative Research: Perspectives From the Developing World, (2006) 6 Developing World Bioethics 33-40 (empirical study on informed consent in collaborative research and need for adaptation of this informed consent to cultural norms).
[108] Graham Lindegger & L. M Richter, "HIV vaccine trials: Critical Issues in Informed Consent" (2000) 96 South African Journal of Science at 313.

Kenyan regulations for HIV vaccine research emphasize voluntary informed consent of participants.[109] However, informed consent is problematic in sub-Saharan Africa and in Kenya given that the *Nyumbani* and *Majengo* incidents occurred despite provisions for informed consent within the legal framework.[110] Andanda and others[111] have discussed *Nyumbani* and questioned whether Father D'Agostino, the home director or the board of governors could give consent to the children's enrolment into research or to consent to the collecting of blood samples from the children. In circumstances where informed consent is a concern, the questions often grow in scope and are linked to other ethical social and political issues.[112] Burniers comment, "[O]ne should keep in mind that a signed informed consent is not sufficient to make clinical research ethical,"[113] is instructive: informed consent is essential for biomedical research, but insufficient to review wider issues.

Within the legislative approach, there are different schools of thought. Dr. Sylvester Chima highlighted the need to interpret international guidelines to address the needs of developing countries.[114] He links the challenges (resource disparity and exploitation) in biomedical research in developing countries to a lack of harmonised regional legislative approach. Adele Langlois discusses the application of the UNESCO declaration of human rights in biomedical research in Kenya and South Africa. In her discussion, she notes that the main challenge for this set of guidelines is that they are not contextualised for sub-Saharan Africa.[115] These scarce but notable perspectives indicate there is a need to hear and make

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[109] *Vaccine Guidelines supra* note 14, Appendix (regulations provide for several standards forms for informed consent such as an enrolment form, signature form and an information checklist)
[110] See Andanda supra note 4 and Siringi *supra* note 19.
[111] Carol Majtenyi, "Kenya Probes HIV-AIDS Children's Home Search by British Universities" *Voice of America News*, online: Voice of America <http://www.voanews.com/english/archive/2004-05/a-2004-05-24-11-1.cfm>.
[112] Nation investigation *supra* note 10 at 389 (investigative report brings up question of research authorization and clearance, publication of results and sharing of benefits).
[113] Michel Burnier, "The Pitfall of Informed Consent in Clinical Research" (2003) 18 TPN 1 at 1.
[114] Sylvester Chima, "The Regulation of Biomedical Research in Africa" (2006) 332 B.M.J. at 841-851.
[115] Adele Langlois, "The UNESCO Universal Declaration on bioethics and Human Rights: Perspectives from Kenya and South Africa" (2008) 16:1 Healthcare Care Anal. at 39-51 (Scholar in regulatory issues in South Africa, Kenya and in southern hemisphere bioethics issues).

space for Kenyan or sub-Saharan Africa views in the international legal and ethical frameworks for vaccine and biomedical research with participants. This would involve a bottom–up development process for regulations that is inclusive of a variety of local and domestic perspectives.

Jurisprudence rarely addresses issues surrounding HIV vaccine research and in the few instances, courts have presented contradictory positions. In *Kenya AIDS Society vs. Arthur Obel*,[116] an AIDS activist group had sued a prominent researcher, Professor Arthur Obel for offering a false cure for HIV, which he claimed to have invented. Despite the fact that Prof. Obel's cure had not met the legal and medical standards for medicines offered to the public, the court supported Prof. Obel because the bench was not willing to deny sufferers the chance of treatment. However, in *Re vs. Lucy Nduta*, a popular evangelical pastor from an independent church was found guilty of fraud by pretending she could offer an HIV cure for money.[117] These precedents have contradictory positions and may obfuscate the responsibilities of state and other parties involved in HIV and vaccine research.

Legislative and regulatory approaches are useful in HIV vaccine research and have identified and resolved issues. However, as HIV/AIDS in Kenya is a "[c]omplex and dynamic"[118] problem, they may need other underpinning theories if they are to be used to analyse and resolve the issues in vaccine research.

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[116] *Kenya AIDS Society v. Arthur Obel*, [1998] N.C.A. 188 of 1997, online: Kenya Law Reports <http://www.kenyalaw.org/update/>, [*Obel*].

[117] *Re vs. Lucy Nduta Mwangi* (2009), Kiambu. (A recent unreported case of preacher found guilty of offering false cure, widely discussed) See, Eric Wainaina and Richard Munguti, Aids 'Cure' Woman Get Two Years in Jail, *Daily Nation*,(30 January 2009) and See also, S. Kiplagat, Aids Cure Pretender Can't raise Cash Bail, *Daily Nation*, (9 March 2009), online: Daily Nation <http://www.nation.co.ke/News/-/1056/543886/-/u33owi/-/index.html>.

[118] *KAIS 2007 supra* note 46 at 3.

Domestic literature on HIV vaccine research

Domestic literature on HIV/AIDS, biomedical research with participants in sub-Saharan Africa, and on HIV-associated vaccine research is scarce and underdeveloped.

Shaffer et al. conducted a study to find out local perspectives on vaccine research at a potential study site in western Kenya.[119] This significant study brought together different groups including potential participants, hospital administrators and clinical researchers. All groups strongly felt it was unfair to discontinue any successful therapy when the trial was over[120] and argued that "[r]esearchers have a long term obligation to treat HIV/AIDS clinical trial participants."[121] Potential participants canvassed in this study expressed concerns about post-trial obligations at the macro level: they wanted issues such as health literacy, access and availability of drugs after the trial, and the socio-economic effects of participation on individuals addressed before the trial.[122] This study squarely states the influence of socioeconomic issues on HIV research and alludes to the need for an overarching analysis of the challenges of vaccine research.

Rachier, a Kenyan lawyer on the forefront of HIV associated research issues, provides an invaluable legal-ethical analysis of HIV vaccine research. He focuses on the IAVI-MRC trials (Majengo trials) and points out a "[n]eed for law reform to incorporate the legal and ethical rules on HIV vaccine research as enunciated in various international instruments." [123] He views the challenges in HIV vaccine research as mainly legal and regulatory and takes an approach centred firmly in biomedical research ethics approaches and argues that there are human rights

[119]Douglas Shaffer et al., "Equitable Treatment for HIV/AIDS Clinical Trial Participants: A Focus Group of Patient, Clinician Researchers and Administrators in Western Kenya " (2006) 32 J.M.E. at 55-60 [Shaffer].
[120] Shaffer *ibid* at 58.
Shaffer *ibid* at 58.
18 at 59.
[122] Shaffer *supra* note 118 at 57-58.
[123] Rachier supra note 3 at para. 1.

issues in HIV vaccine research. Although his discussion covers the period before the publication of research regulations (2004 and 2005) and before the *HIV/AIDS Act*, the issues he raises are still relevant, especially since he argues that there is a lack of concerted political will in government approaches towards HIV, which may hold back implementation of regulatory reforms.[124]

Governance Approaches

Governance theories are familiar approaches in Kenya and are prevalent in other discussions about government activity particularly about politics, civil society, and government administration and regimes. The past 20 years have been a tumultuous period for Kenya and East Africa and with intense changes in political and economic systems. After decades of single-party rule, Kenya moved to a multi-party political system in 1997 and since then, elections and governance has been turbulent. The economy has undergone similar changes.[125] Kenya first adopted the structural adjustment program of the World Bank in order to receive quickly disbursed funds in 1986,[126] and this program required the Kenyan government to change governance methods such as abolishing controls on the exchange rate, to liberalize trade and restructure government administration.[127] Although this program is on-off, re-negotiated and its' cause and effect on the Kenyan economy is debated,[128] it has raised awareness of governance issues in Kenya. These changes and the climate in political and economic sector have brought governance theories into sharp relief. Kenyans are likely to appreciate and engage with an approach that looks into governance issues in HIV vaccine research.

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[124] See, Human Rights Watch *supra* 51 at VIII.
[125] Changes in the Kenyan economy due to SAP's being improperly implemented are reviewed by Gurushi who does a case study of the implementation of SAPs' in Kenya. See, Gurushri Swarmy, *Adjustment in Africa: Lessons From Country Case Studies* (Washington DC: World Bank, 1994) at c. 5. [Swarmy]
[126] Swarmy *ibid* at 3.
[127] Swarmy *supra* note 124 at 4.
[128] World bank has argued that the reason for their failure is patchy intermittent commitment by the Kenyan government. See Swarmy *supra* note 124 c. 5.

Develtere et al. describe "multilevel governance," a new paradigm of governance that in their view, is taking root in Kenya. It involves "[m]ultiple decision-making centres at different levels (sub national, national, supranational, international) and the inter dependent relations among these levels."[129] In their approach, Develtere et al. identify select programs such as the National Poverty Eradication Program and look at the effect multi-layered governance has had on the activities of the major national actors in Kenya, who are listed as "[t]he state; civil society; business community; and the international donor community."[130] Their approach is crucial to this thesis because they acknowledge state domination in other sectors, external influences, and outline a governance model that has multiple decision-making and action sites. Develtere et al. provide a model of governance in Kenya that could work as a basic description of state participation in HIV vaccine research.

In summary, HIV vaccine research is a difficult and often controversial activity in Kenya. The state has a role in HIV vaccine research as part of a multi-pronged government approach to HIV/AIDS but this complex role is unexamined and misunderstood within current approaches to issues in HIV vaccine research. Literature on HIV vaccine research and on biomedical research in Kenya and in sub-Saharan Africa has focused on informed consent. Discussions are dominated by international perspectives, which in many instances fail to investigate local knowledge and to account for the crucial state involvement in, and the legal, ethical and institutional framework for vaccine research. My literature review reveals a lack of ready-made frameworks with which to comprehensively discuss the diversity in state participation, and address the factors in the environment that have shaped state participation.

[129] Patrick Develtere, Hertogen Els and Frederick Wanyama, "The Emergence of Multilevel Governance in Kenya" (2005) Higher Institute of Labour Studies (HIVA) at 6 [Develtere].
[130] Develtere *ibid* at 6-7.

Chapter Two
Contextual Factors and Issues that Influence the Role of the State in HIV/AIDS Vaccine Research.

Introduction

Chapter one briefly described the impact of HIV/AIDS in Kenya, discussed HIV vaccine research as part of a multi-pronged government approach to HIV/AIDS and outlined a general role for the state in HIV vaccine research whose origin is in the duty to fight HIV/AIDS. My literature survey reviewed diverse theoretical approaches to sub-Saharan health issues including HIV/AIDS, biomedical research with participants, HIV research and HIV vaccine research, governance and policy development and implementation.

I noted a gap in literature: there were sparse local perspectives and international perspectives rarely accounted for local contextual issues and neglected to account for state participation in vaccine research in Kenya. Chapter two targets this gap in knowledge and closely examines the environment in which vaccine research is conducted. The local environment surrounding vaccine research is rich with socio-economic, political, ethico-legal; cultural and religious issues that shape key, distinct areas of interest for the state. These issues and events have acted as catalyst parameters and defined the interest areas into distinct roles for the state in vaccine research.

2.1. The Link between the Environment of HIV/AIDS in Kenya and the Development of Multiple Roles for the State in Vaccine Research

The influence of environmental factors on policy choices and implementation are noted in instrument-choice perspectives. Salamon discusses the proliferation of new methods used by governments to cope with public problems,[131] describes a

[131] Tools of Government *supra* note37 at 1.

new governance paradigm that focuses on the collaborative nature of public problem-solving,[132] and notes the challenge of understanding the resulting complex mesh of systems of public action.[133] Salamon highlights a quiet reform in most western governments, which are adopting various forms of this paradigm. This reform can be noted from the prevalence of newer tools being used by governments that are often highly indirect, if compared to earlier more direct forms of policy implementation. Furthermore, this paradigm is aware of a characteristic feature of government policy choices, conceptualizing "[t]ool choice as *political* choices."[134]

Salamon's view of the new governance paradigm is intuitive of the inevitable external aspects to HIV/AIDS vaccine research policy, implementation and their porosity. This paradigm offers insight into the complex web of state actors and instruments. Peters disputes the portrayal of the analysis and selection of policy instruments "[A]s a rational, linear, technical exercise."[135] Salamon notes a common misconception oversimplifies government action as a central and hierarchical activity, whereas in reality it involves interwoven policy tools, public agencies in complex interdependencies with third parties.[136]

State participation in HIV vaccine research is simultaneously comparable to, and distinct from economic policy choices and their implementation discussed by Salmon and Peters. Both scenarios involve inquiries into the choices of governing instruments in the distinct sectors of economics and health, and are comparable because they are essentially government dominated and permeated sectors: economic policies and vaccine research are both specialised, multi dimensional activities that require a complex set of technical instruments to implement decisions in either sector. Furthermore, both sectors are dynamic and have global implications.

