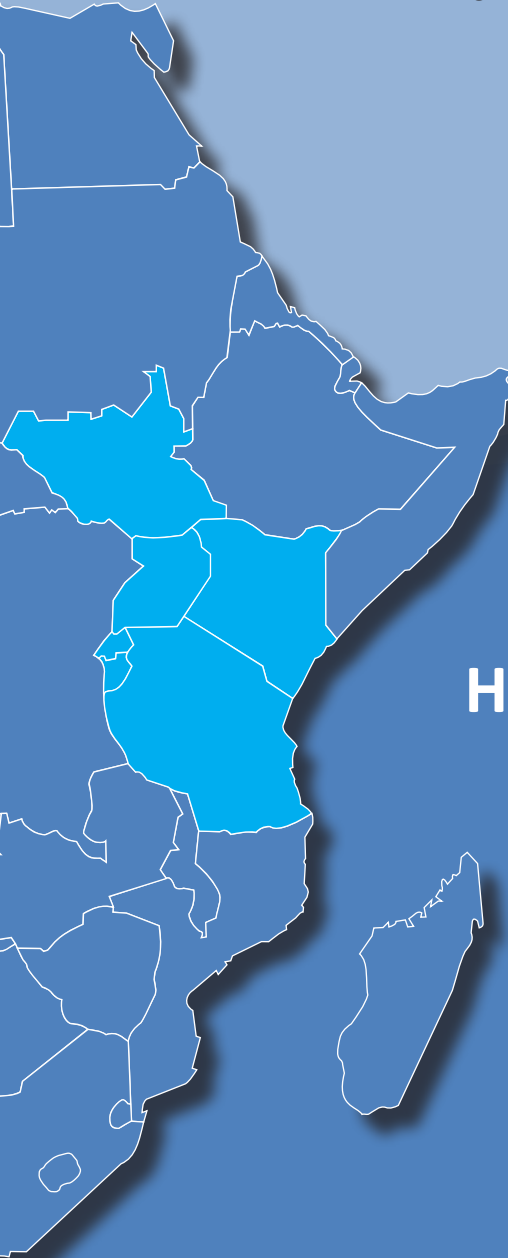




EAST AFRICAN HEALTH RESEARCH COMMISSION



# The Path towards Harmonization of Ethics Review Frameworks in East Africa







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## **The Path towards Harmonization of Ethics Review Framework in East Africa**

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# Abbreviations

COHRED	Council on Health Research for Development
COSTECH	Council for Science and Technology (Tanzania)
EAC	East African Community
EAHRC	East African Health Research Commission Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) ( <a href="http://www.ich.org/products/guidelines.html">http://www.ich.org/products/guidelines.html</a> )
HIV	Human-Immunodeficiency Virus
ICT	Information and Communication Technology
IREC	Institutional Research Ethics Committee
NACOSTI	National Council for Science, Technology, and Innovation (Kenya)
NCST	National Commission for Science and Technology (Rwanda)
NIMR	National Institute for Medical Research (Tanzania)
NREC	National Research Ethics Committee
NRRA	National Research Regulatory Authorities
REC	Research Ethics Committee
RECA	Research Ethics Committee Administrator
SOPs	Standard Operating Procedures
STRI	Science, Technology, Research and Innovation
TANHER	Tanzania National Health Research Forum
TB	Tuberculosis
UNCST	Uganda National Council for Science and Technology
USD	United States Dollars

# 1. Executive Summary

Capacity in health research ethics review is key in Africa, given the increase in research activities, complexity, and use of advanced technologies. Harmonizing ethics review frameworks can address challenges attributable to these complexities. Establishing an effective harmonized framework that is optimum for protection of the research subjects requires assessment of review capacity. The East African Health Research Commission (EAHRC) commissioned an assessment of capacity of Ethics Review Capacity in order to inform the implementation of harmonization of Ethics Reviews in the East African Communities.

The aim of the assessment was to map the ethics review capacity for health research in the East Africa Community (EAC) partner states, to review the existing ethics review frameworks and capacity, to develop an investment case for harmonization of ethics review frameworks in clinical trials in the region, and to guide and advise on priority interventions for capacity development or/ and harmonization of ethics review frameworks in the EAC.

This assessment involved interviews with key stakeholders, mainly representatives of Research Ethics Committees (RECs) and research institutions supported by self-completed questionnaires and telephone interviews.

A total of 69 accredited RECs were mapped within the EAC partner states, including 28 from Kenya, 23 from Uganda, 15 from Tanzania, 2 from Rwanda and 1 from Burundi. South Sudan was not included in this assessment due to non-responsiveness. The number of surveyed RECs included the national regulatory authorities from each country.

In total, 21 quantitative and 22 qualitative interviews were conducted. The response rate was high (>75%) in Rwanda and Burundi, moderate (50% to 75%) in Tanzania and Uganda and low (<25%) in Kenya.

All 21 RECs interviewed had operational ethical policies and guidelines. Of these, 86% (18/21) charged a fee for review, 62% (13/21) compensated their members and 57% (12/21) had a dedicated annual budget for their operations. The same number (57%) had a dedicated budget for office operations. Seventy-six percent (n=16) of the RECs reviewed clinical trials in addition to other studies while the other 24% (n=5) reviewed behavioural research and social science. In addition, 12/21 (57%) of the RECs interviewed reviewed international research while the rest reviewed local studies only.

Major differences were noted in budgets available to RECs, accessibility to resources, and availability of operational support. For example, none of the three RECs from Burundi and Rwanda had dedicated funding for operations, while only 29% (2/7) of the RECs from Tanzania had dedicated funding. Over 72% (8/11) of the RECs from Uganda and Kenya had dedicated funding, although the response rate from Kenya was too low (3/3) to make this finding reliable. Forty-four percent (44%) of RECs from Tanzania (3/7) did not have office space to operate from. This was also the situation for the National Research Ethics Committee (NREC) of Burundi. Review fees were commonly charged. All RECs interviewed charged a fee for review, except 2/7 RECs (28.5%) from Tanzania.

The results show that there are substantial similarities with regards to national operation frameworks, policies, and guidelines. However, there are also major differences in terms of resources, infrastructure and operations in the different partner states, with Burundi, Rwanda, and Tanzania having more capacity gaps compared to Uganda and Kenya.

This baseline assessment has shown marked differences within and across members states with regards to governance and regulation of health research. Notably, there are structural, financial and operational differences, which have important implications for the quality, cost, and efficiency of ethics review in the region. The use of different review frameworks can result into a discordant decision between RECs reviewing the same protocol. RECs that use different policies and guidelines are more likely to give discordant views/decisions, and take a long time when reviewing multisite trials. These differences seem to be largely attributable to differences in the existing legal and ethical frameworks which affect the ethics review process itself, the decisions made and the 'turn-around times' of protocol review by RECs in different countries. All RECs supported harmonization of Ethics and Review Framework in the EAC.

A validation workshop with experts from National Research Regulatory Authorities (NRRAs) and/ or National Research Ethics Committees and RECs reviewed the findings and proposed the following incremental 4 steps towards harmonization of Ethics Reviews in EA: 1) harmonization of policy frameworks and tools; 2) institutionalization of regional joint review mechanisms, 3) standardization of training and capacity strengthening, 4) Review of the REC operational and financing models.

The EAHRC is committed to collaborating with partner states in the implementation of the road map towards harmonization of Ethics Review Framework

# 1. Introduction

## 1.1 Background and Context

Ethics review is central to any health research activity. Given the rapid increase and complexity of inter-disciplinary, multi-partner, cross-border health research taking place in East Africa, it is even more important that there is an increased effort to build and strengthen capacity for competent Research Ethics Committees (RECs) in the region.

A key goal for RECs is to protect human subjects from physical or psychological harm, by reviewing research protocols and related materials. The protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices, to maximize the safety of subjects. Some countries have National Research Regulatory Authorities (NRRAs) and/ or National Research Ethics Committees which other than reviewing protocols, also act as regulators for Institutional RECs that are usually established to coordinate and review research conducted by individual institutions and/or in a given geographic jurisdiction may give direct approval (e.g. in Kenya) or pre-approval research clearance (e.g. in Uganda) prior to the final approval being given by the NRA.

