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Evaluating the Feasibility of Implementing the National Health Research
Act of Zambia

Rachel Lee and Oghenerukeme Asagba

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Abstract

The National Health Research Act was created to provide a regulatory framework for the development, coordination, and regulation of health research in Zambia. On 22 March 2013, the National Health Research Act was enacted by parliament, but to this day, it has not been fully implemented. Thus, it is imperative to determine the feasibility of the laws that have been put forth to regulate health research and the efficacy of these laws in addressing the issues at hand.

To identify the potential barriers to the effective implementation of the Act, a critical review of the National Health Research Act and semi-structured interviews were conducted with key stakeholders over the course of two months (June and July, 2014). Based on the information obtained from various stakeholders, five major areas of concern were identified. These areas include the level of involvement of Zambian residents in international research projects conducted in Zambia, the ethical approval process, inspector power, no fault insurance required for research participants, and incorporation of traditional medicine with biomedicine.

Although the laws in the Act were created to address the challenges to health research, some of them might hinder its progress due to contextual factors that remain unaddressed. Thus, this study evaluates the feasibility of implementing the Act by identifying the contextual factors affecting implementation and the consequences of enforcing these laws without addressing the impeding factors.

Abbreviations

CAB	Community Advisory Board
CDC	Centers for Disease Control
CDH	Cancer Diseases Hospital
CIDRZ	Center for Infectious Disease Research in Zambia
IRB	Institutional Review Board
MOH	Ministry of Health
NAC	National AIDS Council
NHSRC	National Health Sciences Research Committee
SACORE	Southern African Consortium for Research Excellence
SAIPAR	Southern African Institute of Policy and Research
THPAZ	Traditional Health Practitioners Association of Zambia
UN	United Nations
UNZA	University of Zambia
UTH	University Teaching Hospital
ZAMBART	Zambia AIDS Related Tuberculosis Project
ZIPAR	Zambia Institute of Policy Analysis and Research

Introduction

Health research is a promising field with many benefits. Development in health research can increase life expectancy, improve quality of life, decrease incidence and prevalence of diseases, and generate revenue for a country. However, the risks may outweigh the benefits if there are no guidelines to monitor the ethical conduct of research. Vulnerable populations may be exploited and the nation may be prone to endemic diseases. Therefore, to protect Zambia from the potential risks associated with health research, the government instituted the National Health Research Act to provide a regulatory framework to regulate health research in Zambia.

Inevitably, the implementation of the Act would increase government expenditure and taxes. In addition, jobs would be created and systems would be established to enforce the Act. Thus, before incurring high costs and establishing systems to enforce the requirements of the Act, it is important to evaluate the feasibility of implementing the Act and the efficacy of the laws in addressing health related issues.

This paper is structured as follows. First, we provide background on the circumstances leading to the establishment of the National Health Research Act and an overview of the different sections in the Act, followed by the methods used to evaluate the feasibility of implementing the Act. Subsequently, we present the opinions of stakeholders concerning specific laws that may be difficult to implement and the potential barriers to implementing these laws. Then to determine the feasibility of implementing the laws, we evaluate the opinions of stakeholders and compare the laws to those written in other African acts.

Background

The Zambian government formally introduced the National Health Research Act in 2013. Before the Act, there was no government regulation of health research in the country¹. Ethics committees would approve of research studies without a structured set of guidelines, leaving room for bias and unethical practices². Protocols to regulate transfer and storage of biological samples were almost non-existent³. Clinical researchers were not required to provide participant insurance in case of mishaps⁴, and foreign researchers were not required to include local involvement to build capacity⁵.

In Zambia, several research participants contracted HIV during a microbicides gel study in 2010. Although this trial was performed in various locations across the country, Chief Mwanachingwala of Mazabuka was outraged at the results in his district. He called on the government to ban the clinical trial in Mazabuka and demanded the research group to provide compensation to affected participants. To promote peace, the government banned the trial from continuing. Wide media coverage on the study propelled policy makers to create the National Health Research Act as a means to regulate clinical trials and ensure public protection, which is specifically stated as providing “a regulatory framework for the development, regulation, financing, and coordination of health research⁶”.

The Act was put in place by the government in response to public outrage at unethical practices in research⁷. According to Dr. Munthali, Chair of University of Zambia Biomedical Research Ethics Committee, the Mazabuka study had been conducted ethically. Rather, there were three different reasons leading to protests amongst the people: 1) Researchers did not understand or incorporate cultural norms. As a result, they did not receive community consent in addition to individual consent. In Mazabuka, where males were considered to be dominant figures in society, researchers did not mandate female participants to inform their husbands of participation in the trial. 2) Zambian researchers were not ready to disseminate results. They had not received approval to release the results locally by the MOH before partner countries were scheduled to release the results internationally, causing the media to be misinformed by online sources. 3) Participants misunderstood the purpose of the study. Researchers were conducting trials, not providing treatment to trial participants. However, participants had the false conception that the study was effective in protection against HIV. To avoid miscommunication between researchers and participants, an act regulating health research was necessary.

On 22 March 2013, the National Health Research Act was enacted by parliament. This Act consists of ten parts containing laws to guide the different aspects of health research. Part one of the Act is the preliminary section, which contains the short title of the Act, the meaning of terms used in the

¹ Personal Communication, Dr. Munthali (17 June 14), Dr. Nzala (03 July 14)

² Personal Communication, Dr. Nzala (03 July 14)

³ Personal Communication, Dr. Munthali, 17 June 14

⁴ Personal Communication, Dr. Munthali, 17 June 14

⁵ Personal Communication, Dr. Munthali, 17 June 14

⁶ National Health Research Act, 2013

⁷ Regarding implementation of CIDRZ, Mr. Mabvuto

Act, and the scope of applying the Act. The Act applies to all health research conducted in Zambia, which involves biological materials and the use of personal health information. The Act also applies to health research conducted outside Zambia by a person or body established in Zambia (National Health Research Act, 2013).

Subsequently, part two of the Act entails information regarding the establishment of the National Health Research Authority, its functions, and its powers. The National Health Research Authority is a corporate body that regulates, monitors, and evaluates the conduct of health research in Zambia. This Authority has the power to withdraw accreditation of a research institution or researcher, terminate an ongoing health research activity, ban research institutions and health researchers from conducting research in Zambia, seize and destroy biological materials obtained in violation of the laws in the Act, and inspect any institution or research site that has been approved by the ethical board to conduct health research in Zambia. The Council, which consists of representatives from the following sectors, controls the National Health Research Authority in terms of finance, defense, justice, health, education, science and technology, community development, livestock and fisheries development. The Council may also appoint the secretary, inspectors, and other staff of the National Health Research Authority (National Health Research Act, 2013).

Similarly, part three of the Act gives a detailed description of the functions of the National Health Research Ethics System, the tenure for each member, and the circumstances that can lead to vacancy on the board. The ethics board oversees and ensures adherence to health research ethics. To achieve this, it registers and accredits health researchers and health research ethics committees. In addition, it promotes training in health research ethics, reviews research proposals and research protocols, and initiates disciplinary action against any health researcher or institution that violates ethical guidelines for conducting health research in Zambia. The members of the ethics board are appointed by Council to serve on a part-time basis. The board members are diverse and represent various disciplines and sectors. The tenure for each member of the board is three years from the date of appointment. However, a member is eligible for re-appointment for another term. According to part three, the office of a member becomes vacant if the member dies, he becomes bankrupt, he becomes mentally or physically incapable of performing his duties, he is found guilty of professional misconduct, he ceases to be a representative of the organisation organisation that recommended him, and the member is absent from three consecutive meetings without reasonable excuses (National Health Research Act, 2013).

