A Report on Capacity Needs Assessment for Institutional Review Boards in the ECSA-HC region

East Central & Southern Africa Health Community

EDCTP PROJECT

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INTRODUCTION

The East, Central and Southern Africa Health Community (ECSA-HC) is a regional inter-governmental organization, whose membership comprises of; Kenya, Lesotho, Malawi, Mauritius, Swaziland, Seychelles, United Republic of Tanzania, Uganda, Zambia and Zimbabwe. The organization was established in 1974 by the Convention of the East Central and Southern Africa Health Community to promote regional cooperation in health. ECSA's vision is to be the leader in health in East, Central and Southern Africa, contributing towards the attainment of the highest standard of physical, mental and social well- being of the people in the region.

The ECSA countries share almost similar characteristics with respect to health problems including diseases such as HIV/AIDS, TB & Malaria. The countries also share similarities in their health care delivery systems. The cooperation of the ECSA countries therefore necessitates a collective response to health problems. This requires a strong mechanism for sharing health related information, harmonizing policies and practices and building consensus among partner states on the conduct of ethical research.

It is in this regard that the ECSA Secretariat proposes to establish ECSA-Regional Scientific and Ethics Committee (RSEC) which will act as an oversight body charged with the responsibility of approving multi-country research proposals and capacity building of the National Research Ethical Committees (RECs) of the Member States. The expected outcome is strengthened capacity of national scientific and ethical committees to approve and facilitate multi-country research proposals within the region. ECSA conducted a detailed needs-assessment survey for institutional review boards (IRBs) in the partner countries. The aim of this study was to evaluate if there is aneed to establish a regional IRB that could supplement the activities of local IRBs and also review and approval multi-country proposals. We hereby present the findings of this study

Background

What is an IRB?

The general definition of an IRB is an independent committee comprised of at least five members - including scientists, non-scientists, and at least one member who is not affiliated with the institution to which the IRB belongs. Members of the IRB may include employees of the institution, students, as well as members of the local community. The committee is charged with reviewing studies proposals involving human subjects for

compliance with institutional policies and state, local, laws. The review also ensures that all studies adhere to the principles detailed in the Belmont Report. This report emphasizes on respect for persons, beneficence, and justice. The most important function of IRB committee members is to ensure that human subjects participating in a given study are protected from harm. To do so, the IRB receives submitted proposals, reviews them and approves or disapproves their execution. The IRB committee has the authority to approve new studies and may request changes to be made to an ongoing study. The IRB may also terminate an ongoing study if that study faults the rules governing ethical conduct in research.

Why are ethics Important?

Knowledge on research ethics is important because it allows the investigators to know:-

(1) How to behave while conducting research

(2) What constitutes virtues and vices in research

This kind of knowledge provides the researcher with a structure for conducting research, analyzing and disseminating findings. Ethics also guides researchers in making decisions based on research findings. One of the key pillars of research ethics is respect to human (and animal) subjects. Ethics define benefits and risks of participants and allow the investigator and the subject to make decisions based on the equilibrium between potential risks and benefits. A benefit is the positive value or advantage of being part of a study. Most studies will have an aspect of benefit and risk. This value or advantage might be concrete for individual subjects e.g. getting treatment in intervention studies, or non-tangible (for example, a study may determine the burden of a given disease in a population based on a few selected volunteers). In most studies, the risks are assumed by individuals, while the benefits may accrue to the society at large. Generally, risks are evaluated according to the probability and magnitude of any harm that might occur. However, payment for study participation should never be considered a benefit. Evaluating risks *vs.* benefits in some studies may be difficult because neither the potential benefits nor risks may be known in advance.

The principles that guide research ethics are contained in the Belmont report. This is a report published in 1978 by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research (US). The report comprises of three key principles:

(1) Respect for persons (autonomy). This concept has two main ethical convictions: first, individuals, especially the study participants, should be treated as autonomous agents. Second, persons with diminished autonomy are entitled to protection.

(2) Beneficence. The principle of beneficence asks researchers to ensure that participants are not only protected from harm but that their wellbeing is ensured. The guiding formulae for ensuring beneficence include;

    a) Do not harm to study participants or any other person in the course of conducting research
    b) Maximize possible benefits and minimize possible harms

(3) Justice. The principles of justice guide on who bears the burdens of research and who ought to receive the benefits

It is therefore clear that in order for investigators to develop proposals dealing with human subjects, they must have minimum training in ethical issues.. It is therefore understandable, that every country endeavors to establish IRB(s) that can protect study participant. Even within a given country, multiple IRBs affiliated to different institutions may exist. Since each institution often demand that studies carried out in their jurisdiction must be reviewed by their own IRBs for approval, proposals intended for multi-center, multi-country implementation may be subjected to multiple IRB reviews. This presents a bottle-neck and delays approval and implementation. Such delay may compromise the chances of meeting application deadlines for research funds.

Problem statement

Most developing countries, especially those in Sub-Saharan Africa, are yet to develop a critical mass of scientists who can conduct studies especially those dealing with clinical trials. It is therefore important to ensure that proposals dealing with human subjects are properly reviewed before approval. This would ensure that the welfare of participants is protected. However, such reviews may require recruitment of IRB members with special skills and persons from diverse professional backgrounds.

In most countries, ERC/IRBs are affiliated to parent institutions that include universities and research institutes. Since most IRBs cater for proposals generated within the parent institutions, it is possible that they do not exercise administrative and financial independence. As expected, lack of enough resources could be a major factor that hinders the smooth operation of most IRBs in Sub-Saharan Africa. Financial constrains may not allow IRBs to have enough members who can participate in the review of submitted proposals. Such IRBs are

therefore likely to be under-staffed and members may not afford specialized training in ethics. Lack of resources for the IRB and poor remuneration of the investigators could translate to:

(1) Poor training in ethical issues and lack of continued training for IRB members. This could hinder ability of reviewers to identify loopholes that can expose study participants to unnecessary risks.
(2) Poor composition of IRB members in terms of the numbers and gender parity and the inability of IRBs to incorporate members with special skills who can provide objective review of submitted proposal.
(3) Inability to review submitted proposals in an objective and timely manner.
(4) Comprise of the welfare of research participants especially those who expect to gain materially (or medically) from their participation in a given study. Such recruits are likely to be enticed financially to enroll in studies that are not ethically sound.
(5) Inability of the IRB to put measures in place that could eliminate conflicts of interest among investigators and reviewers
(6) Financial conflicts of interest by investigators seeking to gain from their research activities

From the foregoing, it is correct to postulate that since there is no standard reference in Sub-Saharan Africa for establishment and running of IRBs, review and approval of studies that are conducted across more than one country may be inadequate and may experience serious delays in approval and implementation. Majority of investigators conducting multi-country studies face the following problems

(1). Some local IRBs may not have the capacity to critically review complex studies due to lack of appropriate expertise (e.g. stem cell research)

(2). Participating institution in multi-country or multi-institutional studies may demand that the proposal be reviewed in each of the respective IRBs.

(3). The need for parallel approvals in different IRBs may lead to delay or contradicting verdicts in which case, one IRB may approve a study while another may disapprove it.

The problems or bottlenecks faced by these investigators may translate to the following:

(1) A lengthy process of review and approval may delay submission of proposals for funding leading to poor application out comes

(2) In some cases, the investigator may require to have multiple version of the same proposal, each version custom-made to meet approval standards of different IRBs. This makes implementation difficult

(3) Some IRBs may demand changes or modifications on a proposal prior to approval. Such changes may not be in line with the application guidelines for funding.

Justification of the study

Although countries in the Sub-Saharan Africa are generally regarded as poor, the human developed indexes and resource-base differ significantly from one country to another. Since these countries conduct scientific research including those dealing with human subjects, it is possible that socio-economic factors complicate establishment of IRBs that can review proposals objectively and in a timely manner. It is therefore important to assess the modes of operations of different IRBs and to determine factors that complicate the process of development of proposals (especially those dealing with human subjects), review of such proposals, their approval and implementation. Such an assessment would serve the following purposes

(1) Capacity gaps may be identified and such gaps could be addressed in future. This would improve the smooth operations of a given IRB.

(2) The findings of such as study would justify establishment of a regional IRB to cater for multi-Centre or multi-country proposals

(3) Identification and filling of existing gaps may lead to establishment of minimum standards for IRB operations. Such a step would allow acceptance of study approval across IRBS, i.e. reciprocal recognition of study approval across different IRBs/countries.

This study was designed with a view to indentifying gaps in the operation of IRBs in the ECSA region. It is expected that data generated from this study will aid in determining the best strategies that should be employed to fill existing gaps. It is also envisaged that this study will serve as a future reference point during establishment of the ECSA regional IRB that will compliment and support other IRBs in this region. A regional IRB would play a vital role in review and approval of multi-country, multi-centre, multi-disciplinary proposals.

Objectives of the assessment

In order to achieve the aims of this study, we set the following objectives.