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[132] Tools of Government *supra* note 37 at 8.
[133] Tools of Government *supra* note 37 at 552 & 600.
[134] Tools of Government *supra* note 37 at 601.
[135] Tools of Government, *supra* note 37 at 552.
[136] Tools of Government, *supra* note 37 at 3.

Whereas Salamon and Peters have identified political influences as key to choices of policy instruments for public action on problems, my discussion explores a wider range of influences on state participation in HIV vaccine research. My analysis loosely categorizes these influences as global or domestic. These categories and issues are porous and fluid because most of the factors identified are intertwined. My main goal is to identify critical factors and link them to the development of interests and roles. Thus, the issues I identify are descriptive and indicative of the significant influences in the environment surrounding vaccine research.

2.2. Global Issues in HIV Vaccine Research

Johnson identified the link between global issues and HIV/AIDS policy choices made in South Africa and noted that AIDS policymaking in South Africa is situated in a global climate and institutional framework.[137] Several interconnected global factors influence Kenya's policy choices on vaccine research, and include the appearance of global partnerships in the fight against HIV/AIDS, the North-South separation, colonial and post-colonial themes in health issues, resource disparity and unequal relationships between international and domestic parties involved in vaccine research.

Global Partnerships in the Fight against HIV/AIDS

A notable feature of HIV/AIDS has been the globalised response to HIV/AIDS. There are unprecedented partnerships and collaborations in approaches to HIV/AIDS such as The Global Fund to Fight AIDS, Tuberculosis and Malaria [The Global Fund][138] and the Joint United Nations Program on HIV/AIDS [UNAIDS].[139]

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[137] K. Johnson, "The politics of AIDS policy development and implementation in post-apartheid South Africa" (2004) 51 Africa Today 106-128 at 111.
[138] See The Global Fund to Fight AIDS, Tuberculosis and Malaria, "About the Global Fund" (2009) online: The Global fund to Fight AIDS, Tuberculosis and Malaria

The fight against HIV has drawn a wide range of interested parties across traditional boundaries.[140] In vaccine research in Kenya, it has drawn together parties with specialised knowledge and resources to carry out biomedical HIV vaccine such as the US Walter Reed ARMY Research Unit and KEMRI, to share and conserve resources and avoid duplication of efforts, either in a loose agreement, or in formalised arrangements such as the Global HIV/AIDS Vaccine Enterprise.[141] The globalisation of vaccine research is important because the government is committed to conducting vaccine research within this coordinated global framework.[142]

Several issues arise from state involvement within a globalised approach to HIV/AIDS and to vaccine research. There is scarce independent information on the total amount that the Kenyan government spends on HIV vaccine research. The gross Ministry of Health expenditure for 2005 was 23,611 million (Kshs), and over 50 percent of this amount was spent on curative health services. Health expenditure represents 7.67 percent of total gross government budget, which is well below the 15 percent target that was set at the Abuja Declaration of African by African heads of state in 2000.[143]

Judging by the general limited government spending on health, and the focus of the budget on curative services and infrastructure, vaccine research is likely underfunded from the national health budget and indeed, most HIV vaccine

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<http://www.theglobalfund.org/en/about/?lang=en> (a non-profit initiative developed to respond to health challenges in sub-Saharan Africa).

[139] See UNAIDS Joint United Nations Programme on HIV/AIDS, "The report on the global AIDS epidemic"(2008) online: UNAIDS Joint United Nations Programme on HIV/AIDS <http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp> (collects and maintains detailed annual world and country information on HIV/AIDS).

[140] William Makgoba, Nandipha Solomon & Paul Tucker, "Science, Medicine, and the Future: The Search for an HIV Vaccine" (2002) 324 B.M.J. at 211 [Makgoba].

[141] Coordinating Committee of the Global HIV/AIDS Vaccine Enterprise (2005) The Global HIV/AIDS Vaccine Enterprise: Scientific Strategic Plan. PLoS Med 2(2): e25. at para3 & box 1 (formalised arrangement to coordinate vaccine research between 140 countries). Further discussion of the Kenyan framework for vaccine research in chapter 3 below and a list of chart describing participants can be found in the Appendix, below.

[142] *Vaccine Guidelines supra* note 13 at 1.

[143] Ministry of Health, *Health Care Financing & Expenditure 2005,* (Media Report), online: Republic of Kenya, Ministry of Health <http://www.health.go.ke/>.

research programs are substantially funded by international sponsors.[144] Thus, international sponsorship bulwarks an otherwise weak public research sector.

Vaccine research has centred around three public institutions, KEMRI, University of Nairobi and Moi University, which are universities that have adjoined teaching hospitals, research centres and standing research clearance. These institutions have relationships with international parties who provide funds, infrastructure[145] and support vaccine research in Kenya.[146] Globalisation of HIV/AIDS research allows a practical relationship to develop between these two groups, with the result being a substantial traffic of resources that generates a need for facilitation and organisation and suggests a role for the state as a *Facilitator* and as a *Sponsor*.

North-South Separation, Colonial and Post-colonial Issues.

This relationship may seem simple and mutually beneficial, but there are complicating factors such as North–South separation as well as colonial and postcolonial issues, which are deeply rooted in the HIV/AIDS pandemic and in sub-Saharan Africa. These factors surface in most discussions on these issues and influence approaches by governments to HIV/AIDS in sub-Saharan Africa and Kenya and may influence the role of the state in vaccine research.

The influence of the North-South separation, colonial, neo-colonial and postcolonial themes on government approaches to HIV/AIDS is poignantly illustrated in the South African HIV/AIDS landscape where AIDS denialists and dissidents gained prominence in a movement propelled by the north- south separation, colonial and postcolonial issues. The former South African President

[144] UoN Research Activities *supra* note 16.
[145] In order to carry out vaccine research one needs significant epidemiological information and access to a large population with high prevalence of the relevant HIV/AIDS subtypes. See *Vaccine Guidelines* supra note 13 at x & c. 1.
[146] Makgoba describes the exchange relationship and focuses on the needs of sub-Saharan Africa in vaccine research. Makgoba *supra* note 140 at 211-212.

(1999-2008), Thabo Mbeki, has a controversial position, denying that the HIV virus causes AIDS and that ART is effective against HIV.[147] His position deeply divided South Africa, pitting him and the health minister at the time, Dr. Manto Tshabalala-Msimang, against the scientific community and AIDS Activists. This debate grew so acrimonious that he was censured by the African National Congress (his political party), the South African Parliament and the former South African President and Nobel laureate, Nelson Mandela, besides being vilified in national and international press.[148]

Under pressure, President Mbeki withdrew from public debate on HIV/AIDS in 2000. Concurrently, the South African government had refused to provide ARV's to HIV positive expectant women, a position that was influenced by the then Health Minister who advocated for alternative treatments and who supported Mbeki's position. This dispute culminated in an action against the South African government filed by the Treatment Action Campaign, a vocal AIDS activist group, for refusing to provide ART to expectant, HIV-positive women to prevent transmission of HIV from mother to child. During this case, the Ministry of Health argued that ART was toxic, had documented side effects, and that the Ministry did not have an obligation to provide ARV's due to its limited resources. The South African Constitutional Court ruled

> [...] The Constitution requires the government to devise and implement within its available resources, a comprehensive and co-ordinated programme to realise progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV.[149]

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[147]Chris McGreal, "Mbeki admits he is still Aids dissident six years on" *The Guardian*, (6 November 2005), online: The Guardian <http://www.guardian.co.uk/world/2007/nov/06/southafrica.aids>

[148]See generally Adele Baleta, " South African President Criticised for Lack of Focus on AIDS (2004) 363 Lancet 541, at 541.

[149] *Minister of Health and Others v Treatment Action Campaign and Others* (No 1) (CCT9/02) [2002] ZACC 16; 2002 (5) SA 703; 2002 (10) BCLR 1075 (5 July 2002) (5 July 2002) para. 135(2) (a).

This judgement in effect compelled the South African government to change its' policy on ARV's for expectant women with HIV and spelled out a duty for South Africa to take preventative action in the face of HIV/AIDS.

Nattrass describes the HIV landscape in post-apartheid South Africa as being influenced by politics, leadership and postcolonial issues, which is seen in the mistrust of western science by the Health Minister and President Mbeki. In his view, western perceptions of HIV/AIDS pandemic persistently fall back to a colonial definition of the African.[150] Other authors have discussed the root of Thabo Mbeki AIDS denialism as a rejection of a common perception and a colonial characterisation of the African as diseased and helpless.[151] Vaughan examined this issue in depth and found there was justification for this fear; the western account of AIDS in Africa, perpetually perceives Africa as synonymous with disease, death, and uncontrolled sexuality.[152]

Chigwedere et al. estimate that AIDS denialism in the South African government has cost over 300,000 lives.[153] Such studies have not been applied to HIV in Kenya, and in comparison to South Africa, there is little evidence of an explicit AIDS denialism in the Kenyan government approaches on HIV/AIDS and in vaccine research. However, HIV/AIDS in South Africa is comparable to Kenya on many fronts; both countries have a scarred colonial past, are regionally dominant economies in sub-Saharan Africa, have a high prevalence of HIV and are young democracies. The depth of the analyses of the above authors shows that colonial and postcolonial issues, as well as North-South separation, are powerful undercurrents in the environment in which sub-Saharan governments make

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[150] Nattrass, "AIDS, Science and Governance: the battle over antiretroviral therapy in post apartheid South Africa"(2008) African Affairs at 1, online: Oxford Journals African Affairs <http://afraf.oxfordjournals.org/cgi/content/abstract/adm087v1>. [Nattrass]

[151] M. Mbali, "Mbeki's Denialism and the Ghosts of Apartheid and Colonialism for Post-Apartheid AIDS Policy Making"(Durban: University of Natal, Public Health Journal Club Seminar, May 2002) at 9, 24, and Megan Vaughan, *Curing Their Ills: Colonial Power and African Illness* (Stanford University Press, 1991) at 205 [Vaughan].

[152] Vaughan *ibid* at 205.

[153] See Pride Chigwedere et al., "Estimating the Lost Benefits of Antiretroviral Drug Use in South Africa" (2008) 49 JAIDS 410.

choices about HIV/AIDS programs; we may reasonably infer that they are present in Kenya and influence decisions about vaccine research.

In Kenya, postcolonial themes and the north-south separation surface in the mistrust of scientific findings in HIV research and of international links in research, which are perceived to be serving western interests. A recent study[154] done in Kisumu, in western Kenya that found male circumcision greatly reduced the chances of HIV infection faced serious opposition especially in communities with cultural aversions to circumcision. Some communities such as the Luo did not practice circumcision while other communities practice circumcision as a cultural rite of passage. The host community was wary of the intentions of the researchers and suspicious that male circumcision would erode Luo culture and superimpose western practices.[155] Western Kenyan has had high HIV infection rates and the impact of the HIV/AIDS pandemic in this community has been devastating.[156] Local communities may distrust international researchers and their findings because they felt abandoned by the government and international community who did not offer more resources to help address HIV/AIDS.