Part four of the Act deals with the National Health Research Authority, which is responsible for identifying the priorities of health research based on the health needs of the country, the resources available, the cost effectiveness of interventions, and the burden of disease in the country. Part four also provides details on the procedure for disseminating health research information and the Authority's right to access and depose of health research databases. Based on the information in this section, any health research conducted in Zambia has to be disseminated locally before being dispersed outside Zambia. Therefore, any person interested in publishing research information for health research conducted in Zambia has to inform the Authority in writing before publication. The Authority also has the right to access all databases, bio-banks, or any other information obtained by health researchers and research institutions. Furthermore, part four entails the establishment of a

Health Research Trust Account, which will provide financial assistance to the various departments in the ministries, universities, research institutions and researchers involved in health research (National Health Research Act, 2013).

Part five of the Act consists of regulations to guide the conduct of health research on human participants or animal subjects. The Act requires every health research conducted on human participants to be cleared by the ethical board, involve written consent, and comply with the social and cultural norms. Autonomy, beneficence and justice, which are the three universal principles of health research ethics, guide health research in Zambia. Also, this section of the Act provides regulations to guide health research on minors and other vulnerable groups. One of the striking laws in part five states that health research conducted in Zambia has to include a Zambian, who resides in Zambia, as a principal or co-principal investigator. Furthermore, it demands that any research institution hosting foreign individuals for the purpose of health research should ensure that the individuals comply with the Immigration and Deportation Act, 2010 (National Health Research Act, 2013).

Part six of the Act deals with biological materials for health research. The Minister of Health shall assign certain research institutions and sites as bio banks to provide storage services for health researchers to store biological materials. These bio banks shall comply with the Health Professions Act, 2009 and the Environmental Management Act, 2011, and also be inspected by designated law enforcement officers. Regardless, biological materials cannot be imported or exported without the prior approval of the Authority. These materials also have to undergo inspection at the points of entry and exit and can only be collected for purposes included in the research protocol (National Health Research Act, 2013).

In addition, part seven of the Act includes regulations for the conduct of clinical trials in Zambia. All clinical trials undertaken in Zambia have to be approved by an ethical board. If the clinical trial involves the use of medicine, then the drug has to be approved by Zambia Medicines and Regulatory Authority. Notwithstanding, researchers must provide “no fault insurance” for all research participants involved in a clinical trial and ensure that research procedures are conducted in a prescribed manner (National Health Research Act, 2013).

Subsequently, part eight is concerned with regulations to foster health research in traditional, complementary and alternative medicine. The Minister in conjunction with the Authority encourages collaborative research between conventional and traditional health researchers. In addition, the Authority shall ensure that information on traditional, alternative and complementary medicine are widely distributed. Notwithstanding, the Authority shall also ensure that the execution of the Act does not prevent traditional health practitioners from individually or collectively protecting their intellectual property rights.

Likewise, the penultimate section of this Act emphasizes the protection of intellectual property rights. Health researchers and research institutions can obtain a patent and hold rights to all inventions and innovations. Also, they are legally permitted to disseminate information on their research and are entitled to other benefits resulting from the research (National Health Research Act, 2013).

Last but not the least, part ten of the Act covers inspector power, service of notice, authentication of documents and general penalties for offences. Under the provisions of this Act, an inspector must provide reasonable notice to a researcher or research institution before entering a site for inspection. Moreover, any notice that has to be served must be delivered to the person required to be served. If the person is absent, then the notice should be left at the person's place of residence in Zambia. For companies or other corporate bodies, the notice can be sent through registered post, left in the office with an employee, or delivered personally to the principal officer. Also, any authentic document required by this Act must be in writing with the signature of either the director, secretary, or any officer of the Authority authorised by the director. Anyone who commits an offense under this Act with no other penalty can be either imprisoned for not more than three years or given a fine not exceeding three hundred thousand penalty units, or given both. However, for an offense committed by a corporate or unincorporated body, every director or manager of the organisation is blameworthy except in the case that they can prove to the court that the offense was done without their consent or knowledge, or that they made efforts to prevent the offense from occurring (National Health Research Act, 2013).

Although the ten parts of this Act provide a legal framework to guide health research, this research focused on specific laws in certain parts because many stakeholders were concerned about the feasibility of implementing these laws in Zambia. In the last two to three years, the Zambian government has started to regulate health research according to the Act. Bio banks, such as CIDRZ, were put in place to prevent improper conduction of clinical trials in part six of the Act. Ethics committees have convened to review research proposals, which are then passed on to the MOH for final approval to begin research projects (part three). Despite these efforts, concerns about the efficacy of the Act in regulation of inspector power, ethics committees, bio-banks, and international players have risen. Without the allocation of government funds toward locally driven projects, the government's ability to fully implement the Act is questionable. Thus, this paper further evaluates the feasibility of implementing the Act and identifies the potential barriers to regulation of health research.

Methods

Our primary research activities included a critical analysis of the National Health Research Act of Zambia and semi-structured interviews to determine the potential barriers to the implementation of the Act.

Through collaboration with the Southern African Institute of Policy and Research (SAIPAR) and the University Teaching Hospital (UTH), we were able to connect with various stakeholders. Since our research focused on parts three to ten of the Act, which dealt with the National Health Research Ethics System, regulatory framework for health research, health research with human participants and animal subjects, biological materials, clinical trials, research in traditional medicine, intellectual property rights, and inspector power, respectively, we contacted stakeholders that were affected by these sections of the Act. Thus, our stakeholders were representatives of bio-banks, research institutions, ethics committees, international organisations, and traditional healers' associations.

During the interviews, we asked about their general opinions on health research in Zambia and then considering their areas of expertise, we proceeded to more specific questions on the Act. In total, twenty one stakeholders representing Southern African Institute of Policy and Research, University Teaching Hospital, University of Zambia, Southern African Consortium for Research Excellence, Center for Infectious Disease Research in Zambia, Zambia AIDS Related Tuberculosis Project, Cancer laboratories, Zambia Institute of Policy Analysis and Research, United Nations, Traditional Health Practitioners Association of Zambia, and Elizabeth Glaser Pediatric AIDS foundation were interviewed over the course of June and July of 2014, in Lusaka, Zambia.

Results

Based on our interviews, we discuss the concerns of several potential barriers in five major subsections: incorporation of a Zambian Principal/Co-Principal Investigator in international research projects, ethical approval process, inspector power in regulation of bio-banks, no fault insurance requirement for clinical trials, and incorporation of traditional medicine with biomedicine. Positive, neutral, and negative stakeholder opinions are communicated in these subsections.

Incorporation of Zambian Principal/Co-Principal Investigator in International Research Projects

Stakeholders debate whether incorporation of a Zambian resident as a principal/co-principal investigator is necessary towards regulating international research projects and building professional local capacity. In the last fifteen to twenty years, the field of research in Zambia has grown, as there is an interest by international organisations as well as local researchers to finance research on a broad spectrum, from social health research to political economy. However, the government has yet to allocate funds toward locally driven research projects⁸. Generally, conducting research is expensive, and therefore international players are an important component⁹. Projects are mainly funded by international external sources like the World Bank, CDC, and NIH¹⁰. However, international research may not be benefitting the country in the long run; they publish locally relevant research but do not build capacity¹¹.

In part five (no. 45.9) of the Act, it states that health research must include a Zambian resident on the research team as a principal or co-principal investigator. A majority of stakeholders agree that having a Zambian co-principal investigator is a good mechanism to build capacity in the country under the supervision of a more educated international researcher, yet some argue that having a local Zambian PI is unnecessary and that their involvement with the research group gives them more than enough training¹². Because there may not be enough experienced Zambians to co-lead a specialised, internationally funded project, stakeholders fear that this requirement will limit the number of international research projects and funds coming into the country, thus stifling research instead of improving health research conducted in the country. Still others believe that it should be enough to have outsiders conduct research without Zambian contribution, as long as the research is benefiting Zambia and the results are being made accessible in the country, as it is a higher priority to have information available in the country than to increase local participation in research¹³. Others do not support this more extreme proposal, stating that to build capacity and incorporate cultural norms, Zambian researchers should be involved in foreign research.