(1) To document the existence of research ethical committees /IRBs in countries with aim of supporting the country to establish one through the regional body
(2) To assess the capacity gaps in terms of reviews, time taken to get an approval, training capacity of IRB members, and to identify bottle necks that hinder smooth operations an IRB
(3) To review policies, guidelines and strategies on the conduct of ethical research in ECSA Region
(4) To assess the capacity of the Ministries of health in terms of coordination and regulation of ethical resea rch in ECSA region
(5) To identify and document best practices in the coordination & regulation of ethical Research in ECSA
(6) To determine human resource and financial needs for the conduct of ethical research in ECSA e.t.c.
(7) To determine if there is a need to establish a regional IRB for multi-country studies

The research questions for this study were as follows

(1) Do all participating countries have functional IRBs?
(2) How are these IRBs constituted? What is the minimum resource base for each IRB?
(3) What are the major non-conformities that can be identified in each IRBs
(4) Would a regional IRB add value or remove existing bottle necks for the review of multi-country studies

Methodology

In order to answer these broad questions, we developed a data collection tool that had the following sections (the complete data collection tool appears as appendix 1)

1. Organizational aspects of each IRBs
2. Membership & educational training for IRB members and the investigators
3. Resources available to the ERC/IRB
4. Workload in each ERC/IRB
5. Process and modalities for protocol submission in each ERC/IRB
    - 5.1 Guidelines for submission of research protocols in each ERC/IRB
    - 5.2 Materials and documents required during submission of proposals
    - 5.3 Format and content of minutes from ERC/IRB meetings

5.3.1 Policies governing the review process
5.3.2 Policies relating to the actual review process
5.3.3 Scientific design and execution of the study
5.3.4 Matters relating to assessment of risks and benefits of studies
5.3.5 Principles guiding selection of research participants
5.3.6 Issues relating to community engagement
5.3.7 Safety monitoring and adequacy of Insurance to cover Research related injury

Data analysis

The questionnaire was administered to each IRB. A senior member of the IRB filled the questionnaire before submitting it for analysis. The data was filled in excel sheets and analyzed using simple descriptive statistics. Each IRB was evaluated for compliance to major issues regarding IRB operations. Emphasizes was put on short-comings on IRB policies and guidelines, the review process (from submission of proposals to approval), training of investigators and reviewers on ethical issues and resource availability to each IRB. Tables, graphs and pie charts were used for data summary.

Study limitations

The data collection tool failed to capture the following

1) Budget size of each IRB was not determined
2) Budget source of each IRB was not determined
3) The actual review process of each IRB was evaluated (time required for approval)
4) What proportions of proposals reviewed are from outside the parent institution?
5) What are the penalties for non-compliance to ethical standards?
6) Only one IRB per country was evaluated. The data presented here may not therefore reflect the status of other IRBs in the same country

Study finding/Results

Basic information regarding participating IRBs

We carried out a needs-assessment evaluation for IRBS in the following partner countries: Kenya, Tanzania, Uganda, Malawi, Zambia, Lesotho, Swaziland, Seychelles, Mauritius and Zimbabwe. In most countries, ERC/IRBs were affiliated to parent institutions such as universities and research institutes. We selected the most prominent ORB in each participating country in terms of the number of proposals reviewed and their complexity.

Table 1 summarizes the basic information concerning the IRBs evaluated in each country. In Zambia, Mauritius, Lesotho, Swaziland and Seychelles, the IRBs were affiliated to the ministries of health while the rest were affiliated to medical research institutes and medical schools. We could not identify exactly when the IRBs affiliated to the Ministries of health were established. The Medical Research Council of Zimbabwe was the oldest IRB (1976) followed by the Kenya Medical Research Institute IRB (1979)

Table 1. *Basic information concerning each of the IRBs evaluated*

Name of the ERC/IRB	Name of parent organization	Country	What year was the ERC/IRB established?
Medical Research Council of Zimbabwe	Medical Research Council of Zimbabwe	Zimbabwe	1976
KEMRI-ERC	Kenya Medical Research Institute	Kenya	1979
Science and Ethics Committee	Uganda Virus Research Institute (UVRI)	Uganda	1992
IRB - College of Medicine Research and Ethical Committee	College of Medicine	Malawi	1996
IRB - College of Medicine Research and Ethical Committee	College of Medicine	Malawi	1996
NatHREC)	National Institute for Medical Research (NIMR)	Tanzania	2002
National Health Research Ethics Committee	Ministry of Health	Zambia	2007
National Ethics Committee	Ministry of Health & Quality of Life	Mauritius	?
Ministry of Health IRB	Ministry of Health	Lesotho	
Swaziland Scientific and Ethics Committee	Ministry of Health	Swaziland	?
Health Research and Ethics Committee	Ministry of Health & Quality of Life	Seychelles	?

Mandates of IRBs

IRBs are established to carry very specific mandates. The primary mandate is to review and approve/disapprove research studies. Most IRBs carry all or some of the mandates listed below:

(1) Approve research studies
(2) Disapprove research studies.
(3) Approve or disapprove modification of ongoing studies.
(4) Conduct evaluation of continuing reviews.
(5) Observe / verify changes in ongoing studies.
(6) Suspend or terminate approval of an ongoing study.
(7) Observe the consent process and the research procedures for new and ongoing studies.

Establishment and mode of operation of an ERC/IRB may differ from country to country and from one institution to another. However, there are minimum chapters that must be included in the research proposal that allow the IRBs to perform the following tasks:

(1) To evaluate risks /anticipated benefits of studies submitted for approval
(2) To determine whether measures to mitigate any possible risks have been put in place.
(3) To determine whether risks are reasonable in relation to potential benefits.
(4) To ensure that study participants are recruited in an ethical manner and that their welfare is protected.

Table 2 summarizes the mandates of each IRB evaluated. Majority of these IRBs were established to assess compliance to ethical issues related to human subject recruitment and participation in various studies, to oversee ethical issues in ongoing studies, to provide a forum for appeal for aggrieved participants, and to review scientific content of study proposals. It is important to note that some IRBs (e.g. the KEMRI IRB) have two units: the scientific steering committee (SSC) that evaluates scientific content of the submitted proposals and the Ethical Review committee (ERC) that handles ethical issues. It however appears that some IRBs e.g. National Health Research Ethics Committee in Zambia evaluates both scientific and ethical aspects of proposal. It is possible that splitting the KEMRI IRB into two units allows it to handle large volumes of proposals (900 per year). It is therefore possible that this strategy allows the IRB to fast-track reviews. However, this strategy has its own demerits because the review process is much lengthy. In the two-unit IRB setting the investigators can only submit proposals to the

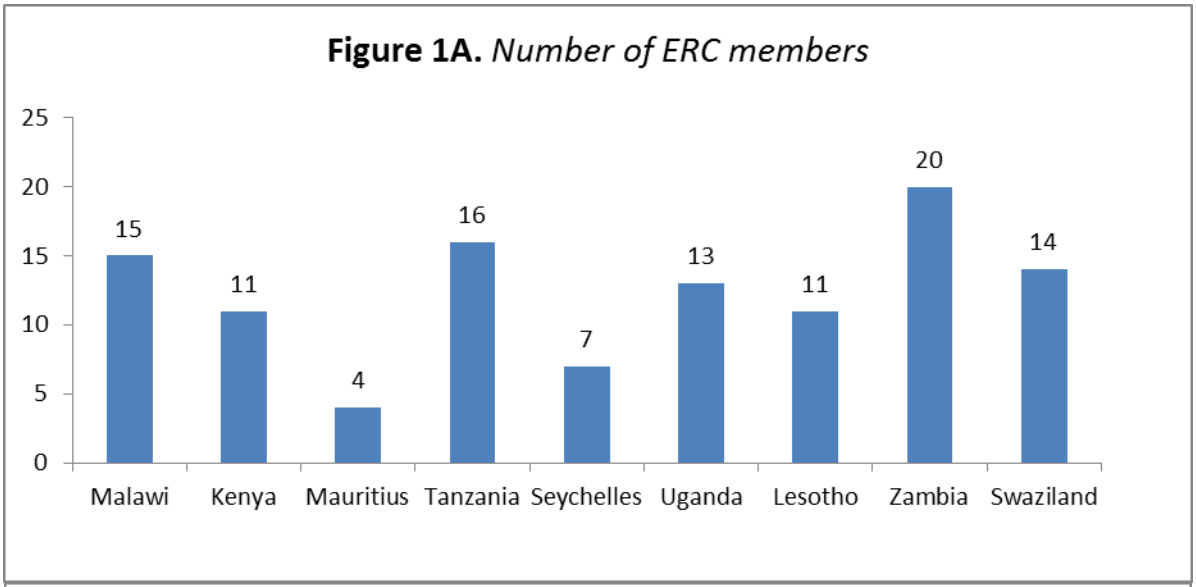
ERC only after SSC approval (approximately 3-4 months depending of the requested changes and modifications). The ERC process may also take between 2-3 months depending on the complexity of the study.

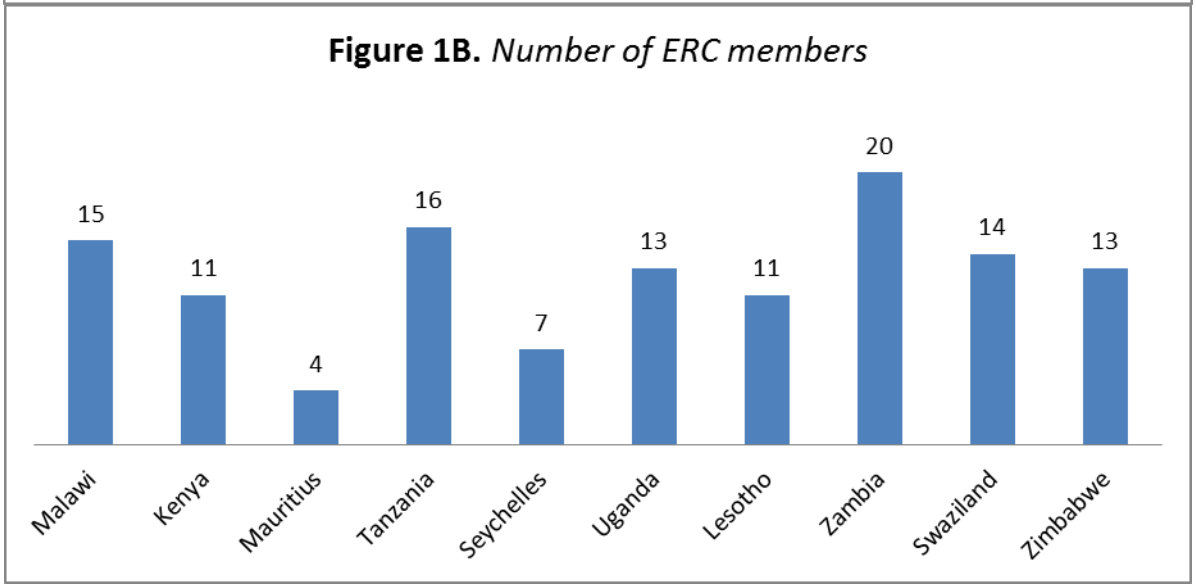
Table 2. *Mandates of various IRBs in participating institutions*