The Chairman of the Luo Council of Elders advised that "[P]eople must be assured that this is purely a medical cut and does not in any way mean that Luos have changed their cultural values."[157] Although the government quickly announced a program for male circumcision to start by mid 2008,[158] strong

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[154] R. C. Bailey et al., "Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial" (2007) 369 The Lancet 643-656. The research team had researchers from UoN, University of Manitoba and University of Illinios.

[155] The Luo Council of Elders is the traditional group of community elders that provide guidance on socio cultural and political issues to the Luo Community. They were initially opposed to government plans to include male circumcision in the prevention program but partly relented after consultations with leaders and the government. IRIN "KENYA: Male circumcision sparks controversy" *IRIN, PlusNews Global HIV/AIDS News and Analysis* (Friday 07 August 2009) (Opposition to male circumcision).

[156] Ironically, communities in Nyanza province with cultural aversion have high HIV prevalence Compared to a national prevalence of 6.7-7.8 %, Nyanza province has a prevalence of 15.1-15.4 % See *KAIS 2007 supra note 46* at 11 & 15.

[157] Muliro Telewa, "Kenyan MPs admit to circumcision" BBC (23 September 2008), online: BBC News<http://news.bbc.co.uk/2/hi/africa/7584269.stm> [Muliro].

[158] National Aids Control Council, "Government to roll out male circumcision", online: National AIDS Control Council <http://www.nacc.or.ke/2007/default2.php?active_page_id=272&id=279>.

resistance to male circumcision is only being overcome with culturally based education approaches and the support of community elders and leaders.[159] Katz and Wright connect colonial and postcolonial issues to public and government attitudes towards male circumcision for HIV prevention of transmission methods and have noted:

> [...] Many public health researchers fear that there are deeper reasons for some African governments' scepticism. Some speculate that Africa's colonialist history has left these leaders with lingering suspicions about possible oppression, which have long taken the form of deep denial regarding HIV treatment and prevention in certain regions of Africa (Vetner)…Others reference the dark history of surgical interventions deployed in the name of public health, citing the Indian sterilization camps of the 1970s. All agree that implementation of circumcision on a national level will require in-country champions and strong political will to succeed. Currently all of the funding is coming from Western nations…and this makes people suspicious (Vetner).[160]

The situation with male circumcision in Kenya is a microcosm of the push and pull that the north-south separation and postcolonial themes have on HIV/AIDS research programs. It is likely that is due to the magnitude of the HIV/AIDS pandemic, the Kenyan government encourages research and this may have resulted to growth and support of HIV vaccine research. On the other hand, the government has to counter deep suspicions harboured in sections of the public towards research with international associations, developing a role for the state as *Guardian* and outlining a role for the state as *Facilitator,* which would carry out activities such as advocacy campaigns to seek community support for clinical trials. Postcolonial themes in AIDS research tie in with cultural factors discussed below.

[159] See Muliro *supra* note 157 (Luo politicians and doctors start advocacy campaign for male circumcision).
[160] Ingrid Katz & Alexei Wright, "Circumcision-A Surgical Strategy for HIV Prevention in Africa" (2008) 359 NEJM 2412 at 2412 [Katz].

Resource Disparity between International/Domestic Parties, Unequal Relationships in Research, and Ethical Variability in Clinical Trials.

An additional factor in the global framework for vaccine research is the unequal relationship between international and domestic parties involved in vaccine research.

Shah describes an unequal relationship in international research as fuelled by "[D]rug companies' quest for speedy results (which) has led to a boom in trials based in developing countries, where ethical standards may be lax and the impoverished sick and abundant."[161]

The relationship between international and domestic parties involved in research is often perceived as conflicted[162] and unequal due to the economic disparity between the international and domestic parties, and the flow of resources in biomedical research is beneficial to the West or to international interests at the expense of local interests.[163] Petryna notes a growing ethical variability in globalised clinical trials, which arises from disparities in resources and leads to harm of vulnerable communities.[164] Both Shah[165] and Petryna[166] use the Trovan clinical trial, which Pfizer carried out in Kano, Nigeria in 1999 to test a new therapy for meningitis during an outbreak, to illustrate a sliding scale of standards applied in international research that is inherently harmful to local interests in low resource settings. During this study, over 200 children died after they were given a new untested therapy or ineffective doses of standard treatment for meningitis during a meningitis outbreak.

[161] Sonia Shah, "Globalization of Clinical Research by the Pharmaceutical Industry" (2003) 33 International Journal of Health Services at 29 [Shah].
[162] See Nicholas Christakis, "The Ethical Design of and AIDS Vaccine Trial in Africa" (1988) 18 The Hastings Center Report.
[163] See David Korn, "Conflicts of interest in biomedical research" (2000) 17 JAMA 2234-2236.
[164] See Petryna *supra* note 101.
[165] Shah *supra* note 161 at 32-34.
[166] Petryna *supra* note 101 at 183-197.

In the fallout after the trial, Nigerian authorities stated that the study was not authorised and brought criminal actions against Pfizer officials for endangering participants. Parents of the deceased children have been fighting for the right to sue Pfizer within the American legal system for the covert enrolment and death of their children. The United States Supreme Court recently affirmed the right of the parents to pursue their claim using the US legal system.[167] Although, a pharmaceutical company sponsored this research, it was conducted through a private-public partnership. The trial site was a local public hospital, the participants were recruited through the public health system, and presumably, the study was authorised by local regulations framework.[168] Vaccine research in Kenya is conducted primarily through partnerships in public and non-profit organisations, but a similar disparity in resources between international parties and local parties involved makes ethical variability is a real concern for Kenya.

Similar issues were raised in the ethically contentious HIV012 NET study[169] conducted by NIH researchers in Kampala, which tested single-dose Nevirapine for the prevention of vertical transmission of HIV from mother to child. In contention was the use of placebos in the trial, which despite the presence of proven treatments such as long course prophylaxis that could have prevented or reduced vertical transmission of HIV, even though these treatments were inaccessible and not the standard of care in Uganda.[170] Varmus and Satcher supported the use of placebo during trials in restricted resource settings arguing they are beneficial, and quickly resolve research questions, but they note that

[167] Abdullahi v. Pfizer Inc., Nos. 05-4863 and 05-6768-c, 2008 WL 214649 (2d Cir. Jan. 30, 2009).
[168] *Ibid*. The extent of the involvement of Nigerian authorities is an issue under dispute, Pfizer argues that the trial was authorised in Nigeria and the suit should have been filed locally.
[169] See, L. A. Guay et al., "Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial" (1999) 354 Lancet 795. [Kampala SDNVP Trial].
[170] The contentious issues of the use of placebo trials and standard of care in the *Kampala SDNVP Trial* and recent revisions of *Helsinki* and CIOMS international ethical guidelines for research with participants- Ruth Macklin, *Double standards in medical research in developing countries*, (Cambridge University Press, 2004) at 13-21 [Macklin].

economic disparities create ethical complexities in research in developing countries.[171]

Other authors have not been as generous, condemning the practice of "[S]afari research,"[172] and in particular the withholding of lifesaving alternatives in order to prove scientific efficacy as a harmful variability that arises whenever international researchers conduct research in developing countries.[173]

HIV NET 012 was carried out in Uganda, the Kenyan government may be keen to avoid comparisons to this study and in countering negative perceptions about HIV research in East Africa. In Kenya, the *Nyumbani* Children's Home incident highlighted the link between resource disparity, research authorisation and exploitative research[174] Dr. Moses Otsyula, a researcher with the Kenyan Institute of Primate Research, was involved with the researchers from the Medical Research Centre (MRC) at University of Oxford in research investigating blood samples drawn from children who were born HIV positive and resisted AIDS despite receiving no treatment.

The relationship between Dr. Otsyula and the Oxford research team soured, Dr. Otsyula sued the Oxford research team for fraud, claiming they had taken blood samples and data dating back several years without his consent and had taken additional samples without applying for appropriate clearance and had published their results[175] from this information.[176] The University of Oxford research team responded by stating Dr. Otsyula was their local partner and had led them to

[171] See Harold Varmus & David Satcher, "Ethical complexities of conducting research in developing countries" (1997) 337 NEJM at 1003-1005.
[172] *Macklin supra* note 170 at 12.
[173] See R. Bayer, The debate over maternal-fetal HIV transmission prevention trials in Africa, Asia, and the Caribbean: racist exploitation or exploitation of racism? "(1998) 88 Am Public Health Assoc. at 567-570 and See also S. Loue and D. Okello, "Research Bioethics in the Ugandan Context II: Procedural and Substantive Reform" (2000) 28 J Law Med Ethics 165-173.
[174] See generally Sunday Nation investigative report *supra* note 10.
[175] Alleged to be - R. Chakraborty et al. "Viral coinfections among African children infected with human immunodeficiency virus type 1," (2003) 36 Clinical In-fectious Diseases 922-924.
[176] See Jared Ogutu, "Dispute over blood samples to go to full trial" *The Standard* (5 march 2009) (continuation of trial).

believe they had necessary authorisation. They rectified their error by applying for the necessary authorisation but admitted that the 2002 clearance obtained was not retroactive.

A number of issues arise from *Nyumbani,* including whether the children in the study and Dr. Moses Otsyula had been exploited and whether the Oxford team had carried out unauthorised research in Kenya and if so, should their results be published or their publications from that period retracted. Not surprisingly, a section of local press, public opinion and government authorities leaned against the Oxford team and international researchers. The local press used phrases such as "[t]heft"[177] and "[s]hame of children used in AIDS experiments"[178] to describe the incident. The postcolonial and colonial themes that underpin the issues raised by this incident are clear as Dr. Mohamed Abdullah, the Chair of the authorising body, the Health Research Committee at the Council critically comments, "[T]hey came to Africa and thought it was the jungle, but we have rules and ethics (here) as well."[179]

The above events highlight concerns that Kenyan researchers, participants and the public are exploited in vaccine research and ground fears that due to an unequal relationship within the global framework for vaccine research, sub-Saharan Africa may not have access to the HIV vaccine when and if it is developed.[180] These concerns are reinforced by media reports in 2000 of a dispute between local researchers from KAVI and UoN, and an international team from the MRC and Oxford University. Local researchers went on strike protesting their sidelining by their foreign counterparts who had filed a patent in the UK without informing or

[177] Jillo Kadida, "Kenyan sues British AIDS team for theft" *Daily Nation [of Kenya]* (4 June 2004).
[178] Sunday Nation Nyumbani report *supra* note 10.
[179] Antony Barnett, "Oxford scientists accused of stealing Aids orphans' blood for illicit research" *The [U.K] Observer*, (30 May 2004), online: The Observer <http://www.guardian.co.uk/society/2004/may/30/health.aids>.
[180] Makgoba *supra* note 140 at 211.

including them in the process.[181] The government quickly organised and supported talks, which resolved the dispute. MRC announced they would include their Kenyan counterpart in sharing the benefits of their research and said they were wrong not to keep their Kenyan counterparts informed. However, the unanswered question is whether the government sanctioned and supported a study for vaccine development without a clear regime for benefit sharing. In addition, the final arrangement between both parties were never made public and thus cannot be analysed or reviewed.

Two issues arise from this incident, in response to the challenges of resource disparity and unequal partnerships, a role for the state as *Facilitator* is developed to bridge the gap between both researchers. Secondly, there is need to ensure researchers as well as participants in HIV vaccine research are not exploited and this calls for a more developed and differentiated role for the state as *Guardian* and as a *Regulator* to cover a wider variety of circumstances. Moreover, these incidents indicate that local parties are unhappy with the implementation (or lack of) of regulations. Events such as Nyumbani push the government to focus more on this role and be more visible in their protection and as a result, a large number of instruments are created to protect participants, local researchers and their local intellectual property in HIV vaccine research.