The availability of robust ethics review systems – nationally and regionally – to efficiently apply up-to-date regulatory and ethical frameworks is crucial to increase science quality and outputs in the region. This is particularly vital if East Africa is to benefit from the research that addresses its burden of existing and emerging health and health care challenges through timely discovery and enhanced access to new technologies and interventions.

Although many RECs apply international guidelines, major challenges persist. These include limited access to knowledge, training, and resources. The two main functions of RECs are i) to ensure that ethical principles are applied during the initial review of the proposed research protocols, i.e. prior to initiation of the projects, and ii) to provide continuing and regular oversight of approved protocols to ensure compliance throughout the implementation of the research. This includes review after referral to the REC of any emerging ethical issues throughout the study. Such on-going reviews should be carried out in accordance with both international guidelines, national regulatory requirements and applicable Standard Operating Procedures (SOPs) of local RECs.

Furthermore, the increase in the volume and complexity of health research in East Africa which is led and often funded by high-income country researchers and research institutions has not necessarily been accompanied by improvements in direct access to funding, infrastructure, oversight systems and Africa-led research. Lack of resources for the provision of quality oversight can lead to abuse/exploitative research – irrespective of who funds it. In summary, the globalization of human subject research over the past decades, particularly where it

concerns collaborative research between Africa-based research institutions and those of high-income countries, as well as the increased demand by research sponsors for increased quality of ethics review, has significantly influenced the pressure on RECs in East Africa to improve their performance.

The East African Health Research Commission commissioned a study to assess the capacity of RECs in the EAC countries, as a step towards strengthening and harmonizing the regions' capacity and review frameworks. Specifically, this project aimed at providing i) a database (list of accredited RECs in each partner state involved in the assessment) ii) a needs assessment, iii) recommendations on strengthening ethics review frameworks in the EAC partner states, and iv) proposals for strategies to effectively implement the recommendations.

Ultimately, this report aims at assisting the East Africa Community to harmonize ethics review frameworks and processes in the EAC partner states.

Specific objectives of this assessment included:

- Mapping the ethics review capacity in health research in East Africa (at institutional and national levels)
- Establishing the first database of ethics review frameworks in the EAC and partner states
- Advising on priority interventions by EAC and Partner States in terms of capacity strengthening of ethics review in the EAC region
- Providing a rationale for harmonization of ethics review frameworks in the region
- Establishing some benchmark indicators for monitoring and evaluation of the impact of the implementation of the proposed harmonization strategies

Using the methodology described below, baseline data was collected on current ethics review frameworks and research ethics capacity as well as information required to guide the development of targeted interventions aimed at strengthening the capacity and frameworks in ethics review in the EAC partner states.

## 1.2 Limitations of the Study

The assessment was limited in scope based on time and financial constraints. As a result, a detailed financial assessment of research and research ethics review was beyond the scope of this study; the database of documentation available in the five countries is limited to what respondents elected to send to EAC and to COHRED; and the development of indicators to measure progress is a first, minimum list only. The assessment relied on EAHRC for the provision of all necessary documentation and contacts and the translation of documents into English.

The assessment relied on EAHRC on the provision of names and contact details. The EAHRC database was out of date hence not all RECs nor respondents were reached.



## 2. Methods Used

### 2.1 Quantitative Data Collection

Desk review of available documentation—national and institutional guidelines, policies, SOPs and frameworks for ethics review and research conduct and coordination from the countries concerned—was conducted. Additionally, a semi-structured questionnaire was used to collect data. Through this process, the ethics review procedures and processes were applied. Challenges faced by different RECs in the region were also identified.

Existing RECs were also mapped and their capacities assessed on the basis of self-reporting. The capacity assessment included but was not limited to RECs skills and competencies, capacity development procedures, skill gaps and capacity needs that could be addressed through various strategies and support, insights and ideas of those interviewed.

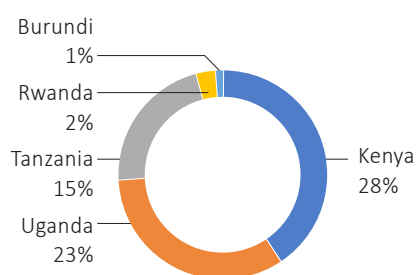
Other information collected included description of the RECs' structural and systemic (national) capacity, number of support staff, number of members, type and number of protocols reviewed, turn-around time for reviewing different types of protocols, annual budget, available resources such as equipment, expertise, utilization of modern technology including ethics review software and annual budget allocation for RECs and their sources.

### 2.2 Qualitative Data Collection

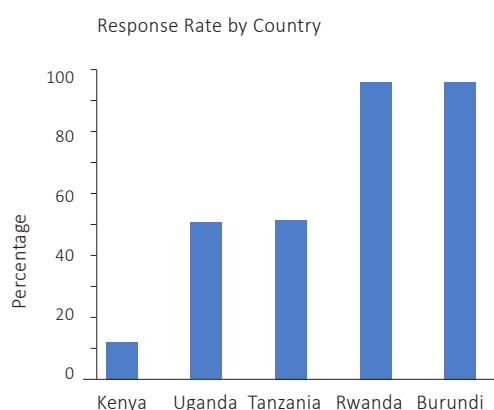
This involved interviews with various key informants and stakeholders including representatives of National Councils of Science and Technology, regional health research officers and representatives, administrators and researchers from different research institutions. The interviews aimed at exploring their views, opinions, and recommendations with regard to harmonization of ethics review frameworks within the EAC partner states.

## 3. Findings

Annex 5 provides a list of all the accredited RECs per country. Names and contact details of the 69 RECs were provided by the national regulatory authorities, through EAHR. All the 69 RECs were contacted through the email addresses provided and were invited to take part in the baseline assessment interview. The pie and bar charts below (fig. 1 and 2) show the total number of accredited RECs per country and their response rate following their invitation to take part in the baseline assessment, respectively. In total, there were 69 accredited RECs in EAC partner states, including 28 in Kenya, 23 in Uganda, 15 in Tanzania, 2 in Rwanda and 1 in Burundi (see Figure 1 below). The response rate was a hundred percent (100%) for Rwanda and Burundi, over Fifty percent (>50%) for Uganda and Tanzania and Ten percent (10%) for Kenya (Figure 2).



**Fig. 1: No of accredited RECs**



**Fig. 2: Response rate by country**

### 3.1 Quantitative findings

#### 3.1.1 Governance and Regulation of Research

All countries confirmed having policies and guidelines for the regulation and conduct of health research. The policies were accessed and reviewed to provide an overview of the national ethics regulatory frameworks.

National Councils for Science and Technology were established by Acts of Parliament in the five EAC countries and are responsible for developing specific national policies to guide health research ethics. In addition, National Councils for Science and Technology hold the overall mandate to regulate how research within their national borders is conducted. Their roles and functions include the registration of research institutions, the issuance of permits to researchers and ensuring that research is conducted in accordance with the national laws, policies, and guidelines. In addition, the councils coordinate and govern institutional RECs (IRECs). To achieve this, they are mandated to develop national guidelines that guide research institutions on the establishment, accreditation and operationalization of IRECs.

The process of registering IRECs was similar across all the countries involved in the assessment. This includes the submission of a registration application, SOPs and membership to the council for review. Once the submitted documents are deemed satisfactory, the IREC is registered and accredited. While the councils are expected to carry out site reviews prior to accrediting IRECs, most of them are hindered by the absence of personnel and resources. In all but one committee, the selection of the committee leadership is dependent on the institution or ministry under which it operates.

Table 1 gives a detailed description of the laws and regulations that govern research and ethics review in each of the five partner states that undertook the assessment.

With regard to legal frameworks, the health research ethics regulation frameworks in Kenya, Uganda, and Tanzania were established through Acts of Parliament, while Rwanda's was established through Ministerial instructions and Burundi's through a Presidential Decree. All countries have specific entities that are responsible for the governance and coordination of research in their countries.