Country	Functions		
Malawi	Protect humans and anima subjects	Assess if studies are ethically sound	
Kenya	Assess ethical issues related to human subjects	Reviewing applications for new projects and amendments to existing studies.	
Mauritius	Assess ethical issues related to human subjects		
Tanzania	Assess ethical issues related to human subjects	Carry out the oversight of studies being carried out	
Seychelles	Reviewing applications for new projects and amendments to existing studies.	Provide ethical and technical assessment to all health research proposals	
Uganda	Maintain ethical standards of practice in research and secure integrity of studies and protect welfare of participants	Protect research participants& investigators	
Lesotho	Reviewing applications for new projects and amendments to existing studies.	Assess adherence to ethical standards in research and ensure integrity of studies and protect welfare of participants	
Zambia	Review Scientific content of proposals	Provide appeal forum for studies in relation to ethical issues	Review biological material transfer agreements
Swaziland	Provide ethical and technical assessment to all health research proposals	Review Scientific content of proposals	
Zimbabwe	Assess ethical issues related to human subjects	Carry out the oversight of studies being carried out	

Composition of participating IRBs

The number of IRB members is of utmost significance as far as timely review of submitted proposals is concerned. An under-staffed IRB may delay reviewing proposals hence compromising the chances of investigators to submit their application for research grant in a timely manner. An under-staffed IRB may also exert a heavy work load on IRB members which could compromise objective review of the submitted documents. Figure 1A indicated that majority of IRBs in the participating countries have over 10 members except for Mauritius (4) and Seychelles (7). However some IRBs only handle a small number of proposals per year despite having a critical mass of reviewer, Figure 1B.





Work load of each IRB

We calculated the theoretical workload for each IRB member by dividing the number of proposals submitted for review by the number of reviewers in each IRB, Table 3. The data suggests that the workload is heaviest in Kenya (82 proposals/person/year), Mauritius (22 Proposals /P/yr), Zimbabwe (19 proposals/p/yr) and Tanzania (13 p/p/yr). It is not clear why some IRBs e.g. in Uganda, Zambia and Malawi review only a few proposals yet they have up to 15 reviewers. Since most IRBs were affiliated to larger institutions such as universities and research institutions, it would be important to establish whether researchers in such institutions are at liberty to submit their proposals to alternative IRBs rather to those of parent institution. This data can be interpreted to mean that scientific activity (development, review and execution of proposals) is much lower in all other countries except in Kenya, Mauritius Zimbabwe and Seychelles.

Table 3. *Workload for reviewers in various IRBs*

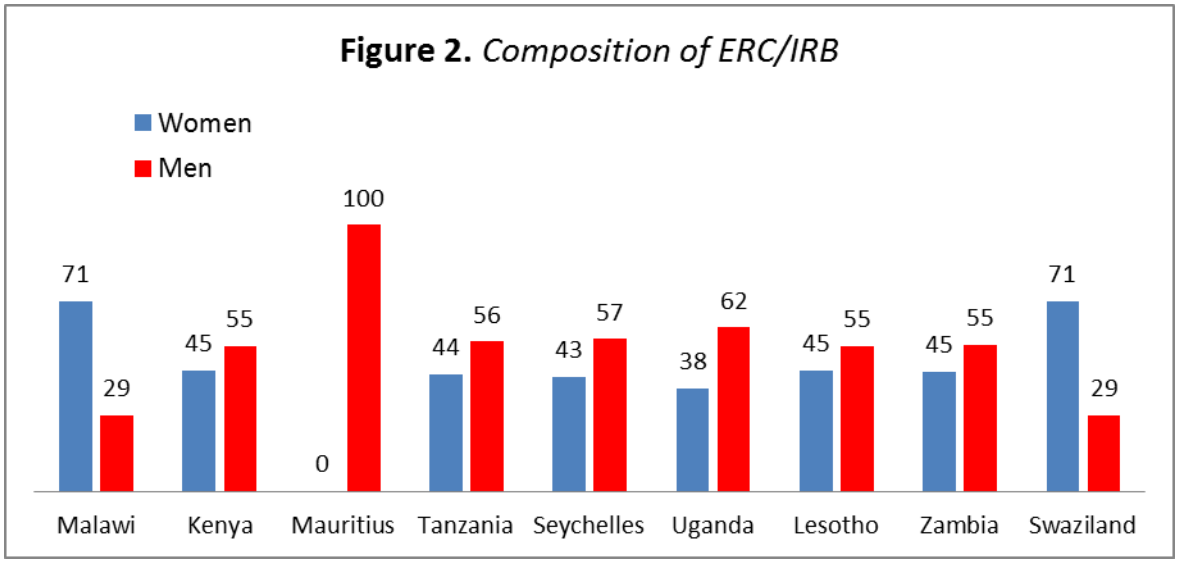
	Number of proposals reviewed per year	Number of IRB members	Workload (number of proposals reviewed)/person/year
Kenya	900	11	82
Mauritius	87	4	22
Zimbabwe	250	13	19
Tanzania	200	16	13
Malawi	101	15	7
Swaziland	80	14	6
Uganda	60	13	5
Zambia	50	20	3
Seychelles	7	7	1
Lesotho	16	11	1

The alternative explanation is that in some of these countries, only a few proposals are developed per year. IRBs with a heavy workload should be encouraged to expand their membership in order to reduce the workload on the reviewers. This could potentially lead to better quality of reviews. It is worth to note that most IRB members have other core duties besides reviewing proposals and therefore, each institution should determine the most appropriate workload per reviewer based on the staffing and the average number of proposals submitted. In that case, there is a need to increase administrative and review staff attached to each IRB, especially those that are currently understaffed. We suggest that each IRB member should review a minimum of 2 proposals per month (24/p/p/yr) and a maximum of 4 proposals per month (28/p/p/yr).

Gender parity in IRBs

As mentioned before, the composition of IRBs is important. The members of the IRB should ideally come from diverse social and academic backgrounds. In the US, an IRB should have at least five members who should be drawn from both sexes. Figure 2 shows that the gender parity is attained in most IRBs except for Mauritius where all members are male. Surprisingly, the IRBs in Malawi and Swaziland have only 29% of members who are males. It is not clear why some IRBs

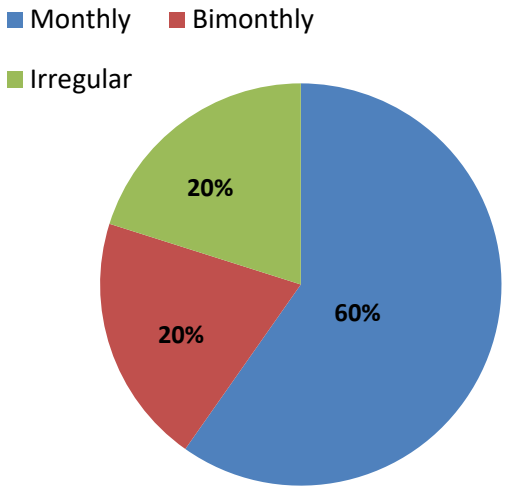
have not attained gender parity. The IRB in Malawi should be encouraged to increase the number of women while the IRBs in Swaziland and Mauritius should increase the number of male members.



Frequency of meetings for each IRB

Figure 3 and the accompanying data table show the frequency of IRB meetings in different countries. Most IRBs hold monthly meetings while 22% of these committees hold meetings in irregular intervals. It is evident that IRBs that review a large volume of proposals (e.g. those in Kenya, Malawi and Tanzania) hold meetings more frequently.

Figure 3: *Frequency of IRB meetings*



Country	Frequency of ERC/IRB meetings
Malawi	Monthly
Kenya	Monthly
Tanzania	Monthly
Uganda	Monthly
Swaziland	Monthly
Zimbabwe	Monthly
Lesotho	Bimonthly
Zambia	Bimonthly
Seychelles	Irregular
Mauritius	Irregular

There is a need to ensure diversity in professional background for members of various IRBs in participating countries. The general rules guiding establishment of IRBs (especially in the US) require an IRB to have:

1) Members that come from diverse professions.
2) At least one member whose primary concern is in nonscientific areas.
3) At least one member whose primary concern is in scientific areas.
4) At least one member who is not otherwise affiliated with the institution

Professional backgrounds of IRB members

The data presented in Table 4 below indicates that most IRBs have incorporated members from diverse background but it is clear that majority of these members have a scientific background. The number of social scientist is still low for majority of these IRBs. It would be helpful to ascertain whether or not the current composition of these IRBs is sufficient providing objective analysis for multi-disciplinary proposals and technically complex studies.

