LEGAL, POLICY AND INSTITUTIONAL FRAMEWORKS REGARDING RESEARCH ETHICS COMMITTEES IN ZAMBIA

By

Nancy Soko

Student Number: **208529731**

Submitted in partial fulfilment of the Degree of Master of Social Science in Health Research Ethics in the School of Psychology, Faculty of Humanities, Development & Social Sciences, University of KwaZulu-Natal.

Supervised by

Prof. Douglas Wassenaar

South African Research Ethics Training Initiative (SARETI)

School of Psychology,

University of KwaZulu-Natal

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DECLARATION

Submitted in partial fulfillment of the requirements for the degree of Master of Social Science, in the Graduate Programme in Psychology, University of KwaZulu-Natal, Pietermaritzburg, South Africa.

I declare that this dissertation is my own unaided work. All citations, references and borrowed ideas have been duly acknowledged. It is being submitted for the degree of Master of Social Science (Research Ethics) in the Faculty of Humanities, Development and Social Science, University of KwaZulu-Natal, Pietermaritzburg, South Africa. None of the present work has been submitted previously for any degree or examination in any other University.

Nancy Soko

(Signature)

Abstract

This study investigated existing legal, policy and institutional frameworks and how they appear to impact on the functioning of research ethics committee in Zambia. It identified and analysed existing national guidelines, policies and legislation; highlighted the strengths and weaknesses and discussed factors contributing to the legal, policy and institutional frameworks regarding research ethics committees in Zambia. The study utilised qualitative methodology for data collection, including in-depth interviews and document reviews.

The study found that the policy, legal and institutional framework guiding the conduct and ethics oversight of public health research in Zambia is weak and fragmented. In Zambia, research ethics committees depend on international guidelines and principles for their formation and functioning. The establishment of a national institution mandated to coordinate public health research, to guide the formulation of policies and legislation, and to oversee the formation/ creation and functioning of RECs in Zambia is recommended.

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1. INTRODUCTION

Health research has experienced unprecedented changes and growth in both the developed and developing countries over the past few decades. However, medical research and its history of abuse and exploitation of human participants, makes the issue of regulating research both topical and important (Plomer, 2005). Furthermore, although the growth in biomedical research has generally been beneficial to humankind, the changes have come with increasing complexities and have increased the challenges faced by research ethics committees (RECs) mandated to protect the increasing numbers of human participants in health research (Nyika, Kilama, Tangwa, Chilengi & Tindana, 2008). When doing research with human participants, there are always uncertainties that raise the prospect of unanticipated harm. There can therefore be conflicts between the need to produce new information to improve health and the requirement to respect and protect individuals who participate in research. Such conflicts and the resulting tensions that can arise within the research enterprise necessitate the need for guidance and oversight (Chima, 2006; Plomer, 2005).

The importance of ethics regulation in ensuring adherence to international and local ethics principles for human research participants' protection has clearly been noted (Chima, 2006). Ethical review by a local REC remains an important aspect of both local and international research involving human participants, and obtaining dual review in multi centre proposals should be of concern to researchers. Therefore, in the case of research in developing countries, a balance has to be found between the duties of external sponsors and what is expected by the host country. The duties of the sponsors concern not only the adequate protection of research participants but also developing the capacity of the host country's ethical review process. Thus,

host country sponsors have in counterpart the obligation to determine and support the strengthening of an adequate system of ethical review of research involving human participants.

Since the end of World War II, ethical and scientific standards for conducting biomedical research on human participants have been enshrined in a number of international guidelines and legally binding conventions, including among others, the *Nuremberg Code* (National Institutes of Health, 2008) the Declaration of Geneva (World Medical Association, 1948), the International Covenant on Civil and Political Rights (United Nations, 1966), the International Code of Medical Ethics of the World Medical Association (World Medical Association, 1949), the *Declaration of Helsinki* (World Medical Organization, 1996, revised 2008, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS, 2002), the WHO Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO, 2000) and the International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice([ICH], 2002), and the Nuffield Council Report (2000).

Of particular interest in more recent years however, has been the emergence of Africa as an area of interest for international collaborative biomedical research (Ayle, 2003; De Cock 2002; Parker & Bull, 2009; Schulz-Baldes, Vayena & Biller-Andorno, 2007). The increase in collaborative research in Africa is not bad in itself. It is clear that these new developments in health research have brought many improvements in public health and research ethics regulations in Africa. "Diseases that had struck fear and dread into the lives of our parents and grandparents – yellow fever, polio, rheumatic fever, etc. – no longer haunt our consciousness as was the case in the past" (Emanuel et al., 2003, p.15). Moreover, progressive-looking governments in Africa have

established mechanisms for coordinating and regulating the growing field of health research in their respective countries (Chima, 2006).

However, this increase in collaborative research in Africa means that existing RECs in Africa probably have to review increasing numbers of protocols and that many studies become more multifaceted than most African RECs are familiar with (Chima, 2006). The fact that such studies are usually undertaken in collaborating institutions in developing countries that generally have inadequate expertise and technology to perform some of the more complicated research procedures, makes it likely that some research participants are bound to be exposed to research that has not been adequately reviewed and in which risks may not have been adequately identified or minimised (Chima, 2006). The possibility that vulnerable people (and even countries) might be exploited is a cause for concern in resource-poor settings that lack sufficient protection for human participants of research (Macklin, 2004). Developments in this regard have tended to vary markedly. In Africa, developments in both policy and practice vary from some developed countries with highly trained ethics experts, highly developed ethics institutional frameworks, policies and legislation, to others where none of these exist (Onuoha, 2007).
The task of this research study therefore was to investigate the legal, policy and institutional frameworks that govern the conduct of research with human participants in Zambia. The study endeavoured to capture the extent to which existing legal, policy and institutional frameworks enhance and/or hinder effective ethics governance in research in Zambia. Understanding how Zambian research ethics committees function and the legal, policy and institutional factors that could affect their establishment and functioning is essential for identifying challenges, strengths

and possible improvements in research ethics governance in the country (De Vries & Forsberg, 2002).

With this introduction, the report will proceed to a detailed review of existing relevant literature before moving on to the methods of the study. After the methods, the results of the study will be presented followed by the discussion of the results. The thesis will end with the conclusions and recommendations for future research.

2. LITERATURE REVIEW

It should be noted from the outset that most literature examining research ethics committees comes from developed wealthier countries (Hyder, Harrison, Kass, & Maman, 2007). However, a number of studies and writings by emerging African ethics experts and others by Western writers interested in Africa-specific experiences and challenges have endeavoured to better understand the landscape of ethics review in Africa (Ahmad, 2003; Chima, 2006; Cleaton-Jones & Wassenaar, 2010; Ikingura, Kruger & Zeleke, 2007; Hyder et al., 2007; Kirigia, Wambebe & Baba-Moussa, 2005; Milford, Wassenaar & Slack, 2006; Nyika et al., 2008). These writers have focused on various areas of interest, including among others, the importance of Research Ethics Committees (RECs) and other policy and regulatory frameworks (Ahmad, 2003; Chima, 2006; Ikingura, Kruger & Zeleke, 2007); the history, structure and functioning of RECs (Kirigia, Wambebe & Baba-Moussa, 2005). The Johns Hopkins Fogarty African Research Ethics Training Program (FABTP), which has trained a number of African research ethics professionals reported on the status of 12 RECs to which some of the trainees were affiliated (Hyder et al., 2007); and those focusing on capacity building, resources and assessments of needs among African RECs (Milford et al., 2006; Nyika et al., 2008). Within these broad categories, many specific issues have been raised. This literature review highlights some of these issues by subject matter and various perspectives that have been raised by different writers.

2.1 Overview of International Guidelines in Research ethics

Although the Hippocratic Oath (Veatch, 1989) is perhaps the most recognised code of ethics that governs the medical profession, the development of the first international instrument on the ethics of medical research took place following the Nazi atrocities committed during the Second

World War. Following the Nuremberg trials of 1947, the *Nuremberg Code* was published to provide the international medical community with a normative framework that set out standards of ethical research and emphasised the fundamental notion of informed consent to research by participants (NIH, 2005). The *Nuremberg Code* thus serves as the basis of subsequent ethics guidelines such as the *Declaration of Helsinki*, which remains one of the most widely consulted ethics document to date (Carlson, Boyd & Webb, 2004; Schüklenk & Ashcroft, 2000). First issued by the World Medical Association (WMA) in 1964, the *Declaration of Helsinki* has undergone a number of revisions including (1975, 1983, 1989, 1996, 2000, and 2008) and sets out ethical guidance for physicians and other research personnel engaged in medical research involving human participants. The *Declaration of Helsinki* is further reinforced by additional international ethics guidelines such as those issued by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). The CIOMS and WHO released the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* in 1982, followed by further revisions in 1993 and 2002 (CIOMS, 2002). These guidelines are particularly geared towards research in developing countries and provide detailed information on various important aspects of ethics processes such as setting up ethics review committees, review of externally sponsored research and obtaining informed consent, as well as guidance on vulnerable populations such as children, pregnant women and populations with limited resources (CIOMS, 2002).

Although international ethics guidelines such as the *Declaration of Helsinki* and the CIOMS guidelines are not legally binding, they function as a 'moral code' that represents a global consensus on the importance of observing fundamental principles of research ethics, particularly

protecting the life, health, privacy and dignity of human participants and ensuring their voluntary participation in health research (Bhutta, 2002; CIOMS, 2002; Schüklenk & Ashcroft, 2000). They are also based on recognised general ethical principles of beneficence, non-maleficence ('do no harm') and justice (Beauchamp & Childress, 2009; CIOMS, 2002; Dopplefeld, 2007).

Since the drafting of the *Nuremburg Code* (1949) and the *Declaration of Helsinki* (1964), additional guidelines and codes of conduct for ethical research have emerged. These include the *Belmont Report* (1979) issued by the National Commission for the Protection of Human participants of Biomedical and Behavioural Research in the United States and similar documents developed by medical and research councils in various countries. In addition, research ethics guidelines are increasingly supported by relevant national policies and legislation. In this respect, the Universal Declaration on Bioethics and Human Rights is a departure from other international guidelines in that the Declaration is all encompassing with more emphasis on governments, groups and other individuals rather than on physicians or researchers alone (Johnson, Realpe, Bouësseau, Solbakk & Saxena, 2008). This may reflect the shift from guidelines (which are normally not easy to enforce) to conventions and/or covenants in international law. Although not legally binding, the Declaration provides an intergovernmental framework for increased alignment of nation level polices and legislation with principals governing the conduct of ethical research internationally (Johnson et al., 2008).

2.2 Basic Ethics Principles for the Protection of Human Participants of Research

As it has been indicated already, although scientific research has produced substantial biomedical and social benefits, it has also posed some troubling ethical questions (Emanuel,

Crouch, Arras, Moreno & Grady, 2003). As a result, a number of principles relevant to research involving human participants have been identified. In certain literature such as in Emanuel et al. (2003), three main principles are highlighted while others, such as in Beauchamp & Childress (2009), four main principles are identified. However, regardless of which position one takes (with this thesis adopting the Beauchamp & Childress position), these are general prescriptive judgements whose objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human participants. Following is a discussion of the four basic principles highlighted by Beauchamp and Childress namely, Respect for persons (autonomy); Nonmaleficence; Beneficence; and Justice. (Note that other literature combine nonmaleficence and beneficence under a common heading of beneficence).

2.2.1 Respect for persons (autonomy): The principle of autonomy "comes, not from the Hippocratic tradition, but from the traditions of Kant and liberal political philosophy" (Veatch, 2003, p. 72). Respect for persons (or autonomy) incorporates at least two moral or ethical convictions, i.e., that any individual should be treated as an autonomous agent capable of making their own decisions concerning their person; and second, that those with diminished autonomy are entitled to even more protection (Emanuel et al., 2003). To respect autonomous agents is to acknowledge their right to hold views, to make choices, and to take actions based on their personal values and beliefs. Such respect involves respectful *action,* not merely a respectful *attitude* (Beauchamp & Childress, 2009).