In Tanzania, the National Institute for Medical Research (NIMR) has the overall mandate of governing health research. In Rwanda, the National Ethics Committee (RNEC) and the National Commission for Science and Technology (NCST) have the mandate to coordinate and monitor all matters related to science, technology, research and innovation, and to manage the national research and innovation fund. In addition, the National Science and Technology Council, which was established as a governing organ of NCST, is mandated to strengthen Science, Technology, Research, and Innovation (STRI) by putting in place a sound national research and innovation system aligned to the STRI. In Burundi, the Health Research Coordination Framework is mandated to coordinate all research through the Health Research Coordination Framework Secretariat as stipulated in the National Health Policy of Burundi.

Thus, even within the five EAC countries, there is substantial variation in the governance of ethics review and in the way such governance has been legislated or regulated.

**Table 1: Legislation and regulations governing research ethics review in five EAC countries**

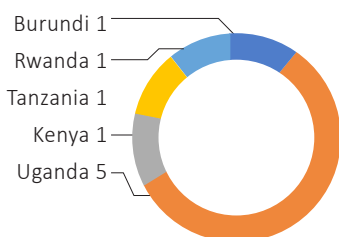
	Burundi	Kenya	Rwanda	Tanzania	Uganda
National Regulatory entity	Burundi National Ethics Committee	National Council on Science, Technology and Innovation (NACOSTI) ( <a href="http://www.nacosti.go.ke">http://www.nacosti.go.ke</a> )	National Health Research Committee of Rwanda and Rwanda National Ethics Committee (RNEC)  ( <a href="https://healthresearchweb.org/en/rwanda/ethics_4209">https://healthresearchweb.org/en/rwanda/ethics_4209</a> )	National Institute for Medical Research, Tanzania (NIMR)  ( <a href="https://www.nimr.or.tz">https://www.nimr.or.tz</a> )	Uganda National Council for Science and Technology (UNCST)  ( <a href="http://uncst.go.ug">http://uncst.go.ug</a> )
Parent Ministry	Ministry of Public Health and the Fight against AIDS; and Ministry of Higher Education and Scientific Research.	Ministry of Education, Science, and Technology.	Ministry of Health and the Directorate of Science, Technology, and Research in the Ministry of Education.	Ministry of Health and the Ministry of Education, Science & Technology.	Ministry of Science, Technology and Innovation.
Legal framework	Presidential Decree No. 100/254 of 4 October 2011.	Science and Technology Act, Cap 250 of the Laws of Kenya in 1977 and the Science, Technology, and Innovation Act, 2013.	Ministerial instructions no. 20/37  (see <a href="http://www.nrecrwanda.org/">http://www.nrecrwanda.org/</a> )	Parliamentary Act No. 23 of 1979 (NIMR) and Act of the National Assembly of Tanzania in 1986 (COSTECH).	Uganda National Council for Science and Technology (UNCST) Act 1990, CAP 209.
Accreditation process	Studies and Research (SER) in the Directorate of the National Health Information System (DSNIS) is responsible for research in collaboration with Institute of Statistics and Economic Studies of Burundi (ISTEEBU).	NACOSTI responsible for registering, coordinating, managing and monitoring the operation of all RECs. Approval for research is given by any accredited RECs. No further clearance is required after approval is given by an accredited REC. However, researchers are required to get a license from NACOSTI - except if exempted by the Act (Sec 12-STI Act No. 28 of 2013).	The Directorate of Science and Technology and Research is responsible for managing and approving all research for students studying from outside Rwanda and giving the research clearance certificate and identification.  National Health Research Committee gives Scientific approval and alignment to national research agenda to all health-related research.  Rwanda National Ethics Committee (RNEC) reviews and gives ethics clearance for all health-related research in Rwanda.	Medical Research Coordination Committee (MRCC) is the national regulatory body responsible for supervising health research. The chairperson is the NIMR Director-General. COSTECH provides research permits to foreign researchers. The National Health Research Ethics Review Sub-Committee of the MRCC focuses on the ethical issues surrounding submitted research protocols for clearance. IRB/REC can only approve health research involving nationals. Research projects with the active involvement of foreign national must be cleared at the national level.	UNCST is responsible for registering, coordinating, managing and monitoring the operation of all RECs.  UNCST must also give clearance to researchers after approval from accredited REC.

### 3.1.2 The Capacity of Ethics Review Committees

The overall response rate for the quantitative interviews was 30%, (21/69) of the total accredited RECs. Although Burundi and Rwanda had the highest response rate, they also had the least number of accredited RECs (Rwanda 2 and Burundi 1). Kenya had the lowest response rate (10%) while over 50% of the accredited RECs in Uganda and Tanzania replied to the assessments. (Figure 2).

The capacity of RECs can be observed by the availability of a sufficient number of members with the right skill mix to conduct high-quality ethics reviews, availability of relevant policies, SOPs and guidelines to support the RECs operations, availability of resources, including funding/budget infrastructure and technology to carry out high quality ethics review. Most of the RECs are led by doctoral degree holders.

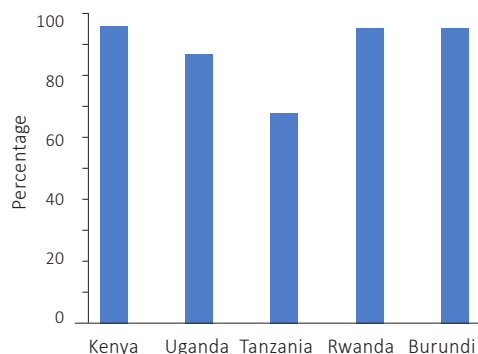
43% (9/21) of the RECs were operating at a national level (NRECs) (Figure 3). while 57% (12/21) were operating at an institutional level (IRECs) and affiliated to either hospitals (60%) or universities (40%). See Figure 4.



**Fig. 3: No of RECs operating at national level**

Uganda had the highest number of RECs (45%; 5/11) operating at a national level while all the rest had only one REC per country.

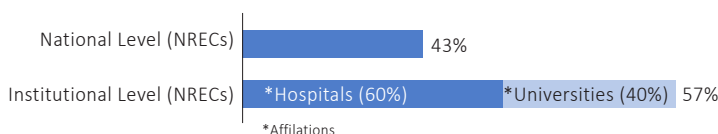
Most RECs (86%; 8/21) reported charging a fee for reviewing protocols (Figure 7). Although all RECs reported either compensating or reimbursing their members. 48% (10/21) did not have a dedicated budget (Figure 5). Most of the RECs derived their income from fees charged for reviewing protocol (86%), while the rest came from budgets allocated by their home institutions (14%).



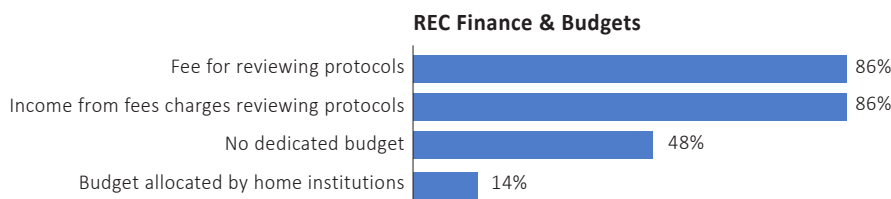
**Fig. 7: Propotion of RECs charging for review per country**

57% (12/21) of RECs reviewed local and international research while 43% (9/21) reviewed local studies only (Figure 6). An average of 91 protocols per year were reviewed across all RECs (range 15 to 200). Membership ranged from 6 to 22 members per REC, with an age range of 29 to 75 years. 76% (16/21) of the RECs interviewed had laypersons and 67% (14/21) had employed staff.

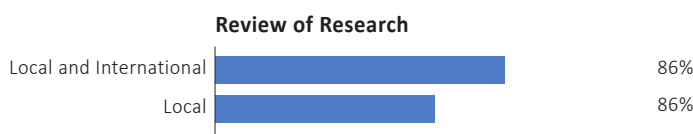
In all RECs, the period of membership was limited to 3 years but all appointments were renewable. The membership of all RECs was multi-disciplinary in nature – at least, in terms of health disciplines. The average turn-around time for reviewing protocols was between 14 and 90 days, with only one REC reporting the use of an online ethics review system.



**Fig. 4: Level of REC Operations within the EAC Partner States**



**Fig.5: REC Finance & Budgets**



**Fig.6: Review of local and international Research**

The majority of RECs (67%; 14/21) received protocols through email and as hard copies, while 24% (5/21) received protocols as hard copies only.