***Table 4** : Diversity of professions among IRB members*

Country	Number
Malawi	
Lay member	1
Professionals	14
Kenya	
Clinicians	5
Lawyer	1
Social Scientist	1
Community representative	1
Biomedical scientists	3
Lesotho	
Senior Researcher	1
Epidemeologist	1
Medical Doctor	1
Members from Development partner	1
Member from Law & Society	1
Member from Private Health Association	1
From the Secretariat	3
Others	2
Zambia	
Research scientist	1
Nursing officer	1
Lab technologist	1
Counsellor	1
Bio ethicist	1
Swaziland	
Laboratory Technologist	1
Medical Doctor	1
Health Research coordinator	1
Health Systems advisor	1
Statistician	1
Human Rights Expert	1
Director of Health Services	1
International NGO	1
Registrar of Nursing Council	1
HMIS Manager, M&e Coordinator	1
Epidemiologist	1
Social Scientist	1

Country	Number
Mauritius	
Director Health Services,	1
Director Pharmaceutical Services	1
Consultant in charge,	1
Training officer	1
Seychelles	
Clinical Psychologist	3
Ministry of Education	1
WHO representative	1
Private consultants	2
Ex-officio secretary	1
Uganda	
Statisticians	2
Clinical specialists/physician	2
Epidemiologies	1
Laboratory scientist	1
Social scientist	1
Tanzania	
Entomologist	1
Sociologists	1
Ethicist	1
Lawyer	1
Medical Doctors	?
Zimbabwe	
Biostatistician	1
Clinician	4
Social sciences	1
Community Rep/CAB member	1
Veterinarian	1
Lawyer	1
Epidemiologist	1
Religious leader	1
Epidemiologist	1

Diversity of proposals reviewed in various IRBs

Figure 4 shows that a significant proportion of proposals submitted to most IRBs are for clinical and epidemiologic studies. All studies reviewed in Seychelles and Lesotho did not fit into any of these two categories. On the contrary, only a small fraction of proposals reviewed in Mauritius, Zambia and Swaziland fit into any of these two categories. No proposals of clinical nature were reviewed in Mauritius, Seychelles and Lesotho. Uganda, Kenya Zimbabwe and Malawi had the highest proportions of epidemiologic/observational studies (between 40%-50%). At least 20% of all proposals reviewed in Kenya, Malawi, Tanzania and Zambia were of clinical nature. It is therefore important to ensure the participating IRBs are provided support in order to develop a critical mass of reviewers who can provide valuable and timely reviews for submitted proposals. It is important to ensure that these IRBs incorporate members who have knowledge on various aspects of clinical trials including recruitment of study subjects and consenting.

Figure 4. *Type of proposals (%) reviewed in various IRBs*

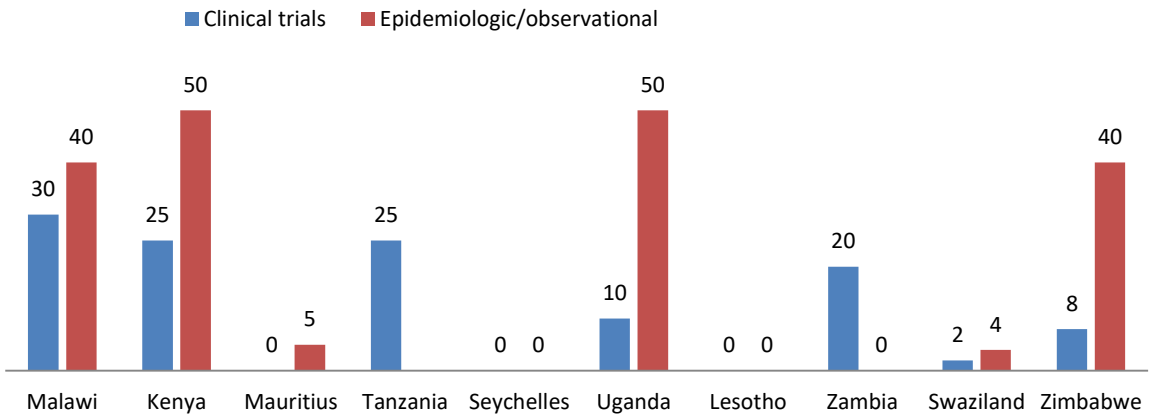


Table 4 indicates whether proposals are also reviewed by other IRBs before or after submission to the institutional IRB. It is however not clear why it is necessary to have proposals reviewed by more than one IRB. There are two possible explanations for this.

(1) Proposals may be reviewed in different IRBs because they are multi-centre studies

(2) A parallel review may ensure that a detailed and objective opinion on the feasibility and suitability of a study is sort from at least two independent IRBs.

(3) Some IRBs may not adequately handle the review of all or some sections of proposals especially those dealing with

a. Human subjects

b. Animal subjects

c. Drug trials and clinical trials

d. Testing of new diagnostic kits and equipments

The fact that proposals in these countries are often submitted to more than one IRB strongly suggest the need to:-

(1) Establish a mechanism of standardization of IRB approvals. Such an undertaking could allow different IRBs to fast-track or exempt review of proposals approved in a different IRB that meets the minimum standards

(2) Establish a regional IRB which can concentrate on approval of multi-country studies.

Table 5: *Other bodies that review proposals before or after IRB review*

Country	ERC/IRB	Parent organization	Review by another body before/after ERC/IRB
Malawi	IRB - College of Medicine Research and Ethical Committee	College of Medicine	The regulatory authority, pharmacy medicines and poisons board for clinical trials
Kenya	KEMRI-ERC	Kenya Medical Research Institute	Clinical Trial Applications, review & approval - Kenyan Drug Regularoty Authority, Pharmacy and Poisons Board's Expert Committee on Clinical Trials (PPB ECT)
Mauritius	National Ethics Committee	Ministry of Health & Quality of Life	Ethics Committee for Clinical Trials
Tanzania	NatHREC)	National Institute for Medical Research (NIMR)	Institutional IRB/REC review at Institutional level, 50% of protocals are reviewed by others
Seychelles	Health Research and Ethics Committee	Ministry of Health & Quality of Life	None
Uganda	Science and Ethics Committee	Uganda Virus Research Institute (UVRI)	None
Lesotho	Ministry of Health IRB	Ministry of Health	None
Zambia	National Health Research Ethics Committee	Ministry of Health	Institutional RECS, 80%, but the national review 100%, Material Transfer agreements
Swaziland	Swaziland Scientific and Ethics Committee	Ministry of Health	Yes, the external IRB's review it like Baylor centre of excellence, and University of Swaziland
Zimbabwe	Medical Research Council of Zimbabwe	Medical Research Council of Zimbabwe	None

Responsibilities of the Principal Investigators and Research Staff

Principal investigators and researchers are required:

1) To protect the rights and welfare of subjects recruited in various studies.
2) To have knowledge on ethical standards and regulations guiding research activities with human subjects.

3) The researchers must personally conduct or supervise the research.
4) They must ensure that all members of the research team are informed about the study content, the regulations governing research, and the appropriate institutional policies.
5) Ensure that they obtain an IRB approval for all research activities before conducting research using human subjects.
6) Maintain written records of IRB reviews and decisions and obtain and keep documented evidence of informed consent of the subjects or their legally authorized representatives. They should also make arrangements for secure retention of research records and all research-related materials
7) Must ensure that the all information obtained from and about human subjects remains confidential.
8) Obtain IRB approval for any proposed change to the original research protocol before those changes are implemented.
9) Must ensure timely reporting of unanticipated problems especially those that expose human subjects to undue risks or risks that were not foreseen at the inception of the study
10) Obtain continuation approval from the IRB on the research schedule and activities post-approval of the study.
11) Notify the IRB regarding intention to use any new investigational drug or device (that was not mentioned during the approval of the protocol) within 5 working days, or sooner. In such cases, the IRB may request to be furnished with the all documentation and description of the test article.

It is common to find investigators who flout these minimum rules. Non-compliance may be due to lack of resources or poor training in ethics. We used a set of questions to determine if investigators submitting proposals to IRBs in different countries have the necessary and minimum training in various aspects of ethics. It is clear that majority of IRB members and investigators who submit proposals to these IRBs acquire ethical training through internet based programs. One of the most popular online programs is the Collaborative Institutional Training Initiative (CITI). The CITI Program is a subscription service providing research ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization. One major challenge with the online training is that in some countries or institutions, the internet connectivity is not always reliable. It is also not clear how often the investigators and reviewers need to do refresher courses on ethics. Furthermore, an investigator from a given institution may not have training in ethics or may have gone

through a different training program rather than the one recommended by the IRB to which he intends to submit proposals for review. There is therefore a need to evaluate the suitability of the ethics training programs recommended by IRBs in the participating countries and efforts made to set minimum standards of acceptable programs.

Table 6: Type of training for ERC/IRB chair

Country		
Malawi	web-based training	
Kenya	web-based training	
Mauritius	Academic qualifications	
Tanzania	workshop in research ethics	Course in Ethics
Seychelles	web-based training	workshop in research ethics
Uganda	web-based training	workshop in research ethics
Lesotho	web-based training	
Zambia	web-based training	
Swaziland	web-based training	
Zimbabwe	Web-based training	Workshops in ethics

Data storage in each IRB

Table 7 shows that majority of IRBs store their information in cabinets and in electronic forms. Others also keep these information on open shelves. It is important to ensure that this information remain confidential and that information stored in electronic platforms is protected from malicious and un warranted access.