⁸ Personal Communication, Mr. Chansa, Dr. Chitah, Dr. Musonda, Dr. Nzala, Ms. Subulwa

⁹ Personal Communication, Ms. Maimbolwa, Dr. Michelo (26 June 14)

¹⁰ Personal Communication, Dr. Chitah

¹¹ Personal Communication, Dr. Bolton

¹² Personal Communication, Mr. Chansa, Dr. Chitah, Ms. Maimbolwa, Dr. Michelo (26 June 14), and Dr. Munthali (17 June 14) support capacity building with a Zambian co-PI. Dr. Musonda, Dr. Bolton, Mr. Ndulo, and Ms. Tembo disagree.

¹³ Personal Communication, Mr. Mwansa, Mr. Ndulo, Ms. Tembo

However, the level of local participation is not widely agreed upon. Ginny Bond, a ZAMBART representative, proposes flexibility in the Act that requires involvement of a local co-principle investigator in highly specialized research projects, such as epilepsy studies. Since the cost of pursuing a PhD education for Zambians is expensive, Zambian researchers cannot fill certain specialised positions, and to mandate inexperienced local researchers to fill these positions may produce in-genuine participation that would harm research interests in Zambia. However, others believe that the interest in specialised projects exist, and it would be sufficient to have internationals share their knowledge of the subject matter to build up students to obtain PhDs in the case where there is a lack of education¹⁴. Thus, it is possible to have local co-principal investigators that do not have PhDs, as long as international researchers are incorporating local Zambians into their research projects by providing the necessary basic training. However, requiring local co-PIs could stifle research activity because it could potentially overload Zambians with research projects and counteract the benefits that local researchers could contribute (i.e. addressing participant rights and cultural practices). In order to address this issue, ZIPAR staff members propose the incorporation of safeguards to ensure local PIs are limited to a maximum number of projects at one time.

Many stakeholders believe that having a local co-PI provides an accountability mechanism that regulates foreign research by protecting participant rights, ensuring ethical conduct, and effectively building capacity in the country¹⁵. After Zambians have developed capacity in conducting research independently, it would be beneficial to change the current system by having senior local researchers mentor junior international researchers instead¹⁶. The ultimate goal is to have Zambians lead all future research projects as the main principal investigator¹⁷.

Ethical Approval Process

In order to increase regulation of international research by the Zambian government, Dr. Likwa, Senior Lecturer and Researcher on Population Studies at the University Teaching Hospital (UTH), proposes biomedical research ethics boards to give approval locally, even if researchers have already received international approval. Part seven (no. 54.4) of the Act states that researchers must first acquire approval by relevant ethics committees and then a second approval by the National Health Research Ethics Board. Although this two-approval system was created to protect participant rights, it causes delay in the reviewing of proposals and indirectly contributes to the delay in publication of manuscripts¹⁸. Public IRBs like UTH take about two months to review proposals because the board convenes only once a month, whereas private boards may give responses in two weeks¹⁹. Gaining the second approval from a national ethics board causes an even longer delay in the commencement of research. Right now, the approval process takes more than

¹⁴ Personal Communication, Dr. Chitah, Ms. Choolwe, Ms. Maimbolwa, Dr. Michelo (26 June 14)

¹⁵ Personal Communication, Mr. Chansa, Ms. Maimbolwa, Dr. Nzala (03 July 14), Ms. Subulwa, Ms. Tembo, Dr. Tshuma

¹⁶ Personal Communication, Dr. Ahmed (10 June 14), Ms. Maimbolwa

¹⁷ Personal Communication, Ms. Choolwe

¹⁸ Personal Communication, Dr. Munthali (17 June 14), Dr. Nzala (03 July 14)

¹⁹ Personal Communication, Dr. Nzala, 03 July 14

three months to approve community-benefiting research, and over six months to approve academic research not directly improving the community²⁰.

To hasten the approval process, most recommend decentralisation of ethical clearance procedures by several mechanisms. Some recommend increasing the number of IRBs across major local institutions (i.e. UTH, UNZA) and limiting MOH involvement to reviewing and keeping a comprehensive record of approved proposals, instead of initiating a second approval process as indicated by the Act²¹. According to Dr. Musonda, an international research collaborator at UTH, the primary role of the Ministry of Health (MOH) should be to check conducted research against proposals approved by IRBs. Mabvuto Phiri, CIDRZ Central Lab Operations Manager, on the other hand, recommended centralisation by strengthening the National Board and removing IRB approvals. However, majority of the stakeholders suggest that the current two-approval system is the better option. In the past, the ethics board was independent from the MOH, but due to compromises in participant protection, government combined the two boards²². Most stakeholders believe that the approval process can be improved in two ways: a more neutral governing body should review ethical conduct of research (not MOH)²³ and research should be allowed to commence after receiving IRB approval but before receiving the second MOH approval²⁴. According to Ireene Subulwa, UNZA Assistant Registrar of Research at the Directorate of Research and Graduate Studies, if research proposals obtain IRB clearance, it usually does not have a problem with obtaining MOH approval. But in the case where research is not in line with the national review board, it would not be too late to stop the progression of that research study²⁵.

To ensure ethical, appropriate research, better communication between researchers and political leaders is necessary, as research goals passed every year should be in line with research activity in the country²⁶. Dr. Chitah, UNZA Public Health and Health Economics Researcher, believes that MOH approval could bridge the gap between policy and research in an effort to improve community health. However, others point to the bias that results when politics gets too involved. Dr. Michelo, Director of Community Medicine Department at UTH, proposes that a more neutral board not involved in health research activities, like the Ministry of Justice, should regulate research ethics, as the MOH should not be allowed to regulate their own activities. However, Dr. Chitah argues that the Ministry of Justice does not constitute as a neutral board because ethics would still be mixed in with political interests. Dr. Tshuma, Acting Head of Obstetrics and Gynecology Department at UTH, proposes the provision of a separate Ministry of Research as a means to promote independent bodies that can regulate research. She states, "Decentralisation may be challenging, but vital to ensure autonomy of the provisions of the Act".²⁷

²⁰ Personal Communication, Ms. Bond, Mr. Mabvuto

²¹ Personal Communication, Dr. Bolton, Dr. Chitah, Dr. Likwa, Dr. Munthali (17 June 14), Dr. Musonda, Dr. Tshuma

²² Personal Communication, Ms. Maimbolwa

²³ Personal Communication, Dr. Bolton, Dr. Chitah, Dr. Michelo (26 June 14), Mr. Ndulo

²⁴ Personal Communication, Ms. Bond, Mr. Ndulo

²⁵ Personal Communication, Ms. Bond, Mr. Ndulo

²⁶ Personal Communication Dr. Bolton, Dr. Chitah

²⁷ Ibid.

Another mechanism to speed the approval process has been to increase the number of members on the research ethics committee²⁸, or to provide sitting allowances for authorities to give approval as cases come up instead of reviewing proposals in bulk²⁹. However, Maimbolwa, SACORE International Liaison Officer, points out that to increase the number of IRB committee meetings to expand regulation of health research requires more funding. Dr. Nzala, Assistant Dean of Post-Graduate Medical Education at UNZA, states the possibility of receiving Johns Hopkins University grants to increase the number of people trained in bioethics.

Overall, it is necessary for researchers to be approved by an ethics board to ensure that proper consent forms have been gathered. In certain villages, community consent is just as important as obtaining individual written consents to conduct research³⁰. Bond suggests structuring community advisory boards to obtain genuine community consent, while Subulwa states that the UNZA IRB already includes this aspect of representation across various departments.

The interpretation of the need for research clearance has revealed differences across research disciplines. According to ZIPAR and SAIPAR staff, social science research is only required to receive ethical approvals from independent boards (internal clearance) and consent from participants, but according to MOH Board members, the government now requires social science research dealing with individuals in any way, to be evaluated by the National Ethics Board in the same approval process as clinical research trials. However, it may be more beneficial for the National Board to only review sensitive community-based cases through a set of established guidelines, so as to regulate ethicality in research proposals on a timely basis.