2.3. Domestic Issues in HIV Vaccine Research

A wide variety of issues in the domestic environment where HIV vaccine trials are conducted influence state participation in vaccine research. Some of these issues are general and may be replicated in comparable settings in other countries with similar circumstances; other issues are specific to the domestic environment surrounding HIV research. This section discusses historical factors related to

[181] See BBC Health Team, "Row over AIDS Vaccine" *BBC* (19 October 2000), online: BBC <http://news.bbc.co.uk/2/hi/health/980187.stm>, (media report and description of an intellectual property dispute). See Cathy Jenkins, "Truce over AIDS Vaccine Row" News Report BBC (20 October 2000), online: BBC <http://news.bbc.co.uk/2/hi/africa/982323.stm>, (resolution of dispute over patent rights).

publicly funded research in Kenya, past research ethics controversies, contested treatments for HIV/AIDS and the role of religion within Kenyan society and their influence on the interests and role for the state in vaccine research.

Historical influences in Kenya

Kenya has a rich tradition of state participation in biomedical research involving human subjects and in research on HIV/AIDS, which is rooted in her colonial past. By the late 19th century, settlers were flocking to the "[w]hite highlands"[182] and to the East African Protectorate, attracted by the relatively mild climate and the generous grants of vast tracts of rich farmland, which were issued by the colonial government under liberal terms.[183] Many of the farms settled were experimental in nature and introduced large-scale farming of crops such as coffee, tea and wheat, and animal husbandry.

Local research grew out of early settler experiments into an integrated activity and led to the establishment of research institutions such as the Forest Department in 1902, the Agricultural Laboratories in 1903, the Coffee Research Services in 1910, the Njoro Plant Breeding Station in 1927 and the Tea Research Foundation in 1951.[184] In 1958, the colonial government set up Medical research laboratories to conduct research in human health.[185] The post-independence government later set up the National Council for Science and Technology and the Kenyan Medical Research Institute[186] as well as the University of Nairobi,[187] which had a medical college, to carry out research in human health. The role of the publicly funded

[182] White highlands is a term commonly used to refer to a fertile area located mainly in the present day central province and rift valley province that the colonial government reserved for white settlers-W. T. W. Morgan, "The 'White Highlands' of Kenya" (1963) Geographical Journal at 140.
[183] See generally Marjorie. R. Dilley *British policy in Kenya colony*, (Routledge, 1966). See also W. T. W. Morgan, "The 'White Highlands' of Kenya" (1963) Geographical Journal 140-155.(settler policy in colonial Kenya)
[184] See Essau Bailey, et al, National Council of Science and Technology, *Policy Development in Kenya, A Report to the Ministry of Education, Science and Technology of the Government of Kenya* (Nairobi 2004) Appendix A [*Essau*].
[185] See Essau *ibid*.
[186] These institutions are examined in detail in chapter 3, below.
[187] *University of Nairobi Act* 1995 s. 7(1) & (2). (duty to research).

Researcher originates in Kenya's colonial past and was developed by the post-independence government.

Early studies[188] in HIV were conducted at the University of Nairobi Teaching hospital and through the KEMRI setup to find out more about the transmission and effects of HIV. This led to the growth and development of an internationally respected technical capacity for research in HIV/AIDS within and linked to the public research system.[189] Pioneer researchers, such as Professor Bwayo[190] who co-founded the Kenya AIDS Vaccine Initiative,[191] have firmly established a place for Kenya in international vaccine research. Early Kenyan research has been instrumental in understanding the HIV virus and in setting the ground for vaccine research and even led to the development of a candidate vaccine in a collaborative initiative.[192] This rich history of vaccine research is self -renewing. It attracts significant resources and increases Kenyan technical capacity to carry out vaccine research, further strengthening and defining the role for the state as *Researcher*.

The state is heavily invested in vaccine research and would be keen to ensure that HIV research proceeds to its logical conclusion, that of the development of a preventative HIV vaccine. This has lead to a growth of policy and institutions in HIV vaccine research that focus on the government intention to keep abreast and retain a stake in international vaccine research. The government has encouraged and sponsored researchers and research institutions. The leads to the growth of the

[188] Earliest record of HIV vaccine research- See Neil J. Simonse et al., "HIV infection among lower socioeconomic strata prostitutes in Nairobi" (1990) 4 AIDS 139 [Simonse]. See also Greenblatt *supra* note 2.
[189] Established Kenyan HIV researchers who conduct groundbreaking research are Professor Bwayo and Professor Jacob Ndinya Achola and Professor Godfrey Anzala who have been investigators in numerous HIV vaccine research and HIV immunogenicity studies and publishing over 100 articles on HIV research each.
[190] See, P. Moszynski, "Job Joab Bwayo" (2007) 334 BMJ 590 at 590 (eulogy of renowned Kenyan vaccine researcher)
[191] KAVI, News Release, "Bullets failed to kill research on Aids Gunman may have cut short scientist's life but this did not block Prof Bwayo's award" (2008), online: KAVI <http://www.kaviuon.org/About_HIV_AIDS/Bwayo.htm>.
[192] Clare Kapp, "Job Joab Bwayo" (2007) 369:9563 The Lancet, at 736. (eulogy of renowned vaccine researcher.)

state as *Researcher* and *Facilitator* and close interaction and deep linkages between the scientific and medical community and the role of *Researcher.*
HIV vaccine research includes numerous publicly funded or publicly associated social sciences studies and epidemiological, transmission and treatment studies that provide an essential foundation for vaccine research.[193] The state collects and manages information from these studies, establishes information pathways for HIV vaccine research, and thus sponsors and evaluates activities essential for vaccine research. In recent times, institutions such as the National AIDS Control Council and National AIDS Control Program (NASCOP) support and facilitate research.*[194]*

Past HIV Research Ethics Controversies

Intertwined with Kenya's history of vaccine research is a controversial past especially in the protection of participants in HIV research. The earliest recorded vaccine research is the *Majengo* study.[195] The study continually exposed study participants to HIV infection, and to complicate matters, later studies showed that when these women changed their risky lifestyles, they lost their immunity and tested HIV positive and in some cases developed AIDS.[196] HIV/AIDS and vaccine research has consistently involved vulnerable populations such as orphaned and abandoned children in *Nyumbani* and low-income commercial sex workers, which may be due to the high prevalence of HIV in these populations but has implications on government strategy in vaccine research and highlights a gap in protection.

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[193] See Jose Esparza et al., "Past, present and future of HIV vaccine trials in developing countries" (2002) 20 Vaccine 1897-98.
[194] See participation chart 1 in chapter one for details on the activities carried out by these institutions.
[195] Rupert Kaul et al., "HIV-1-Specific Mucosal CD8+ Lymphocyte Responses in the Cervix of HIV-1-Resistant Prostitutes in Nairobi 1" (2000) 164 The Journal of Immunology 1602 at 1611 [Kaul resistance]
[196] R. Kaul et al., "Late seroconversion in HIV-resistant Nairobi prostitutes despite pre-existing HIV-specific CD8+ responses" (2001) 107 Journal of Clinical Investigation 341 at 349 [Kaul seroconversion]

This history discussed above and below, have raised awareness, knowledge and suspicion in HIV/AIDS approaches among the public and created a negative image of biomedical research in HIV/AIDS, which creates a need and scope for a strong role of the state as *Guardian.* Kenya history may have led to the focus of law as a tool to address issues HIV vaccine research.

Contested and alternative approaches in treatments for HIV/AIDS

Tied into a history of ethical conflicts in vaccine research, is a history of contested cures, studies and alternative treatments for HIV/AIDS. As early as 1986, Dr. Basil Wainwright marketed his infamous cure, Polyatomic Apheresis,[197] which he alleged worked by bombarding the blood with oxygen and that would then convert one's status from HIV positive to negative.[198] He claimed to have conducted extensive studies abroad and to have received authorisation to treat people living with HIV/AIDS (PLWHA). Under pressure from the public and the scientific and medical community, the Ministry of Health investigated his background including his claims about a research partnership with UoN, and about the research, use and accreditation of Polyatomic Aphaeresis in other countries.[199] He was discovered to be a fraud and a wanted person in the United States and United Kingdom; Polyatomic Aphaeresis was banned and a deportation order was issued against him.[200]

In another case, in 1996, Professor Arthur Obel, a prominent virologist at the University of Nairobi, announced his invention of "pearl omega", claiming he had treated or carried out trials with 77, 000 PLWHA who had benefited from or had

[197] See generally Zachary Ochieng, "Controversy mars search for Aids cure in Africa; Pseudo-science and money mania have clouded past efforts aimed at coming up with an Aids cure" *News from Africa* (7 August 2006) online: News from Africa <http://www.newsfromafrica.org/newsfromafrica/articles/art_10749.html>.
[198] Vaishalee Patel, "Clinical Trials in Kenya" (Report on study, SOMO Centre for Research on Multinational Corporations Amsterdam, Amsterdam May 2006) at 38, online: SOMO <http://somo.nl/publications-en/Publication_3012/?searchterm=>. [Patel].
[199] *ibid* at 38-39.
[200] Kwena *supra* note 83 at para. 31-43.

been cured by this treatment. Professor Obel refused to reveal the formula and information on the clinical trials he had conducted, stating that he feared his invention would be stolen. He also refused to present "pearl omega" for registration with the Pharmacy and Poisons Board or to publish his results in medical journals.[201] The Minister for Health and the Poisons and Pharmacy Board of Kenya banned the sale of pearl omega stating, "[P]rof. Obel's behaviour has been unorthodox and against all protocol and etiquette in a field where the rules are clear cut, his unorthodox procedure is not expected of researchers."[202]

An activist group, the Kenya AIDS Society, was not satisfied with the government position, and sued Professor Obel for fraudulently marketing "pearl omega", a false cure.[203] In a surprising turn of events, the court supported Professor Obel, stating that it was willing to take its chances with any treatment that offered a cure and that the Kenya Aids Society had no interest in the suit. No doubt the court was persuaded by Professor Obel's professional standing at the time. Two competing interests emerge in this case, the need to encourage and protect research and the need to protect participants and PLWHA. This finding indicates that the legal system would tolerate HIV approaches that combine alternative treatments with scientific approaches, due to the potential for benefit and to public pressure. In this respect, the judgement encourages researchers who are linked to the public system.

Dr. Basil Stone and Professor Obel had supporters, among them prominent public figures who argued that since "pearl omega" was not harmful, Prof. Obel should be given a chance to treat PLWHA.[204] Rachier has discussed other HIV/AIDS research associated events where products such as Immunex, KEMRON, Pearl omega regarded as ineffective cures were marketed in Kenya and notes the

[201] Patel *supra* note 198 at 38.
[202] Kwena *supra* note 90 at para. 31- 43
[203] *Arthur Obel supra* note 115.
[204] Kwena *supra* note 90 at para. 31- 43 (Assistant Minister of Health Basil Criticos, Vice-chairman of Pharmaceutical Society of Kenya, Mt. Kenya branch Dr. Edward Kamamia and a leading psychiatrist Dr. David Ndetei are some public figures who supported Prof. Obel).

"[e]thics of research were grossly abused, in most cases ethical clearance committees' approval was ignored" highlighting an urgent need for more regulations and protections.[205]

The implications of this history of controversial cures in HIV/AIDS and of alternative HIV/AIDS treatments and cures has been twofold: (1) in response to the concern and outcry about the exploitation of public and PLWHA using pseudo science to market sham cures, the government has developed strong mechanisms to protect participants in vaccine research, and (2) there is an unmet need for updated and timely information about scientific developments in vaccine research, evidenced by the willingness of the public and some authorities to trust alternative approaches so long as there is a sheer patina of scientific research.[206]

Religion and HIV/AIDS

Faith healing for HIV in Kenya is a growing concern; newspapers reports, advertisements and jurisprudence indicate that faith healing for HIV/AIDS is on the increase,[207] and may draw the public away from scientific and state sponsored approaches to HIV/AIDS. In a recent criminal case, *Re v. Lucy Nduta*, a self-proclaimed prophetess was sentenced to two years in prison after being found guilty of defrauding her victims of property by pretending she could cure HIV through prayer.[208] In a well-designed operation carried out between 2004 and 2005, Lucy Nduta had promised to convert the status of persons living with HIV/AIDS through prayer in exchange for payment. She would then arrange for the "cured" person to undergo a HIV test at a clinic with which she had previously arranged to falsify test results. She was discovered when one believer

[205] Rachier *supra* note 3 at 1.
[206] Both Wainwright and Obel claimed to have carried out studies and in *Arthur Obel*, the defence succeeded in part because Obel claimed to have carried out studies with over 50,000 people, which claim that the court took at face value, *Arthur Obel supra* note 115 (court did not investigate claims that Pearl omega had been undergone successful trial with a large cohort of PLWHA).
[207] See generally, Natoro Kamau & Juma Namlola, "Clerics dismiss AIDS-healing claim" *Daily Nation [Kenya]* (22 May 2006) online: Daily Nation <http://www.nation.co.ke/>.
[208] *Re v. Lucy Nduta*, 2009 HCC, See generally, Sam Kiplagat, "Aids cure pretender can't raise cash bail" *Daily Nation* (9 March 2009) online: Daily Nation <http://www.nation.co.ke/>.

who had transferred her property in exchange for a prayer cure, went to an alternative clinic for an HIV test and found she was still HIV positive. Further police investigations revealed that there were several victims.
The court found that there was a duty to protect citizens from those who wish to take advantage of the urgency and despair surrounding HIV. This decision raises the standards of protection for research participants in HIV vaccine research, indicates a change in attitude for state institutions and a willingness of the law to engage with HIV to protect the public, reflecting the growth and maturation of the *Guardian* role.