Table 7:Method of data storage in different IRBs

Country	**Data storage method**		
Malawi	paperwork in cabinets	Electronic (password)	
Kenya	paperwork in cabinets	Electronic (password)	On an open shelf
Mauritius	Paperwork in cabinets	Electronic (password)	
Tanzania	Paperwork in cabinets		
Seychelles	Paperwork in cabinets	Electronic (password)	
Uganda	Paperwork in cabinets		
Lesotho	Paperwork in cabinets		
Zambia	paperwork in cabinets	Electronic (password)	On an open shelf
Swaziland	Paperwork in cabinets	Electronic (password)	
Zimbabwe	Paperwork in cabinets		

Identifying major gaps in the operation of IRBs included in the study

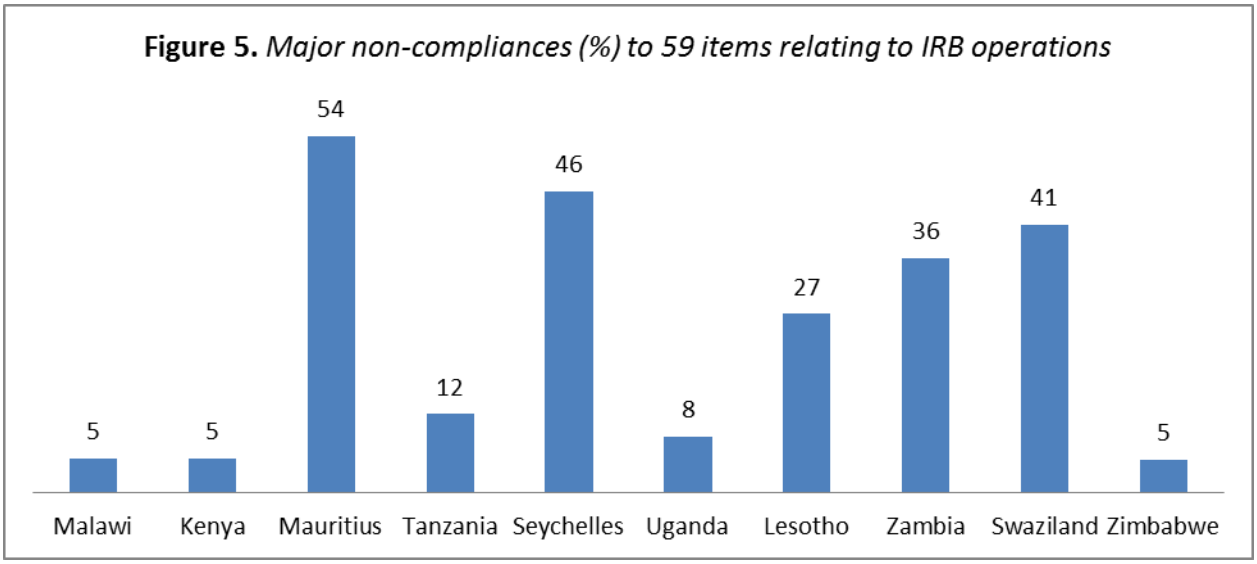
We evaluated each IRB for major non-conformities that could hinder the operations of the IRB and compromise the quality of reviews. In order to do this, we selected 59 items that were identified as major elements of an IRB review. These items were further classified into major categories such as

(1) Composition and independence of the IRB
(2) How issues relating to consenting, recruiting and protection of subject are handled
(3) Protection of venerable subjects and community engagement
(4) Steps and requirements for submitting proposals for review and the actual review process
(5) Disclosure of conflict of interest and resolving issues regarding conflicts of interest
(6) Conduct of IRBs including documentation, quorum requirements and proper taking of minutes during IRB meetings.

IRB with highest level of compliances

Figure 5 below summarized the findings regarding non-compliances the 59 elements. Major noncompliances were found for Mauritius, Seychelles, Zambia and Swaziland. The IRBs in these countries did not comply with over 30% of minimum requirements for IRB operations. The IRB in Lesotho did not comply with at least 27% of the key 59 items. Interestingly, majority of these non-compliant IRBs were affiliated to the Ministries of Health and not to medical research institutes and universities. The IRBs in Kenya, Malawi, Zimbabwe, Tanzania and Uganda were compliant to at least 87% of the minimum requirements. A detailed report on noncompliance by each IRB appear in Table 8 to 17

Figure 5. *Major non-compliances (%) to 59 items relating to IRB operations*



The IRBs in Kenya, Uganda, Zimbabwe and Malawi had the highest level of compliance to minimum standards for IRB operations. The IRB in Zimbabwe was compliant in all major items including having an internal self-improvement program. This IRB had the necessary resources including dedicated offices, administration staff members and training programs for reviewers and investigators. We were able to access extra information on the operation of KEMRI IRB and therefore present an overview of the KEMRI IRB in this paragraph. This IRB is unique in that although it has 11 members at the ERC, it is complaint to most of the requirements and reviews the highest number of proposals. Table 8 summarizes the major non-conformities identified at the Kenya Medical Research Institute. As presented elsewhere in this report, this IRB is one of the oldest among those evaluated. The ERC has 11 members and this translates to a workload of 82 proposals/ person/yr. Our data shows that this IRB also handles a high proportion of clinical trials and epidemiologic studies. The investigators undergo ethical training every two years and the IRB has a separate budget for its operations. As mentioned before, the KEMRI IRB has two units: the scientific steering committee that handles scientific and technical aspects of proposals under review and the ethical review committee that scrutinizes ethical issues.

Table 8. List of Major non-conformities in the Kenya Medical Research Institute IRB, Kenya

1	ERC-No national ethical approval required
2	No policy of process and modalities for appointment of a member to ERC/IRB
3	No clear policies on the Terms of References for IRB members
4	No quality improvement for self

The major non-conformities identified in KEMRI includes lack of an external body that can provide an alternative opinion on proposals reviewed within the IRB, lack of proper guidelines for appointing IRB members and lack of clear terms of references for the members. There are no internal quality improvement strategies for the KEMRI IRB. Only the IRB in Zimbabwe was found to have a self-improvement program. It is possible that all proposals developed in KEMRI are reviewed by the institutional IRB without the input from other IRBs. It is however worth to note that clinical studies in KEMRI must also be reviewed and approved by the Pharmacy and Poisons Board's Expert Committee on Clinical Trials (PPB ECT). Studies dealing with animal subjects also require review and approval from animal welfare committees. Proper mechanisms have been put in place to ensure that human subjects are protected from harm and there exists a channel for study subjects to air their concerns during and after a study. We therefore identify this IRB as a model from which other IRBs must learn.

The IRB in Zimbabwe was the oldest among those evaluated. This IRB was the most compliant among its peers. This IRB has an independent budget, has proper training programs for members and investigators, has dedicated team of administrative staff and has a self-improvement program, Table 10. It was however interesting to note that the chair of

this IRB need not have training in ethical issues. This IRB handles the second largest volume of proposals of 250 against 900 reviewed in KEMRI.

The IRB in Tanzania was also found to have only a few non-conformities regarding the process of submission of proposals for review and the actual review process, Table 11. This IRB that was established in 2002 handles the third largest volume of 200 proposals per year (after KEMRI's 900 and Zimbabwe's 250 proposals). Considering that this IRB has one of the highest numbers of reviewers (16), the workload per person is 13 proposals per year. At least 25% of the proposals reviewed in this IRB are clinical studies. The operations of this IRB are not regularly evaluated by the parent body and there is no strategy for self-improvement of the operations of the IRB. There is no budget set aside for regular training of the administrative staff and members of the IRB. Documentation of minutes was also found inadequate.

The College of Medical Research and the Ethical Committee affiliated to the College of Medicine, Malawi, was established in 1996. This IRB has 15 members and reviews an average of 101 proposals per year. This translates to a workload of 7 proposals per person per year. At least 30% of these proposals are for clinical studies while 40% are epidemiologic and observational studies. A total of four major non-conformities were found for this IRB, Table12. Despite the low number, some of these non-conformities may seriously jeopardize operations and integrity of the IRB. For example, there is no need for investigators to have ethical training in order to submit protocols and there are no mechanisms for assessing conflict of interest for the investigator. Therefore, major efforts must be made to improve on ethical training of IRB members and investigators on ethical issues including conflicts of interest.

Table 9. List of Major non-conformities in the Science and Ethics Committee, Uganda

1. No national ERC dealing with health issues
2. No continuing education for ERC/IRB member in research ethics
3. Proposals not reviewed by regional or international bodies before or after ERC/IRB approval

Table 10. Major non-compliances for IRB in Zimbabwe

1	ERC/IRB need not register with a national body
2	ERC-No national ethical approval required
3	No need for IRB chair to have ethical training

Table 11. List of Major non-conformities in the IRB affiliated to the National Institute for Medical Research (NIMR), Tanzania

1	No quality improvement for self
2	No regular evaluation of operations of ERC/IRB by parent body
3	Budget not available for training administrative staff f and members of ERC/IRB
4	Minutes do not document the name of member who abstained from decision making and the reasons for that action
5	Minutes do not document the name of member who abstained from decision making and the reasons for that action
6	No policy on how decisions are made (consensus or vote)

Table 12. List of Major non-conformities in the College of Medicine Research and Ethical Committee Malawi

1	No need for authors to have ethical training in order to submit protocols
2	No approval from department chair prior to submission of protocol to ERC/IRB
3	No conflict of interest form for members of the writing team
4	ERC/IRB does not consider whether or not the protocol has a community engagement aspect

IRBs with least level of conformity

Tables 13 to 17 summarize the major non-conformities found in IRBs in Seychelles, Mauritius, Swaziland, Zambia and Lesotho. The IRBs in these countries had more than 27% major non-conformities against the selected 59 items. These major non-conformities included:-

(1) Poor composition of the IRB
(2) Lack of proper mechanisms for protection of subjects are not in place
(3) Poor documentation of IRB minutes
(4) No mechanism set for investigators and reviewers to declare conflicts of interest and no mechanisms to resolve such conflicts have been put into place.
(5) Lack of proper and continues training on ethics for investigators and IRB reviewers

The present status of these IRBs compromise quality review and provides loop holes for approval of studies that do not comply with basic principles of ethical research. It is possible that most of these IRBs are not currently prepared to

review and approve clinical trial studies. It is particularly worrying to note that most of these IRBs may currently not be able to assess if submitted studies provides mechanisms for protection of human subjects. It is not clear why the IRBs in these countries have not put in place basic measures that guarantee quality review of scientific studies but the following factors appear to apply to majority of these review committees

It is clear that most of these IRBs require a major overhaul. Efforts should be put in order to ensure that investigators and IRB members in these institutions receive proper training in research ethics. It is also important to grant this committee some independence from the parent institutions. This could also include establishing a yearly budget for this committee. We also recommend that IRBs in these countries should also interact with those in Kenya, Uganda, Tanzania and Malawi in order to learn from these relatively successful IRBs. A regional IRB could also provide support in review of proposals from these countries.