A graphical presentation of these parameters is shown below. Worth noting is that charging fees to review protocols could enable RECs to independently generate revenue and facilitate their activities without relying on their parent institutions for financial support. In addition, compensating REC members could contribute to enhanced REC members' motivation and commitment.

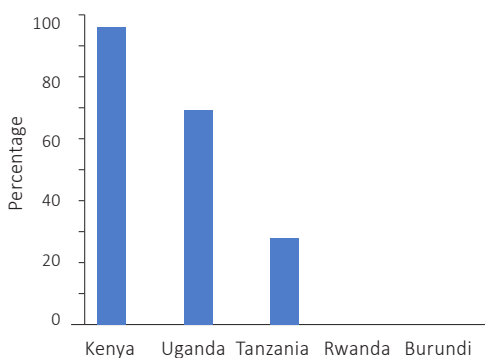
Although 15 out of 21 (71%) of RECs reported having continuous education policies and capacity building programmes for their members in place, only 41% (9/21) of RECs had members who had received formal training in ethics review in the past – and the highest reporting that 30% of their members had received formal training in research ethics. The REC in Burundi and 71% (5/7) of the RECs in Tanzania reported having no continuing professional development policy in place. All RECs confirmed they had relevant policies and guidelines to support them in decision making and promote the protection of research participants.

### 3.1.3 Financial Resources

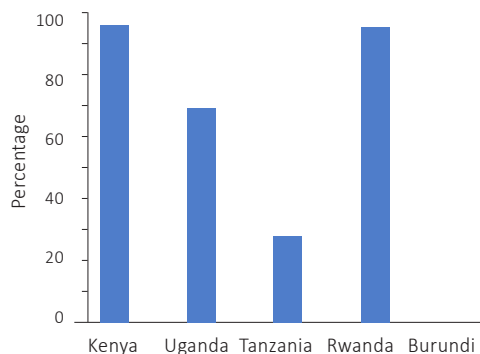
There were marked differences in terms of financial resources available to RECs across institutions: 10 out of 21 RECs had no annual budget allocation (48%), while for those that did have an annual budget allocation, the budget ranged from USD \$3000 to USD \$2.9M (total income at the national level), financed through either review fees (84%) and/or institutional budget (14%). As can be seen in Figure 5, Kenya had the highest proportion of RECs with a dedicated budget allocation (100%), followed by Uganda (73%; 8/11 ) and lastly, Tanzania (29%; 2/7). Neither RECs in Rwanda nor Burundi had any budget allocation.

Overall, 43% (9/21) did not have budget allocation for office operations. Kenya and Rwanda had the highest proportion (100%) of RECs with a dedicated budget allocation for office operations, while 73% (8/11) and 29% (2/7) of RECs in Uganda and Tanzania respectively, had a dedicated budget for office operations. The only REC in Burundi did not have a dedicated budget for office operations, despite operating at a national level (see Figure8).

RECs that depended on fees charged for reviewing protocols as their only source of income had smaller annual budgets compared to those that had budget allocations from their institutions and charged for review. No RECs received external financial support.



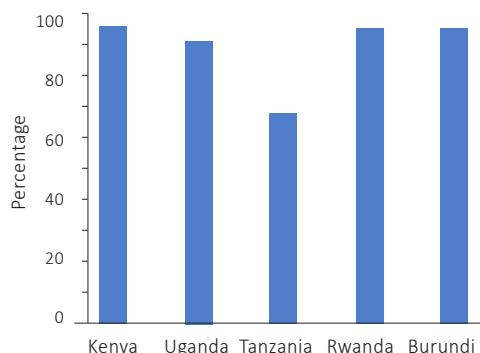
**Fig. 8: Proportion of RECs with dedicated budget allocation**



**Fig. 6: Proportion of RECs with allocated budget for office operation**

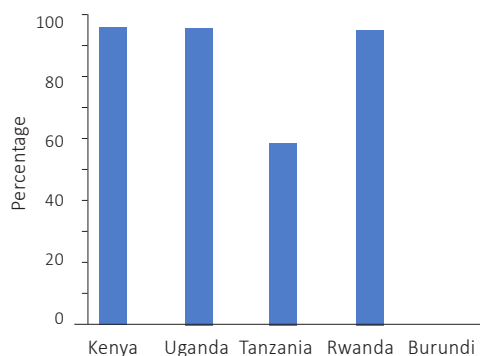
Most RECs charged for reviewing protocols—this was also their main source of income. All the RECs interviewed in Kenya, Rwanda and Burundi, and 91% (10/11) in Uganda and 71% (5/7) in Tanzania, charged to review protocols (see Figure 9). The charges for reviews ranged from USD \$50 to USD \$1,000 depending on the type of study and whether it was 'locally' or 'internationally' funded research. Some RECs charged up to 10% of the research budget.

The number of protocols reviewed by each REC ranged from 15 to 150 per annum. The protocols reviewed included biomedical, behavioural research and clinical trials on a wide range of topics, including palliative care, malaria, HIV, and TB. The turn-around time for reviewing these protocols ranged from 14 to 90 days.



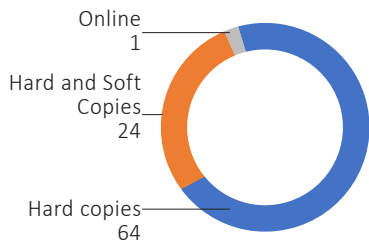
**Fig. 9: Proportion of RECs charging for review per country**

All RECs in Kenya, Uganda and Rwanda reported having access to the internet. Forty-three percent (43%; 3/7) of RECs in Tanzania and all RECs in Burundi did not have internet access (see Figure 10).



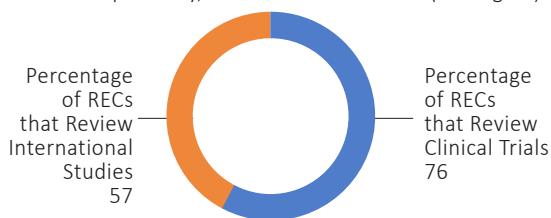
**Fig. 10: Proportion of RECs with access to the internet per country**

Overall, 24% (5/21) of RECs still received protocols exclusively as hard copies while 62% (13/21) received a combination of hard copies and electronic copies (through emails). Only one REC reported using online protocol submission and review (see Fig 11). Over 76% (16/21) of RECs review clinical trials while 12/21 (57%) review internationally funded research (see Fig 12).

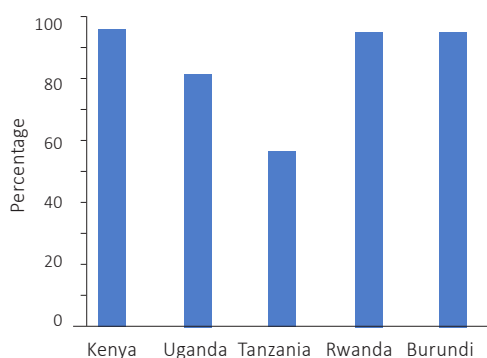


**Fig. 11: Methods of Submission used by RECs**

All RECs interviewed in Kenya, Burundi and Rwanda reviewed clinical trials while 82% (9/11) and 57% (4/7) in Uganda and Tanzania respectively, reviewed clinical trials (see Fig 13).



**Fig. 12: Proportion of RECs that review clinical trials and international research**



**Fig. 13: Proportion of RECs that review clinical trials per country**

Overall, the quantitative assessment demonstrated major discrepancies in terms of resources, infrastructure and access to operational support, especially with regard to how individual RECs operated in the different partner states. Burundi, Rwanda, and Tanzania seem to have more capacity gaps compared to Uganda and Kenya. Many RECs have the financial means to afford to change to digital platforms and to provide training for members—based on income generated through charges for reviews.

### 3.2 Qualitative findings

In total, 43 interviews were conducted, including 21 quantitative interviews and 22 qualitative interviews.

Key stakeholders and informants from all five countries were interviewed about their views on harmonization of ethics review frameworks within the EAC partner states. No one from South Sudan responded to our numerous emails hence South Sudan was excluded from this assessment. Those interviewed included members of national research ethics committees, national councils for research and technology and research institutions.