Inspector Power in Regulation of Bio-Banks

Before the Act, there was no monitoring mechanism to regulate distribution and storage of samples at a central location.³¹ The Zambian government began addressing these concerns by creating bio-banks such as CIDRZ as a means of ensuring that ethical practices were adhered to uniformly.³² However, inspector power has been limited since the regulations were released³³. CIDRZ stores samples based on what the research protocols entail, but to Dr. Bolton's knowledge, inspectors have not yet checked on these institutions to be sure they are following the rules, indicating that regulation is based on an honor system. Dr. Bolton, CIDRZ Chief Medical Officer, states that she believes it would be beneficial for all if regular inspections were carried out in the future.

In part ten (no. 57.1), the Act states that an inspector should give "reasonable notice to a health researcher or person responsible for a research institution" before site investigation. Dr. Tshuma proposes that in addition to having reasonable notice given before inspection, a component that allows inspectors to enter without notice if contravention or offence is suspected is a necessary addendum to the Act. Others argue that inspectors should follow random monitoring timelines to ensure researchers are following the protocols on a daily basis, and thus all visits should be

²⁸ Personal Communication, Ms. Maimbolwa, Dr. Munthali (17 June 14), Dr. Nzala (03 July 14)

²⁹ Personal Communication, Mr. Mabvuto

³⁰ Personal Communication, Dr. Munthali (17 June 14)

³¹ Personal Communication, Dr. Nzala, 03 July 14

³² Personal Communication, Mr. Mabvuto

³³ Personal Communication, Dr. Bolton

unannounced. Several stakeholders say that if researchers knew when inspector checks would occur, they would fix problems beforehand, reducing the efficacy of this monitoring mechanism³⁴. The only downfall to having unannounced visits would be the possibility of conducting an inspection without the presence of the person in charge³⁵. However, Maimbolwa states that the focus is not on whether inspectors show up announced or unannounced, but rather on whether the inspectors are regularly monitoring distribution and storage of biological samples.

Another component of the Act specifies a Material Transfer Agreement (MTA) that gives government a say in how samples are used, by restricting collection of samples and decreasing tissue storage duration to less than ten years³⁶. According to Chansa, Radiation Laboratory Scientist at CDH, it is only proper for the government to have a say in how samples are used because each sample represents an individual. Although the MTA is well policed, it is not well inspected³⁷. Thus, inspectors should be made aware of ethical guidelines³⁸ to be able to identify and prosecute unethical conditions³⁹.

The Act also addresses the need for inspection of biological samples at entry and exit sites, but fails to specify exact locations. Chansa assumes that these sites are at country borders and airports. However, Dr. Bolton would like the Act to specify ports of entry/exit, and see that those areas are well monitored.

Last but not least, Dr. Tshuma urges the importance of introducing a separate clause in the Act to address research dealing with fetuses. Conventionally, vulnerable populations include: prisoners, children, pregnant women and fetuses, nursing mothers, and people afflicted with mental illness or a behavioral disorder. The Zambian Act briefly mentions some vulnerable populations but does not give explicit guidelines to regulate research involving the interests of vulnerable groups. Currently, the Act places fetuses under “products of conception” (taken from the definition of biomaterials, article 48), which is listed in the same category as bodily fluids. This could potentially enable researchers dealing with collection of fetuses to abuse this component of the Act by disguising the content of their research protocols under the heading “bodily fluids”. To prevent exploitation of this vulnerable population in health research, fetuses should be protected under a separate clause in the Act.

No Fault Insurance Required for Clinical Trials

Several stakeholders suggest that this “no fault insurance” component of the Act may protect participants by having researchers pay a cost, whilst others mention several underlying issues that cannot be resolved solely with the requirement of participant insurance. In order to conduct clinical trials, researchers have to provide no fault insurance for all research participants according to part seven (no. 54.4f) of the Act. This component ensures a form of compensation for the participant in case of injury contracted during the study, while protecting the researcher from losing their license

³⁴ Personal Communication, Mr. Chansa, Ms. Choolwe

³⁵ Personal Communication, Mr. Chansa

³⁶ Personal Communication, Mr. Chansa, Mr. Mabvuto, Dr. Munthali

³⁷ Personal Communication, Dr. Bolton

³⁸ Personal Communication, Dr. Michelo

³⁹ Personal Communication, Dr. Munthali

to conduct research in Zambia⁴⁰. The inclusion of no fault insurance is an improvement, considering how participants in the past were not entitled to compensation without engaging in a court trial⁴¹. However, Dr. Tshuma points out that this component is unique to the Zambian Act, as other Southern African countries lack this deprivation of rights by participants to sue; rather, she believes health research should take full responsibility of its participants.

Providing insurance to research participants can be a costly practice for the researchers, yet Dr. Nzala states that researchers should have insurance upfront to avoid heavier costs that may arise later. As insurance costs may be high for individuals and some institutions, Kenneth Mwansa proposes that the government (through research councils) should cover these costs for research projects that are beneficial to the populace. Dr. Ahmed, on the other hand, argues that having a no fault insurance policy may discourage people from participating in research trials because in case of injury, they would not be able to fault the researcher. The Act is ambiguous about the level of compensation that participants are entitled to in extreme cases, as in the event of participant death, which Subulwa would like the Act to specifically address.

Incorporation of Traditional Medicine with Biomedicine

Traditional medicine has been and still is an integral part of community health in Zambia, but has not yet been effectively integrated into patient care in the biomedical community⁴². Recently, there has been a government movement to incorporate traditional medicine into the biomedical research field. In part eight (no. 55.1c) of the new Act, the MOH has made collaboration between traditional and conventional health researchers a priority. However, many factors compromise this collaboration. Distribution of non-standardised traditional medicine is a livelihood⁴³, and to package herbal medicines into pharmaceuticals poses an issue with intellectual property rights. Each group is prone to guard their own interests. To allow distribution of traditional medicine into the biomedical community, some argue that more time and research need to be dedicated to the field⁴⁴. However, Simon Nyoni, THPAZ Publicity Chair, states that there simply needs to be increased awareness on intellectual property rights being extended to traditional healers as indicated by part eight (no. 55.1d) of the Act, in order to reduce secrecy of traditional healing practices and medicines. Traditional healers do not share their knowledge of herbs for fear of losing ownership rights and monetary benefits that come with distribution by pharmaceutical industries⁴⁵. By protecting their property rights, traditional healers may be more open to allowing clinical research on the efficacy of herbal medicine.

As of yet, there has been no formal mechanism of conducting clinical trials on traditional medicine⁴⁶. There has been an increased desire by the medical community to make traditional

⁴⁰ Personal Communication, Dr. Munthali, 17 June 14

⁴¹ Personal Communication, Dr. Munthali, 17 June 14

⁴² Personal Communication, Ms. Bond, Dr. Likwa, Dr. Michelo (26 June 14), Dr. Munthali (17 June 14), ZIPAR

⁴³ Personal Communication, Dr. Ahmed (10 June 14), Dr. Michelo (26 June 14), Dr. Tshuma

⁴⁴ Personal Communication, Ms. Maimbolwa, Dr. Nzala (03 July 14), Dr. Tshuma

⁴⁵ Personal Communication, Mr. Nyoni

⁴⁶ Personal Communication, Dr. Ahmed (10 June 14), Ms. Choolwe, Dr. Michelo (26 June 14), Dr. Munthali (17 June 14), Mr. Nyoni, Dr. Tshuma

medicine strictly evidence-based, being sensitive to local traditions while removing non-scientifically sound beliefs⁴⁷. Dr. Likwa proposes that healers bring evidence of their work through a feedback system to evaluate the effectiveness of their treatment regimes. In other words, if the biomedical community can see that herbalist treatment regimes are effective, traditional medicine can contribute to the health system. However, traditional healers do not understand the long process of evaluation and have limited understanding of science⁴⁸. As a result, doctors approach traditional medicine with a negative connotation, but still refer their patients to traditional healers for unexplainable and incurable diseases⁴⁹. Other doctors will not go so far as to refer patients to traditional healers, but will allow patients to seek the services of traditional healers if they so wish⁵⁰.