Table 13. List of Major non-conformities in Health Research and Ethics Committee, Seychelles

1	No other national ERC dealing with health issues
2	ERC/IRB need not register with a national body
3	ERC-No national ethical approval required
4	No policy for appointing ERC/IRB chair
5	No mechanisms for research participants to file complaints or raise issues on human protection
6	No need for authors to have ethical training in order to submit protocols
7	No continuing education for ERC/IRB member in research ethics
8	ERC/IRB does not document training on human protection by its members
9	Administrative staff assigned to ERC/IRB not full time
10	No clinical trials reviews annually
11	No epidemiologic/observational studies reviewed annually
12	ERC/IRB does not publish guidelines for submission of protocols for review
13	No conflict of interest form for members of the writing team
14	No evidence in the minutes that at least one scientist included in decision making or action
15	No evidence in the minutes that at least one non-scientist included in the review or decision making or implementation of action
16	Minutes do not show that at least one person not affiliated to the institution was included in decision making
17	No evidence in the minutes that at least one non-scientist included in the review or decision making or implementation of action
18	Minutes do not show that at least one person not affiliated to the institution was included in decision making
19	No policy on expedited ERC/IRB review
20	Interval of continued review for risky studies has not been determined
21	No policy on follow-up review
22	ERC/IRB does not consider the suitability of research environment for the study to continue
23	ERC/IRB does not take into consideration on the level of "minimum risk" before approval of the protocol
24	ERC/IRB does not consider if there will be a product or utility available to the community based on the study after
25	ERC/IRB does not consider whether or not the protocol has a community engagement aspect

Table 14. List of Major non-conformities in the National Ethics Committee Mauritius

1	No written ERC/IRB SOP
2	No mechanisms for research participants to file complaints or raise issues on human protection
3	All members of ERC/IRB employed or affiliated to the parent institution
4	Not a must for ERC/IRB chair to have formal training in ethics
5	No need for authors to have ethical training in order to submit protocols
6	No continuing education for ERC/IRB member in research ethics
7	ERC/IRB does not document training on human protection by its members
8	ERC/IRB does not have its own yearly budget
9	Budget not available for training admin staff f and members of ERC/IRB
10	Proposals not reviewed by regional or international bodies before or after ERC/IRB approval
11	ERC/IRB does not publish guidelines for submission of protocols for review
12	No specific application form available for submission of protocol for approval
13	No informed consent template available to guide authors
14	Members of ERC/IRB not asked to disclose conflict of interest during meeting prior to review discussion
15	No documentation of quorum in the minutes of the review committee
16	No evidence in the minutes that at least one scientist included in decision making or action
17	No evidence in the minutes that at least one non-scientist included in the review or decision making or implementation of action
18	Minutes do not show that at least one person not affiliated to the institution was included in decision making
19	Minutes do not document the name of member who abstained from decision making and the reasons for that action
20	No evidence in the minutes that at least one non-scientist included in the review or decision making or implementation of action
21	Minutes do not document the name of member who abstained from decision making and the reasons for that action
22	No policy at ERC/IRB on how the protocol will be reviewed
23	No check list for authors to confirm their compliance to requirements before submission
24	No policy on expedited REC/IRB review
25	Members not asked if they had conflict or interest in any protocol before the review meeting begins
26	No policy of communicating a decision by the ERC/IRB
27	ERC/IRB does not consider if there will be a product or utility available to the community based on the study after

Table 15. List of Major non-conformities in the Scientific and Ethics Committee the Swaziland

1	No written ERC/IRB SOP
2	No policy of process and modalities for appointment of a member to ERC/IRB and related TORs
3	No policy on conflict of interest and management of conflicts for ERC members
4	No quality improvement for self
5	No regular evaluation of operations of ERC/IRB by parent body
6	No mechanisms for research participants to file complaints or raise issues on human protection
7	One need not to have training in ethics in order to become a member
8	No need for authors to have ethical training in order to submit protocols
9	No continuing education for ERC/IRB member in research ethics
10	ERC/IRB does not have its own yearly budget
11	No admin staff assigned to ERC/IRB
12	Proposals not reviewed by regional or international bodies before or after ERC/IRB approval
13	ERC/IRB does not publish guidelines for submission of protocols for review
14	No specific application form available for submission of protocol for approval
15	No informed consent template available to guide authors
16	Members of ERC/IRB not asked to disclose conflict of interest during meeting prior to review discussion
17	No documentation of quorum in the minutes of the review committee
18	No evidence in the minutes that at least one scientist included in decision making or action
19	No evidence in the minutes that at least one non-scientist included in the review or decision making or implementation of action
20	Minutes do not show that at least one person not affiliated to the institution was included in decision making
21	Minutes do not document the name of member who abstained from decision making and the reasons for that action
22	No evidence in the minutes that at least one non-scientist included in the review or decision making or implementation of action
23	Minutes do not document the name of member who abstained from decision making and the reasons for that action
24	No policy at ERC/IRB on how the protocol will be reviewed
25	No check list for authors to confirm their compliance to requirements before submission
26	No policy on expedited REC/IRB review
27	No policy on how decisions are made (consensus or vote)
28	Members not asked if they had conflict or interest in any protocol before the review meeting begins
29	No policy on follow-up review
30	No policy of communicating a decision by the ERC/IRB
31	ERC/IRB does not consider if there will be a product or utility available to the community based on the study after

Table 16. List of Major non-conformities in the National Health Research Ethics Committee Zambia

1	No quality improvement for self
2	Admin staff assigned to ERC/IRB not full time
3	No epidemiologic/observational studies reviewed annually
4	Proposals not reviewed by regional or international bodies before or after ERC/IRB approval
5	No specific application form available for submission of protocol for approval
6	No informed consent template available to guide authors
7	No recruitment materials needed
8	No policy at ERC/IRB on how the protocol will be reviewed
9	No check list for authors to confirm their compliance to requirements before submission
10	No policy on expedited REC/IRB review
11	Interval of continued review for risky studies has not been determined
12	No policy on how decisions are made (consensus or vote)
13	No policy on follow-up review
14	ERC/IRB does not review the qualification of the author to conduct research
15	ERC/IRB does not consider the suitability of research environment for the study to continue
16	ERC/IRB does not consider if there will be a product or utility available to the community based on the study after
17	ERC/IRB does not consider whether or not the protocol has a community engagement aspect

Table 17. List of Major non-conformities in the Ministry of Health IRB Lesotho

1	No quality improvement for self
2	No need for authors to have ethical training in order to submit protocols
3	No continuing education for ERC/IRB member in research ethics
4	ERC/IRB does not document training on human protection by its members
5	Budget not available for training admin staff f and members of ERC/IRB
6	No clinical trials reviews annually
7	No epidemiologic/observational studies reviewed annually
8	No informed consent template available to guide authors
9	No evidence in the minutes that at least one scientist included in decision making or action
10	Minutes do not show that at least one person not affiliated to the institution was included in decision making
11	Minutes do not show that at least one person not affiliated to the institution was included in decision making
12	Interval of continued review for risky studies has not been determined

13	No policy on how decisions are made (consensus or vote)
14	No policy on follow-up review
15	ERC/IRB does not review recruitment criteria to ensure equity especially to disadvantaged populations
16	ERC/IRB does not have a policy to ensure that participants are insured on the treatment of injury

Major conclusions

This exercise revealed critical information concerning the status of the IRBs evaluated

(1) Most IRBs lack financial and administrative independence from the parent institutions.

(2) Most IRBs are understaffed and most administrative staff work part-time

(3) The review process may be lengthy due to shortage of reviewers and due to lack of a critical mass of administrative staff

(4) Most IRBs have not achieved gender parity and many do not have enough members from other institutions. The professional diversity of these IRBs is also poor.

(5) The IRBs in Zimbabwe, Kenya, Tanzania, and Malawi are more compliant than those from other countries . These IRBs are however understaffed

(6) This complicated review and approval of studies targeted for implementation in different institutions and countries.

(7) There is no uniform training standards for IRB reviewers and investigators in these countries. There is a need to establish minimum training standards that will ensure that proposals are properly formulated, and that the reviews are objective and constructive.

(8) Most proposals are subjected to parallel reviews in different IRBs. A regional IRB, such as that suggested by ECSA, will help in eliminating this bottle neck.

Recommendations

This evaluation exercise reveals that most of the IRBs in the participating countries have major non-compliances. For some IRBs, the non-compliances are serious enough to compromise the quality of the approval. The data presented here therefore supports the idea of:

(1) Establishment of mechanisms to ensure that all IRBs meet minimum standards. But this is logistically difficult because most IRBs are affiliated to parent institutions.

(2) Establishing a regional IRB that can handle review of regional proposals

Why is a regional IRB necessary?