The majority of those interviewed agreed with and were in support of the need to harmonize ethics review frameworks. However, a few participants expressed concerns like:

*“I don’t support harmonization 100%. We should allow some country-specific areas such as how to approach the society on sensitive issues.”*

Another national regulatory member said:

*“I would rather make regulatory frameworks compatible and make it easy for non-locals to make applications for review. There is no possibility of making them totally similar in every country as ethical issues are largely local and relate to cultures which remain different.”*

#### 3.2.1 Views in support of harmonization

Most respondents strongly supported having harmonized ethics review frameworks within the region. They noted that cross-border research and clinical trials take inordinately long periods of time to be approved because approval must be sought from each country. In addition, different policies and guidelines across countries, means certain projects though approved in one country and can be rejected in another. Harmonization would avoid such delays.

*“Variance in ethics review tools continues to be a weakness that cuts across all review committees. Different ethics review committees adopt formats that are not in line with research work in our setting. Harmonization and providing training on standard tools will increase performance and lead to proper utilization.”*

#### 3.2.2 Similarities and discrepancies of ethics review frameworks between partner states

Annex 1 gives a detailed description of the similarities and differences in the governance and coordination of health research ethics review among the partner states. Generally, all partner states have regulatory frameworks to guide the conduct of health research in their countries (Table 2).

#### 3.2.3 Opportunities for harmonization

Respondents made it clear that the expectation of a harmonized research ethics review framework would reduce discrepancies between countries. It is also likely to reduce the cost of doing research within the EAC, especially by reducing the time required to approve protocols, particularly in instances of multi-centre and multi-country research. Additionally, considering the frequency of epidemics in the region and the need to carry out studies to support responses by health authorities, respondents felt that it was important to be able to carry out reviews and get research going rapidly and across borders.

Harmonization of research ethics frameworks in the region could promote the efficiency of the EAC ethics review committees. It was noted that while national databases for research were available, access to such databases was limited. Investing in the internet and online platforms would greatly increase accessibility of these existing databases, as noted by a national REC member who said.

**Table 2: Similarities and discrepancies of ethics review frameworks between partner states**

	Similarities	Differences
<b>Regulatory Framework</b>	Established through Acts of Parliament (Kenya, Uganda, Tanzania)	Established through Ministerial instruction (Rwanda) Established through a Presidential Decree (Burundi)
<b>Governance Structure</b>	The National Councils have the overall mandate to register RECs and regulate their operations, although they fall under different ministries: <b>Kenya:</b> Ministry of Education, Science and Technology <b>Rwanda:</b> Ministry of Health and the Directorate of Science, Technology, and Research in the Ministry of Education <b>Uganda:</b> Ministry of Science, Technology and Innovation	<b>Tanzania:</b> Regulated by the Tanzania National Health Research Forum (TANHER)
<b>Coordination and Approval of Research Ethics Review</b>	<b>Rwanda:</b> Coordination delegated to the National Ethics Review Committee of Rwanda. <b>Tanzania:</b> The National Health Research Ethics Committee (NHREC), an arm of TANHER, is responsible for accrediting, monitoring and coordinating the activities of RECs.	<b>Kenya:</b> National Council for Science Technology and Innovation (NACOSTI) devolved approval of research to the accredited institutional RECs <b>Uganda:</b> National Council for Science and Technology (NCST) in Uganda reviews and gives clearance for all research conducted in the country, upon getting approval from the institutional RECs.

*“It is of the utmost importance and extreme necessity to have a harmonized framework for Ethics Reviews within East Africa; or for any other, similar, regional, geographic entity. The step is, in effect, long overdue. The benefits of such a framework are myriad, and any disadvantages are hard to envisage. Even as early as the 1970’s, when research studies were considerably fewer, it was valuable to share issues on research ethics reviews – inter alia, for mutual learning - amongst members of the East African Medical Research Council. National Institutional Review Boards (NRBs/IRBs) were then still few and far between.”*

Harmonizing research ethics review frameworks would discourage researchers from moving from one REC to another after receiving an unfavourable review in one REC (“Ethics Committee Shopping”). A harmonized research ethics review framework could facilitate an integrated electronic/digital database that can be accessed and updated in real-time by all RECs, which would provide all stakeholders with timely information and progress status of various research projects in the different countries in the region. It could also benefit the regional overview of research and research ethics review. Harmonization would possibly also encourage the uptake of digital REC administration systems.

*“I support the harmonization of ethics review in East Africa. I believe that it would be useful for researchers and research regulators in the region. Considering the frequency of epidemics in the region and indeed the whole of Africa and the need to carry out studies to support responses by health authorities, it would be important to be able to carry out reviews and get research going in good time. This is only possible if researchers know and understand the review processes of other countries in the region. Furthermore, the EAC and its institutions (EAHRC and others) provide a framework for easy harmonization.”*

A harmonized research ethics review framework would enable the region to be more attractive to clinical trial sponsors. This could result in the region attracting funding from researchers and funding agencies that are willing to support large, cross-border research and clinical trials – with their larger opportunities for research capacity development in the EAC.

*“Harmonization will create a large single region that would be particularly attractive for clinical trials. This is because of the population, the simplified review processes and the fact that a Principal Investigator would have to deal with only one ethics review committee. This is an opportunity for researchers to work in the region. It would attract research funding agencies to support cross-border research or clinical trials. This is an opportunity for funding not just of what the financier would want but also the local ideas that would be brought out by indigenous researchers. It would create an opportunity for students of ethics to access vast amounts of data generated by many RECs”*

Overall, those interviewed felt that it might not be ‘too challenging’ to develop and implement regional harmonization given the already existing collaboration among the EAC countries concerned.

### 3.2.4 Potential challenges

During the assessment of the ethics review process in East Africa, a number of challenges were identified. Table 3 highlights these challenges and offers possible mitigation.

#### Strategies for harmonization of research ethics review frameworks – as proposed by respondents

**i) Improve efficiency of ethics review process:** The turn-around time for reviewing protocols was said to be the most important challenge raised by researchers in the region. To ensure the process of harmonization is supported by researchers, the harmonization process must clearly result in a more simple, effective and efficient process of research ethics review.

*“It is important to harmonize frameworks within East Africa; however, I feel that it is important to have harmonization within the country first. Currently, there is no harmonization of ethics review within the countries.”*

**ii) Conduct Joint Reviews:** It was noted that any harmonized research ethics review framework should eliminate unnecessary repetitive processes. Having a joint review committee with representation from every member state or accepting reviews

done by other RECs that use SOPs, policies, and guidelines that are respected and accepted across the other committees would ensure the process is smooth and devoid of unnecessary repetition. There possibility of a joint EAC Ethics Review Board could be addressed to accredit one or more Regional RECs with the mandate to review cross-border protocols for clinical trials conducted within EAC partner states. Researchers would need no further approval from individual EAC partner states once their protocols are approved by the regional RECs.

**iii) Consultation and Engagement:** The success of a harmonized research ethics review framework in the EAC partner states would largely depend on having the support of national governments and health research regulatory authorities. EAHRC should, therefore, organize consultation meetings with national RECs and other national bodies involved in research regulation to collect their views and contributions and to initiate a gradual process leading to harmonization. Experts could assist in this process by analyzing existing laws and policies in the different partner states and recommend changes of such laws that would make harmonization easier to achieve.

*“We need all RECs to participate and to contribute to the building blocks of the framework so that they own it.”*

Another stakeholder said:

*“It is very important that stakeholders value the role of research and ethics committees in National development by providing the regulatory framework for this to happen and at the same time protecting the research participants and researchers. It is therefore imperative that they make considerations for funding support to this cause.”*

It was noted that more intricate issues might be encountered at institutional and local REC levels than at the national level, given the current extent of awareness. Wide, on-site engagement may, therefore, be necessary. EAHRC should prioritize to build political will and leadership on harmonization from the ministries of education, science and technologies; ministries of health, NRECs and other key stakeholders.

In addition, it might be beneficial to involve inter-governmental agencies within the EAC. Authoritative national research policy/regulatory bodies concerned with research at the country level, within the region and outside, were identified as important partners. National government departments must also be engaged to ensure there is national support and to increase the sense of national ownership and the sustainability of the initiative.