However, not every individual is capable of self-determination. This capacity for self determination may be compromised because of being either too young, ill, mentally disabled, or

from circumstances that severely restrict liberty. As Hans Jonas once noted, "...the ideal research participant from an ethical perspective is one who can identify with the purpose of the research, understand and appreciate the details, and make a free choice about participation. Such participants can give informed consent based on a determination that research participation is compatible with their own interests" (Emanuel et al., 2003, p. 225). Thus, children (often legally and developmentally incapable of protecting their own interests), captive populations (such as soldiers, prisoners, students, etc., whose choices may be less than voluntary), persons with mental disorders, etc., need even more protection than individuals falling in the bracket described by Jonas in the previous statement. "Respect for immature and the incapacitated may require protecting them as they mature or while they remain incapacitated" (Emanuel et al., 2003, p. 34). There are debates on issues related to capacity for autonomous choice, the concept of competence, standards of competence, the meaning and justification for informed consent, standards of disclosure, and intentional nondisclosure (Beauchamp & Childress, 2009). However, in most cases, respect for persons demands that participants enter into the research voluntarily and with adequate information about the research. On the other hand, the principle of respect for persons (autonomy) requires that the vulnerable should also not be denied the opportunity to volunteer to participate in research if they so wish. There are strong moral reasons for permitting vulnerable populations such as children, prisoners, students, and the mentally ill to participate in research, especially possible long-term benefits to the individuals concerned and society at large. However, adequate protection for such research participants must be in place to ensure ethical conduct of research. Thus, in most cases, respect for persons is a matter of balancing claims urged by the principle of respect itself (Emanuel et al., 2003).

2.2.2 Nonmaleficence: The principle of nonmaleficence imposes an obligation not to inflict harm on others. In medical ethics, it has been closely associated with the maxim *primum non nocere* – meaning, "above all (or first) do no harm" (Beauchamp & Childress, 2009, p. 149). As was noted above, some philosophers combine nonmaleficence and beneficence to form a single principle. However, Beauchamp and Childress note that conflating nonmaleficence and beneficence into one principle only obscures important distinctions. They note that obligations not to harm (those related with prohibiting theft, disablement, killing, etc.) are distinct from those to help others (those related to providing benefits, protecting interests, and promoting welfare) (Beauchamp & Childress, 2009).

It would appear that the obligation to do no harm to others is more stringently applied than the obligation to help them. However, the reverse is also true. In general however, causing some risk – e.g., introducing some surgical harm, introducing social costs, and placing burdens on some research participants can be justified by the benefits of the actions (Beauchamp & Childress, 2009). The problem posed by the imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be forgone because of the risks (Emanuel et al., 2003).

2.2.3 Beneficence: It should be noted that persons are treated ethically not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their wellbeing – making them better-off. This relates to "maximizing possible benefits and minimising possible harm (Emanuel et al., 2003). In this regard, investigators and their institutions must give forethought to the maximisation of the benefits and the reduction of risk

that might occur from the research investigation. These beneficial actions fall under the heading of “beneficence” (Beauchamp & Childress).

It should be noted that the application of the principle of beneficence is not unambiguous. There are studies that present more than minimal risk and yet present no immediate direct benefits to the participants (e.g. Phase I clinical trials with healthy volunteers). Some have argued that such research is inadmissible, while others have pointed out that this limitation would rule out much research promising greater benefits to society in the future. Without such research, many valuable advances in medicine, treatment procedures and medical equipment could not have been developed. Medical research with human participants is therefore justified not only because it will benefit actual research participants but also because it seeks to generate knowledge that not only is of theoretical value but also will benefit many people and society as a whole. In this regard, like in many other situations, the principles covered by beneficence may come into conflict and force difficult choices (Emanuel et al., 2003). However, these principles do help researchers grapple with ethical dilemmas in that they provide some important concepts, tools, principles, and methods that can be useful in resolving such dilemmas (Resnik, 2010).

2.2.4 Justice: Such terms as *fairness, desert* (what is deserved), and *entitlement* have been used by various philosophers in attempts to explicate *justice* (Beauchamp & Childress, 2009). These accounts interpret justice as *fair, equitable,* and *appropriate* treatment in light of what is due or owed to persons. In the context of research, questions of justice mainly revolve around “who ought to receive the benefits of research and bear its burdens”. In this regard, “an injustice occurs

when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly" (Emanuel et al., 2003, p. 35).

Debates about injustices have revolved around instances where burdens of serving as research participants fall largely upon poor ward patients, minority groups, less developed countries' populations, etc., while the benefits of improved medical care flow primarily to rich private patients, privileged populations and the developed world. The selection of research participants needs to be scrutinized in order to determine whether some classes (say, welfare patients, particular racial and ethnic minorities, persons confined in institutions, or the very poor and underprivileged regions) are being systematically targeted simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied (Emanuel et al., 2003).

Finally, whenever research leads to the development of improved therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups that are unlikely to be among the beneficiaries of subsequent applications of the research (Emanuel et al., 2003). The preceding discussion on principles of biomedical ethics will lead the report to the subsequent discussion on the history of institutional review boards or research ethics committees.

2.3 History of institutional review boards (IRBs) in the USA

In the United States, research ethics committees are referred to as institutional review boards. An institutional review board (IRB), also known as an independent ethics committee (IEC) or ethical

review board (ERB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects (NIH, 2005) . IRBs were developed in direct response to research abuses earlier in the twentieth century. Two of the most notorious of these abuses were the experiments of Nazi physicians that became a focus of the post world war trial (Annas & Grodin, 1992), and the Tuskegee Syphilis study (Centers for Diseases Control [CDC], 2008), a project conducted between 1932 and 1972 by the US Public Service on black men in rural Alabama.

The IRBs in the USA are governed by Title 45 CFR (Code of Federal Regulations) Part 46 (NIH, 2005). These regulations implement provisions of the National Research Act of 1974 (National Institutes of Health [NIH], 2005), for example defining IRBs and requiring them for all research that receives support, directly or indirectly, from what was the Department of Health, Education, and Welfare at the time, and is now the Department of Health and Human Services (HHS). IRBs are themselves regulated by the Office for Human Research Protections (OHRP) within HHS (NIH, 2005). Title 21 Part 56 has additional requirements for IRBs that oversee clinical trials of drugs involved in new drug applications (NIH, 2005).

African countries, as has been indicated in this thesis, have also seen significant growth in collaborative health research in recent decades. This, as noted in earlier sections, has brought about new and more complicated ethical challenges for African countries. There is therefore need for African countries to learn (but not necessarily emulate) from the experiences and

occurrences in the developed world like the USA in order for them to avoid similar ethical abuses.

2.4 The History of RECs in Africa

According to the European Parliament, a research ethics committee (REC) is an independent body consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety, and well-being of human participants in clinical research (Chima, 2006; Directive 2001/20/EC). RECs are designed, among other things, to provide independent review, thereby helping to minimise conflicts of interest; to protect the welfare of research participants through attention to risks and benefits, and ensuring an effective informed consent process; and avoiding exploitation of vulnerable individuals and populations (Hyder et al., 2007). However, as recently as the 1980s, there were no RECs in many countries in Africa (Ikingura, Kruger & Zeleke, 2007). A study of 12 RECs from 9 African countries, namely, Democratic Republic of the Congo, Ghana (2), Kenya, Nigeria, South Africa (2), Sudan (2), Tanzania, Zambia, and Zimbabwe revealed that the oldest committee was from South Africa, established in 1966 (Cleaton-Jones & Wassenaar, 2010), while the majority (8) were established within the last five years prior to the study (Hyder et al., 2007). In 2005, the South African National Health Act, Act No. 61 of 2003 made it mandatory that research ethics approval of all human participant research is compulsory (Cleaton-Jones & Wassenaar, 2010). For some countries, RECs were established because of the requirement by scientific journals of proof of ethics committee approval. This compelled researchers who wanted to publish their findings to push for local REC formation in their countries (Aksoy & Aksoy, 2003). Others have been established as requirements for international collaboration. For instance, at the Second Symposium on "Ethical

Issues in Health Research in Developing Countries" held in Karachi, Pakistan from August 14th to 18th, 2003 "leading ethicists called for the establishment of effective national and institutional RECs in developing countries to protect biomedical research participants from any possible harm or exploitation" (Ahmad, 2003).

The requirement that all biomedical research involving human participants must be reviewed by independent research ethics committees (RECs) has been repeatedly highlighted in biomedical literature (Ikingura, Kruger & Zeleke, 2007; Hyder et al., 2007; WHO, 2000). Unfortunately, it is not clear how many RECs exist in Africa. However, a new European and Developing Countries Clinical Trials Partnership (EDCTP) project called Mapping African Research Ethics Capacity (MARC). This project is currently identifying and listing all RECs in Africa. As at 12th April 2011, approximately 107 RECs around Africa had been identified and listed on the MARC website (see hhtp://www.healthresearchweb.org/ethics/results.htm).

Although awareness regarding the importance and role of RECs has increased across Africa, as reflected by the large number of RECs being established in various African countries (Nyika et al., 2008; MARC, 2011), there is a need to ensure that such committees are effective in carrying out their mandate to review protocols that are ethically acceptable. RECs have to operate effectively, transparently and independently for them to fulfil their mandate (Nyika et al., 2008). Many African countries have established RECs to oversee research in their countries, however, these research ethics committees tend to be resource-intensive, which may make them unsustainable for most African countries (Chima, 2006).

Literature on the history of RECs in Africa has also highlighted that establishing RECs in many African countries has not been without constraints (Ikingura, Kruger & Zeleke, 2007). To start with, the multiplicity of international ethics guidelines has been a challenge in itself. This has led to uncertainties on which guidelines and/or procedures the established RECs should follow (Chima, 2006). Further, the lack of ethics expertise; lack of clear job descriptions; lack of and/or inconsistent funding, inadequate training, poor infrastructure, and even absence of local ethics policies and legislation have made the process of establishing and running new RECs even more challenging (McPherson, 2001; Milford et al., 2006). Of course, Africa being the huge continent it is, there are bound to be marked variations in both REC capacities and developments in ethics regulatory and institutional frameworks.

With this background, good ethics stewardship demands that every country, whatever its level of economic development, should have a functional research ethics review system for protecting the dignity, integrity and health safety of all its citizens participating in research (Kirigia, Wambebe & Baba-Moussa, 2005). Unfortunately, in most of the developing world, there is no robust mechanism in place for ethical review of any research. Ahmed (2003) asserted that it is surprising that even India, which has made great strides in biomedical research among developing countries, about 50% of its biomedical institutions do not have RECs, and where they do exist, they do not function as they should. It is against this backdrop that the next section of literature review will go into detail of the expectations of a research ethics committee.

2.5 Research Ethics Committees – an overview

Research ethics committees (RECs) are a key component of research ethics governance. They are mechanisms through which independent review of research proposals can take place and whose purpose is to protect the safety and welfare of research participants. In most countries where RECs exist, almost all clinical, biomedical and social research is required by governmental authorities to go through ethics review by a REC. In addition, REC review of research proposals is required by many funding institutions and is often a precondition for funding. Ethics review of research can take place at different levels: national and local, or a mixture of both. Typically, 'local' ethics review takes place in health institutions, such as universities, medical institutions and hospitals. They constitute the lowest level of research governance in countries where these are the only research oversight structures available. As the CIOMS (2002), guidelines state, RECs can function at the institutional, local, regional or national level and this reflects the current organisation of RECs in most countries, which typically employ a combination of institutional and national ethics committees. There are relatively few empirical studies that audit or evaluate the effectiveness of RECs, including compliance with operational protocols contained in national guidance documents compared with descriptive data on how these are set up (WHO, 2000). However, these descriptive studies do provide a very helpful insight of gaps in research ethics governance such as the absence of over-arching policies and legislation. The setting up of RECs as a safeguard against unethical research practices is insufficient if these are not sustained and supported. Otherwise, as Caniza and colleagues point out, the credibility of such bodies can be compromised (Caniza, Clara, Maron, Navarro-Marin, Rivera, Howard, Camp & Barfield, 2006). The next section of the literature review discusses the structure of research ethics committees.

2.6 Structure of ethics committees

When it comes to the system of ethics review, this varies from country to country. Some countries, such as Canada, Mexico, Japan, Belgium and India, have a 'decentralised' system of ethics review where institutional ethics committees review the majority of research protocols (Akabayashi, Slingsby, Nagao, Kai & Sato, 2007; Bevan, 2002; Long, Kontic, Barroso & Brinza, 2006). In Canada, for example, institutional research ethics committees are empowered to refuse or give approval, or to withdraw approval from a study (Bevan, 2002). A decentralised structure of ethics review may mean that individual RECs operate 'independently' and with internal 'jurisdiction' where they decide their own internal structure and processes. As a result, in the absence of central oversight or regulatory mechanisms, this may lead to varying standards of ethics review. Bevan, writing on research ethics boards (REBs) in Canada, has highlighted that the decentralised approach to governance of research has produced a multiplicity of REC structures without public accountability or transparency. She therefore concludes that reliance on local REC mechanisms without a central, national approach to ethical standardisation and the lack of regulatory enforcement is no longer workable (Bevan, 2002). Anecdotal evidence also indicates a similar scenario in other countries. Another major concern in countries where there is a lack of effective national or central research ethics stewardship is the lack of support to ethics committees at the institutional level and therefore an inability to operate effectively (Elsayed & Kass, 2007; Milford et al., 2006; Rivera & Ezcurra, 2001). Literature also highlights many instances where foreign (and sometimes local) researchers have taken advantage of the lack of local legislation and have ignored rudimentary developed local statutes (Baraza, 1998; Chima, 2006). For some, this tendency by some researchers and sponsors to circumvent international

guidelines has been taken as a form of paternalism and double standards (Chima, 2006; Macklin, 2004). The issue of policy and regulation is the main emphasis of the next section.