The differences in legal approaches between the case of *Arthur Obel* and that of *Re vs. Lucy Nduta* points to a diversity of roles for state in HIV/AIDS including in HIV vaccine research and highlights the competition between two interests associated with different roles. In one case, the court stepped in to protect PLWHA whereas in the Obel case, the court supported the researcher. Alternative treatments and faith healing have drawn support away from preventative methods that rely on science, and their popularity may be influenced by the lack of affordable and accessible HIV treatment and prevention methods.

A prominent issue affecting approaches to HIV/AIDS in Kenya is the clash between religious doctrines that prohibit the use of condoms and science-based prevention approaches that promote their use. This clash exists despite the accommodation of faith-based approaches into the national education and awareness programs. Two established religious groups, the Catholic Church and the Council of Imams of Kenya have been vocal against the promotion of condoms to prevent HIV transmission arguing that it encourages promiscuity among the youth.[209] In a recent statement that supported the Catholic Church's position in Kenya, Pope Benedict XVI denounced the use of condoms to prevent HIV and discredited their efficacy in preventing HIV.[210] The influence of this

[209] See Kwena *supra* note 83.
[210] Riazut Butt, "Pope claims condoms could make African Aids crisis worse, Pontiff's remarks on first visit to continent outrage health agencies trying to halt spread of HIV and Aids" *The*

religious position on state participation in vaccine research is not clear and few studies look at this issue. Nevertheless, because of the increasing public discordance on this issue, it is questionable whether religious influences that oppose non faith-based approaches can continue to coexist within the state program for HIV/AIDS.

Religious influences may be detrimental to HIV vaccine research in that when established religious groups and popular religious leaders discredit the efficacy of condoms and ART treatment, they question scientific approaches and undermine public faith in the use of science in HIV/AIDS, conflating with suspicions arising from colonial and postcolonial issues. On the other hand, the government may avoid engaging the religious groups on the issue of condoms so as not to loose their support on other HIV/AIDS issues including vaccine research.

Culture and tradition

An underlying thread of the domestic and global issues in HIV/AIDS and in vaccine research is the impact of culture and tradition on HIV Vaccine research. Karori Mbugua, a Kenyan philosopher looking at ethical issues in health, asks the pertinent question: "[I]s there an African bioethics."[211] He argues that African bioethics should be firmly rooted in African philosophy and should avoid "bioethical colonialism"[212] where a western bioethical approach superimposes western values and culture over African values and culture. Mbugua points out "[o]ne important characteristic that should distinguish African bioethics from western bioethics is that African culture places considerable value on conformity of the individual to a social group,"[213] which is in contrast to the western values of autonomy and a more individualistic culture.

Guardian, (17 March 2009), online: The guardian <http://www.guardian.co.uk/world/2009/mar/17/pope-africa-condoms-aids>.

[211] Karori Mbugua "Is There an African Bioethics?" (2009) 19 EUBIOS 2 at 2-5 [Mbugua].

[212] *ibid* at para 3.

[213] Mbugua *supra* note 211 at para. 18.

To illustrate the difference in values and culture and the effect of western bioethics, Mbugua notes the standard practice for research in African communities, which is to secure the consent of the whole community in addition to the consent of the individual participant. In such circumstances, seeking only individual informed consent will isolate the individual from their community and its' social support system and perpetuate the vulnerability of marginalised individuals who are often enrolled in vaccine research. The influence of cultural values on the framework for vaccine research is evident in the *Vaccine Guidelines,* which mention the need for cultural sensitivity when carrying out research.[214] However, there is a need for in-depth studies that focus on the impact and effect of culture on the vaccine research framework and on the role for the state in HIV vaccine research.

Summary

Chapter two identified powerful undercurrents in HIV vaccine research that would not have been easily visible had I approached the role of the state in vaccine research as singular, linear and hierarchical. In the domestic environment, I found that historical influences were formative to the role of the state as *Researcher* and past events had led to a strong state as *Researcher* taking up position in the international frontline of HIV vaccine research.

Moreover, the role of *Regulator* and *Guardian* has developed to meet a perceived gap in protection. Religion and alternative HIV/AIDS treatments and approaches emerged as notable interests influencing Kenyan attitudes and beliefs towards scientific approaches in HIV/AIDS including vaccine research. The government is aware of religious influences and the popularity of alternative approaches. The state overtly allows for religious and alternative approaches in HIV/AIDS prevention and tacitly allows some of the contested cures and thus compromises some roles: (1) the *Researcher*, by allowing unregulated "researchers" to make scientific claims, and (2) by allowing for religious influences and alternative

[214] *Vaccine Guidelines* supra note 13 c. 3 (discussion of social cultural issues to be addressed).

treatments in HIV/AIDS prevention and treatment national approach which makes it difficult to regulate these influences in the vaccine approach. Other roles such as the *Facilitator-Sponsor* and *Participant* are developed to bridge the gap in resource disparity and the distance between the researchers and participants.

Chapter Three
Multiple Roles for the State in HIV Vaccine Research in Kenya.

Introduction

Chapter three synthesizes in detail the multiple roles for the state within the current HIV vaccine research framework. I outline the instruments used for each role, and map out the legal, regulatory and policy provisions for each role, their active parties and institutions and outlines the activities and practices for each role. In addition, I explain the linkages among the roles and among the instruments and note the gaps among roles and the interdependencies among the roles.

3.1 The Vaccine Research Framework in Kenya

Chapter two showed that state participation in vaccine research is indelibly shaped by contextual influences from as early as pre-independence Kenya. The legal and institutional framework for HIV vaccine research has mainly developed in the last ten years (1998-2008). Prior to 2004, HIV vaccine research was carried out under the general biomedical research framework regulated by the defunct "*The Research Clearance Procedures and Guidelines in Kenya*," 1984 edition,[215] and administered by the National Council for Science and Technology (the Council). Around the time HIV/AIDS was declared a national emergency[216] the HIV vaccine framework went through significant and rapid changes that coincided with a series of tumultuous events in HIV/AIDS research and in vaccine research.

[215] *NCST Guidelines* supra 86 note 15 at iv.
[216] *KAIS 2007* supra note 46 at 3 (date that HIV/AIDS was declared a national emergency).

Other changes in the HIV /AIDS environment included a proliferation of policy,[217] law,[218] regulations,[219] institutions and programs for HIV/AIDS and vaccine research.
In 2004, the Council updated the 1984 edition of guidelines into the *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya, No. 45*, (*NCST Guidelines).*[220] The following year, the Ministry of Health (MoH) developed the *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, 2005,*[221] (*Vaccine Guidelines*).

The vaccine guidelines were developed to address a perceived regulatory vacuum[222] and serve as a policy document.[223] The *Vaccine Guidelines* are subject to NCST Guidelines and other prevailing Kenyan laws,[224] whilst the *NCST Guidelines* cover biomedical research with participants generally but specifically refer to HIV vaccine trials.[225] Below, I describe and synthesize the multiple roles for the state.

Roles for the State in HIV Vaccine Research.

3.2. The Role of the State as *Guardian*

The role of the state as *Guardian* in biomedical research with participants is based on the common law duty of the state to protect her citizens and to safeguard her interests. This includes the duty to prevent harm to those citizens participating in research and to ensure that Kenya benefits from participation. The primary tool of

[217] *Kenya National HIV and AIDS Strategic Plan (KNASP)* 2005/06 – 2009/10 (Nairobi: National AIDS Control Council, 2006).
[218] *HIV/AIDS* Act supra note 58.
[219] See *Vaccines Guidelines supra* note 13.
[220] *NCST Guidelines supra* note 86 at iv.
[221] *Vaccines guidelines supra* note 13.
[222] *Vaccines guidelines supra* note 13 at vi.
[223] *Vaccines guidelines supra* note 13 at x (one of the functions of the vaccine guidelines is to "spell out policy issues affecting vaccine research).
[224] *Vaccine Guidelines supra* note 13 at 20.
[225] *NCST Guidelines supra* note 86 at 15 (regulations to have jurisdiction over vaccine development).

this role is law and includes the *Constitution of Kenya*, the *HIV /AIDS Prevention and Control Act* (*HIV/AIDS Act*), the *Science and Technology Act* (*S & T Act*),[226] the *Vaccine Guidelines* and *NCST Guidelines*.

The general legal basis for the *Guardian* is rooted in the *Constitution of Kenya*, which lays out the fundamental rights and freedoms and guarantees the right to "[l]ife, liberty, security of the person… and the protection of the law."[227] Citizens are entitled to protection from harm, confinement, and "[i]nhuman treatment,"[228] in all activities including HIV vaccine research. The *HIV/AIDS Act* supports this role by providing that:

> […] No person shall undertake HIV or AIDS related human biomedical research on another person or on any tissue or blood removed from such person except...(1) with the written informed consent of that other person…(and, 2.) unless such research conforms to the requirements under the Science and Technology Act or any other written law for the time in force.[229]

The above provision highlights the common tendency among the public, in government and in law to highlight the role of *Guardian* in comparison to other roles,[230] and may be in response by the negative image and incidents surrounding HIV and vaccine research.

The *S & T Act* sets up the Council,[231] which in turn developed the *NCST Guidelines*. The *NCST Guidelines* detail the rights and protection mechanisms for participants in all biomedical research, and the activities for the state with regard to the duty of protection of participants.[232] The *NCST Guidelines* delineate the

[226] *S & T Act supra* note 59.
[227] *The Constitution supra* note 59, s. 70 (a).
[228] *The Constitution supra* note 54 s. 71, s 72 & s74.
[229] *HIV/AIDS Act supra* note 58 s. 39 & s.40.
[230] The *HIV/AIDS Act* provides specifically for the protection of participants and in general calls for the state to take action against HIV/AIDS thus focusing on the role of guardian in comparison to other roles which do not have explicit legal provision in the Act.
[231] *S & T Act supra* note 59 s. 3.
[232] *NCST Guidelines supra* note 86 at iv.