**Table 3: Potential challenges related to harmonization of frameworks reported through the qualitative questionnaire**

Summary of reported challenges	How to mitigate the challenge
Limited collaboration among partner states	Involve inter-governmental agencies involved in research
Inadequate knowledge and awareness on the importance of harmonization	Wide engagement at the institutional and national level
Restricted international uptake if the harmonization process is dissimilar to any approved standards	Begin with harmonization around internationally accepted systems for harmonized review such as the GCP
Disorganisation when the EAC and institutions from other regions do not agree on whether or not there should be an IRB from one or both of the institutions	Wide engagement and involvement of key stakeholders. Institutions to be sensitized about the need for harmonization; clarity on national (regional EAC) authority for ethics review
Time-consuming review process due to basic similarities and the differences in countries, e.g. language, norms and cultural diversity.	Wide engagement and involvement of key stakeholders, Intensive engagement for buy-in
Discrepancies in legislation and policies, including conflicting roles among bodies that govern research within each country.	Review legislation, SOPs, and guidelines to ensure they are similar across the board
Unclearness on the responsibilities of the national RECs in each country and their relationship with the regional structure if created	Hold regular meetings with key stakeholders to address the challenges and come up with a common understanding
Variations in levels of development for the different countries in the region need an alignment if regional research is to inform policy at the regional level	Ensure progressive capacity strengthening of countries that are lagging behind with the support of countries that are more advanced.
Peculiarity of individual RECs may render a generic framework inapplicable to all	Establish an inter-country joined committee to lead the process and ensure all RECs are involved
Inadequate funding to support the proposed activities	Need for EAHRC to lead the efforts to solicit and generate resources to support the Ethics review framework
Divergent ideologies among partner states	East African Assembly to incorporate harmonization activities in its planning and Budgeting
Scarcity of resources and capacity to monitor-ongoing studies	EAHRC to develop a resource mobilization strategy and prioritize allocation of budget to capacity strengthening of ERCS and M&E.



## 4. Priority Interventions for Capacity Strengthening of Ethics Review

### Budget Allocation to RECs

An important challenge reported by most RECs was an insufficient or absent budget ring-fenced for REC operations. The absence of a dedicated budget allocation causes a lack of autonomy among RECs and impacts negatively on their ability to undertake some of their critical functions, including but not limited to monitoring of approved studies. There is a need to ensure RECs have adequate budgets to support their activities – including the day-to-day operations as well as continuing education, digitization of REC operations, and maintaining links with international resources and expertise. This would improve their efficiency as well as their autonomy – and is essential to enabling them deal with the growing number of complex, multi-centre and even global research collaborations in health. An important recommendation from those interviewed was the need to ensure the roles of the national regulatory authorities were clear and that the entities were adequately resourced and empowered to carry out their functions effectively.

Most RECs interviewed depend on moderate fees charged for reviewing protocols and budgetary support from their institutional anchors. To improve this situation – the following can be done at relatively short notice:

- Define ‘fair’ charges and harmonize the fees charged across institutions and countries in EAC, especially for clinical research and clinical trials.
- In addition, RECs must lobby institutions and governments for adequate budget and resource provision. EAHRC should establish a regional cost guideline of REC operations.
- It is also important for RECs to diversify their sources of income by engaging in competitive proposal writing and submitting applications to compete for the resources available from international donors that aim at strengthening ethics review in Africa. EAHRC should take the lead in strengthening the capacity of RECs to access additional funds through competitive proposals.

### Digitizing REC administration

This assessment has shown that most RECs in EAC have a limited investment in modern online review platforms and do not have regular access to Internet-based resources that support research ethics review and (continuing) education. Except for one REC, all the other RECs interviewed either received protocols manually or through email. This is despite the fact that online platforms have been shown to improve quality of the review, accelerate ethics review processes and improve communication, enable RECs to capture key performance indicators and improve storage and management of data within and across RECs, beyond national borders.

The East African Community should invest in a common online ethics review platform that is able to allow online submission of protocols, screening of submitted protocols by the administrators and enable onward distribution of submitted protocols without requiring printing of the submitted protocols. The online

platform should also enable national regulatory bodies to monitor institutional RECs and accredit new and existing RECs. This will accelerate EAHRC’s efforts to harmonize ethics review frameworks within the EAC. An online ethics review platform will actualize the aspiration of having a joint review committee as it will enable joint review committee members to carry out a review without having to travel to a central place or wait for the protocols to be delivered before starting the review. REC members who travel frequently are often not able to review large paper-based protocols. However, when the protocols are submitted online, such REC members would be able to review them while in transit, thus reducing the review time and increasing REC efficiency.

### Continuing capacity strengthening

Although most RECs interviewed confirmed they had policies and guidelines specifying requirements for members to be continuously trained, a large number of the RECs members had never been trained in research ethics and the protection of research participants. This is a serious gap, given that the effectiveness of the RECs depends on the skills and knowledge of members.

Continuing capacity strengthening policies should be developed and adhered to ensure members are able to carry out their roles effectively. Harmonization efforts could set a minimum number of people without ethics or relevant training that can be allowed to join a REC. This will ensure the capacity of RECs, in terms of their skill-set is gradually improved and comparable among all RECs within the EAC partner states.

Training of REC members will also build their confidence in dealing with harmonization. Given the rapid advancements in science, REC members should undergo regular and continuous training to enable them to keep up with the ethical challenges posed by progress in science. Digitizing research ethics review will make it easier to access existing and future training courses to improve the research ethics expertise of REC membership and that of researchers who submit protocols.

### REC membership compensation model

The membership of RECs in the EAC has traditionally been voluntary, with most RECs providing a moderate compensation for travel costs. This practice stems from the intention to ensure the independence of reviewers and to promote volunteerism for REC members. Unfortunately, the result is that RECs can often attract only a few expert individuals who are willing to volunteer. This can lead to lack of motivation and commitment for RECs to operate efficiently and professionally. There is, therefore, a need to review the model of compensation for members to ensure RECs attract more committed and motivated professionals to discharge the functions of RECs effectively and efficiently. If payment of members and fees are structured in a way that creates sufficient distance (“arms-length”), independence is very possible, as has been shown in many committees that reimburse members.

## Professionalization of secretariat

One key challenge identified was the lack of (full time and) competent support staff for RECs, a consequence of diminished financial resources for RECs and high staff turnover. Most REC secretariats depend on volunteer services. To improve efficiency, there is a need for RECs to look for dedicated funding to support their operations and to employ professionals to manage and coordinate the activities of the secretariat. This would ensure stability, continuity, and professionalization of the REC operations.

REC Administrators (RECA) should be considered as the key to high-quality review and successful harmonization. RECA can be the pillars of continuity in RECs where members and chairs may change.

For complex trial review, the challenge is even more clear – RECs that need to review clinical trials need to have a competent secretariat to ensure rapid review, issuing of exceptions, dealing with Serious Adverse Events, and more. An ideal online platform could offer the additional services of a ‘Virtual REC Administrator’ – someone who can manage the complex administrative requirements of review of clinical trials from a distance while the REC members continue to be responsible for the conduct of the research ethics review itself. In this way, new RECs could begin to handle complex trials quickly, while existing RECs could use this service for the especially demanding studies, and RECs with staff changes could continue to operate at a high level of efficiency and quality while looking for and training a new REC Administrator.

# 5. Developing Indicators to Measure Project Impact

There are few, if any, internationally agreed standards for research ethics review systems and performance. Even on such basic issues as using ethics guidelines, there are substantial differences between countries. There is, therefore, no ‘universal’ set of indicators to guide EAHRC. However, given the findings presented and the differences in key ethics review parameters between the five EAC countries that participated in this assessment, we propose the following set of measurements of performance to inform EAHRC about the process milestones, outcomes and possible impact of any interventions. These will need to be validated before implementation.

## 5.1 Stakeholder engagement and buy-in

The success of EAC’s harmonization project depends on how the different stakeholders are made aware of this initiative and appreciate its value. Harmonization of ethics review in EAC is unlikely to succeed if key stakeholders do not feel that they co-own this initiative. Continuous involvement and engagement through consultative fora and workshops are key to ensuring all stakeholders own the process. This will ensure sustainability of the project.