2.7 Ethics policy and regulations in Africa

In order to promote ethical research in Africa, appropriate legislative controls, increases in research capacity, new career structures, and appropriate allocation of resources are needed (Chima, 2006; Nyika et al., 2008). Countries in Africa need to introduce frameworks for research ethics governance based on international guidelines but adapted to local cultural, medical and legal realities. These regulations should also provide guidance on the formation of local RECs, standard operating procedures (SOPs), informed consent procedures, standards of care in biomedical research, and aspects of distributive justice, and many other issues crucial to the protection of research participants' interests (Chima, 2006).

Some commentators (Sisay-Joof & Crawley, 2009) have noted that the proposed African Union legislation and directives for regulating health research is a step in the right direction (Economic Commission for Africa & African Union, 2008). It was the original intention of the CIOMS Guidelines (CIOMS, 2002) to provide interpretations of international ethical principles and guidelines in the context of resource-poor environments. Similarly, the WHO Guidelines aim to reflect the conditions and the needs of low-resource countries (WHO, 2000), and the implications for multinational research in which they may be partners (CIOMS, 2002). However, in as much as both the CIOMS and WHO Guidelines are said to be applicable to all countries, they do not replace national laws and regulations. In effect, they support the creation of local

guidelines specific to different countries and regions. Thus, WHO Guidelines are intended to facilitate and support ethical review in all countries around the world (WHO, 2000).

Any efforts to develop local policies and guidelines should include guidelines on a system of ethics review that is suitable for African countries. National and regional policies on research, which reflect local realities and can be applied by local RECs, should be developed. As it has been argued, it is pointless to have many local research ethics committees if no effective national or regional policies exist to guide them. Reliance on international legislation and guidelines does not adequately protect research participants in Africa (Chima, 2006). These policies and guidelines must be specific enough in order to avoid being inapplicable to local settings for example, guidance on forming local research ethics committees, informed consent procedures, standards of care, and distributive justice such as post-trial benefits or compensation for injuries arising from research, (Chima, 2006). All the Africa-specific ethical issues must be clearly defined and procedures for reconciling conflicts should be clearly specified (Alliance for Human Research Protection, 2003; Chima, 2006; Ford & Tomossy, 2004; Plomer, 2005). As earlier mentioned, it is pointless to have many local research ethics committees if no effective national policies exist to guide them and thus, national research ethics regulatory frameworks will be the focus of the next section of literature review.

2.8 National research ethics regulatory frameworks

Research ethics regulations and mechanisms at national level are necessary not only for maintaining credibility and high quality of research but also for maintaining public trust in the purpose and conduct of health research (Johnson et al., 2008). Similarly, the UK Department of

Health has developed a research governance framework that stipulates that research governance is one of the core standards that all health care organisations should achieve and that the ethics principles and requirements of the framework must be consistently applied by all institutions that lead or participate in health research (UK Department of Health, 2005). Good governance in research ethics can improve research and safeguard the public in such ways as enhancing ethical awareness and scientific quality, promoting good practice, reducing adverse incidents and ensuring lessons are learned, as well as forestalling poor performance and misconduct by researchers. The generation and production of knowledge for the health system, not only involves the expenditure of public money (as in many public goods), but unlike many other publicly supported activities, it also involves the engagement of the public as research participants in activities that may often involve more than minimal risk. .

One of the ways of earning public trust is by demonstrating that the research enterprise upholds high moral principles, (e.g. by consistently promoting and supporting the ethical conduct of research) and by putting in place regulatory instruments to support the research enterprise. The South African Health Act, Act No. 61 of 2003, requires that all health-related (including social and behavioural) research conducted in South Africa must be reviewed by a research ethics committee that is registered with the NHREC, and must comply with the provisions of the South African Research Ethics guidelines and with the South African guidelines on good clinical practice (GCP) (Cleaton-Jones & Wassenaar, 2010). The foregoing section on national research ethics regulatory frameworks sets the pace for the following discussion on national research ethics guidelines.

2.9 National research ethics guidelines

Many countries such as India, the United Kingdom, Kenya, South Africa, Nigeria and others have developed national guidelines on research ethics (UNESCO, 2008). However not all these countries have legislation that mandates that these guidelines must be followed, nor are there punitive measures for research misconduct or infraction of these guidelines. In such instances, the impact of guidelines on improving the ethical conduct of research is difficult to assess and there are some concerns about the implementation of research ethics in contexts where there are only non-binding guidelines and an absence of legislation (Chima, 2006; NEBRA, 2006). For example, in the USA, OHRP guidance and 45 CFR 46 only apply to federally funded research (Cleaton-Jones & Wassenaar, 2010) or to other US researchers or institutions that choose to adhere to it.

In countries where national guidance documents on research involving human subjects is nonexistent, researchers and members of ethics review committees probably draw upon various sources of ethical guidelines such as the CIOMS guidelines, the WHO's Operational Guidelines for Ethics Committees that Review Biomedical Research, and the *Declaration of Helsinki* (Long et al., 2006; NEBRA, 2006). Although compliance with international standards is helpful, local guidelines and standards must be developed to strengthen the research ethics framework and compliance to research ethics principles and practices (Mullings, 2007). Some researchers also question the cultural sensitivity of guidelines developed in external countries and applied in local contexts in developing countries (Benatar, 2002; Hyder, Akhter, & Qayyum, 2003). There are recommendations therefore, that international guidelines be contextualised and interpreted

legislatively at local and regional levels (Chima, 2006; Langlois, 2007). The next section leads the discussion to a summary of developments in research ethics review in Nigeria.

2.10 Developments of research ethics review in Nigeria

The earliest attempts to set up a national ethics regulatory infrastructure in Nigeria took place in 1980. However, this effort faltered largely because of lack of sustained interest and funding (Adebamowo, Mafe, Yakubu, Adekeye, & Jiya, 2008). Subsequent attempts were also unsuccessful because the 1980s and 1990s were marked by military misrule and socio-economic dislocation. The advent of civilian democracy in Nigeria in 1999 coincided with a period of increased international attention to the problems of unethical health research that occurred particularly in developing countries (Anonymous, 2000). By 2004, several Nigerians had graduated from the U.S. National Institutes of Health/Fogarty International Centre (NIH/FIC) funded international research ethics training programmes in the United States, Canada, and South Africa, and they increased pressure on their institutions to set up ethics committees where there were none and strengthen existing ones even as they started to provide local bioethics training (Adebamowo et al., 2008). These efforts gathered momentum such that during a 2006 Presidential Retreat on the Health of Nigerians, the fact that Nigeria needed an ethics regulatory infrastructure for health research to meet its United Nations Millennium Development Goals targets was strongly highlighted. In response, the Federal Government of Nigeria reconstituted and strengthened the National Health Research Ethics Committee (NHREC) and backed it with legislation to enable it function effectively (Adebamowo et al., 2008).

Prior to the development of the National Health Code in Nigeria, interested parties and institutions in Nigeria set up ethical committees according to institutional and international guidelines. There was therefore, a lack of uniformity and minimum standards. There was also no coordinating and legally binding enforcement mechanism (Adebamowo et al., 2008). More recently, largely in response to increased research funding from foreign governments and organizations, institutions have either established or re-modeled their committees after the U.S. institutional review boards systems and in accordance with the U. S. Common Rule. This often occurred at the behest of international collaborators, who needed to satisfy their home countries' regulatory agencies (Hyder et al., 2007)

Nigeria is one of the leaders in health research in Africa and it is in furtherance of its leadership role and commitment to health research. It was in this regard that the Federal Ministry of Health established Nigeria's National Health Research Ethics Committee (NHREC), (Adebamowo et al., 2008). From the foregoing, it is clear that Nigeria has made tremendous efforts in the development of research ethics laws at institutional and national level. The next section sets the pace for discussion of local research ethics laws and policies.

2.11 Local research ethics laws and policies

In a number of countries, adherence to research ethics principles and processes is required through laws, policies or a mixture of both. These typically specify the establishment of RECs as the primary mechanism through which to monitor attention to research ethics but provide a legal framework within which ethics committees can function (NEBRA, 2006). For example, in 2001, the European Parliament passed Directive 2001/20/EC that requires member states to harmonise

their regulations and administrative provisions on good clinical practice in the conduct of clinical trials on medicinal products for human use, including the process of approvals through RECs (Directive 2000/20/EC, 2001).

In some countries, legislation on research ethics is implemented through the establishment of over-arching oversight bodies such as National (research) ethics councils or committees. These bodies are often charged with the responsibility of ensuring that norms and guidelines are developed and followed and that quality assurance mechanisms to oversee ethics committees are in place. For example, in South Africa, the parliament passed a National Health Act in 2003 (Act No. 61 of 2003) that established the National Health Research Ethics Council. The overall functions of this council are to advise the government and regulate research ethics through the registration, accreditation and regular auditing of all ethics committees, developing appeal mechanisms, as well as supporting capacity building in research ethics (South Africa Department of Health, 2004; Cleaton-Jones & Wassenaar, 2010). In contrast, recent research from some regions has demonstrated that a number of countries do not have legislation on health research including that related to research ethics. For example, a study of the WHO Eastern Mediterranean region (EMRO) by Abdur Rab and colleagues that looked at the ethics review practices of researchers from 12 countries found that only 3 countries had national regulations mandating the existence of research ethics committees (Abdur Rab, Afzal, Abou-zeid, & Silverman, 2008). Similarly, a study by Kirigia and Wambebe of 10 countries in the WHO African region found that 9 out of 10 did not have research legislation for protecting the safety and well being of human research participants (Kirigia & Wambebe, 2006). These findings are also supported by the recent research undertaken by WHO/AFRO (WHO/AFRO unpublished),

where the majority of countries (73%, n= 32) reported not having legislation relating to health research. Of the seven countries that reported having a law on health research, six of these addressed ethical issues (WHO/AFRO unpublished). This is particularly of concern given that many countries in the region are host to a number of clinical trials particularly in the area of HIV/AID, tuberculosis and other infectious diseases and involve thousands of research participants, who are often exposed to potentially risky interventions with a potential for stigmatisation through participation in research studies ((Kent, Mwamburi, Bennish, Kupelnick & Ioannidis, 2004)

Furthermore, even where policies and guidelines regulating health research may exist at the national level, without legal enforcement mechanisms, this creates the potential for bypassing the ethics review process (Kirigia, Wambebe & Baba-Moussa, 2005). In the absence of national legislation and policies, many health research institutions have developed written policies that require researchers to follow ethics procedures when conducting research involving human participants. Preceding sections of the literature review have brought to the fore various attempts of the functioning of RECs in African countries, however challenges still hinder these efforts and some of these are discussed in the next section.

2.12 Shortcomings and challenges

RECs in Africa face many functional challenges procedurally and administratively. To start with, while many claim to have basic administrative capabilities, many others lack administrative infrastructure while a lot more do not even have standard operating procedures (Chima, 2006). The absence of national and institutional guidelines in many African countries only adds to the

challenges in the work of RECs (Hyder et al., 2007). A number of articles highlight the lack of capacity to review research proposals and the difficulty of applying the law in a clear, efficient and well-organised manner among most African RECs as a frequent problem (Brinkerhoff, 2003; Milford et al., 2006; Rugemalila, 2001). They note that most RECs in resource-poor environments operate amid a myriad of challenges that could affect their effectiveness. Often, RECs operate in complex environments characterised by power inequalities in the midst of governments, funders, researchers, and or communities; money, prestige, custom, or ignorance may also compromise independent ethical review (Milford et al., 2006); RECs may lack transparency, expertise, accountability, and in most cases, RECs lack appropriate technologies, financial resources and trained ethics personnel (Benatar, 2002; Hyder et al., 2007; Loff, 2002; Loff, Hofman & Muthuswamy, 2001; Milford et al., 2006; Nyika et al., 2008).