Council as the hub[233] for research authorisation. Activities associated with the *Guardian* role centre at the Council and are carried out by its' the health research committee. They include research authorization, clearance and review for biomedical research with participants.[234]

However, the *Vaccine Guidelines*,[235] introduced the HIV Vaccine Subcommittee (VSC)[236] into the regulatory framework. The VSC is significantly involved in the research authorization and clearance process,[237] which was previously performed, and are still performed by the Council. The VSC has significantly changed the research authorization, review, and clearance process. Researchers intending to carry out vaccine research are now required to send a concept note of their research proposal to the VSC for preview. They receive feedback on this concept note which is "[I] n the form of advice and should not be construed to represent formal approval of the trial"[238] and thereafter submit their application for a research permit simultaneously to the Council, the VSC and the Pharmacy and Poisons Board.[239]

The VSC is intended to shorten and fast track research authorization, but the preview process used by the VSC may be repetitious, as it requires researchers to prepare and submit a concept note to the VSC and a full proposal to the Council. In addition, the feedback of the VSC is "merely advice" and thus serves a limited purpose in the authorization process and may create conflicts. There is no provision on what should happen if researchers seeking authorization ignore,

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[233] *NCST Guidelines supra* note 86 at 17 (should an application for research process be denied, the appeals process for research authorization ends with the decision of an extraordinary ethical review committee called by the council)
[234] National Council for Science and Technology "Research committee," online: National Council for Science and Technology <http://www.ncst.go.ke/research.htm> (details of the duties and functions for the council' research committee).
[235] *Vaccine Guidelines supra* note 13.
[236] *Vaccine Guidelines supra* note 13 at 25-6 (terms of reference and the role for the Kenya HIV Vaccine subcommittee in vaccine research).
[237] *Vaccine Guidelines supra* note 13 at 20 & 25-6 (the role of the VSC in the vaccine research authorisation process).
[238] *Vaccine Guidelines supra* note 13 at 20, (described as stage 1 of the new process of research authorization and clearance).
[239] *Vaccine Guidelines supra* note 13 c. 3 (role of the VSC).

disagree with, or disregard the VSC input and submit their application to the Council and the PPB anyway. According to the *Vaccine Guidelines*, the Council would have final veto power but differing views between the Council and the VSC disrupts the authorization process and introduces disharmony.

This authorization and clearance process is complicated and has many levels whose hierarchy is unresolved and this may lead to gaps in protection. For instance, local institutions such as KEMRI partner in international vaccine research but have independent and mandated review boards. It is unclear whether researchers working with KEMRI send concept notes to the VSC and receive feedback from VSC, and in the case that they do so, how to resolve the hierarchy and any differences in assessments between the VSC, the Council and the KEMRI Review Board.

Moreover, the VSC is a committee made up of government officers seconded from the Council, the PPB, and the Ministry of Health. Their terms of references do not clarify whether officers have the VSC committee added to their normal duties or they give up their original posting and duties, and there is high likelihood seconded officers may have other interests arising from other duties. In either case, it is likely that the officers who preview the concept note for facilitation may be involved in authorizing a research application.

Although neither regulation directly contradicts the other, their provisions for the process of research authorisation differ significantly. The *NCST Guidelines* were developed earlier and thus do not acknowledge the additional and valuable provisions in the *Vaccine Guidelines* for the research authorisation process such as standard forms for application, the policy on political, economic and socio-cultural issues, policy and regulations on training of human capacity and the regulations for the pre-trial activities.[240] There is a need to reconcile the *NCST* and

[240] *Vaccine Guidelines supra* note 13 Appendix 2-5, c.2c.9 and c.5 (provisions present in the Vaccine Guidelines but absent in the NCST Guidelines).

Vaccine Guidelines or at the very least carry out an impact assessment investigation that would look into the implementation and interaction of both guidelines as they fulfil the role of the *Guardian.*

One of the key duties of the *Guardian* is the protection of participants. The law, practice and public attention has been preoccupied with the concept of informed consent as the key instrument to achieve protection duties.[241] The *NCST Guidelines* emphasize the require informed consent from every recruited participant.[242] The *Vaccine Guidelines* strengthen the provisions for protection of participants. They provide detailed requirements for informed consent and include standard forms such as an informed consent checklist, sample consent information guidelines which investigators and research teams must conform to when obtaining consent, and a standard form of participants' rights. [243]

The other provision for Kenyan interests in vaccine research is the biological material transfer agreement[244] (MTA), which must be used for all transfers of material from Kenya to international destinations.[245] The above standards are supported by the requirement that all Kenyan collaboration must be acknowledged in all publications emanating from that research,[246] and the *NCST Guidelines*' provision for ethical review at mandated institutional Ethical Review Board (ERB), or at the Council.[247]

However, these provisions offer limited protection of Kenyan research interests. MTA's do not cover exchanges between local researchers and international researchers involving non-biological material such as the exchange of data. They may offer little protection and may even enshrine unequal relationships between

[241] HIV ACT *supra* note 58 Section 39. Also *NCST Guidelines supra* note 84 at 7 (guidelines note emphasis on the requirement for informed consent).
[242] *NCST Guidelines supra* note 86 at 7 &10.
[243] *Vaccine Guidelines supra* note 13 at 52-3, 54-9 & 61.
[244] *Vaccine Guidelines supra* note 13 at 63-65 (standard form for material transfer agreement).
[245] *Vaccine Guidelines supra* note 13 at 62-6
[246] *Vaccine Guidelines supra* note 13 at 15.
[247] *NCST Guidelines supra* note 86 at guideline 2.

local parties and international parties because they are often secret, and do not have designated procedures for negotiations, nor do they lay out a minimum standard of protection for local parties. Domestic parties can easily enter an unfair agreement or voluntarily give up significant rights to partners who may be better versed in protection of intellectual property procedures and may have well developed intellectual property systems in their home countries and institutions.

Furthermore, these provisions do not account for significant government involvement in vaccine research and the MTA does not address the fact that most of the researchers in a position to sign the agreement are public servants. Little is known about institutional practices such as KEMRI and UoN with regard to MTA or other agreements with international researchers to share benefits of research. Media reports of disagreements between local researchers based at KAVI and researchers from MRC, UK and the *Nyumbani* case highlight the vulnerability of local researchers carrying out research in a globalised environment. These incidents indicate that local researchers are unhappy with the current status quo and that the *Guardian* is falling short in its' aim to protect Kenyan researchers and Kenyan bio resources.[248]

The main challenge is that the *Vaccine Guidelines* and *NCST Guidelines* duplicate provisions for the role of the Guardian. This results to a confusion in responsibilities: the VSC and the Council both carry out research authorization, clearance duties, and in the case of the VSC, added facilitation duties.[249] Moreover, the focus on the protection of participants results in a missed opportunity to protect domestic researchers, host research institutions and the general interest of the public.

[248] In the *Nyumbani* incident, that occurred before the Vaccine Guidelines were prepared and updating of NCST Guidelines, a local partner, Dr. Moses Otsyula alleged that his data had been taken without his permission and an article published from information derived from his data. See chapter one and two

[249] Facilitation activities carried out by the VSC are discussed below under the *Facilitator* role.

3.3 The Role of the State as a *Regulator*

The role of the *Regulator* is closely linked to the role of *Guardian*: the duties of the *Guardian* and instruments used to implement the role of *Guardian* are based on regulations. The ability to protect any party in vaccine research depends upon a set of clear rules and regulations that outline rights and responsibilities for all the parties involved. The duty to regulate research falls intuitively on the state. The role for the state as *Regulator* and *Guardian* have the same legal basis and this creates confusion in understanding the aim of either or both roles.

The important distinction between these roles is that the *Regulator* creates a regulatory framework where safe and efficacious vaccine research can be carried out, while the *Guardian* uses the regulatory framework created to ensure participants, domestic researchers as well as host communities are protected and benefit from their participation in vaccine research. Most approaches in domestic literature do not differentiate the aims of these roles and thus conflate the roles of the *Guardian* into the *Regulator*: to regulate is seen as to protect.

The authority to regulate comes from two sources: the *HIV/AIDS Act* in section 39[250] affirms the responsibility of the council to regulate HIV research and the *S & T Act*[251] mandates the council to regulate a wide variety of issues including research for human health.

In order to fulfil its duty to regulate, the state has prepared two main instruments, the *NCST Guidelines* and the *Vaccine Guidelines*. The *NCST Guidelines* have three important features that augment the regulatory framework and expand the role of the state as *Regulator.* I focus on three aspects of regulatory framework as outlined by the *NCST Guidelines* because they are key to understanding the role of the state as *Regulator* and the gaps in fulfilment and implementation. These

[250] See *HIV/AIDS Act supra* note 58.
[251] *S & T Act supra* note 59 s.3 & 4.

aspects are rarely explored or discussed and yet they dispel commonly held perceptions that the vaccine framework is under-regulated.

Under the *NCST Guidelines*, research is to conform to international guidelines and thus International law such as the *Nuremberg Code* will apply in Kenya and may be used to supplement grey areas or provide clarification where Kenyan guidelines are silent. Secondly, the *NCST Guidelines* require that all international researchers should adhere to regulatory, scientific and ethical standards and practices in their home countries as well as in Kenya.[252] In addition, Kenya is a common law jurisdiction, and this allows for the application of case laws from other common law jurisdictions and even in from non common law jurisdictions if the question before the court is unique and unprecedented in common law jurisdictions. Although questions about research regulations, implementation and their interpretation have yet to be brought to court either in a civil cause or criminal court, the common law approach should influence the scope and practice of the state as *Regulator*. These aspects dispel the notion of Kenya as a regulatory vacuum. The perception of a regulatory vacuum may be due to the global and domestic contextual factors such as resource disparity, which prevent the regulatory reforms and implementations.

The *NCST Guidelines* provide "[a]ll research involving human subjects must be conducted in accordance with three basic ethical principles: respect for persons, beneficence and justice."[253] Using these principles, *NCST Guidelines* outline 15 basic rules for research[254] and provide for the "developmental processes" to be followed for all clinical drug trials including HIV/AIDS vaccine trials.[255] The Council carries out other regulatory activities such as setting research priorities areas, scrutinising research protocols for scientific validity, research clearance and

[252] *NCST Guidelines supra* note 86 at 16 (externally supported research must conform to the standards of the sponsoring country and international standards).
[253] *NSCT Guidelines supra* note 86 at 9.
[254] *NCST Guidelines supra* note 86 at 10-15.
[255] *NCST supra* note 86 at 15.

authorisation, and advice to government on research issues.[256] The *Vaccine Guidelines* incorporate most of the provisions outlined above, and go into more detail.

The main challenge for the *Regulator* role is the focus of regulation on the researcher–participant relationship, the underdevelopment of regulations in other areas and the lack of inbuilt mechanisms for implementation. There are limited provisions for the policing, prosecuting, remedying or punishing the flouting of regulations. It is unclear how the state would initiate a successful investigation and prosecution for wrongdoing in research.

3.4 The Role of the State as a *Participant*

The *Participant* is sometimes referred to as a "human research subject"[257] or the "research subject" in literature and regulations.[258] Two unique features in Kenya affect the fulfilment of multiple roles for the state in Kenya: an over emphasis on the protection of the individual participant in vaccine research through the principle of informed consent, and the emerging role for the state as a collective *Participant*.

In general, participants are volunteers with full knowledge of the study, the risks and benefits. Participants in clinical trials for candidate vaccines are HIV negative individuals in good health, and at high risk of acquiring HIV.[259] The *NCST Guidelines* emphasize informed consent. Guideline 6 requires that

> […] For all biomedical research with involving human subjects, the investigator must obtain the informed consent of the prospective subject, or in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorized representative.[260]

[256] *S & T Act supra* note 59.
[257] *NSCT Guidelines supra* note 86.
[258] See, *Nuremberg Code supra* note 28.
[259] *Vaccine Guidelines supra* note 13 at 8.
[260] *NCST Guidelines supra* note 86 at 10-5.

Other provisions include the requirement of the provision of essential information to the participant, the prohibition against inducement of volunteers and a moratorium against activities that may unduly influence vulnerable groups.[261]

The interpretation of the above requirements has been problematic in the Kenyan vaccine framework, because individuals who are of scientific interest to researchers have to be at high risk of contracting HIV/AIDS or PLWHA who resist developing HIV despite high exposure and they have tended to be from vulnerable groups. Chapter two highlighted factors that may result in exploitation of vulnerable participants enrolled in vaccine research. For instance, vulnerable participants may consent while under a false perception that there are hidden benefits to participation or may downplay or accept the risks involved, due to socioeconomic circumstances.