This study shows that some IRBs are not adequately prepared to handle review and approval of proposals, especially those dealing with clinical trials. The composition, independence and resource available to some IRBs are so inadequate that the operations of these IRBs are seriously compromised. Although IRBs such as that of KEMRI and Zimbabwe are quite independent, resources endowed, well organized and professionally managed, the review process is long and the burden for reviewers (especially the ERC) is big. Some of these IRBs may need a lot of support in order to fill the existing gaps and this should include, but not limited to:-

(1) Proper training for reviewers and investigators

(2) Establishment of an independent budget for each IRB

(3) Removal of bottle necks that delay the review process

(4) Availability of resources for expansion of the IRB membership, hiring of administrative staff that can run the IRB and availability of budget to provide physical infrastructure for the IRB secretariat in terms of offices, computers, etc.

The study also reveals that most IRBs require the input of a second review body before or after the IRB approval. It is also clear that multi-country, multi-region, multi-institutional proposals are subjected to review in multiple IRBs because there exists no standard review process across different IRBs.

It is on these bases that we propose the establishment of an IRB to cater for regional proposals. We propose that the regional IRB should have the following attributes

(1) The regional IRB should set high standards in its operation and the approval from such a body should be acceptable within other IRBs

(2) The IRB should act as a bench mark for all other IRBs in the participating countries. It should be a model from which other IRBs can learn

(3) The IRB may draw its membership from other IRBs from the region. This will help the IRB gain regional acceptance

(4) The regional IRB may recruit individuals not currently affiliated to other IRBs. The IRB should have a dedicated set of administrative staff and should have independence in terms of resources and budget

(5) The IRB should directly or indirectly facilitate its members and that of other IRBs access ethical training (online or otherwise)

(6) Should provide a forum through which members of other IRBs can interact and exchange ideas

(7) Should provide exemplary review and approval services that are acceptable in different institutions. This will eliminate the need for review of regional proposals by different country IRBs

Should the regional IRB have a single unit or two units (one for scientific content and the other for Ethical issues)?

The single unit IRB has several advantages

(a) The review period can be relatively short.

(b) The Scientific content and the ethical issues are reviewed simultaneously allowing members to make an objective and holistic critique on a proposal.

The disadvantages of a single-unit IRB is that (1) the burden on the reviewer is heavy since he/she is supposed to review both the scientific and ethical contents (2) The membership of this IRB is closed because only people with knowledge on ethical issues may act as reviewers. But people trained in ethics may not have the necessary background in science or on other disciplines required for objective review of a given proposal

The two-unit IRB also have the following advantages

(1) One team of reviewers handle scientific content while the other review the ethical aspects of a proposal

(2) The burden of each reviewer is less because they only review specific sections of the proposal.

(3) The scientific unit can have many members and not all must have in-depth knowledge in ethical issues

The two-unit IRB has several disadvantages and these include

(1) The review process is long because proposals can take up to 3 months in each unit

(2) Two secretariats are needed, one for each unit

(3) The budget for running each unit could be high

We therefore propose that the regional IRB should have a single unit but bottle necks must be identified and removed in order to fast tract reviews while at the same time, preserving the quality of reviews

Where should the regional IRB located?

We propose that ECSA should house the regional IRB. This is prudent because ECSA already has a framework for operation in different countries in the region. While the administrative staff may permanently be stationed at ECSA, reviewers can travel to ECSA head quarters for meetings

How often should the regional IRB meet?

If we settle for a single-unit IRB, the meetings can be held on a monthly basis. This will give all reviewers ample time to review both scientific and ethical issues. If the two-unit IRB is adapted, each unit should meet once a month and the scientific unit should meet before the ethical unit. All the meetings can be held at ECSA headquarters or the meetings can be held in each participating country on a rotational basis

Should the regional IRB replace local IRBs?

No. The regional IRB should only compliment local IRBs and should concentrate on multi-centre, multi-country proposals. The regional IRBs should strengthen the local IRBs in terms of training, facilitation and logistics. The regional IRB should also accept proposals referred from local IRBs for a second opinion or for review of specific sections.

How can the regional IRB gain acceptance across other IRBs and ECSA region?

The regional IRB should not be a competitor with other IRBs. The IRB should not be over bearing on others and decisions should be done after consultations and consensus building. The regional IRB should always inform the local IRBs on the review progress and recommendations for studies intended for multiple countries. We also suggest that the chairpersons and secretaries of various regional IRBs should be included in the regional IRB. These people can provide an important bridge between the regional and local IRB

Should there be a common accreditation system for regional and local IRBs?

The regional IRB, together with local IRBs should establish a consortium that oversees the standardization of IRB operations across the region. If possible, ECSA should facilitate accreditation of each participating IRB. Such a step could allow different IRBs to accept the review and approval decision arrived in different IRBs.

How can reviews of regional proposals be fast-tracked?

There are two strategies to ensure that review of regional proposals is fast-tracked.

(1) A regional IRB that has been syndicated by other IRBs can solely review proposals and communicate the decision to local IRBs. In that case, because the standards of the regional IRB are acceptable in the region, the decisions arrived by these IRBs are binding. The only challenge with this strategy is that the regional IRB may approval studies that could require special modifications in order for them to be conducted in each country. Such modifications could be scientific, special consideration of socio-political environments in each country, availability of special facilities and infrastructures in different countries and institutions, and special consideration of socio-cultural aspects of the study population or participants in each country.

(2) The regional IRB can review and approve proposals and requested for an “expedited review” in local IRBs in participating countries. In order for the expedited review to be granted, the request should furnish the local IRB with the comments of the reviewers who evaluated the regional study and show how the investigators addressed the comments.

Way forward

This study recommends that the local IRBs should be supported in order to be compliant with minimum standards of IRBs. There is a need to create harmony in the operation of all IRBs in the ECSA region. This can partially be achieved through facilitated interactions between different IRBs and accreditation of IRBs in ECSA region. There is a need to establish a regional IRB that can handle regional proposals. This will not only fast-track review and approval of study proposal but will also remove the bottle necks associated with review of a given proposal in multiple institutions. The regional IRB should not necessarily replace regional IRBs but should support such bodies and facilitate establishment of minimum acceptable standards for all IRBs.

Appendix: Data collection tool

East Central & Southern Africa Health Community

EDCTP PROJECT

CAPACITY NEEDS ASSESSMENT TOOL

ECSA-HC Research Ethics Committee (REC)/Institutional Review Boards (IRB) Quality and Capacity Needs Assessment Tool

Country name:

Questionnaire Administrator:

Name:

_____

Address:

Filled in: **Month** **Year**

INTRODUCTION

The East, Central and Southern Africa Health Community (ECSA-HC) is a regional inter-governmental organization, whose membership comprises of; Kenya, Lesotho, Malawi, Mauritius, Swaziland, Seychelles, United Republic of Tanzania, Uganda, Zambia and Zimbabwe. The organization was established in 1974 by the Convention of the East Central and Southern Africa Health Community to promote regional cooperation in health. ECSA's vision is to be the leader in health in East, Central and Southern Africa, contributing towards the attainment of the highest standard of physical, mental and social well-being of the people in the region.

The ECSA countries share almost similar characteristics with respect to health problems including such diseases as HIV/AIDS, TB & Malaria. The countries also share similarities in their health care delivery systems. The cooperation of the ECSA countries therefore necessitates a collective response to health problems. This requires a strong mechanism for sharing health related information, harmonizing policies and practices and building consensus among partner states on the conduct of ethical research.

It is in this regard that the ECSA Secretariat proposes to establish ECSA-Regional Scientific and Ethics Committee (RSEC) which will act as an oversight body charged with the responsibility of approving multi-country research proposals and capacity building of the National Ethical Committees (NECs) of the Member States. The expected outcome is strengthened capacity of national scientific and ethical committees to approve and facilitate of multi-country research proposals within the region.

OBJECTIVES OF THE ASSESSMENT

To document the existence of research ethical committees /IRBs in countries with aim of supporting the country to establish one through the regional body

To assess the capacity gaps in terms of reviews, time take to get the process through, capacity of the members, any bottle necks

To review policies, guidelines and strategies on the conduct of ethical research in ECSA region

To assess the capacity of the Ministries of health in terms of coordination and regulation of ethical research in ECSA region

To identify and document best practices in the coordination & regulation of ethical Research in ECSA

To determine human resource and financial needs for the conduct of ethical research in ECSA e.t.c.

ASSESSMENT TOOL

ORGANIZATIONAL ASPECTS

Do you have a National Ethical committee in your country dealing with Health issues?

Yes----------

No----------

Don't know----------

Name of the Ethics Committee/IRB_____

Organization _____

Country_____

Address of the committee/body_____

_____Telephone_____

Fax_____ e-mail address_____

What year was the REC/IRB established? _____

Is the REC/IRB subject to registration with a national authority?

___ Yes

___ No

What are the main functions of the ethics committee?

_____

_____

_____

How often does the REC/IRB meet as a full committee to review research studies?

___ once/week

___ twice/month

___ once/month

___ every two months

___ other

___ has not yet met to review protocol

Is a national ethical approval required for proposal implementation in your country?

Yes [ ] b. No [ ] c. don't know [ ]

Was the REC/IRB established under a high ranking authority (e.g., President's office, Ministry of Health, etc.)?

___ Yes

___ No

Does the REC/IRB have written Standard Operating Procedures?

__ Yes

__ No

Does the REC/IRB have a policy that outlines the process for appointing the REC/IRB Chair?

Yes ___

No------

Which of the following criteria are used to select the Chair of the REC? (Check all that apply.)

___ prior training in ethics

___ publication in ethics

___ prior research experience

___ other (please describe) _____

Does the REC/IRB have a policy that describes the process for appointing the members of the REC/IRB and details the membership requirements and the terms of appointment?