Another aspect often cited is the difficulty most African RECs face when reviewing highly technical HIV vaccine trials designed to test safety, immunogenicity, and efficacy of candidate vaccines in preventing HIV infection (or disease) in healthy, uninfected volunteers. Knowledge of local legal frameworks governing research is inconsistent and unclear (Milford et al., 2006). Experiences from Ugandan researchers highlight many social, political, legal, ethical, and behavioural barriers to effective REC functioning. They assert that these problems mainly arise from public misconceptions and media misinformation; abnormally lengthy review processes; and inadequate or even lack of national regulatory mechanisms (Milford et al., 2006; Mugerwa, Kaleebu, Mugyeni, Schmidt, Sentongo, Hom, Salata, George, Mbidde, & Ellner, 2002). In Kenya and Zambia alike, there is evidence that most REC members often do not have the

necessary ethics training to understand complicated immunology concepts used in some protocols (Bhatt, 2003; Milford et al., 2006; GRZ/MoH, 2004).

The lack of training in ethics in African RECs is so pervasive such that there are many REC members with no ethics training at all. According to Milford et al. (2006), less than 40% of all members of RECs studied received ethics training prior to joining their committees, while only 52% had received training after assuming their position on the committees. Nyika et al. (2008) report similar shortcomings in training. They note that although respondents considered training upon joining the REC to be important, 35.4% of the committees did not offer any training to new members, and 54.8% lacked continuing training for existing members (Nyika et al., 2008). Although focusing on training in the ethics of HIV vaccine trials, Milford et al. (2006) report that overall, 97% of the RECs they studied agreed that committee members had inadequate training. These challenges are not peculiar to the mentioned countries alone. In most of Africa, RECs find it difficult to effectively review and monitor approved protocols because of such conspiring challenges. Significantly, more than 70% of RECs reviewed using self-assessment methodologies "reported moderate, limited, or no capacity to review HIV vaccine trial protocols". In addition, all RECs, except one that reported excellent capacity, agreed that a lack of training in ethics applied to HIV vaccine trials was a great challenge (Milford et al., 2006). Therefore, whereas training upon joining the REC is necessary to acquaint new members with ethical review processes, continuing training is even more critical to keep committee members abreast of new developments both in the health sector and other changes arising from new ethical issues (Nyika et al., 2008).

Beyond highlighting the problems arising from the lack of training and expertise among African RECs, Nyika et al. (2008, p. 4) also recommend the need for more investment in this area. They note that "for excellence in ethics review processes to be achieved in Africa much more investment will be required". They argue further that "career structures for REC members also need to be changed so that research ethics is recognised as a career that young Africans may be willing to take professionally" (Nyika et al., 2008, p. 3). They propose that for all these to be realised, "revenue and support for RECs need to be addressed so they meet the real operational demands that satisfy international standards" (p. 3). In addressing biomedical research stakeholders, including funding organisations, argue that these stakeholders "need to recognise that parallel and equal investment is necessary for research ethics committees that support the research environment in Africa. In other words, ethical review of health research should be considered to be as important as the actual health research, and should be equally funded" (Nyika et al., 2008, p. 7).

Furthermore, almost all the literature on RECs in Africa acknowledges that funding is a great challenge (Kass et al., 2007; Kirigia, Wambebe & Baba-Moussa, 2005; Macklin, 2004; Milford et al., 2006; Nyika et al., 2008). This is not surprising because this is a problem which even developed country Institutional Review Boards (IRBs) grapple with. However, RECs in resource-poor countries are more likely to experience these problems more acutely (Hyder et al., 2007). There are some RECs which have no operating funds whatsoever while those which had some funding, regard it as mainly insufficient to ensure effective functioning (Hyder et al., 2007). Another study by Milford et al. (2006), also aimed to identify perceived resource and capacity building needs of African RECs for the review of HIV vaccine trial protocols and found

that only a third [fewer] of RECs (32%) reported they received funding whereas RECs in six of the 12 countries represented had no access to funding This scenario has several implications for ethics regulation; including inadequate ability to monitor approved research (Ofori-Anyinam, 2001) and poor infrastructure for effective protocol review (Nyika et al., 2008). By implication, underfunding could suggest that ethical review may not be regarded as a core component of research or of effective health research systems in most of these African countries. In a number of African countries, including Zambia, RECs levy research institutions and individual researchers for protocols they review as a means of raising money. However, this has not proven to be an effective means to adequate funding. Almost all institutional RECs in Zambia continue to suffer from the common limitation of inadequate funding (Nkandu, 2008). Therefore, if research ethics is to be taken seriously, support and funding for RECs should be increased to meet the costs of the relevant functional activities for which RECs have been constituted.

It is however critical to reemphasise that these problems of finances are not evenly shared even among African RECs. As Milford et al (2006) note in their study, funding sometimes differed by the type of studies that RECs reviewed. For instance, those committees that had reviewed HIV vaccine trial protocols were generally better resourced than those that had not. Furthermore, the Southern region was reported as best resourced, followed by East Africa, with West Africa having the greatest infrastructure needs. However, it should be appreciated that the statement of Southern Africa being well-resourced and with highly developed infrastructure could be misleading. This is because South Africa is not a typical Sub-Saharan country. Thus, most of the capacity and infrastructure captured in the study mainly represent developments in South Africa as a country rather than the Southern region as a whole.

Lack of dedicated office space and other facilities are other challenges highlighted in most literature on RECs in Africa regardless of region. Milford et al. (2006), report that although most of the RECs they studied said they had access to some resources, over 40% did not have dedicated office space and many only had access to computers, email, and the Internet through institutional and personal support (see also Hyder et al., 2007). These results approximate what Nyika et al. (2008) reported from their study. They revealed that almost all of the RECs they studied had poor data management and archiving systems in place. "All the committees surveyed relied on paper-based data management and archiving systems, which could compromise the ability of the committees to effectively follow-up and monitor approved studies" (Nyika et al., 2008, p. 4). Additionally, keeping REC documents in offices which are not specifically designated "for the committees potentially compromises the privacy and confidentiality of their work" (Nyika et al., 2008, p. 5).

Related to the above challenges is the problem of increasing workloads faced by most RECs in Africa (Nyika et al., 2008). In the wake of the increased workload, most RECs have been overwhelmed by the number and complexity of studies that they review a problem that could compound inadequate training of the committee members (Kirigia & Wambebe, 2006; Pickworth, 2000). Given that nearly almost all REC members and staff are part-time volunteers who are invariably committed to their respective professions, the problem of workload can only become worse (Pickworth, 2000; Kirigia & Wambebe, 2006). Thus, it would be difficult to guarantee that part-time members of RECs would be able to review protocols thoroughly and render the required protection of human participants (Schuppli & Fraser, 2007).

Another challenge relates to governments' lack of awareness of the importance of research ethics. As a result, many governments are still not convinced that they need to set aside funds for RECs, and ensure that they develop appropriate legislation, institutional frameworks and policies for supporting ethical research (Hyder et al., 2007). Several writers have mentioned that it was not uncommon for REC members in Africa to hold multiple responsibilities – where being an REC member is largely on part-time basis and without pay. Where serving on the REC might actually deny members income they would otherwise have received for that time, members are more likely to commit themselves to their full-time income-generating jobs rather than commit to the REC. It is with this background that many writers have argued for payment for serving on the REC to ensure commitment (Hyder et al., 2007).

Additionally, and as far as functionality of African RECs is concerned, the tendency by a few RECs to "rubber stamp" approvals in order to secure international funding has also been highlighted (Hyder et al., 2007; Macklin, 2004). It is in this context that many experts have raised concern about African RECs' independence.

2.13 Agenda for action

Despite the fact that some Western countries also do not have well-regulated systems for research ethics governance (Cleaton-Jones & Wassenaar, 2010), almost all writings about RECs on Africa have endeavoured to recommend, one way or another, an agenda for action that needs to be taken by African countries if ethical review is to close the gaps in this area. Given the challenges raised in most of the literature on African RECs, it is not surprising to note that

suggestions for future improvements almost always include, among other things, the need for more training, more funding, more independence, and more political commitment to RECs and supporting legal and institutional frameworks (Hyder et al., 2007). Those countries that do not currently have systems for ethics review have been urged to urgently leverage the services provided by such initiatives as the WHO Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) (WHO, 2002) and others highlighted in this review to develop capacities for ensuring ethical research practices (Kirigia et al., 2005). The call for more empirical research on ethics and African research is another aspect that is repeatedly highlighted (Hyder et al., 2007).

The literature further reveals that the development of national policies and regulatory frameworks is more likely to be enhanced when international funders, aid agencies, and scholarly journals establish that RECs are required and prior review and approval must be the norm. National and institutional commitment must be set as policy and implemented through deliberate influx of resources for REC support (Hyder et al., 2007).

Among other things, policy and legislative issues have been high on the list of priorities. It has been advised (Economic & Social Research Council [ESRC], 2004) that African countries should adapt international guidelines for biomedical research involving human participants as appropriately as possible and then make them available to all national health and health-related research institutions and health facilities that need to use them. However, for international guidelines to make any mark, all countries should make sure that they develop appropriate local policies and legislation to guide and give authority to national and local ethics research review systems (Kirigia et al., 2005). Thus, as good national ethics stewards, African governments should ensure that they develop operational bioethics research review systems at the regional,

national, provincial, district and institutional (health facility) levels. Governments should therefore provide policy and legislative leadership while at the same time ensure institutional and financial support to ensure independent and competent RECs (Benatar, 2002; Kirigia et al., 2005). Another aspect that has been highlighted as a necessary government opportunity for ensuring stronger and more effective functioning RECs is the institutionalisation of ethics training at all stages of the education and training of all health workers, including medicine, public health workers, nurses and social scientists (CIOMS, 1997; Kirigia, et al., 2005).

2.14 Ethics training initiatives in Africa

In recent years, there has been more interest in the international research community to offer capacity building in research ethics in Africa. As a result, there are now a number of initiatives that have been taken to create ethics awareness in different countries of Africa. *The Institute of Advanced Medical Research and Training* (IMRAT), College of Medicine, University of Ibadan has held national bioethics workshops for researchers of the Ethics Review Committees since June 2004 and launched the *Nigeria Bioethics Initiative* (NBIN) (Onuoha 2007). NBIN is an organisation that aims to improve capacities of researchers and members of RECs on how to conduct ethically acceptable research involving human participants. Then there is the US NIH Fogarty funded *West African Bioethics Training Program*, also based in Ibadan. Its main aim is to help organisations with establishing institutional review boards (IRBs), (Onuoha, 2007). In South Africa, the South African Research Ethics Training Initiative (SARETI) and the International Research Ethics Network for Southern Africa (IRENSA) has been training African scholars in research ethics at various levels, among others, PhD, Masters, and other short-term certificate and diplomas. In other parts of Africa, and with help from different international

agencies such as Wellcome Trust, the European and Developing Countries Clinical Trials Partnership (EDCTP), United Nations Educational, Scientific and Cultural Organisation (UNESCO), Africa Malaria Network (AMANET), and the National Institutes of Health (NIH) Fogarty, some ethics initiatives in the form of training programs, conferences and workshops have been put in place in the past to train health professionals and researchers to raise awareness on various questions related to research ethics in Africa.

For instance, the Wellcome Trust has been supporting initiatives that address the capacity to conduct research into/or that involve scholarly discussion of the ethical, legal, social, cultural or public policy aspects of biomedical research in developing or restructuring countries (Wellcome Trust, 2009). The National Institutes of Health (NIH) Fogarty International Center (FIC) also launched an initiative to train scholars from the developing world in bioethics in response to this problem, and has been developing capacity in research ethics in Africa through its various programs (Hyder et al., 2007). Another international agency that has been contributing to ethics capacity building in the developing world is UNESCO, through its Regional Expert Meetings on Ethics Teaching under the auspices of its Ethics Education Program (UNESCO, 2008). Further, EDCTP has been promoting the establishment and strengthening of National Ethics Committees (NECs) and IRBs that are competent and independent in sub-Saharan countries (EDCTP, 2011). The NECs and the IRBs are encouraged to establish themselves administratively and financially to ensure sustained optimal function beyond the EDCTP funding. Many other Foundations, Trusts and Universities have been supporting initiatives for ethics capacity building in different specific countries in Africa.

These have however been irregular and mostly foreign initiated and or funded. The *Pan African Bioethics Initiative* (PABIN) has been pioneering in this regard. The pan-African oriented organization was founded in 2001 to spearhead the development of bioethics (particularly research ethics) in Africa (Onuoha, 2007) and has held several pan-African meetings to date, mostly sponsored by SIDCER.

In spite of the many initiatives mentioned above aimed at capacity building for ethical review, little empirical research has been conducted in most developing countries to determine REC capacity to review and approve health research, including protocols for HIV vaccine trials (Milford et al., 2006). A review of literature also reveals that there is still a need to develop appropriate local ethical guidelines and standard operating procedures (SOPs) (Kass & Hyder, 2001; Milford et al., 2006); and policy (Kim, Park, Lee et al., 2003; Milford et al., 2006); to train REC members (Kass, Dawson & Loyo-Berrios, 2003; Milford et al., 2006); and to increase REC independence, diversity of membership, and monitoring of approved protocols (Benatar, 2002; Kim et al., 2003; Milford et al., 2006).