The second important feature of the *Participant,* is a growing consensus and understanding in government approaches and practice to HIV/AIDS that defines a role for the state as a collective *Participant*. Globalisation of HIV/AIDS, has globalised the competition for resources to conduct research, and builds an emerging understanding of the role of the state as collective *Participant* that is supported by regulations, socio-economic policies, institutional mechanisms and activities. The *Vaccine Guidelines* require that overall permission must be sought from the *Regulator* before individual participants are recruited and that the candidate vaccine must be relevant and suitable for the whole region.[262] This suggests consent is being sought from a collective *Participant.* Other provisions in the *NCST Guidelines* support this understanding. For epidemiological studies or large studies, researchers are required to seek the agreement and cooperation of provincial authorities and are advised to pay courtesy calls to area authorities such

[261] *NCST Guidelines supra* note 86 at 12.
[262] *Vaccine Guidelines supra* note 13 at 24.

as chiefs.[263] Some researchers such as IAVI/KAVI now visit host sites and talk with local host communities and elders before recruiting participants.

This added interpretation of the state role as *Participant* in vaccine research is brought out in the *Vaccine Guidelines*, which provide for a new group, the Community Advisory Board (CAB). The CAB is described as:

> […] (A board) to facilitate dialogue between community members, study volunteers and researcher. Such a board is a committee of community representatives who are selected to advise and guide the implementation of a given research protocol.[264]

This is a previously unexplored angle in state participation and government practice that is quietly developing. There is a need to highlight this role and evaluate its' significance in the vaccine framework. This would include recording and reviewing the activities of CABs and publishing information about current CABs.

Although I have included the CAB as the main instrument of the state as *Participant*, the description given in the *Vaccine Guidelines* of the CAB functions suggest a use of the CAB in the role of *Facilitator*. Some functions of CABs, such as providing input on protocol design to researchers, feedback to researchers from the community, and providing information regarding traditional health beliefs of the population[265] suggests that the CAB is fulfilling the duties of the state as *Facilitator*.

On the other hand, the *Vaccine Guidelines* requires that members of CABs should be individuals and groups such as human rights activists, ethicists, lawyers, gender advocacy representative and community representatives. CAB members do not take part in the clinical trials but influence community attitudes and are chosen from the target population for recruitment. These guidelines for the

[263] *Vaccine Guidelines supra* note 13 at 14.
[264] *Vaccine Guidelines supra* note 13 at 14.
[265] *Vaccine Guidelines supra* note 13 at 14 (list of CAB functions that meet facilitation duties).

composition of the CAB suggest a role as *Participant*, and provide an unprecedented opportunity to receive direct input from potential participants. However, the CAB does not manage to realise the full potential of this opportunity. Although research teams are required to form a CAB they are not bound by the input of the CAB, reducing the potential impact of their input. In addition, CAB members are supposed to be identified through community forums, but are appointed by the principal investigator who also draws up their terms of reference. Without the provision of a clear process to identify and choose members, the CAB may be perceived as open to influence from researchers and a tool to serve their interests.

Due to the double orientation of the CAB, its' perceived lack of autonomy and its underdeveloped mechanisms, neither of these roles achieves full effect in the CAB. However, the state already has strong institutions such as the National AIDS Control Council who implement the role of *Facilitator* while the role of state as *Participant* can only be expressed through CABs. For this reason, I would recommend the CAB be dedicated and empowered to achieve its full potential as *Participant.*

3.5 The Role of the State as *Researcher.*

The instrumental regulations and policy for the *Researcher* are found in the *Vaccine Guidelines* and *NCST Guidelines*. The NCST Guidelines require all researchers to be

> "[s]cientifically qualified persons … under the supervision of clinically competent person."[266]

In practice, this means every researcher conducting vaccine research must either be a trained certified physician or trained in the specific area they will be investigating. For example, individuals wishing to carry out research looking into the HIV virus may be virologists. Researchers are required to submit their

[266] *N.C.S.T Guidelines supra* note 86 at 10.

curriculum vitae in their application. The *Vaccine Guidelines* provide a detailed list of the mandatory training and skills-set for the research team, which envisages a comprehensive team with a diverse and thorough set of skills.[267] The obligation to maintain this skills set is an ongoing duty for researchers and sponsors.

Certain public institutes, listed as KEMRI,[268] Kenyatta National Hospital, UoN and Eldoret Referral Hospital have standing research clearance that the Council will recognize.[269] All other individuals and parties, including non-profit organisations and foreign public research institutes (such as IAVI, NIH & MRC) must obtain research permits and seek affiliations with public institutions who have standing research clearance.[270] These regulatory provisions generate a role for the state as *Researcher* by requiring affiliations with public institutions. These legal and regulatory provisions effectively ensure the state has a monopoly on HIV vaccine research and lock out any independent, privately-sponsored, international or domestic HIV vaccine research.

Most vaccine studies have included international scientists in lead roles alongside senior local scientists with the skills, education, training and stature equivalent to that of the international researcher. These provisions and practices allow the state as *Researcher* to address some of the issues outlined in chapter two, such as a lack of resources, the need for training, the urgent need for a vaccine and allows the government to capitalise on existing infrastructure.[271]

In some respects, these provisions have led an unhealthy definition and understanding of researchers in Kenya. The combined effect of government

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[267] See *Vaccine Guidelines supra* note 13 c. 9. (list of mandatory skills: basic science research training for the scientists in cell and molecular biology, virology, immunology and vaccinology, public relations, clinical research, epidemiology, social and behavioural sciences)
[268] *S & T Act supra* note 59 s. 4 & fourth schedule (List of institutions with standing clearance to carry out biomedical research with participants).
[269] *N.C.S.T Guidelines supra* note 86 at 10.
[270] *N.C.S.T Guidelines supra* note 86 at 10.
[271] See *Vaccine Guidelines supra* note 13 c. 5 (research activities in preparation of vaccine trails.) Local teams often have ongoing or past research and have noted important information such as virological and epidemiological data that can cut years from vaccine research).

efforts to channel all vaccine research into a tightly knitted framework, and of state domination of vaccine research inhibits the growth of independent possibilities for vaccine research, and curtail the domestic capacity for the review and criticism of the government's agenda and results from research. Local scientists rarely review HIV vaccine studies and results and this may because most of the scientific capacity to review vaccine research may be involved or linked to state funded vaccine research.

In addition, the law, regulations and institutions for the state as *Researcher* avoid engaging traditional and herbal medicine, by strictly interpreting the requirement that only scientifically qualified persons can obtain research authorization. This discourages herbal and traditional medicine practitioners from applying for research permits. In addition, public research institutes have been unable or unwilling to host traditional and herbal practitioners in biomedical research. The marginalisation of traditional medicine and herbal approaches in the HIV vaccine framework and the current orientation of the role of *Researcher* has harmful effects.

Scientists, herbalists and traditional medicine practitioners who use and research in alternative therapies and traditional medicine for HIV/AIDS are unregulated, and this has led to the rise of imposters and fraudulent practitioners who offer sham services and exploit desperate members of the public. A cursory examination of the advertisements in local newspapers, public notices and signboard in the major Kenyan towns show there are many such individuals who offer treatment, cures or prevention treatments for HIV/AIDS. This trend exploits public goodwill and hopes for an HIV vaccine and may lead to fatigue in HIV approaches and saturation of public interest in HIV research.

The sidelining of the herbalists and traditional medicine from the vaccine framework may lead to the loss of vital resources that could be co-opted into the search for an HIV vaccine. Traditional medicine relies on local knowledge of

plant properties and other local materials, and local culture. This knowledge may disappear and while it is difficult to speculate on what traditional medicine may offer, ignoring the potential of this knowledge is wasteful.

The domination of vaccine research by the state makes it difficult to implement other roles for the state because the framework does not acknowledge this monopoly. For instance, the provisions for protection of participants are geared towards protecting participants in interaction with international researchers or unidentified local researchers through an informed consent agreement. This ignores the high likelihood that most participants in vaccine research may only interact with public researchers at public institutions such as UoN or KEMRI. The law, regulations and mechanisms in vaccine research should be adapted to reflect this understanding of the *Researcher* and other roles developed to balance this understanding.

3.6 The Role of the State as a *Sponsor* and as *Facilitator*.

Facilitation and sponsorship are key features of modern research and especially of vaccine research. The Vaccine Guidelines have stated their mission and objective clearly:

> […] To promote ethical research, production and evaluation of suitable HIV/AIDS vaccines ...to facilitate research and development of vaccines that can either prevent HIV infection or delay the progression of disease,"[272]

and thus create a role for the state as *Facilitator* and as *Sponsor.* The lack of resources, resource disparities and the unequal relationships in international research create a need for sponsorship. Other factors such as religion, culture and politics all bring competing interests to vaccine research, which requires facilitation and mediation so that ethical and efficacious vaccine research can continue.

[272] *Vaccine Guidelines supra* note 13 at 1.

Local public institutions that sponsor and facilitate vaccine research include the Ministry of Health, KEMRI and the UoN, which serve as research sites and support research by providing staff to work in research teams by receiving and disbursing government funds and resources. International sponsors include IAVI-KAVI, the Walter Reed Army Institute, which fund vaccine research activities often through government institutions and departments such as UoN and KEMRI. Close interactions and resource disparity between local and international parties creates vulnerability that the state as *Sponsor* and *Facilitator* aims to address.

The main institution in the role of *Facilitator* is the VSC, which draws members from the Council, the PPB and the MoH. Terms of reference for the VSC outline the main function which is "[t]o advice and assist the Ministry of Health in formulating a national framework for HIV/AIDS vaccine research and development."[273]

The Council, NACC, NAVCSOP, and the Ministry of Health are instrumental institutions for these roles. They identify sites, participants for clinical trials and potential local partners, and provide the epidemiological, social behavioural data about HIV/AIDS required for vaccine research. The state as *Facilitator* has been immensely successful, if we go by the amount of HIV vaccine research activities facilitated and the challenge is to develop performance of other roles to be at par with the *Facilitator*.

Due their relative success, some of the institutions implementing the *Facilitator and Sponsor* become powerful in comparison to other institutions implementing other roles. The VSC and NACC are well-funded and international funds to HIV/AIDS programs (which form the bulk of the HIV/AIDS budget) are channelled directly through these institutions. This creates an imbalance of resources between roles: the roles of *Guardian and Regulator* are carried out by institutions such as the Council that are mainly supported through government

[273] See *Vaccine Guidelines supra* note 13 at 25 (outline of tasks for the vaccine that fulfil facilitation duties).

budget lines and receive much less direct international funds. The comparative financial success and independence (from government funding) of the *Facilitator* and *Sponsor* may undermine the independence of other roles, and push forward the interests of the state as *Facilitator* at the expense of other roles. For example, a hypothetical scenario would be if NACC and VSC encouraged researchers to submit a concept note and received substantial funds to support this research. They may push local researchers to become involved and for research authorisation because otherwise they may be required to return the funds if the research is not approved.

In addition, the role of *Facilitator* and *Sponsor* has a very narrow focus on addressing issues related to funding and research authorization and clearance and facilitating mainly the participation of international sponsors and researchers. This may be an unhealthy, since there are other equally pressing issues in vaccine research that the government needs to facilitate. This is a missed opportunity to address other issues and facilitate other interests. For instance, activities such as gazetting of research applications and research results, strengthening of the CAB, providing advice and support to local researchers and institutes entering agreements to conduct research may facilitate the participation of local participants and researchers.

Summary

Having previously noted the influence of the environment on state participation in vaccine research, Chapter three mapped out the law, regulations, policies, and institutions, mechanisms used in each role. I highlighted the interdependencies among the roles and the instruments and identified gaps and duplicities in each role that may cause issues and conflicts in vaccine research.

CONCLUSION

Discussion and Summary

This study examined vaccine research in Kenya and provided a background to HIV vaccine research in Kenya, wove together all the issues surrounding vaccine research into a strong narrative about the multiple role of the state in vaccine research. My synthesis is robust and can be easily adapted to other ongoing discussions about HIV research and vaccine research in Kenya and in sub-Saharan Africa. Specifically, my synthesis provides a useful perspective that may be incorporated into legal theories and regulatory approaches in vaccine research.