In order to reduce discrimination of traditional medicine by the medical body, some stakeholders state that both fields should understand the basic practices that define each field⁵¹. First, the Act should accurately distinguish traditional healing practices from witchcraft as a means to dissolve a long-standing myth that these two fields are related⁵². Then, herbalists should remove misconceptions from their practices (i.e. sickness being an aftermath of greed)⁵³. When these misconceptions are cleared, conventionalists can then be trained on the importance of traditional medicine in providing holistic treatment⁵⁴. For example, doctors can draw from an herbalist's ability to provide psychological management of patients. According to Nyoni, traditional medicine has not been incorporated into the formal sector because of "professional jealousy". This jealousy, per se, leads to a one-way patient referral process from traditional healers to doctors. However, he believes the referrals should be reciprocated. Examples of this reciprocated process can be seen in palliative care,⁵⁵ and it is only a matter of time before the two medical groups work together in clinical research settings.

Another way of promoting biomedical respect for traditional medicine is to increase the educational background of traditional healers. By introducing traditional medicine into the formal sector, isolation of traditional healers can be removed and acceptance by the medical community may be achieved⁵⁶. Nyoni is a proponent of educating healers in conventional medicine because he feels the education could integrate the two fields and give healers a greater advantage in providing quality patient care. The government could work with modern medicine to clear training for herbal scientists⁵⁷ by incorporating a subsection of treatment and care under "community medicine"⁵⁸. Another option would be to train healers to identify serious conditions that should be referred to

⁴⁷ Personal Communication, Dr. Ahmed (10 June 14), Dr. Musonda

⁴⁸ Personal Communication, Dr. Michelo (26 June 14)

⁴⁹ Personal Communication, Dr. Ahmed, (10 June 14), Dr. Nzala (03 July 14), Dr. Tshuma

⁵⁰ Personal Communication, Dr. Munthali, 17 June 14

⁵¹ Personal Communication, Dr. Bolton, Dr. Likwa

⁵² Personal Communication, Mr. Nyoni, Dr. Tshuma

⁵³ Personal Communication, Dr. Likwa

⁵⁴ Personal Communication, Dr. Likwa, Mr. Ndulo, Dr. Nzala (03 July 14)

⁵⁵ Personal Communication, Ms. Tembo

⁵⁶ Personal Communication, Mr. Chansa, Dr. Chitah, Mr. Nyoni, ZIPAR staff

⁵⁷ Personal Communication, Mr. Chansa, Dr. Michelo (26 June 14)

⁵⁸ Personal Communication, Dr. Bolton

the hospital and less serious conditions that they can treat⁵⁹. In this way, traditional healers can continue to play an integral role in patient care, but prevent patients in serious conditions from waiting too long to seek biomedical attention⁶⁰. On the other hand, Maimbolwa states that education may not be the best solution for incorporating the two disciplines because most traditional healers are illiterate. She believes that informing healers on the usage of herbs in the biomedical community would be sufficient enough to initiate a collaboration of traditional medicine with conventional medicine. Thus, collaboration is feasible, but implementation still poses a challenge.

⁵⁹ Personal Communication, Mr. Ndulo

⁶⁰ Personal Communication, Dr. Munthali (17 June 14)

Discussion

According to Emmanuel et al. (2004), developing countries have experienced a greater risk of exploitation due to poverty, illiteracy, cultural, and linguistic differences, limited health-care services, and a limited understanding of the nature of scientific research. In 1964, the declaration of Helsinki was established by the World Medical Association to guide the conduct of biomedical research involving human subjects (History of Ethics, 2014). Despite the existence of these documents and many more written after them, vulnerable populations were still being exploited, and some research procedures were not ethically sound. Thus, various countries delineated rules and regulations to guide the conduct of research on its grounds. In Zambia, the challenges of health research are as follows: obtaining informed consent, inspecting research sites, regulating research conducted by foreigners, protecting vulnerable populations, approving research protocols in a timely fashion, and protecting the legal rights of research participants. As a basis for discussion, several other African acts are included for comparison against the National Health Research Act in Zambia.

Over the years, a substantial number of research projects conducted in Africa have been funded and controlled by external sources, which have resulted in poor capacity building, exploitation of participants, and inaccessibility of results that could facilitate research progress. To combat this issue, the Zambian Act states that for research to be conducted in Zambia, a Zambian resident should be included as a principal or co-principal investigator (National Health Research Act, 2013), which has similarly been stated in the Uganda Act (National Guidelines for Research Involving Humans as Research Participants, 2007). Having a Zambian researcher as a co-principal investigator is more beneficial than simply having a resident contributing to the research team because it involves an interactive role that requires skill, extensive knowledge of the subject matter, and regulation of foreign researchers to conduct research that is ethically approved. In order to build capacity, researchers must be capable of conducting a research topic of similar background independent from foreign researchers, and adequately trained to submit their own proposals as principal investigators. Only by knowing the inner-workings of a research project and contributing heavily to how the research is carried out will the Zambian resident receive ownership of the publication. Without a Zambian co-principal investigator, it is more difficult for the government or Zambian members on the research team to demand local dissemination of results. In order to benefit the Zambian community, results from research studies must remain in the country. Thus, this part of the Act is better achieved by incorporating more local involvement in foreign research projects.

Another significant problem in health research is the protection of vulnerable participants because it is difficult to access laws that enforce researchers to provide protection. Granted, every act includes laws to protect the rights of its vulnerable population, but some susceptible cohorts are still excluded from the list of vulnerable populations. Conventionally, vulnerable populations include: prisoners, children, pregnant women and fetuses, nursing mothers, and people afflicted with mental illness or a behavioral disorder. Unlike the Kenyan and Ugandan Act, the Zambian Act

briefly mentions some vulnerable populations but does not give explicit guidelines to regulate research involving the interests of this group. Meanwhile, the Kenyan Act includes laws to protect under-developed communities (Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya, 2004), and the Ugandan Act includes laws to protect the homeless, mature and emancipated minors, and armed forces (National Guidelines for Research Involving Humans as Research Participants, 2007). In addition, both acts explicitly state guidelines to protect each group. Since these groups are also susceptible to exploitation and undue coercion, creating specific laws to protect them may provide great benefit.

Based on the different cultural norms in various communities, the process of obtaining informed consent from research participants can be quite complex. In male dominated societies such as the Mazabuka community in Zambia, the husband has to give his consent before his wife can participate in research studies. Also, in most rural areas, the community leader has to provide consent for research to be conducted in his community. Thus, due to the significance of community consent, the National Health Research Act for Zambia states that in addition to obtaining individual consent from each research participant, the investigator should comply with the cultural norms at his research site and obtain consent from all parties involved.

Secondly, most consent forms are written in English, which makes comprehension difficult for those with little or no understanding of the language. Although investigators employ translators, pertinent information can be lost during translation. The Zambian Act does not address this issue, but this problem is properly addressed in the Malawian Act. According to the Malawian Act, a qualified individual should do the written translation of the consent documents. In addition, it requires a back translation to English to validate the accuracy of the translation, and authorises all back translation documents to be reviewed by the National Health Sciences Research Committee (The National Health Sciences Research Committee General Guidelines on Health Research, 2007). In addition, to increase awareness of research ethics among rural dwellers, the Nigerian Act states “The national code of health research ethics shall be available in different Nigerian languages, even though the English version shall be the only correct interpretation of the provisions of the code” (National Code of Health Research Ethics, 2007). Therefore, by providing the code of ethics and consent forms in local languages, research participants in rural areas can be empowered to protect their rights and interests.