In Zambia in particular, and unlike South Africa in the same region, the ethical-legal framework is just in the first stages of development. As a country, Zambia only has three institutional RECs[1] while the National REC has been struggling to operate effectively (GRZ/MoH, 2004), though there are some indications showing that the National REC is now operational (P. Mumba, personal communication, January 18, 2010). Additionally, in Zambia, there is no specific

[1] One at the University of Zambia School of Medicine(for both medical and social sciences), one at Tropical Diseases Research Centre and one at Macha Mission Hospital

legislation that deals with informed consent to medical treatment and research (Andanda, Awah, Ndebele, Onigbogi, Udatinya, & Mwondela, Unpublished).

This study therefore aims to investigate the existing legal, policy and institutional frameworks regarding research ethics committees in Zambia. The aim was to get a snapshot of the current status of existing legal, policy and institutional frameworks guiding the formation and functioning of RECs in Zambia.

3. RATIONALE FOR THE STUDY

The significance of functionally prescribed standards for the conduct of research involving human participants, coupled with the plausible administration of country-specific legal, policy and institutional frameworks cannot be over-emphasised (Chima, 2006; Kirigia et al., 2005; Macklin, 2004; Milford et al., 2006; Nyika et al., 2008; Plomer, 2005;). This is because in addition to the principles and guidelines guiding research, researchers should be responsible for ascertaining and complying with all applicable legal and regulatory frameworks specific to the country where the research is being conducted. The law affects and regulates the standards and conduct of research involving humans in a variety of areas, including, but not limited to privacy, confidentiality, intellectual property and the capacity of participants. However, in spite of the importance of ethical legal, policy and institutional frameworks in ensuring the quality of research and the protection of research participants, not much research has been undertaken in Zambia in this area (GRZ/MoH, 2004). Anecdotal indications show that inappropriate, inadequate and/or ineffective legal, policy and institutional frameworks may undermine functioning of RECs in fulfilling their mandates.

This study aims to investigate the existing legal, policy and institutional frameworks regarding RECs in Zambia and to discuss about how they impact on the functioning of RECs within the country.

4. AIMS AND OBJECTIVES

The major aim of this research study was to identify and highlight the strengths, weaknesses, and gaps with regard to legislation, policies and institutional frameworks that relate to the formation and functioning of RECs in Zambia.

4.1 General Objective:

To investigate the existing legal, policy and institutional frameworks and to consider how they appear to impact on the functioning of RECs in Zambia.

4.2 Specific Objectives:

- To identify and analyse existing national guidelines, policies and legislation guiding the conduct and ethics oversight of public health research in Zambia;

- To highlight the strengths, weaknesses, and gaps in the legislation, policies and institutional frameworks that guide the formation and functioning of RECs in Zambia.

- To investigate factors that have contributed to the existing state of legal, policy and institutional frameworks regarding RECs in Zambia

5. METHODS

5.1 Research Study Design

This study utilised a qualitative research design, where reliability was not the main goal in the study. According to Patton (2002), reliability entails the consistency of measurement no matter how many times the study is repeated. On the contrary, the qualitative research design adopted in this study is meant to help understand the actual legal, policy, and institutional realities relating to research ethics committees in Zambia. Therefore, validity of the research design is more appropriate in this context. Validity here refers to the strength of the propositions made or the likely outcomes, conclusions, and inferences (Creswell & Miller, 2000).

The research design adopted in this study has significant internal validity in that the relationships between the research objectives, rationale and methods of data collection and analysis to be applied are consistent enough to achieve the overall purpose of this study. The study aimed to investigate the legal, policy and institutional frameworks that govern the conduct of research with human subjects in Zambia. Its main aim was to capture the extent to which existing legal, policy and institutional frameworks enhance and/or hinder effective ethics governance in research in Zambia. Understanding how ethics review committees function and the legal, policy and institutional factors that could affect their establishment and functioning is critical for identifying challenges, strengths and possible improvements in research ethics governance in the country. Although the study generally takes a case study approach, findings from this work may be relevant to countries, RECs and regulatory bodies in other but similar settings.

5.2 Participants and inclusion and exclusion criteria

A sample of 13 in-depth interviews with key stakeholders from identified institutions was done that is, two from each of the four RECs and one person each from the Ministry of Health (MoH), General Nursing Council (GNC), Health Professionals Council of Zambia (HPCZ), National Science and Technology Council (NSTC) and Zambia Forum for Health Research (ZAMFOHR). All the participants were included by purposive sampling (Marshall, 1996). This is because only those institutions which were relevant to the topic of the study were targeted. In the same vein, the individuals who participated in the in-depth interviews were selected by virtue of their positions in these institutions.

The study collected information from participants critical to ethics regulation and oversight in Zambia. Within RECs, chairpersons and secretaries were included; in research institutions, i.e., NSTC and ZAMFOHR, Directors of research were included; in the MoH, the Director of Public Health and Research was included; while Secretary Generals were targeted from the GNC and HPCZ. Thus, only those officials directly involved in (or knowledgeable about) aspects of the legal, policy and institutional functioning (or oversight) of RECs in Zambia were selected. Preliminary discussions were held with all the identified institutions before the actual respondents were identified.

5.3 Measures and procedures of data collection

The study mainly utilised qualitative methods of data collection. Specifically, document review and in-depth interviews were used to collect information in this study. The selected methods were critical because the study aimed at investigating existing legal, policy and institutional

frameworks that inform the formation and functioning of RECs in Zambia. Thus, a review of relevant documents and interviews with key institutional stakeholders was believed to be ideal and sufficient to answer the main research objectives of this study.

5.3.1 Document Review:

Document review was a major source of data used to answer the objectives of this study. It entailed identifying, accessing and critically reading the relevant documents such as national and institutional ethics procedures and guidelines; national and institutional policies and legislation; institutional and other government reports; journals and books; and many other relevant documents on ethics regulation and governance in general, and the formation and functioning of RECs in general.

5.3.2 In-depth Interviews:

Interviews performed a complementary role in the process of data collection. In-depth interviews were used to fill in and/or clarify issues that arose from the review of relevant documents or those issues that were not captured from the literature. In-depth interviews were conducted face-to-face and involved one interviewer and one participant. A draft interview guide was developed (see Appendix II) and used to guide the interviews. The items included mainly arose from extensive review of existing relevant literature. Before the commencement of the interview, the participants were taken through the informed consent form (see Appendix I) which they voluntarily signed upon accepting to take part in the interview. The participants were also requested to consent to tape recordings.

5.4 Data Analysis

Data collected through document review was sorted and arranged by theme of focus (e.g. laws, regulations, guidelines, etc.). 'Content analysis' (Taylor-Powell & Renner, 2003), was therefore used as a preliminary method of analysis to facilitate identification of the major themes of analysis. Data collected through in-depth interviews were analysed manually using emergent themes that came out during the interviews.

5.5 Ethical Considerations

This research study drew upon the basic philosophies underlying major codes, declarations, and other documents relevant to research with human participants. Specifically, it ensured that the research was scientifically valid, meaning that the research was methodologically rigorous; it also ensured fair selection of participants based on scientific objectives, not vulnerability or privilege. Independent review of the research proposal and approval was sought and granted from the University of KwaZulu-Natal HDSS REC and the Tropical Diseases Research Centre REC in Ndola, Zambia (see Appendices III & IV). The participants were informed about the research interview and they provided their voluntary consent to participate. Respect for all enrolled participants was observed by making sure that their privacy was protected through the use of no personal identifiers in the report, and they had the freedom and opportunity to withdraw from the interviews at any time without any threat to their wellbeing.

6. RESULTS

The results of the data collected both through in-depth interviews and document reviews was sorted and analyzed. For ease of organization, this results section is logically presented in line with the specific objectives of the study. Immediately following are the results obtained on the existing national policies, legislation, and institutional framework guiding the conduct and ethics oversight of public health research in Zambia. Thereafter the thesis will highlight the strengths, weaknesses, and gaps in the policies, legislation, and institutional frameworks that guide the formation and functioning of RECs in Zambia, before finally presenting the factors contributing to the present status quo in the policy, legal, and institutional frameworks regarding RECs in Zambia.

6.1 National policies, legislation and institutional frameworks guiding the conduct and ethics oversight of public health research in Zambia

It is important here to highlight that there have been relatively few clinical trials in Zambia, especially Phase I and II trials (GRZ/MoH 2004). Most clinical trials in Zambia have tended to be Phase III studies conducted within the TDRC on the Copper-belt, the University Teaching Hospital, School of Medicine of the University of Zambia in Lusaka, the Malaria Control centre also in Lusaka, and other research institutes such as the Macha Mission Hospital in Southern Province.

Health research, especially social science based, is also undertaken in various settings, especially at undergraduate and postgraduate levels, and within different Non-Governmental Organisations (NGOs) and international agencies operating in Zambia. Most of this research is conducted

amongst people who are 'vulnerable', not very literate (as being able to read and or write) or do not fully understand their rights pertaining to research. In a developing country such as Zambia, there is great need for those participating in such research to be adequately protected from physical and other non-physical harm and from any violation of their rights (Nkandu, 2008). To this effect, appropriate policies, legislation, and institutional frameworks are necessary to oversee the conduct of health research, and the creation and functioning of RECs in the country. However, as the next few paragraphs show, the policy, legislative, and institutional framework for public health research oversight remains largely undeveloped. A number of policy documents have been developed (although most of them are still in draft form) but they remain fragmented and only partially adopted (GRZ/MoH, 2008).

6.1.1 Policy environment

All research in Zambia is currently governed by the National Science and Technology Policy (GRZ/MoH, 2008). The Health Sector Research Policy has been finalised pending adoption. The National Health Strategic Plan (NHSP) 2008–2011 gives general guidelines for health research development in Zambia (GRZ/MoH, 2008). The National Health Systems Research Strategic Plan notes that "Health care-related research rests on two fundamental moral commitments; sustainable improvement in human welfare through expansion of frontiers of scientific knowledge and understanding of disease patterns and changing human conditions; and preservation and protection of the dignity and health interests of participants in research programs" (GRZ/MoH, 2004, p. 6; GRZ/MoH, 2008, p. 18).

There is also a national policy in the context of the HIV/AIDS National Response that is specifically focused on ensuring that HIV/AIDS-related research protocols involving human participants are reviewed and approved by an ethics committee (National AIDS/HIV/STI/TB Council (NAC), 2005). Beyond these two general policy guidelines, the Zambian Government also acknowledges the importance of international ethics guidelines and standards in health research conducted in Zambia. Among others, those clearly identified in the context of the National Health Systems Research Strategic Plan include "Good Clinical Practice (GCP)"; "Good Laboratory Practice (GLP)"; and "Good Manufacturing Practice (GMP)" (GRZ/MoH, 2008, p. 19).

6.1.2 Legal framework

Currently, the Science and Technology Act No. 26 of 1997 is one of the acts that provide the legal and regulatory framework for research in Zambia. The Act was the culmination of the Science and Technology Policy which saw the formation of the National Science and Technology Council whose main function is to advise the Government on science and technology policy and coordinate and oversee research institutions in Zambia (GRZ/MoH, 2008).

Other acts of parliament that directly or indirectly govern health research oversight include the Public Health Act and its subsidiary Regulations Cap 295 of the Laws of Zambia; the Environmental Protection and Pollution Control Act No. 12 of 1990, which addresses issues of infectious diseases, public health nuisances, water and sanitation; and the Patents Act, CAP 400 of the Laws of the Republic of Zambia. In addition, Zambia is a member of the World

Intellectual Property Organization (WIPO) and is a signatory to the Paris Convention for the Protection of Industrial Property (PCPIP), which provides important guidelines for the legal handling of research outcomes (GRZ/MoH, 2004; GRZ/MoH, 2008). However, the issue of health research and ethics oversight in particular, is not adequately covered in any of these acts. There appears to be a scarcity of health research and ethics expertise in the country. Moreover, ethics is a relatively new phenomenon in most local health research discussions and is infrequently referred to. There seems to be a lack of the necessary critical mass of ethics experts to champion the need for ethics in policy debates and implementation. Thus, it appears currently that health research is mainly an *ad hoc* activity and concern for the protection of human research participants is mainly influenced by availability of external funding and experts. Generally therefore, the legal/ethical oversight mechanism is very weak.