___ Yes

___ No

Which of the following criteria are used to select REC/IRB members? (Check all that apply.)

___ prior training in ethics

___ publication in ethics

___ prior research experience

___ other (please describe) _____

Does the REC/IRB have a policy for disclosure and management of potential conflicts of interest for the members of the REC?

___ Yes

___ No

Does the REC/IRB have a policy for disclosure and management of potential conflicts of interest for members of the research team?

___ Yes

___No

Does the REC/IRB have a quality improvement (QI) program for itself?

___ Yes

___ No.

If yes, describe what was done in the last year and any changes that were made as a result of the QI program.

_____

Does the institution/organization regularly evaluate the operations of the REC/IRB (e.g., budgetary needs, adequacy of material resources, adequacy of policies and procedures and practices, appropriateness of the membership given the research being reviewed, and documentation of the training requirements of the REC/IRB members)?

___ Yes

___ No

Does the REC/IRB have a mechanism whereby enrolled research participants can file complaints or direct questions regarding human subject's protection issues?

___ Yes

___No

If yes, please describe the mechanism._____

How are records of the REC/IRB stored?

____ Paper folders in a locked file cabinet

____ Electronic in a password-protected computer

____ On an open shelf

____ Other

Quorum: Does the REC/IRB require that there be a certain number of members present in order to make the meeting official to review protocols?

___ Yes

___ No

MEMBERSHIP & EDUCATIONAL TRAINING

How many members are there on the REC?

What is the composition of the committee/body (number of persons participating, titles)?

_____

_____

_____

_____

_____

_____

How many are women? _____ How many are men? ____

Are any of the members not affiliated with the institution, that is, the member is not employed by the institution and is not related to a person who is employed? ___ Yes ___ No

Are any of the members considered to be a non-scientist? ___Yes ___ No (A **Non-Scientific Member** is any member who does not have a terminal degree in a medical or scientific field.)

Is there a requirement that the REC/IRB Chair (or the designee who is in charge of running the committee) has any prior formal training in research ethics? ___ Yes ___ No

If yes, what type of training is required? (Check all that apply.)

___ web-based training

___ workshop in research ethics

___ course

___ other (please describe) _____

Does the institution require that REC/IRB members have training in research ethics in order to be a member of the REC?

___ Yes

___ No

If yes, what type of training is required? (Check all that apply.)

___ web-based training ___ workshop in research ethics

___ course

___ other (please describe)

_____

Does the institution require that investigators have training in research ethics in order to submit protocols for review by the REC?

___ Yes

___ No

If yes, what type of training is required? (Check all that apply.)

___ web-based training

___ workshop in research ethics

___ lecture

___ course

___ other (please describe)_____

Does the REC/IRB conduct continuing education in research ethics for its members on a regular basis?

___ Yes

___ No

Does the REC/IRB document the human subjects' protection training received by its members?

___ Yes

___ No

REC/IRB RESOURCES

Does the REC(s) have its own yearly budget?

__ Yes

__ No

If yes, is there a budget for training of administrative staff and REC/IRB members?

__ Yes

__ No

Please check below the physical resources of the REC/IRB (check all that apply):

__ access to a meeting room

__ access to a computer and printer

__ access to the internet

__ access to a facsimile

__ access to cabinets for storage of the protocol files

Does the REC/IRB have administrative staff assigned to the REC?

__ Yes

__ No

If yes: Is the person full-time?

__ Yes

__ No

Is the person half-time?

__ Yes

__ No

WORKLOAD OF THE REC/IRB

Average number of protocols reviewed annually? _____

Average number of clinical trials reviewed annually? _____

Average number of epidemiologic/observational studies reviewed annually? _____

Does any other national body (e.g., university/government agency, etc.) review any of the proposals before or after the national ERC? If so, please indicate which body, and what percentage of the proposals a reviewed by another body..

_____

_____

_____

_____

Does any other regional or international body (e.g., WHO/TDR university/government agency, etc.) review any of the proposals before or after the national ERC? If so, please indicate which body and what percentage of the proposals a reviewed by another body.

_____
_____

_____

_____

SUBMISSION ARRANGEMENT AND MATERIALS

Submission Arrangements of Research Protocols	**Yes**	**No**
Does the REC/IRB publish guidelines for submission of applications for the review by the REC?		
Does the REC/IRB require investigators to use a specific application form for the submission of their protocols to the REC?		
Does the REC/IRB have an informed consent template to help guide investigators in the writing of their informed consent forms?		
Does the REC/IRB require approval and signature of the department chair (or another individual) of the research protocol prior to the submission?		
Does the REC/IRB require a deadline for investigators to submit protocols for full committee review?		
Submission Materials		
Which of the following items are requested from the Principal Investigators when they submit their research protocol to the REC?	**Yes**	**No**
Full protocol		
Informed consent form		
Investigator's qualifications [e.g., CV, medical license(s), etc.]		
Conflict of interests disclosure forms for members of the research team		
Recruitment material (e.g., advertisements, signs, posters, etc.), if applicable		
Questionnaires/surveys that will be used in the research, if applicable		
Investigators' Drug Brochure or materials describing the nature of the drug being used in a clinical trial, if applicable		
Minutes	**Yes**	**No**
Does the REC/IRB maintain minutes of each meeting? ___Yes ___No If minutes are kept, please answer the following questions regarding the minutes.		
Do the minutes reflect that members were asked whether they had a conflict of interest regarding any of the protocols to be discussed and indicate that such members did not participate in the decision making process of the relevant		

protocols?		
Do the minutes document that a quorum was present for all actions requiring a decision?		
Do the minutes document that all actions included at least one scientist in the review and participated in the decision making process?		
Do the minutes document that all actions included at least one non-scientist in the review who participated in the decision making process?		
Do the minutes document that all actions included at least one person who is not affiliated with the institution in the review and participated in the decision making process?		
Do the minutes record the name of REC/IRB members who abstained from the decision making process and provided the reason for abstention?		
Do the minutes record the name of REC/IRB members who were excused from the discussion and decision making process due to a conflict of interest?		
Do the minutes reflect, when applicable, a discussion of the controversial aspects of the research protocol?		
Policies for Review Procedures	**Yes**	**No**
Policies Referring to Review Procedures		
Does the REC/IRB have a policy regarding how protocols will be reviewed?		
Does the REC/IRB bring in a consultant when necessary to provide scientific or other relevant expertise for review of a particular protocol?		
Do REC/IRB members receive the protocol and other materials at a specified time prior to the meeting?		
Does the REC/IRB require that reviewers use a checklist to document their ethical assessment of the research submission?		
Does the REC/IRB have a policy on the conditions for expedited REC/IRB review?		
Does the REC/IRB have a policy on the conditions for when studies may qualify for exempt status?		
Does the REC/IRB determine the interval of continuing review based on the risk		

of the study?		
Does the REC/IRB have a policy for how decisions are made (e.g., consensus or a vote)?		
Are members asked at the beginning interest regarding any the meeting as to whether they had a conflict of the protocols to be discussed and indicate that such members did not participate in the decision on the relevant protocols?		
Does the REC/IRB have a policy for follow-up review?		
Does the REC/IRB have a policy for communicating a decision?		
Scientific Design and Conduct of the Study		
Does the REC/IRB review the suitability of the investigators' qualifications to conduct the study?		
Does the REC/IRB review the adequacy of the clinical site, including the supporting staff, available facilities, and emergency procedures?		
Does the REC/IRB take into account prior scientific reviews or do they review the appropriateness of the study design in relation to the objectives of the study, the statistical methodology, and the potential for addressing the objectives with the smallest number of research participants?		
Considerations of Risks and Benefits		
Does the REC/IRB identify the different risks of the research protocol?		
Does the REC/IRB determine whether risks have been minimized?		
Does the REC/IRB determine whether the risks are greater than minimal risk based on a written definition of minimal risk?		
Does the REC/IRB evaluate the probable benefits of the research to the participants?		
Does the REC/IRB evaluate the importance of the knowledge to society that may reasonably be expected to result from the research?		
Does the REC/IRB evaluate whether the risks to research participants are reasonable in relation to any anticipated benefits to participants and the importance of the knowledge to be gained by society?		

Selection of Research Participants		
Does the REC/IRB review the methods to identify and recruit potential participants?		
Does the REC/IRB review recruitment processes to ensure that the selection of subjects will be equitable in regards to gender, religion, and ethnicity?		
Does the REC/IRB identify the potential of the research for enrolling participants who are likely to be vulnerable to coercion or undue influence (such as children, prisoners, persons with mental disabilities, or persons who are economically or educationally disadvantaged)?		
Does the REC/IRB consider the justification for including vulnerable populations in the research?		
Does the REC/IRB consider and require that additional safeguards be included in the study to protect the rights and welfare of the subjects?		
Does the REC/IRB consider the appropriateness of any financial or material incentives offered to participants for their participation in the research?		
Does the REC/IRB preserve privacy by evaluating the setting in which participants are recruited?		
Does the REC/IRB evaluate the methods for protecting the confidentiality of the collected research data?		
Community Consultation		
Does the REC/IRB review whether the potential benefits of the research are relevant to the health needs of the local community/country?		
Does the REC/IRB review whether any successful study product will be reasonably available to the concerned communities after the research?		
Does the REC/IRB review whether the community was consulted regarding the design and implementation of the research, if applicable?		
Safety Monitoring and Adequacy of Insurance to Cover Research-Related Injury		
Does the REC/IRB require, when appropriate, that the research plan include adequate provisions for monitoring the data collected to ensure the safety of subjects?		

Does the REC/IRB consider whether the sponsors of the research have adequate insurance to cover the treatments of injury related to the research?		

Thank you for your cooperation.