In fact, the ethical approval process in the Act was established to reduce bias leading to unethical practices in health research. The reasoning behind mandating a two-approval process was for the local ethics boards to regulate research proposals and for the second ethics board to monitor the ethics committees through a national framework. However, the involvement of policy makers in regulating research activities may encourage political bias in approval of research proposals that are in line with government interests, which may not necessarily be beneficial for the community or academic interests. In Malawi, this issue is addressed by decentralising the ethical board (The National Health Sciences Research Committee General Guidelines on Health Research, 2007). By removing the necessity of obtaining a second ethical clearance from the MOH in Zambia, a greater variety of research topics may be conducted despite the sensitivity or specialty of topics. Rather, IRB approvals should be submitted to the National Board as a way to record all research activity in

the country, and ensure ethical conduct. This National Board should include a variety of professions to review proposals and set ethical guidelines. Although the one-approval process did not effectively regulate research in the past, this new proposal is highly feasible because it would reduce the waiting time involved in the approval process, would reduce MOH involvement in approving controversial research topics, and would still allow the government to gauge a general overview of research topics in-country and regulate conduction of research.

Another hindrance to the implementation of the National Health Research Act is inspection. The purpose of inspector power inclusion in the Act was to ensure that inspectors properly regulated distribution and storage of biological samples. Unlike other acts, the Zambian Act requires the inspector to give reasonable notice to a health researcher or the individual in charge of a research institution before inspection (National Health Research Act, 2013). However, this gives organisations time to make arrangements that comply with ethical guidelines during inspector visits, but which may not be imposed regularly. The more effective monitoring mechanism is where organisations cannot predict inspector visits, and thus must maintain sanitary conditions in coordination with ethical guidelines to avoid losing accreditation as a bio-bank. The best way to measure true compliance would be to have both announced and unannounced inspector visitations, which has already been effectively implemented in the South African Act (National Health Act, 2003).

Although the Zambian Act is lacking in certain areas, it has some laws that are not included in other acts. A striking feature of the Zambian Act is the “no-fault insurance” that researchers have to obtain for research participants involved in clinical trials. “No fault insurance” was incorporated into the Act as a means to protect research participants from exploitation, as well as researchers from losing their license to conduct research if the study was conducted within ethical boundaries. Although this component of the Act provides better insurance coverage and injury compensation for participants, it discourages participants from finding blame in the researcher or research institution. The Act addresses ethical guidelines, but does not state what types of mistakes, responsible for participant injuries, can be pardoned. By allowing participants to make claims in court about who is at fault, participants would be able to gain a second perspective by the judicial system in defining what research activity is deemed ethical.

In addition, the National Health Research Act (2013) delineates laws to foster research in traditional medicine, to ensure dissemination of information on traditional medicine, and to protect the intellectual property rights of traditional healers, which is not seen in other related African acts. The purpose of integrating traditional medicine with biomedicine in the Zambian Act was to improve healthcare practices and healthcare delivery. For many years, Zambians have resorted to traditional medicine, as it is deeply rooted in cultural beliefs and incorporates a holistic view of patient care. Biomedicine, a relatively new branch that emphasises a scientific approach, has not focused on the individual’s illness but separated the disease from the person. Although research institutions have not formally evaluated the efficacy of herbal medicines, medical practitioners have noticed the potency of traditional medicine and the delay of patients with serious complications in seeking healthcare. To reduce the level of delay in healthcare delivery, it is essential that traditional healers become familiar with the basics of biomedical practices and become trained in identifying

critical from minor medical conditions. By integrating these two disciplines, a Zambian approach to quality healthcare may be achieved.

Overall, stakeholders have suggested that the Zambian Act should consider the balance between researcher interests and research participant rights to protection, but the main issue lies with the feasibility in implementation of the National Health Research Act. There are some areas of the Act that need to be clarified through specific details, while other areas need to address possible exemptions to the Act. As the Act is not a restrictive document, policy makers should include more specific guidelines that explicitly state the boundaries. For example, creating special clauses in the Act for research dealing with fetuses and other vulnerable populations with communication barriers (i.e. non-English speakers) will protect vulnerable groups from exploitation. Revising the current MOH board to act as a national review board that provides a check and balances system to local IRBs will ease the transition into decentralisation and speed up the ethical approval process. By including “unannounced” inspector visits to the original clause in the Act, inspectors would be able to effectively monitor true compliance. To ensure proper inspection is conducted, inspectors can be trained in ethics. Also, the “no fault compensation” component of the Act can be clarified in areas regarding what mistakes are deemed excusable, and what consequences are in place for more extreme cases of participant injury. That way, participants are made aware of their rights to protection before participation in a trial and can make claims in court about who is at fault. Last but not least, challenges associated with the integration of traditional medicine with biomedicine include difficulty in removing social stigmas, altering traditional medicine by removing non-scientifically sound practices, providing educational opportunities for herbalists, incorporating herbal scientist training into university curriculums, and protecting traditional healers’ intellectual property rights before conduction of research on herbal efficacy. Thus, implementation of the Act as a whole is challenging, but feasible with the inclusion of several recommendations listed above that address the current state of affairs in Zambia.

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Appendix

Table 1. Conducted Interviews

Stakeholders	Zambian Co-Researcher	International researchers	Ethics Board	Approval Process	Human tissue; Bio-banks	No fault compensation; liability insurance	Traditional Medicine Incorporation	General Concerns & Thoughts
Dr. Yusuf Ahmed, MMED (master of medicine) Research Coordinator at UTH	Ownership issues	Senior local researchers should mentor junior international researchers				Needs to be addressed	Traditional med. not standardized; no clinical research on traditional med. Doctors think negatively of traditional healers, but still use their services	Act is not enforced well
Dr. Munthali, Chair of UNZA Biomedical Research Ethics Committee	Builds capacity	Mazabuka trial: Local researchers were not ready to disseminate results because they did not have MOH approval	Community Consent necessary; Necessary for researchers to be approved by ethics board	2-approval process delay publications. Initial consent by ethics should be enough. Good that national board overlooks local boards – more regulation.	Good that act includes persecution of improper distribution; MTA gives government say in how samples are used, but makes it more difficult for researchers. Act restricts collection of samples & shorter storage duration	Insurance for participants allows protection and compensation, but costly to researchers. Cost of insurance has increased for clinical trials.	No formal mech. of trials on traditional med; should integrate traditional med with modern med. Doctors have neg. view of traditional healers, but are aware that they play an integral role in caring for patients that wait too long to seek biomed.	To implement Act, need to increase members on ethics board, increase awareness of act, and have strong monitoring mech.
Dr. Selestine Nzala, Assistant Dean of Post-Graduate Medical Education at UNZA	Accountability mech.; ensures participant protection by local researcher		Grant from JHU funds to increase # of people trained in bioethics.	UTH ethics (public): approval takes 2 months b/c board only meets once a month. Private ethics board gives response in 2 weeks	How will tissue be stored at a central place? Enforcement issue	Good that researchers have insurance upfront to avoid heavier costs later. Cost determines type of research conducted.	There has been a government movement to incorporate, but each group guards their own interests – need time and research on traditional med to	1) There needs to be regulations to state what are exemptions to Act – it is not a restrictive doc 2) local research not well funded (no government funds) – stifles progress 3) conventionalists not trained on importance of