6.1.3 Institutional framework

Given the importance of ethics in health research, Zambia has been attempting to establish institutional structures to govern and oversee health research ethics (GRZ/MoH, 2008). The Science and Technology Act No. 26 of 1997 currently provide the institutional framework for all national public health research in Zambia (GRZ/MoH, 2008). The Science and Technology Act created the NSTC, whose main function is to advise Government on science and technology policy and to coordinate and oversee research institutions in the country. In addition to this structure, there is the National Health Research Advisory Committee (NHRAC), whose overall responsibility is to advise the MoH on all matters related to heath research in Zambia (GRZ/MoH, 2008). Further, following concerns regarding research misconduct by some researchers in the country in 2008, the MoH (by way of Ministerial directive) mandated itself the

role of approving all research involving human participants (especially those involving drawing blood, tissues or any such substances) proposing to take place in the country (GRZ/MoH, 2008). The Ministerial directive required that upon obtaining ethical approval from an institutional REC (both in the sponsoring country and in Zambia), the researchers had to seek final approval from the MoH – Lusaka headquarters, before such a study could commence. However, despite this move, the MoH is not legally mandated to review and approve health research in the country.

So far there appear to be only three functional institutionally based RECs[2]. The University of Zambia Research Ethics Committee (UNZAREC) based at the medical school has for some time acted as a national research ethics committee (Nkandu, 2008). These institutional RECs have developed operational guidelines and standard operating procedures (SOPs) under their specific institutional authorities. As has been noted already, the MoH in Zambia launched a National Research Ethics Committee (NREC) in 2006, but it has remained largely nonfunctional. The NREC was supposed to deal with issues of policy and accreditation of institutional RECs and further consolidate the legal framework for conducting research in the country. Because this national oversight body has remained effectively nonfunctional, all these proposed roles have not been fulfilled. Technically therefore, Zambia does not have an overarching framework for supervising and/or overseeing health research, ethics, and the formation and functioning of RECs in various research institutions in the country (GRZ/MoH, 2008).

Apparently, nothing has been said about REC formation or their role in ensuring the adherence to ethical conduct in research in the National Heath Research Policy (2008), the National Research

[2] These have already been noted earlier. They include one REC at the University of Zambia School of medicine; one at TDRC, and another at Macha Hospital

Systems Strategic Plan (2008–2011), or any other policy document. It is therefore not surprising that most institutions that undertake health research in the country do not have ethics review mechanisms (GRZ/MoH, 2004). As a result, "some health research work does not go through any ethics review and that, where they do, there is no institutional capacity to monitor approved health research for their ethical rigor" (GRZ/MoH, 2004, p. 6). The National Health Research Policy also acknowledges "that health research ethics is inadequately covered in pre-and post-basic training of medical students and other health [professionals]" (GRZ/MoH, 2004, p. 12). Surprisingly, in spite of the foregoing problems, research ethics and oversight policy still do not feature at all on the list of health sector priorities, key implementation principles, and strategies for improving health research which are listed in the 2006–2010 National Health Strategic Plan (GRZ/MoH, 2006).

This is in line with the findings obtained from in-depth interviews in the field. When asked to comment on whether any of the REC members have received any policy guidance on the formation and functioning of RECs in Zambia, all 13 (100%) of the respondents answered 'No'. Furthermore, when asked on whether or not they were aware of any legislation that guides and supports the formation of RECs in Zambia, the same result was obtained. None of the members interviewed was aware of any legislation that specifically guides and supports the formation and functioning of RECs in Zambia.

When asked about where they got guidance on the functioning of the RECs in Zambia, 10 (77%) of the respondents said RECs usually got guidance on how to function from international guidelines on research ethics. When probed further on the international guidelines from which

the guidance to function is obtained, the following were frequently mentioned; Guidelines on Good Clinical Practice (GCP) (10 [77%] respondents); the *Declaration of Helsinki* with (7 [54%] respondents) and; and the Council for International Organization of Medical Sciences (CIOMS) (4 [31%] respondents).

Guidelines informing the formation and functioning of RECs in Zambia

Guideline Used	Number of Respondents	Percentage
Good Clinical Practice (GCP)	10	77%
Declaration of Helsinki	07	54%
CIOMS	04	31%

The majority of the respondents from the RECs (that is, 8/13 [62%]), felt that it was very important to have national and/or institutional ethics guidelines. Three (3) institutional RECs, excluding the NHREC (which we have noted is not functional), had their own Standard Operating Procedures for committee members[3].

Furthermore, only 2 (15%) of the 13 respondents were aware of some sort of legislation and ethics policy that guide research in Zambia. The rest of the respondents had no idea of any legislation and/or policy guiding health research in the country.

[3] Copies of these were made available.

6.2 Gaps in the policy, legislation and institutional framework

A significant amount of Phase III research has been undertaken by international researchers and institutions (GRZ/MoH, 2004). However, in Zambia, public health research and its oversight has been overwhelmed by many weaknesses, gaps and/or problems. To start with, the majority of researchers lack capacity in basic research skills such as proposal development; data collection and analysis; report writing and dissemination of research findings. It has been revealed that "most pre- and post-basic training of health professionals does not adequately prepare them to appreciate, let alone to undertake, ethically rigorous public health research" (GRZ/MoH, 2004, p. 4).

The other issue that is worth noting here is the lack of clearly defined measures for punishing and/or correcting research misconduct. Petra (2007) claims that that there has been an increase in research that is not ethically reviewed in Zambia. Ngandwe (2005) has also reported that some researchers in Zambia have been able to avoid ethical review. This is in line with the position taken by the MoH, which argues that a significant amount of research in Zambia is going on without ethical approval (GRZ/MoH, 2008). Ngandwe reports further that most misconduct observed by RECs in Zambia goes unpunished, a situation that does not help in deterring offenders from repeating their malpractice in future. Ngandwe continues to argue that all forms of misconduct or malpractice should result in fines or discontinuation of the projects and that, where necessary, the researchers involved should be forbidden from conducting further research in the country (Ngandwe, 2005). Table 1 shows the documents that were consulted for review of literature.

Table 1: Documents consulted

No	Document title	Publishing institution	Year of publication
1	Strengthening Human Resources for Health: Occasional paper series No. 1	USAID	2006
2	National Health Strategic Plan 2006 - 2010	MoH/GRZ	2005
3	Roadmap for the development of a comprehensive National Health Policy and Drafting of the National Health Services Bill	MoH	2008
4	Sixth National Development Plan 2011 – 2015	MFNP/GRZ	2010
5	Vision 2030	GRZ	2006
6	National Health Research Policy	MoH	2008
7	Fifth National Development Plan 2006 – 2010	MFNP/GRZ	2006
8	2000 Census - Epidemiological Report	CSO/GRZ	2000
9	The Paris Declaration in Practice: Challenges of Health Sector Aid coordination at the District level in Zambia	BioMed Central	2009

What has been analysed from document reviews above does not differ from what was collected from in-depth interviews with the key informants in the field. When asked to identify the strengths and weakness of the policy and legislative framework guiding health research in the country, 10 (77%) of the respondents reported the lack of policy and legislative guidelines for research ethics as the major weakness. Three (3) others (23%) reported low allocation of funding to research ethics from the government another major weakness. The respondents noted that the combination of these factors was a very retrogressive state of affairs and that this was negatively impacting on the growth of research ethics in Zambia. “As long as there are no policies and laws to guide the conduct of ethical health research, ethics will always be relegated to less priority areas and people would think it is not important in health research”, noted one participant.

However, in spite of this general criticism of the overall policy and legislative framework, a significant number (9) or 69% reported that the favourable health research ethics environment in the country, whereby most of the players appear to agree that research ethics is critical in all research, could be taken as the main strength in Zambia. It was noted that the receptive posture towards research ethics taken by many players, including government, is fertile ground for the development of appropriate policies and laws and the promotion of research ethics. The progress, albeit slow, that has been made in the drafting of the health research policy and related documents must be appreciated. All that is required is to ensure that these policies take into account the noticeable gap and/or absence of appropriate research ethics policies and laws, especially regarding the creation and functioning of RECs.

When commenting on the institutional framework for research ethics oversight in the country, 6 respondents (46%) highlighted that the progress that the country had made in the past few years, where the number of RECs in the country has grown from 2 to 4 is the major strength. This shows that the country is moving in the right direction as far as building the institutional capacity is concerned. It was also noted that the number of REC members that have been exposed to some form of ethics training has increased. Out of the 13 REC members interviewed, the majority (10 or 77%) reported receiving some ethics training of some sort, either locally of outside the country. With regard to procedures they use for overseeing health research ethics, 8 (62%) of the respondents said they applied international ethical principles and regulations in the review of research proposals. When probed if the mechanisms they reported were adequate for overseeing health research ethics in their institutions, 8 (62%) respondents said 'No' and emphasised the importance for guidelines specific to local settings. Among the major weaknesses cited with

regards to institutional capacity to oversee research in the country, inadequate or complete lack of training among some REC members was highlighted. Ten (77%) of the respondents noted that although there has been some training activities conducted, especially by the UNZA medical REC, the lack of training for most REC members continues to be a major weakness. This is especially true for in-coming members whose training needs are even more acute. Eleven (85%) cited the lack of funds both for day-to-day functioning and especially for continued monitoring of the approved researched a major weaknesses constraining their institutional capacity to effectively oversee health research.

Again, the lack of financial support and inadequate training opportunities for REC members were noted as the major weaknesses facing the national research and ethics oversight institutions. All 13 (100%) of the respondents reported "lack of financial support to monitor RECs and the research they approve and inadequately trained REC members. Furthermore, while the 3 institutional RECs had dedicated office space for research ethics work, the National Health REC did not have office space dedicated to research ethics. Moreover, almost all but one of the people co-opted in the NHREC have full-time office responsibilities elsewhere. Also, 1(8%) respondent showed concern about the long processes involved in legislating health research in the country. As in the other areas discussed in this report, strong government commitment regarding research ethics oversight, particularly the upcoming Health Research Bill and the overall conducive health research and ethics environment in the country was highlighted as the main strength overall.

6.3 Factors that contribute to the current legal, policy and institutional frameworks regarding RECs in Zambia

In 1991, the National Health Policies and Strategies Committee recommended the setting up of a review commission to revise all legislation impacting on the health sector, including health research (GRZ/MoH, 2008). To date this has not been done. The situation has impacted negatively on the operations of the various health institutions. Currently there are about 29 pieces of legislation impacting on the health sector. A few have been revised in piece-meal in the past five years but a lot remains to be done.

With regard to policy, the period 1999 to 2009 witnessed a proliferation of policy documents in the health sector. This in part could be attributed to the fact that polices were being developed within the context of the MoH internal planning units on the one hand and under the influence of the donors or cooperating partners on the other hand. Currently the MoH has about 27 different policy documents at various stages of development and implementation. Although these policies are supposed to influence or support specific areas of ministry operations, there remains a gap in creating synergies for optimal application of these piece meal and programme tailored policies. These policies therefore remain practically unimplemented GRZ/(MoH, 2008).

There is also a leadership gap in public health research ethics. There seems to be a very limited cadre of ethicists championing the elevation of health ethics to the level it should be in medical and public health research. This translates into an apparent lack of effort to promote public health research and ethics at the various levels of the national health delivery system (GRZ/MoH, 2008). The lack of ethics teaching in medical and other health training programmes only adds to

the dire shortage of research ethics knowledge and expertise in Zambia. Without the relevant knowledge and expertise in research ethics, it has been almost impossible to harness the required critical mass of individuals who could influence policy, legislation and even health research practice.

Furthermore, the inactive posture taken by the 2006-launched NHREC has had a huge impact on the failure to develop policies and legislation to guide research oversight in Zambia. The overarching objective of the NHREC was to deal with issues of policy and accreditation and further consolidate the legal framework for conducting research in the country (Nkandu, 2008). Thus, the fact that the NHREC has not been effectively operational since its launch, it has meant that the opportunity to develop, revise and consolidate the policy and legal framework for research oversight has been lost.

7. DISCUSSION

The results discussed above show that the national policies, legislation and institutional framework guiding the conduct and ethics oversight of public health research in Zambia, especially for the creation and functioning of RECs, remain underdeveloped. While rhetorically and theoretically a lot of progress has been made in acknowledging and accepting the importance of ethics oversight in public health research, in practice, a lot needs to be done to bring practice to the level where rhetoric is. One would argue that the fact that Zambia now has four RECs and not two as was previously the case is an indication that the country is moving in the right direction. While this may be true, given the opportunities that are available for progress, there is a need for genuine political will on the part of government and all stakeholders to invest resources in the development of appropriate policies, legislation and the necessary institutional capacities for overseeing public health research.