*“The best advice is to initiate a coalition among the National Ethics Committees that will bring the various ethics committees in each country on board; once guidelines are harmonized, the remaining hurdle would then only be implementation.”*

The following indicators could guide the implementation of the harmonization roadmap:

### 5.1.1 Establishing and maintaining an up-to-date listing of stakeholders

An established and up-to-date database of all NREC, RECS, IRBS; their capacity, their SOPs, and track records.

### 5.1.2 Communication of this information

The number of published opinion pieces, case studies and articles on EAC harmonization processes.

### 5.1.3 List an agenda of activities

At least two surveys (mid-line and end-line evaluation) conducted in the course of the next 5 years to collect stakeholders’ perspectives on impact or outcomes of harmonization processes.

## 5.2 Digitization of RECs in EAC

The success of this project will depend on the ability of all RECs to access web-based services. At this moment, all EAC RECs interviewed operate on manual systems. These are clumsy, leading to delays and unnecessary errors, and do not allow cross-border comparisons and use. Even though Africa is lagging behind in digital infrastructure compared to the rest of the world, the available infrastructure is good enough to begin to digitize REC operations. EAHRC must encourage RECs in EAC partner states to acquire necessary equipment and arrange for training to use it to facilitate the transition to the harmonized ethics review frameworks, improve national and

regional performance management, and facilitate access to online learning. The use of an online ethics review platform by RECs should be an important milestone as this would define the roadmap to having harmonized framework within the region. By utilizing an online ethics review platform, generic ethics review policies, guidelines and templates can be developed, shared and accessed in real time, hence improve the operations of such an initiative. Multi-centre clinical trials can be reviewed more quickly, and it is quite possible to link ethics review systems to medicine regulatory agencies in partner states to accelerate approval of new medicines, biologicals, and technologies.

Possible Indicators:

### 5.2.1 Number of RECs that are changing over to online systems

A key Indicator is a proportion or number of RECs with an exclusive online protocol submission system (not email).

### 5.2.2 Increased efficiency and quality of reviews through adoption of digital technologies

Performance indicators to look for include the number of protocols reviewed; the time between submission and review; the time between submission and approval or disapproval; and REC administrative measures such as membership, training, gender distribution, turn over.

### 5.2.3 Budgets available for this

– regionally, nationally or locally.

## 5.3 Standardized quality and efficiency of regional and national ethics review

This report has shown that there is a great support for and a need to harmonize ethics review frameworks in EAC partner states. To date, although some national policies and guidelines exist, the application of such policies are at institutional level and remains fragmented hence harmonization often does not exist even at national level. The success of this project will be enhanced if efforts at the national level are made to ensure all RECs adhere to same standards, and use the same SOPs and guidelines for similar activities. This will make it easy to integrate all country-level processes into regional frameworks.

Possible Indicators include:

### 5.3.1 A validated and complete database of harmonized regional and national policies, guidelines and tools

Develop a TWG composed of experts from different partner states with the objective of conducting a comparative analysis and suggest areas of harmonization of policy and tools.

### 5.3.2 Number of consultative meetings with other African Union and NEPAD led initiatives and WHO initiatives on harmonization as evidenced by publications on lessons learnt.

Adoption of internationally accepted harmonization guides is a good strategy as it serves two purposes at the same time: firstly, it brings EAC in line with the rest of

the world in terms of clinical trial review, and, secondly, if all partner states of EAC agree on an internationally accepted model, then the pathway towards regional harmonization is one step shorter.

## 5.4 Resource mobilization

This assessment has shown marked differences in budget allocation and resources, which affects the operations of individual RECs. To ensure optimal levels of operation and comparability, it is preferable to have some minimum standards for funding, training, equipment, and facilities. Efficiency and quality will not be achieved where RECs are not adequately resourced. Targets for resource mobilization should be set and be reviewed within specific timelines. Minimum requirements such as availability of office space, dedicated staff, computer, and internet connectivity must be set and monitored to ensure all RECs operate at least within the optimal resource capacity requirement. Fortunately, this assessment also provides evidence that the RECs that do charge for reviews can generate more than sufficient revenue and fund other requirements such as member remuneration and regular training.

Possible Indicators include:

- 5.4.1 Add a “Financial/Equipment/Facilities” record to the list of RECs established in 5.1.1.** – Proportion of NRECs/ RECs in the EAC that have established a harmonized review fee structure in line with the EAHRC guidelines  
2) Proportion of NRECs/RECs in EAC that receive budget support from their respective ministries  
3) Proportion of NRECs/RECs  
4) Percentage of EAHRC budget allocated to strengthening capacity of RECs

## 5.5 Regional REC / joint reviews

While the use of harmonized research ethics review frameworks can be implemented using institutional and national RECs in every member state once the required infrastructure such as harmonized SOPs, Policies, and Guidelines are available, the ability to carry out a joint review or establish a regional REC could be the apex milestone of this project.

*“I would recommend that we move gradually from recognition of the other country’s structures, procedures, and laws to developing regional guidelines, to developing more binding regional conventions. This will allow everyone to move together and ensure compliance at every stage.”*

Possible Indicators include:

- 5.5.1 An established framework for joint recognition mechanisms;**
- 5.5.2 an established EAC joint review policy and framework; and**
- 5.5.3 an established data base of all multi-country studies within EAC and between EAC and other region.**

## 6. A Case for Harmonization

This baseline has shown marked differences within and across member states with regards to governance and regulation of health research. Notably, there are structural and operational differences that have important implications for the quality, cost, and efficiency of ethics review in the region. Multinational research projects were reportedly the worst affected by these differences. Differences attributable to the existing legal and ethical frameworks have implications on turn-around time for multinational research projects. In addition, variations in skills, SOPs, members training, budget and access to resources such as technology, as well as differences in fees charged by RECs for reviewing protocol could influence researchers to do “REC shopping” or redirect their research to other settings altogether, where review systems are reliable and efficient. This could have implications on the volume of research conducted within the EAC partner states, as well as the timely discovery of novel medical interventions for the region.

Harmonization will greatly encourage more science in EAC – both from internal and external sources – to the benefit of all. EAC’s populations will benefit because their health (and other) problems are more likely to be addressed. EAC’s health research systems will benefit because more challenging research will come to the region as review processes become more efficient. And EAC’s economic activity may grow as clinical research drives clinical innovation.

### Harmonization process roadmap

Based on these findings, below is a proposed harmonization roadmap by technical expert working group from the EAC partner states. It offers important steps to be considered in realizing the harmonization of ethics review framework within the EAC partner states.

It is important for stakeholders to lobby for harmonization of ethics regulatory frameworks among EAC partner states and at the same time allow for context-specific issues to thrive. In addition, the existing research ethics policies and guidelines, including REC accreditation, standard operating procedures for reviewing research and other relevant guidelines should be reasonably comparable, to avoid conflicts among partner states. Doing this would be an important foundation for harmonization, as partner states would be using more or less the same processes.

Figure 14 shows a possible harmonization pipeline that could be considered to ensure the process is successfully implemented within the EAC. As such in Figure 12, the pipeline must first ensure the existing legal frameworks for ethics review as well as the national ethical guidelines and policies are well aligned and where necessary, as comparable as possible. This will ensure partner states have similar or comparable structures, systems and processes that govern and regulate research and the ethics review process. This would then lay the foundation for harmonization. Additionally, once this is achieved, efforts to support local and regional structures and processes for harmonization would continue, through the development of SOPs, guidelines as well as multinational REC accreditation systems. This would set the standards for RECs that review multinational research, including SOPs, required resources, infrastructure, budgets, members’ skills/expertise and access to online platforms and technology. Additionally, this would lay the ground for developing a joint EAC ethics review board, that would either operate on an *ad hoc* basis, whenever there is a multinational research to be conducted in partner states, or permanently, whichever is necessary. A joint review board of this nature would eliminate the redundancy of unnecessary multiple reviews, save time and improve efficiency in health research review within the EAC partner states. A dedicated regional structure would need to be established to lead and oversee this process.