Stakeholders	Zambian Co-Researcher	International researchers	Ethics Board	Approval Process	Human tissue; Bio-banks	No fault compensation; liability insurance	Traditional Medicine Incorporation	General Concerns & Thoughts
							provide clearance.	traditional med
Dr. Charles Michelo, Director of UTH Department of Community Medicine	Locals can learn from international researchers (expertise, knowledge, skills). Local training is limited, so draw on international partners' training; capacity building	Research is expensive, so need international players	Need to have a body governing ethical conduct of research NOT by MoH but a more neutral board like Ministry of Justice b/c MoH should not regulate their own activities; need neutral board to clear ethics				Collaboration feasible, but implementation is a challenge. Traditional healers do not understand the long process of evaluation, have limited scientific understanding, and give treatment the day they are sought out (livelihood). Government could work with modern med to clear training for herbal scientists.	1) Act not universally distributed 2) Inspectors need to be aware of ethics.
Dr. P Musonda, visiting prof from UK	Helps int. orgs to know local practices. Research should build capacity and benefit local people. Local researcher not as PI, but key player in int. research to gain independence in applying to grants	Need to consult Zambia, a stakeholder by default, through 1) local partners or, 2) basing org setup in Zambia (not operating from a distance)	Inspectors can check actual research being done against research approved by ethics committee				Be sensitive to local tradition, but remove non-scientifically sound beliefs. Do research in this area (make traditional med. evidence-based).	1) Professors should conduct research to impart knowledge to students 2) Government does not allocate budget for research. Need local funds to compete competitively and for government to have say in implementation.
Dr. Rosemary Ndonyo Likwa, Senior lecturer and researcher on population studies	Give local people resources by decentralization			Should be approved by biomedical research ethics locally, even if approved by international boards.			Understand how traditional med works, and remove misconceptions that herbalists make with illness (i.e. sickness because of greed). Herbalists have good	1) Initiate a national health research advisory (directorate of national health research). MOH structure is not organized – too broad. 2) Research activity profile should be kept 3) Guidance is necessary before recruitment of researchers 4) Raise

Stakeholders	Zambian Co-Researcher	International researchers	Ethics Board	Approval Process	Human tissue; Bio-banks	No fault compensation; liability insurance	Traditional Medicine Incorporation	General Concerns & Thoughts
							public relations and include psychological management. Doctors can learn holistic treatment. Have healers bring evidence of work (feedback system to evaluate effectiveness)	awareness of Act
CIDRZ local branch near UTH		Works with int. and local groups			Store samples based on researcher protocol			
Mabvuto Phiri, CIDRZ Central Lab Operations Manager		HIV, NIH-funded studies, PMTC - community		Hasten process by strengthening 1 board (MOH) instead of having various bodies. For approval to store materials: 3+ months to approve community-benefiting research. 6+ months to approve academic research not directly improving community	CIDRZ started from Mazabuka trial to prevent recurrence. MTA gives government more say in research			1) Challenges with resources – maybe give sitting allowances for authorities to give approval as cases come up, instead of waiting until they have a lot of cases to process approvals.
Dr. Carolyn Bolton, CIDRZ Chief Medical Officer	We need to ensure that research is benefitting the country. International researchers residing in Zambia are contributing already through paying tax, employing staff and	Need to ensure that they publish locally relevant research and also build capacity	Should be objective and independent from MOH (politics). To ensure ethical research, have better communication between researchers and policy makers. Research	Hard to get approval from ministry. Make more efficient by managing internally (ex: have one research body to submit proposal to, and have them	MTA is well policed but not well inspected.		Politics: traditional med want more control but traditional doctors want them to understand science of germ theory. Should understand basics, not details of both	1) Improve communication by email – faster, more eco-friendly process. 2) There is inherent suspicion of research. 3) Act is outdated. Should be reviewed and updated. 4) Need more people to ensure implementation of act 5) Port of entry and exit should be

Stakeholders	Zambian Co-Researcher	International researchers	Ethics Board	Approval Process	Human tissue; Bio-banks	No fault compensation; liability insurance	Traditional Medicine Incorporation	General Concerns & Thoughts
	answering locally relevant questions. However, there needs to be more focus on building local capacity both to conduct research and publish in peer reviewed journals. It is important that a Zambian is included in all publications (not necessarily in co-PI role). Need government involvement and support		proposals approved every year should be in line with research priorities in country	distribute to appropriate boards			practices. Have subsection of treatment and care under "community medicine"	specified and well policed
Ginny Bond, ZAMBART Representative & Social Anthropologist	Capacity building imp, but cost of PhD for locals is expensive so hard to find people to fill specialty positions. Need flexibility. As a Zambian resident, she feels this would strengthen research.	The more funding is provided, the more say they have in projects. Act is pushing against outsiders taking responsibility of local research by introducing Zambian co-PI, but this may lead to in-genuine participation of local researchers	Get genuine community consent through community advisory boards. Average – 6mon to get ethics and MOH approval	Should be allowed to do research after getting ethics approval, then MOH later.		Could be prosecuted for ethical breeches, but too draconian regarding aspect of informed consent, as there will always be some slips.	Make social aspect of traditional med more explicit in Act, and look into relationships rather than just research for med aspects. Research in DEPTH, not just conduct a rapid survey.	1) Include social science component to health research. 2) Act addresses intellectual prop rights so that they lie in Zambia and not outside
Manenga Ndulo, SAIPAR Director & UNZA Professor of Economics	Could stifle research activity b/c overloading Zambians with research; it is ok to have outsiders do research without	Give private researchers independence to conduct research (ex: epilepsy studies). Involve local researchers - doesn't have to	Ethics board should be separate from government; Have independent researchers start as long as they are supervised,	Social science: get authority from ethics, then consent from individuals		More relevant for clinical trials. Social science researchers do not get insurance for participants.	Traditional med can be paired with psychological diseases (areas not dangerous). Should train healers to identify serious	1) Address better communication b/w diff ethics boards 2) research should be supervised 3) Have balance b/w government and private researchers 4) there is a delay in pushing the act forward → need a

Stakeholders	Zambian Co-Researcher	International researchers	Ethics Board	Approval Process	Human tissue; Bio-banks	No fault compensation; liability insurance	Traditional Medicine Incorporation	General Concerns & Thoughts
	Zambians, as long as research is benefiting Zambia and making results accessible → having info remain in Zambia is more imp than having Zambian co-researchers	be co-PI	and just wait for 2 nd approval (from superior board) as they conduct research.				conditions and refer to hospital; treat less serious conditions	full consultation w/ stakeholders in health research. 5) Inspectors need consultation from stakeholders to know what's feasible, so act can be properly enforced. Most laws are written on paper, but not feasible b/c just copied from other countries
ZIPAR Staff	Need local rep at the technical level. Have safeguards to ensure local PI is limited to a max # of projects at one time		Independent ethics board/internal clearance board so no need approval like other researchers, maybe b/c ZIPAR is partly government-run	Ethical approval process for clinical trials = barrier to implementation			Good. Need integration of traditional med (rich history) w/ modern med. Introduce traditional med to formal institution to gain acceptance by medical community – remove discrimination	1) How effective is inspection?
Veronica Tembo, Technical Advisor for Glaser Foundation	Build capacity. Need continuity to continue research after foreign researchers are gone. Position not so imp as general presence b/c they would provide checks and balances regarding cultural issues	Projects improve community healthcare. Zambia have lots to learn	Protection of client's rights in cohorts	Speed up approval process. Generally, not easy to get approval, but had rapid syphilis testing in past funded by CDC.			Traditional healers have lack of education and generally (-) influence on HIV clients. They integrate traditional healers w/ conventional med to strengthen referral system (as partners in palliative care).	1) No funding to train the 2 med groups to work together. At national level, no law to integrate diff forms of med.
Kenneth Mwansa, UNAIDS Country community mobilization and networking			Consent is imp!			Government (through research councils) should cover cost of some research if beneficial to		1) UN provides technical support for Zambian research, and does routine monitoring of activities, but not regulated by legal requirements. Stats