This study has endeavoured to establish the extent to which the policy, legal, and institutional frameworks are influencing the formation and functioning of RECs in Zambia. Clearly, while three RECs are trying to review and oversee health research in the country, there is no coordinated oversight of on what basis and how these RECs are functioning. Attempts by the MoH to take over what could have been the natural roles of the NREC have not provided any real solution. In Zambia the RECs were found to be operating independently, without guidance from any legal framework. While fragmented pieces of policies do exist regarding health research in general – sometimes only indirectly influencing it – there is no consolidated policy on research ethics and the formation and functioning of RECs in the country. This makes it very difficult for RECs, especially newly formed RECs, to function effectively.

It is pointless to create more local RECs if no effective national or regional policies and legislation exist to register, regulate, guide them, and ensure that they function effectively. Reliance on international legislation and guidelines alone may not adequately protect research participants in Zambia because of some contextual realities that may need specific application of ethical principles (Chima, 2006). Furthermore, dependence on international guidelines and principles poses the danger of different interpretations, which may lead to confusion both within the RECs and among researchers seeking ethical clearance. The same is likely to result from the fragmented and sometimes contradictory policies that have been developed in Zambia. The sheer numbers of policy documents creates difficulties for any institution trying to follow or implement them as sifting through the myriad of documents complicates the whole process of adopting and implementing policy directives provided by government.

Research ethics regulations and mechanisms at national level are necessary not only for maintaining credibility and a high quality of research but also for maintaining public trust in the purpose and conduct of health research (Johnson et al. 2008). This is important if the research enterprise is to continue receiving public support in terms of willing research participants, and even funding from private enterprises.

Unfortunately in the case of Zambia, unlike South Africa, there is currently no Act of Parliament that directly regulates health research in the country. In addition, and possibly as a partial consequence, the overall health research governance structure for health research is weak. Although generally taken as the closest Act under which health research falls, the health sector has not fully exploited the existing Science and Technology Act No. 26 of 1997. Moreover, those

RECs which are currently in place in Zambia are not legally framed and have no regulatory mandate beyond their host institutions (GRZ/MoH, 2008). It should be noted that while structural and organisational reforms have been implemented successfully over the years since 1991, the policy and legislative reforms to support the changing roles of the MoH and its institutions and statutory bodies have lagged behind. This has resulted in weak regulatory frameworks and poor functional linkages between the center and its statutory bodies and institutions (GRZ/MoH, 2008).

The MoH also acknowledges that the requisite skills for scrutinising and reviewing research proposals for their scientific and ethical rigor are still a scarce commodity in the public health research sub-sector (GRZ/MoH, 2008). This is made even worse by the fact that "improvement of the capacity of researchers in health research institutes, and that of researchers undertaking public health-related research in non-health sector institutions does not prominently feature on the health sector research agenda" (GRZ/MoH, 2004, p. 4). Incidentally, even the National 10-year Human Resource Plan for the Public Health Sector does not address the need for public health research and ethics skills (both for researchers and those involved in research oversight) as important requisites to achieving the objectives of the health sector. Consequently, most health professionals undertake research oversight as a 'part-time' activity which is not integral to their work (GRZ/MoH, 2004).

It should be noted that while the NSTC Act of 1997 provides for the registration and regulation of health research institutions and their activities, it does not provide any legal framework for the formation, functions and powers of RECs. Further, under the NSTC Act, the NSTC is mandated

with the responsibility of coordinating health research and harmonising research priorities at the national level. However, there is no health sector specific coordination mechanism to enable the council do so (GRZ/MoH, 2004). Additionally, despite the Science and Technology Act stipulating that all health research institutions and their activities be registered and regulated by the National Science and Technology Council, none of the research ethics committees and institutions interviewed were registered let alone regulated by the NSTC.

Furthermore, although much collaborative research involving international researchers and institutions has been conducted for some time, there are no institutional mechanisms for identifying or regulating the different people conducting public health research in the country. There is also a lack of guidelines and capacity for coordinating research activities and outputs, and in many instances, there is no awareness as to what is happening at national, provincial and/or district levels of the system (GRZ/MoH, 2004). There are no institutional arrangements for overseeing health research connecting the Ministry of Health headquarters to provincial and district levels, making it difficult for the nation to take stock of ongoing research activities and therefore difficult to effectively utilise research outcomes to inform health policy and programme implementation (GRZ/MoH, 2008). This is worsened by the lack of a functional National REC, which leads to the challenges of regulation, coordination, and monitoring of health research in the country. In most instances therefore, public health-related research funded by various external agencies takes place in local Non-Governmental Organizations (NGOs) without the knowledge of the MoH. As a result, health research in Zambia is generally fragmented, ineffectively coordinated, and inadequately monitored (GRZ/MoH, 2008).

Additionally, most medical and health institutions undertaking and/or overseeing research in the country do not have infrastructural prerequisites, such as laboratories, equipment, supplies, including storage and library facilities to enable them undertake biomedical research that requires state-of-the-art equipment and supplies (GRZ/MoH, 2008). In a national survey conducted in 2001 by the National Science and Technology Council (NSTC), it was revealed that many of these institutions lacked basic research requirements (NSTC, 2001; GRZ/MoH, 2008). In the majority of cases, research equipment, infrastructure and facilities were found to be obsolete and poorly maintained, researchers had no access to international health research journals, and shortage of skilled instructors was also rampant (GRZ/MoH, 2004; GRZ/MoH, 2008). In particular, RECs face a number of challenges, ranging from inadequate resources and personnel for inspection and monitoring of ongoing approved research activities to inadequate funding for other administrative REC functions. Other challenges relate to issues of exportation of samples (human tissue) for undisclosed future research – mainly DNA research – which is not adequately regulated (Nkandu, 2008).

The lack of adequate funding for health research and research oversight is also apparent in all institutions undertaking public health research. Government budgetary allocations to health research have been critically inadequate, at times not even available. The international recommendation of 2% to 5% of government and cooperating partners budgets respectively have not been adhered to. The Ministry of Science, Technology and Vocational Training (MSTVT) and the NSTC, which should be the pioneering institutions in research and development (R&D), have also not been sufficiently funded for them to perform their roles effectively (GRZ/MoH, 2008). A number of bilateral and multilateral development players have tried to come in and

close the gap through various funding mechanisms for public health research and its oversight in the country. Unfortunately, these efforts are not well coordinated. There is no institutional, policy, or legal mechanism for coordinating in-coming funds or for identifying health research priorities that should benefit from such funds. In most cases, oversight for ethical rigor in research is not even considered (GRZ/MoH, 2004; GRZ/MoH, 2008).

When one looks at the functioning of the National Health Research Advisory Committee, it has been noted that its Secretariat is quite weak in that it does not have full time staff, there is no specific office for it, and no operational funds are allocated for it to function effectively. To these weaknesses, one could also add the fact that there is no well-defined National Health Research Operation System (GRZ/MoH, 2008).

Furthermore, it is important to note that research ethics and the role of RECs have only been sparingly mentioned in all national policies guiding health research and practice. For example, in the National Research Policy there is a paragraph labeled "guiding principles" where ethics and the protection of research participants are directly mentioned. The National Research Policy notes:

- "All research involving human participants should be conducted in accordance with the three ethical considerations of *respect for persons, beneficence* and *justice*";

- "Health research and health research outcomes should be for the benefit of nationals whose interests they should fully address"; and

- "Because Zambia is part of the international health research community, all health research in the country should strictly abide by the international ethical guidelines for bio-medical research involving human participants. In this respect, emphasis should be on informed consent, equitable distribution of burdens and benefits, and safeguarding confidentiality" (GRZ/MoH, 2008, p.23).

Further, Zambia is currently operating under a 'decentralised' structure of ethics review where individual RECs operate independently and with internal institutional jurisdiction. This means that RECs decide their own internal structures and processes (SOPs). As a result, in the absence of central oversight or regulatory mechanisms, this may lead to varying procedures and standards of ethics review (Bevan, 2002; Elsayed & Kass, 2007). Furthermore, the absence of an overarching oversight body in the country may be compromising the quality of ethics oversight at institutional level as RECs appear not to have any higher body to guide them or be accountable to. The Government established the National Health Research Ethics Committee (NHREC) to be an accreditation and regulatory body of the institutional RECs in the country. It was also tasked to develop and harmonise national policies and recommend legislation regarding health research and ethics oversight. As has been highlighted in many places in this report, evidence indicates that the NHREC is not operational. There is hope that it will become operational when the Health Research Bill is passed in Parliament and becomes law.

Additionally, although the MoH mandated itself with the role of granting final approval for all research involving human participants proposing to take place in the country since 2008, the MoH is not legally mandated to do so (MOH, 2008). Moreover, the research unit within the

MoH does not have the human resource capacity required to handle the ethics review of protocols. Thus, their involvement in ethics oversight has only resulted in delays in the implementation of researches even after they have been approved by institutional RECs.

One issue that deserves emphasis here is that the role of each of the institutional stakeholders visited for in-depth interviews in the national institutional framework remains unclear. This is mainly because, by design, all functioning RECs at the moment are supposed to be institutional in character. Thus, there is divergence between their original mandate and the roles that they now find themselves playing in national research and ethics oversight. When asked to state the capacity in which the institutions were involved in health research ethics oversight, UNZA Medical REC claimed it was the overseer of all research in the country. This is not surprising in that historically, the institution has been involved in research ethics oversight for all research in the country. Another institution, the NSTC said its oversight of research was more on registration and regulation of health research institutions than on RECs and research ethics. The incumbent NHREC claimed it is supposed to be accrediting RECs but has not started doing so yet.

It has already been established in the literature that the highlighted weaknesses and gaps in the policy, legislation, and institutional framework for overseeing public health research, ethics and the creation and functioning of RECs are fertile ground for ethical misconduct and abuse of research participants. Already, there is evidence that there is a significant number of health studies that are being undertaken in Zambia without going through any ethical review. At worst, there are circumstances when health research is conducted in Zambia without the knowledge of any REC, including the MoH itself! It is not the aim of this report to accuse researchers in

Zambia of acting unethically; however, it is also true that in the developing world most "deviations" from ethical conduct or "research misconduct" usually occur in research as a result of ignorance and failure to understand the special ethical requirements by researchers (Resnik, 2010). Research ethics oversight policies, legislation, and institutions therefore provide opportunities for information, training, and a regulatory framework to ensure that health research is conducted as ethically as possible.

8. LIMITATIONS OF THE STUDY

The restricted number of functional RECs in Zambia meant that only a small sample could be contacted for this study. As a result, the findings of this study are the views and experiences of a few individuals involved in research oversight in their institutions. However, efforts were made to locate persons with relevant experience and positions.

9. CONCLUSIONS

It is clear from the foregoing discussion that the policy, legal and institutional framework guiding the conduct and ethics oversight of public health research in Zambia remains too weak and fragmented to offer effective oversight and guidance in the formation and functioning of RECs in the country. Most of the policies and legal frameworks being used to guide public health research and ethics oversight do not directly focus on the formation and functioning of RECs. As a result, it has been very difficult for institutions and individuals interested in forming RECs to know exactly what is required before a REC is created. In most cases, REC formation and functionality has depended on international ethics guidelines and principles. This has created a number of challenges for RECs in the country.

The greatest gap in this regard therefore is the fact that Zambia as a country does not have a national policy that directly governs the formation and functioning of RECs. The three RECs that are functional at the moment operate according to their institutional guidelines. The inadequate specific training in ethics means that many of the REC members do not possess the requisite skills and experience for scrutinizing and reviewing research proposals for their scientific and ethical rigour. A related issue is the fact that most REC members in the four RECs undertake their research oversight functions as 'part-time' activities besides their main line of duties. Moreover, Zambia has no capacity for coordinating research activities and outputs. In many cases, the RECs are not even aware of some research that is being undertaken by various institutions and/or individuals at national, provincial and district levels.

The situation has been worsened by the fact that no functional national institutional structure exists to offer guidance and/or oversight to RECs, institutions and researchers involved in research with human participants. The national REC which was supposed to offer such guidance remains dysfunctional. Without such a national oversight body, development of an effective policy and legal framework will remain questionable as this will perpetuate the leadership vacuum that has so far hindered the development of new policies and legislation and the harmonization of existing but fragmented pieces of policy and legislation. As things are, the policies and legislation will continue to be fragmented. Coordination of research activities and outcomes will also remain complicated and the situation where studies are going on without ethical review will continue, if not worsen.

10. RECOMMENDATIONS

Firstly, probably the most critical recommendation is the need for a national oversight institution to coordinate public health research, policy and legislation formulation, and the formation and functioning of RECs in the country. This national body should offer leadership in the development of policies, legislation and the coordination of RECs at national level. Without such a national body, it is unrealistic to expect the situation to improve.

Secondly, there is need to re-look at existing policies to identify those policies that are relevant to public health research and ethics oversight so that they could be harmonized into a comprehensive single policy document. This could be an opportunity for further research – to identify these policies, the inherent gaps and how best they could be harmonised.