In my study, I found that there was a history of problems in HIV vaccine-associated research, which a proliferation of law, policy, regulations and practices had failed to address. Few discussions accounted for, or addressed, the complex involvement of the state in vaccine research, or understood the multiple roles for the state in vaccine research. There was an implicit understanding in discussions surrounding HIV vaccine associated research that the state had a general role in vaccine research and that the state participated in a hierarchical and direct manner in vaccine research. The pervasive understanding was that the main role for the state in vaccine research was to protect participants enrolled in vaccine research and a subsidiary role was to protect local researchers involved in vaccine research and to facilitate the international sponsorship of vaccine research.

Using theoretical tools outlined in the introduction, I unpacked and mapped out the complex participation in vaccine research into multiple roles for the state in HIV vaccine research, which I then described and analysed to find that the state's fulfilment of these roles is not uniform or coherent. Often there are gaps and duplications in implementation of these roles. Some of the interests that the state has in vaccine research are pursued to the detriment of other interests, leading to a discordant development of roles.

The common perception of the role of the state in vaccine research is of the state as a *Guardian-Regulator*, and this is directly related to Kenya's controversial history in vaccine research, postcolonial issues, and the North-South separation. Law is the primary tool for the implementation of this role. This has led to a limited understanding of the *Guardian*, which is oriented towards the protection of participants, and the overreliance on promulgation of regulations as the primary means to fulfil this role.

Law and subsidiary regulations are the primary instruments for the state as *Regulator*. Two major regulations surround this role; the *Vaccine Guidelines*, which focus on facilitation and sponsorship duties in addition to research authorisation and clearance, and the *NSCT Guidelines,* which provide generally for all biomedical research with participants. These guidelines do not directly collide, but their provisions are confusing especially with regard to the authorisation process and the HIV vaccine subcommittee (VSC). They need to be reconciled for the uniform implementation of all roles.

The state as *Facilitator* is closely intertwined with the state as *Spons*or, and its' main instruments are the *Vaccine Guidelines*, the VSC, NACC, and the Ministry of Health. This role is comparatively strong and active within the vaccine research framework and this is related to its' relative financial independence. Furthermore, institutions associated with the *Facilitator-Sponsor* such as the VSC and CAB are used to implement multiple roles, the VSC is used in the authorisation process and to facilitate HIV vaccine research while the CAB is used to facilitate research and has the potential to include local participation in research. The CAB has an underutilised potential in the role of *Participant*.

The *Researcher* is one of the oldest roles in vaccine research in *Kenya*, and the most notable aspect of this role is that it is unacknowledged and as a result, rarely evaluated. The regulations for vaccine research, the activities of the Council and

VSC are geared towards international research and thus fails to address aspects arising from direct state involvement in vaccine research. This is a primary gap in the vaccine framework and contributes to conflicts, and issues such as those discussed in chapter one and two.

In brief, the present environment causes the development of diverse roles for the state whereby: (1) the state focuses on implementing the role of *Facilitato*r such that it eclipses other roles in performance, (2) there is a limited understanding that the main role of the state is to protect participants and (3) there is a lack of acknowledgement of significant involvement of the state as *Researcher*.

My discussion can be read as a basic description and explanation of vaccine research in Kenya, and as a map to orient or ground other discussions on the moral, ethical framework for vaccine research. The descriptive synthesis of the HIV background in my study brings a rich local perspective to approaches in medical and research ethics. It can be read as a tool to evaluate the governance model in HIV vaccine research and the social, health, ethical, legal outcomes of this model.

Limitations and Recommendations

My discussion revealed there is an urgent need for further investigation on the issues in HIV vaccine research and on the role of the state in HIV vaccine research in Kenya. I found that many areas that I looked at were under-examined, some issues are forgotten and yet the stakes involved in issues surrounding HIV vaccine research are very high. Due to the limitations in scope and size, I had to be brief in my investigation of issues. For instance, while I was able to identify key factors in the environment that influence vaccine research, I could only skirt their interaction and impact and would have liked to examine further issues such as religion and culture in depth, and evaluate their effect on HIV vaccine research and on the role of the state. For the same reason, my description of the roles for

the state in vaccine research had to be brief so as to accommodate a discussion about the formative environment and I believe each of these roles deserved a detailed, in-depth synthesis as their implication for vaccine research Kenya are profound.

Another serious limitation in this study was the lack of literature, limited access to literature available, and a lack of variety of local perspectives on vaccine research and related topics. There are few publications in sub-Saharan Africa: only one medical journal in East Africa, several medical journals in sub-Saharan Africa and a handful of law journals in Sub-Saharan Africa. All monographs published on these issues are published and distributed outside Kenya in small, limited circles. My intention was to maintain a Kenyan and pan-African perspective. As a result, I relied on literature from conferences attended by local authors, and on reports commissioned largely by local and international NGO's and public institutions, which I obtained through extensive research over the internet, through word of mouth and networking.

Two issues arise from my literature review and my discussion. Due to under development of domestic literature and the lack of local perspectives, valuable insights and irreplaceable expertise in this region and on this topic are lost and with it, a conduit for the voice of those who should be most concerned about vaccine research. In addition, the lack of domestic literature on HIV/AIDS and vaccine issues, suggesting that only state sponsored perspectives are likely to prevail. In both respects, this study has addressed an important issue, it has highlighted a crucial gap in literature and outlined areas that could benefit from further study.

During my study, it was difficult to maintain a balance between the scope and depth of my synthesis. Few commentators and authors have applied governance approaches to HIV research and vaccine research issues, looked comprehensively into policy development and implementation for health and research issues in

Africa or approached the role of the state from a governance or multidimensional perspective. Combining these approaches was challenging but necessary to provide a true representation of vaccine research in Kenya. My synthesis highlighted issues in vaccine research and sometimes raised more questions than it provided answers. This is an unexpected benefit, questions on HIV vaccine research are not being articulated despite their significance and this may encourage further study on issues in HIV vaccine research.

In brief, I would recommend the development and adaptation of regulations to support: 1) a collective understanding of the role of *Participant*, 2) the monopoly of public institutions in its role as *Researcher*, *3*) the distinction between the duty to regulate and of protection, and 4) the harmonisation of the *Vaccine Guidelines* and *NCST Guidelines.* Institutions that would benefit from a review of the goals, and practices include the VSC, the Council and the CAB.

Although the government shows an awareness of its' multiples role in vaccine research, there is a need to fully adopt and maintain this nuanced understanding, and this would enable the state to maintain diversified interests in vaccine research.

APPENDIX

1. HIV Vaccine Research Participation Chart

Roles	PARTIES	Legal and regulatory provisions	Activities carried out in this capacity,	Mechanisms used and/or programs
Guardian	National Council for Science & Technology **(**the Council)	*HIV & AIDS Control & Prevention Act (HIV Act) section 39, Constitution of Kenya, Chapter 74.*	Research authorisation & clearance, advising government, monitoring HIV vaccine research & developing of research priorities.	Research permit, inspection of research sites,
		Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines.	Safeguard interest of Kenya researchers, research institutions & participants.	Biological material transfer agreement
Regulator	National Council for Science and Technology (the Council)	*Guidelines for Ethical conduct of Biomedical Research Involving Human Subjects in Kenya.*	Research authorisation & clearance, advising government on HIV vaccine, maintain research reports.	Research permit, inspections of research sites, recommendations to Government offices.
		Science and Technology Act section 4 & fourth schedule.		
		HIV & AIDS Control & Prevention Act (HIV Act) Section 3 & Section 40.		
	Kenya HIV Vaccine Subcommittee (VSC)	*Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines.*	Review of concept note of HIV vaccine clinical trial.	Preview research proposal.
	Poison and Pharmacy Board (PPB)	*Poisons and Pharmacy Act, Cap 244 (2002). Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines*.	Evaluate HIV candidate vaccines for safety, immunogenicity, potential efficacy, and review clinical and preclinical data.	Research authorization & clearance.
	Data and Safety Monitoring Boards DSMB	*Kenya National Guidelines for Research Development of HIV/AIDS Vaccines.*	Monitor data from Vaccine trials for safety of participants & validity & integrity of data.	Mechanism yet to be recorded or observed.
	KEMRI Ethical review	Have standing research clearance to	Authorize and review HIV vaccine	ERC authorization &

	board (ERC), Kenyatta National Hospital ERC	self regulate through institutional Ethical Review Boards.	research within institution, Review ongoing HIV vaccine studies.	clearance.
Physician	Ministry of health, Public healthcare system: Kenyatta National Hospital & Eldoret Referral Hospital.	*HIV & AIDS Control & Prevention Act (HIV Act) Section 3. Constitution of Kenya, chapter 71, 74.*	Treatment of HIV/AIDS, collection of HIV/AIDS data, Create government policies, & strategies for HIV/AIDS.	Kenya National HIV & AIDS Strategic Plan KNASP, Kenya demographic Health Survey (KDHS).
	Aga khan Hospital- University of Aga khan. (Private hospital)		Capacity to carry out HIV research	No recorded HIV /AIDS research.
Researcher.	**University of Nairobi- Kenyatta National hospital. Kenya Medical**	*University of Nairobi Act, Section 7.*	Host vaccine trials, host research site and conduct vaccine research.	
	Research Institute KEMRI- Walter reed Project.	*Science and Technology Act fourth schedule.*		
	Wellcome Trust, Harvard AIDS Institute, United States Centre for Disease Control & prevention (CDC), National Institute for Health (NIH) HIV/AIDS Vaccine trial network.		Conducting HIV/AIDS vaccine research in Kenya.	
Participants	Individuals		Participate in vaccine trials as human subjects.	Informed consent.
	Community Advisory Boards (CAB)		Facilitate dialogue between researchers, participants, & the community hosting	

			the research site.	
	People Living With HIV/AIDS (PLWHA)& other activists		Activism & Advocating for HIV/AIDS issues	
Sponsor	National AIDS Control Council NACC	NACC Mandate/ Terms of reference	Fund & provide resources for HIV vaccine research,	National AIDS & STD Control Programme NASCOP Kenya HIV/AIDS Research Coordination Mechanism (KARSCOM).
	Kenya AIDS Vaccine Initiative (KAVI) – International AIDS Vaccine Initiative (IAVI).		Fund HIV vaccine trials in Kenya.	
Facilitator	National AIDS Control Council NACC	NACC mandate		Kenya National HIV & AIDS Strategic Plan (KNASP).
	Kenya HIV Vaccine Subcommittee VSC	*Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines*.	Expedite review of research proposal.	Preview of concept note.
	Ministry of Health		Collect and maintain epidemiological information about HIV /AIDS, indentify cohorts or research sites	**National AIDS and STD Control Programme NASCOP**
	Kenya AIDS Vaccine Initiative & International AIDS Vaccine initiative. KAVI, IAVI		KAVI liaises between the state & International sponsors, IAVI, advocate for partnerships with public institutions.	

2. List of ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretrovirals
CAB	Community Advisory Boards
CDC	Centre for Disease Control and Prevention, U.S.
ERC	Ethical Review Committee
IAVI	International AIDS Vaccine Initiative
IRB	Institutional Review Boards
HIV	Human Immuno-Deficiency Virus
KAVI	Kenya AIDS Vaccine Initiative
KEMRI	Kenya Medical Research Institute
MoH	Ministry of Health, Kenya
MRC	Medical Research Council, UK.
MTA	Material Transfer Agreement
NACC	National AIDS Control Council, Kenya
NASCOP	National AIDS/STD Control Programme, Kenya
NCST/ The Council	National Council for Science and Technology, Kenya
NCST Guidelines	Guidelines for the Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya
NIH	National Institutes for Health Research, US
Nuremberg Trials	Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 Vol 2, Nuremberg
PLWHA	People Living With HIV/AIDS
PPB	Pharmacy and Poisons Board
S & T Act	Science and Technology Act, Kenya
UNAIDS	Joint United Nations program on HIV/AIDS
UoN	University of Nairobi, Kenya
VCT	Voluntary Council and Testing

VSC	Vaccine Sub-Committee, Ministry of Health
WHO	World Health Organization
Vaccine Guidelines	Kenya National Guidelines for the Research and Development HIV/AIDS Vaccines

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