Stakeholders	Zambian Co-Researcher	International researchers	Ethics Board	Approval Process	Human tissue; Bio-banks	No fault compensation; liability insurance	Traditional Medicine Incorporation	General Concerns & Thoughts
advisor						populace, like insurance costs		help government know where country is lacking 2) control local research dissemination to foreign countries and how research is conducted. To regulate anything, there is a cost – researchers should pay fees (reasonable). 3) Researcher right to awareness of Act's limitations
Dr. Bona Chitah, UNZA Public health and health economics researcher	Needs more independence. Needs more interactive system to develop research field. Educating in research may create autonomy for local researchers and build capacity. Maybe having Co-PI is necessary, given where we are. To be Co-PI, you must be capable. If not capable, learn process from starting as postgrad student and work your way up.	External funding = key source. External sources come with pre-designed projects, not letting locals drive the research, given country's needs. But should be allowed to feed into international requirements	Ethics should be neutral board (not linked to MOH). Not in Ministry of Justice either b/c biased when policy is involved.	Ethics approval always takes some time, but we can live with that. If approval has gone through ethics, MOH (2 nd) approval is unnecessary. But this is not a limiting factor – MOH approval could bridge gap b/w policy and research			Traditional med integration into formal sector has been marginalized –this needs to change. Potential in traditional med to feedback into some health products. Remove traditional med isolation	1) Social scientists in health sector limited! 2) Resources for research are limited; Maybe local institutions should have research budget (ex: UNZA, UTH). Hard to get government funding
Ireene Subulwa, UNZA Assistant registrar of research (Directorate of research and graduate studies)	Necessary. Prefers having Zambian co-PI to ensure foreigners are following procedures and are protecting Zambians	No answer. Most funding is external (i.e. Danida for school of vet, Japanese government in school of vet)	External researchers get research clearance from UNZA, then MOH. Ethics board now represents various departments: doctors, professors,	Reasonable. Fast track takes 10 working days in UNZA; normal track takes a month. Once UNZA approves, MOH usually				1) Funding is a major barrier. No government funds for past 6 years. Only 20,000 kwacha is given per school (natural and applied science, biomed research, and social science) for research 2) Act should include what

Stakeholders	Zambian Co-Researcher	International researchers	Ethics Board	Approval Process	Human tissue; Bio-banks	No fault compensation; liability insurance	Traditional Medicine Incorporation	General Concerns & Thoughts
			etc.	approves.				happens in the event that a participant dies. 3) Encourage research by increasing funding, helping students find external funds, and holding award ceremonies at postgrad level
Maimbolwa, SACORE International Liaison Officer (Aim: train students in country to obtain PhDs at UTH- funded by Welcome trust)	If overloaded with work, senior local researchers can have students under them to carry out research. Needs to have local PI to build capacity and should understand research context to be held responsible for ethical matters	Senior local researchers should mentor junior international researchers b/c they know Zambian context. Int. researchers necessary b/c capacity building, in grant apps (the name of int. org opens doors for local researcher). Even in the case with lack of local PI education, int. researchers can train them.	Initially, ethics board was independent from MOH, but there were problems because ethics not controlled. Now, MOH ethics committee looks at transportation of products and int. research = better system now.	Ethics approval can be improved by having more people on committee, and more committees. IRBs also need more money, so to expand regulation of act, need more \$. MOH approval needed to use hospital facilities	No inspector problems. We need sanitation & research of standard, so control should be good! Inspectors coming announced vs. not does not matter. Just make sure inspectors are timely in monitoring – have regulation		Barrier: Property Rights. When pharmaceuticals take herbs and translate to tablets, who gets the credit? MOH needs to find a storage facility for traditional med. Traditional & modern doctors need to work together: education not the solution b/c most healers are illiterate, but if they see how herbs are being used, they will be open to working with conventional med.	1) Before act, Zambian research could not be assessed. 2) Hard for young researchers to get limited funds because of competition with senior researchers. 3) Locals should have access to research info conducted in Zambia. 4) To implement act, need resources (\$) and advocacy. Need to disseminate info on act to various parts of country
Choolwe, SACORE Representative	Good idea, but in future, have Zambians as main PI. Interest is not a problem; it's the lack of training (int. researchers can share educ.). The few with PhD's can train juniors to build interest & experience,				Inspectors should come unannounced to reduce bias and make regulation more efficient. If researchers know inspectors are coming, they will fix problems then (not a good		Not enough research done on traditional med (no evidence on efficacy). With enough research, incorporation not a problem.	1) Financial challenges! 2) Supervision of students doing research is a problem.

Stakeholders	Zambian Co-Researcher	International researchers	Ethics Board	Approval Process	Human tissue; Bio-banks	No fault compensation; liability insurance	Traditional Medicine Incorporation	General Concerns & Thoughts
	which would also increase interest in PhD's amongst trainees				monitoring mech.)			
Chansa, Radiation Laboratory Scientist at CDH	Co-PI is good b/c Zambians should be able to give details of research to community & regulate foreign research. They need to have a top position to gain exposure – makes it easier for locals to conduct similar research in the future. Don't need properly trained PI's since int. researchers can teach necessary skills	Ownership should be based on extent of contribution. Lot – ownership; little-recognized in paper.		No idea.	Regulation of samples: institutions should keep details and reflect this info at entry/exit sites (ex: borders, airport). Government should have say in samples b/c samples represent individuals. Random timing is best by inspectors; only downfall is that they may not meet the person in charge.		No training. Modern med looks down on them b/c no educ. background	1) Health research should be a priority area, but government would rather use funds to build hospital (immediate results) instead of research (long term results) 2) Increase research training and make investment in research equipment to do substantial scientific research (rather than social research in health sector)
Simon Nyoni, THPAZ Publicity Chair							Has MOH support, but would like to see more government support (judicial system). Public needs to be able to differentiate b/w witchcraft and traditional healing (myth). Challenge: professional jealousy from bio-medicals b/c they provide	1) Act does not distinguish b/w traditional healers and witchcraft. 2) Intellectual prop rights extended to traditional healers, but they are still secretive b/c not sure if these rights are protected (raise awareness that they are protected, and they will share knowledge). They want benefits and patents to drugs they create. 3) Traditional healing (spiritual aspect) is largely inherited, but use of

Stakeholders	Zambian Co-Researcher	International researchers	Ethics Board	Approval Process	Human tissue; Bio-banks	No fault compensation; liability insurance	Traditional Medicine Incorporation	General Concerns & Thoughts
							<p>holistic treatment. Written referral process is one-way (healers to doctors).</p> <p>Belief: biomed is child of traditional med; even though they question efficacy, fear of traditional healers in society is diminishing.</p> <p>THPAZ open to research, and working with biomed to produce cures for people. Advantageous to mix biomed with traditional med (proponent of education).</p>	herbs can be taught.
Dr. Tshuma, Acting Head of OBGYN Department at UTH	May regulate who comes to do research and for what purpose. There must be local expertise within the team to guide research based on local conditions. Int. research may be more embraced as a Zambian product.	Int. funding should never turn into slavery. Some int. orgs have a tendency to control and manipulate, while others come to get desired results by the presence of a few Zambian residents on the team with limited research or technical understanding.	Act could make provision for a separate ministry of research. We need independent bodies for research b/c politics is dynamic, and each party carries its own agenda that could affect research. Let politicians remain in their political area, off research.	Decentralization is challenging, but vital to ensure autonomy of the provisions of the act. Have a stakeholders meeting, where act can be subjected to consensus agreement before implementation.	The clause is stated clearly – have reasonable notice given, but enter without notice if contravention or offence is suspected. Part VI: separate “products of conception” referring to fetuses from being listed w/ bodily fluids from	Not sure how many acts worldwide demand this deprivation of rights by participants to sue. Opinion: research must take responsibility of its subjects.	Lack of collaboration; Traditional med is associated w/ witchcraft & there is a lack of research in standard dosing & side effects; modern med perceived to be superior. Traditional med. distribution is not regulated – meds sold for an income (i.e. sex enhancing drugs)	1) Traditional healers well represented in Council, Health REB, and clinical trials. But need more representation from community in religious aspects b/c more patients seek church before traditional healers (an observation).

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					definition of bio materials, and introduce a separate clause addressing research dealing with fetuses -in this case, collection of samples cannot be based on just content of research protocol (b/c can abuse article 48 of act)			