Thirdly, there is need for new legislation specifically focusing on research ethics oversight and the formation and functioning of RECs in the country. This legislation must mandate all institutions undertaking research to create institutional RECs and provide detailed guidelines on their functioning.

Fourthly, it is important to ensure that research ethics is elevated as an important training priority in all training institutions in the country. Research ethics training should be made mandatory for all types of researchers in the country. This would also ensure the development of the necessary cadre of ethics experts to fill up positions in institutional and the national RECs.

10.1 Recommendations for Further research

Situation analysis

A detailed survey and evaluation should be undertaken of the effectiveness and efficiency of the entire ethics review system (both institutional and national). It would be important to evaluate:

i. the organization, financing and functionality of the whole ethics review system;

ii. the extent to which RECs are involved in monitoring every stage/step in a research project cycle, including protocol design, implementation, archival of data, analysis and public dissemination of results;

iii. the effects of recent information and technology developments on RECs' mode of operating; and

iv. challenges faced by RECs in the country.

Institutionalisation of ethics education and training

A review of the existing international ethics review guidelines should be undertaken with a view to designing appropriate undergraduate and postgraduate curricula on research ethics. As Fischer and Zigmund (1996) argued that research ethics should be taught throughout the graduate curriculum. In addition, they were of the opinion that in Africa where a majority of the health and allied sciences undergraduates do not proceed to postgraduate studies, it is critically important to introduce undergraduates also to research ethics (Fischer & Zigmund, 1996). After obtaining their degrees, most undergraduates are normally deployed in rural areas where, by virtue of being the most educated, they often bear the burden of assuring that human rights of their actual and potential clients are respected and protected in the course of their clinical work and research carried out by others.

Ways of improving REC performance

There is need for studies that explore the cost and benefits (effectiveness) of alternative ways of leveraging the recent advances in technology (teleconferencing, video conferencing, e-mail) to boost the work of RECs. Where these technologies exist, they would not only reduce the cost of face-to-face meetings but will also ensure timely review of research protocols.

Partnerships

An exploration of the modalities of South-South and North-South cooperation to strengthen the capacities of bioethics review systems in the Region should be made. For example, the WHO Regional Committee for Africa identified the need for effective inter-country mechanisms to monitor health research in order to ensure that existing national and international bioethics guidelines were adhered to (WHO/AFRO, 2001). In addition, countries with limited bioethics capacities could easily tap into the internationally available bioethics expertise through the Internet. The emphasis laid on capacity-building for national ethics committees by the European and Developing Countries Clinical Trials Partnership (EDCTP) is very encouraging.

Financing of REC work

The effectiveness of RECs in many countries is greatly constrained by lack of resources (Dickens & Cook, 2003). The situation is not different in Zambia. Thus, there is urgent need for research into finding innovative mechanisms for ethically financing REC activities.

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APPENDICES

APPENDIX I

THE UNIVERSITY OF KWAZULU-NATAL AND UNIVERSITY OF PRETORIA

CONSENT FORM FOR IN-DEPTH INTERVIEWS WITH INSTITUTIONAL STAKEHOLDERS

Title of study: Legal, Policy and Institutional Frameworks Regarding Research Ethics Committees in Zambia
Student Investigator: Nancy Soko
Supervisor: Prof. Doug Wassenaar
REC No.:
Version Date: **20/10/2009**

Hello Dr/Mr./Mrs. ……., my name is Nancy Soko from the Tropical Diseases Research Centre. I am conducting a research as part of my academic requirements at the University of KwaZulu-Natal in South Africa. I am doing interviews with all the RECs and related institutions. You have been included in the sample by virtue of your position in this institution. Your due cooperation will therefore be highly appreciated..

What you should know about this study
This informed consent form explains the study you are being asked to take part in. It also explains your part in the study. Please, read it carefully and take your time to consider your decision to participate. Be informed that you are free to choose to participate or not. You are also free to ask questions at any time about any words or information you do not understand.

Purpose of research project
The main goal of this study is to identify and analyse existing national guidelines, policies and legislation guiding the conduct and ethics oversight of public health research in Zambia. We also want to find out what strengths, weaknesses, and/or gaps might exist in the legislation, policies and institutional frameworks that guide the formation and functioning of RECs in the country. This study is being done by Miss Nancy Soko, a Staff Development Fellow (SDF) at the Tropical Diseases Research Centre (TDRC) (as Student Investigator), in conjunction with the University of Pretoria/University of KwaZulu-Natal in South Africa. The study is funded by the South African Research Ethics Training Initiative (SARETI) and is done in partial fulfilment of the Masters in Social Sciences (Research Ethics) degree..

Why you are being asked to participate?
We are investigating existing national guidelines, policies and legislation guiding the conduct and ethics oversight of public health research in Zambia. We are asking you to take part in the

study because you meet the selection criteria. Your institution has been identified among the critical stakeholders involved in either research and/or ethics oversight in the country. Therefore, your knowledge, experiences, and opinions in research ethics oversight in Zambia will be very important in this study.

Procedures
Your participation in the study involves responding to a number of questions during in-depth interviews. The in-depth interviews will last a maximum of 45 minutes. The in-depth interviews will cover topics on existing legal, policy and institutional frameworks for ethics oversight in Zambia; legislation, policies and institutional frameworks guiding the formation and functioning of RECs in Zambia; the gaps, weaknesses and strengths in the legal, policy and institutional frameworks that guide the formation and functioning of RECs in Zambia. With your permission, all in-depth interviews will be recorded using a voice recorder.

Risks/discomforts
This study does not have any physical risks to you as a participant except taking a bit of your valuable time. The study does not involve any biomedical actions or personal data collection. You will not be expected to give away any personal information. Only information that relates to your official duties will be collected. Note that everything you say will not be attributable to you as an individual.

Benefits
In terms of benefits, you may not personally get any benefits from taking part in this study. However, you may find satisfaction in participating knowing that you are helping produce new information that will help in future interventions aimed at improving ethics oversight and the functioning of RECs in Zambia.

Payment
There is no financial payment for taking part in this study.

Protecting data confidentiality
Confidentiality will be ensured in several ways. First, no personal information will be collected about you as a participant. To further ensure confidentiality: 1) participants' names will not be used on any materials in the study; 2) all study data files will be kept in locked file cabinets and on password protected computers; 3) your respective institutions will be coded with unique identification numbers only known by the researcher; 4) the two lists of names of institutions and identification numbers will be kept in two separate locked file cabinets; and 5) at the end of the study, the data will be destroyed.

Only information relating to your day-to-day work will be collected. All personal views shared in the interviews will not be attributable to you as participants. However, the data may be seen by Research Ethics Committee members and may be published in a journal and elsewhere without giving your name or disclosing your identity.

Protecting subject privacy during data collection
In-depth interviews will be conducted in prearranged secluded office space to ensure that you have the privacy and freedom to respond to the questions without the presence of third parties.

Permission to record the in-depth interview
Note that I am planning to record all in-depth interviews. Your permission is therefore sought for your interview to be recorded by voice recorder. Recording of interviews is very important in order not to lose any of the valuable contributions you will make.

Alternatives to procedures or treatments
Please, be informed that participating in this study is completely voluntary. You are free to decide not to take part and you also have the right to stop participation in the study at any time. You may also choose not to respond to some of the questions during the in-depth interview if you feel uncomfortable answering them. There will be no punishment or loss of benefits on your part whether you participate or not. If you have any questions or concerns about taking part in the study, please feel free to ask questions at any time in the course of the study. The contact number and e-mail address for the student investigator and the TDRC REC are provided below so that you can talk to them on the phone whenever you feel like doing so.

What happens if you leave the study early?
Please be assured that your participation, non-response to certain questions or early exit from the study will be of no consequence whatsoever for you as an individual or your position in your institution.

Who do I call if I have questions or problems?

- Call the Student Investigator, Miss Nancy Soko, at 0955 928 449 if you have questions or complaints regarding this study.

- Call or contact the TDRC Research Ethics Committee (REC) Office if you have questions about your rights as a study participant. Contact the REC if you feel you have not been treated fairly or if you have other concerns. The REC contact information is:

  Address: TDCR Research Ethics Committee
  Ndola Central Hospital (6th floor)
  P.O Box 71769
  Ndola
  Tel: +260 212 615 444

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

_____	_____	_____
Print name of Participant	Signature of Participant	Date

_____	_____	_____
Print name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

APPENDIX II

THE UNIVERSITY OF KWAZULU-NATAL AND UNIVERSITY OF PRETORIA INTERVIEW GUIDE FOR INSTITUTIONAL STAKEHOLDERS

Title of study: Legal, Policy and Institutional Frameworks Regarding Research Ethics Committees in Zambia
Student Investigator: Nancy Soko
Supervisor: Prof. Doug Wassenaar
REC No.:
Version Date: 20/10/2010

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a) Institutional level

1. What is the main function of your institution?

2. What is the institutional authority under which your institution was established and empowered to function?

3. Are you aware of any legislation(s) that inform/guide the formation of RECs in Zambia? (Probe for specific examples)

   If yes, please give some examples.

4. Do you have any ethics guidelines that guide public health research in your institution?

   If yes, please give some examples. If no, skip to Question 6.

5. Would you say these ethics guidelines are adequate/appropriate for guiding Public Health research?

   If yes, please give some examples.

6. What do you think are the strengths? Weaknesses? Or Gaps in these ethics guidelines?

7. Do you have any ethics policies that guide public health research in your institution?

   If yes, please give some examples. If no skip to question 9.

8. Would you say these ethics policies are adequate/appropriate?

   If yes, please give some examples.

9. What would you say are the strengths/ Weaknesses/ or Gaps in these policies?

10. Are you aware of any legislation that guides public health research and the activities of your institution?

If yes, please give some examples. If no, skip to question 12.

11. Would you say these ethics legislations are adequate/ appropriate?
If yes, please give some examples.

12. What would you say are the strengths? Weaknesses? Or gaps in these legislation?

13. What would you say are the factors that cause the weaknesses you have identified in the legal, policy and institutional frameworks at institutional level?

b) National level

14. Are you aware of any ethics guidelines that guide public health research and the functioning of RECs in Zambia?

If yes, please give some examples.

15. Would you say the existing ethics guidelines are adequate and/or appropriate for guiding public health research in Zambia?

Please explain why.

16. What would you say are the strengths? Weaknesses? Gaps? … in the existing ethics guidelines? (Please give specific examples)

17. Are you aware of any ethics policies that guide public health research in Zambia? (Probe for specific examples)
If yes, please give some examples.

18. Would you say the existing ethics policies are adequate/appropriate/etc? (Probe for specific examples)

If yes, please give some examples.

19. What would you say are the strengths? Weaknesses? Gaps? … in the existing ethics policies (Please give specific examples)

20. Are you aware of any legislation that guides public health research in Zambia?

If yes, please give some examples.

21. Would you say the existing ethics legislation(s) are adequate/appropriate/etc? (Probe for specific examples)
    If yes, please give some examples.

22. What would you say are the strengths? Weaknesses? Gaps? … in the existing ethics legislation(s) (Probe for specific examples)

23. What would you say are the major factors that cause weaknesses you have identified in the legal, policy and institutional frameworks at national level?

c) Institutional Research Ethics Oversight

24. In what capacity are you involved in research ethics oversight in your institution?

25. What institutional structures/frameworks do you have for overseeing public health research and the upholding of ethics in your institution? (Please give specific examples)

26. Would you say these ethics institutional structure/framework(s) for overseeing public health research are adequate/appropriate?

    Please explain why?

27. What would you say are the strengths? Weaknesses? Or gaps in these institutional frameworks for overseeing public health research? Please site specific examples)

28. In your opinion, what is the significance of strong ethics oversight in research at institutional level?

d) National Research Ethics Oversight

29. In what capacity is your institution involved in research ethics oversight?

30. Are you aware of any structures/frameworks that are responsible for overseeing public health research and the upholding of ethics in Zambia?

31. Would you say these ethics structures/framework(s) for overseeing public health research in Zambia are adequate/appropriate?

32. What would you say are the strengths? Weaknesses? Or gaps in these national frameworks for overseeing public health research? Please site specific examples)

33. In your opinion, what is the significance of strong ethics oversight in research at national level?

e) Conclusion and Recommendations

34. How does the scenario you have discussed above affect the functioning of your institution? (Or Research Ethics Committees in general)?
35. How can the functioning of Research Ethics Committees be improved in Zambia? (Please give specific recommendations)

36. What should be done to improve/strengthen the legal, policy and institutional frameworks for ethics oversight in Zambia? (Give specific recommendations)

37. Is there anything you want to add which we have not discussed?

THANK YOU VERY MUCH FOR YOUR TIME.