In summary, there is need to engage key stakeholders, including donors, researchers, regulators, and policymakers in order to develop acceptable guidelines for accrediting regionally recognized RECs within the EAC. The guidelines would involve the inclusion criteria for accrediting a regional REC and the regional body that would be responsible for accrediting such RECs. Importantly, such regional RECs would need to have reasonable similarities in terms of their resource and financial capacities; the skill mix of their members, as well as the infrastructure and technology to ensure their review, are acceptable among all EAC partner states. At the apex of this journey would be the need to come up with some guidelines on how to select members of a Joint REC with representatives from across all EAC partner states. The operationalization of this structure would be agreed by experts selected to actualize this process.

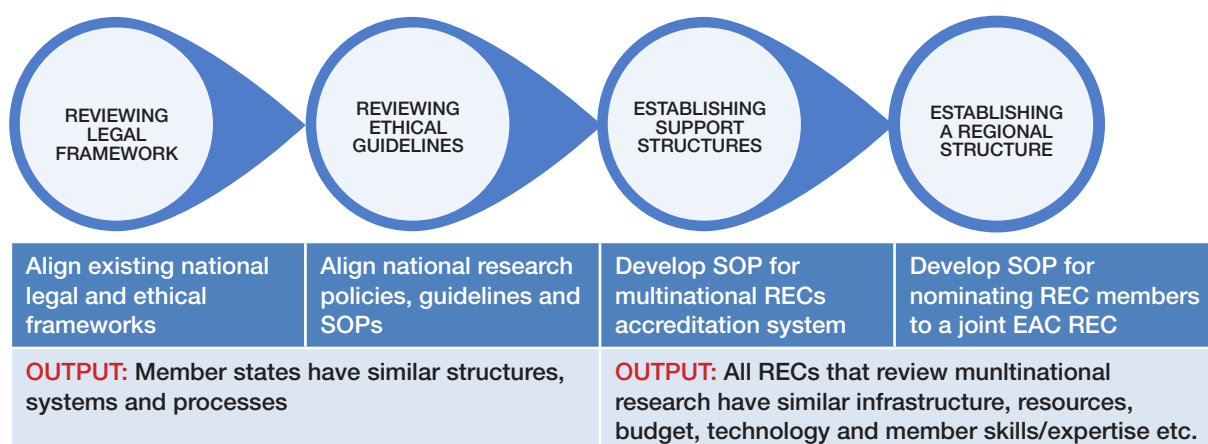


Fig. 14: Harmonization process pipeline

## 7. Limitations

- The budget and timeline for this assessment were not sufficient to conduct on-site inspections, reviews, and face-to-face interviews. This study is, therefore, based on: telephone and self-reporting interviews; self-completed questionnaires; and document review. It is unlikely that these methods affected the quality of the data collected but it affected the assessment response rate. Nevertheless, the overall findings and recommendations are solid – though there could be errors and omissions in the details.
- There was a low response rate from the initial contact list obtained from EAHRC. The current database of RECs by EAHRC was incomplete and at times inaccurate. This in turn contributed to the low response rate and challenges with follow-up.
- Focal persons indicated by EAHRC were required to provide all necessary information in time for this assessment. However, there were many delays and in some instances limitations in sharing this information which affected the timelines and timely completion of this consultancy.

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## 9. Annexes

Annex 1. National capacities and policies in research ethics in 5 EAC partner states

Annex 2. Interview – schedule of questions and requests for information

Annex 3. Qualitative interview questionnaire

Annex 4. Approach to Desk Top Reviews

Annex 5. List of accredited RECs by country



## Annex 1. National capacities and policies in research ethics in six EAC partner states

Country	Medicine Regulation	Ethics Review	Research Finance
<b>Kenya</b>	<ul style="list-style-type: none"> <li>Pharmacy and Poisons Board (PPB) mandated, by Cap 244 Laws of Kenya, to regulate clinical trials</li> <li>PPB sets the requirements and procedures for approval of clinical trials and registration of new drugs</li> <li>Approval subject to conditional approval by National Commission for Science, Technology and Innovation (NACOSTI)</li> <li>Guidelines for application and conduct of clinical trial available</li> </ul>	<ul style="list-style-type: none"> <li>National Commission for Science, Technology and Innovation (NACOSTI) is mandated to coordinate research nationally</li> <li>Ethical clearance is mandatory for all biomedical research</li> <li>Ethical clearance is done by Institutional ethical clearance committees accredited by NACOSTI</li> <li>All research must adhere to a systematic and coherent framework for determining whether a study is ethical and guidelines for ethical conduct of biomedical research involving human subjects in Kenya</li> </ul>	<ul style="list-style-type: none"> <li>Up to 2% of the country's GDP to be set aside for research annually; 30% of which should be for health research</li> </ul>
<b>Uganda</b>	<ul style="list-style-type: none"> <li>The National Drug Authority (NDA) regulates the safety, quality, efficacy, handling and use of drugs or drug-related products in research</li> <li>National Drug Authority (NDA) has oversight responsibility for all clinical trials</li> <li>NDA issue authorization certificate to any person for the purpose of carrying out clinical trials for all experimental drugs/devices, irrespective of whether the drug/device has previously been licensed for use in humans or not</li> </ul>	<ul style="list-style-type: none"> <li>Uganda National Council for Science and Technology (UNCST) has oversight of research involving humans as research participants in Uganda</li> <li>UNCST accredits Institutional Review Committees</li> <li>UNCST liaises with the Research Secretariat in the Office of the President, for national security reasons, to clear researchers</li> <li>UNCST issues permits to conduct research in Uganda</li> <li>UNCST registers and gives permits to all researchers intending to carry out research in Uganda</li> <li>Institutional Review Committees (IRCs) established by institutions that carry out research conduct initial and continuing review and approval of research projects</li> <li>Other committees that support the conduct of research include Scientific Committees, Data and Safety Monitoring Board, Community Advisory Boards and Institutional Bio-safety Committees</li> </ul>	<ul style="list-style-type: none"> <li>0.05% of national health expenditures allocated to health research</li> </ul>
<b>Tanzania</b>	<ul style="list-style-type: none"> <li>Tanzania Food and Drug Authority (TFDA) is mandated to regulate the quality, safety and efficacy of food, medicines, cosmetics and medical devices</li> <li>Has guidelines for registration of products, inspection, surveillance and laboratory analysis of product samples prior to market authorization</li> </ul>	<ul style="list-style-type: none"> <li>Medical Research Coordination Committee (MRCC) is the national regulatory body responsible for supervising health research.</li> <li>The chairperson is the NIMR Director-General.</li> <li>COSTECH provides research permits to foreign researchers.</li> <li>The National Health Research Ethics Review Sub-Committee of the MRCC focuses on the ethical issues surrounding submitted research protocols for clearance</li> </ul>	<ul style="list-style-type: none"> <li>0.7% cent of GDP</li> </ul>

Country	Medicine Regulation	Ethics Review	Research Finance
<b>Rwanda</b>	<ul style="list-style-type: none"> <li>• Pharmacy services in the Ministry of Health regulate all clinical trials with the support of the Rwanda National Ethics Committee</li> </ul>	<ul style="list-style-type: none"> <li>• The MoH champions health research for equity and social justice</li> <li>• The NHRC coordinate the review of medical research protocols from Rwandan and foreign researchers before being implemented. Scientific clearance is granted by NHRC to the investigators</li> <li>• NHRC coordinates the review of the scientific part of every research proposal</li> <li>• Research requiring data nationally submitted to National Institute of Statistics of Rwanda</li> <li>• National Ethics Committee safeguards the dignity, rights, health and well-being of those participating in biomedical research and responsible for carrying out a review of proposed research before the commencement of research</li> <li>• Scientific review committees and ethical review committees are available in all institutions which have health research in their mandate</li> <li>• Institutional Review Board (IRB), or ethics committee associated with the same institution review protocols approved by the SRC</li> <li>• All IRBs are overseen by Rwanda National Ethics Committee</li> <li>• Ministry of Health and research institutions in charge of managing research agenda in Rwanda provides a framework and required insights for ethical standards</li> <li>• Ministry of Health is a central registry for all health research in Rwanda</li> <li>• Minister of Health can ask for assembly of an ad hoc SRC for research initiated at the ministry of health</li> <li>• Reviewed protocols submitted to Minister of Health and submitted to the Ministry of Health, Medical Education and Research Department in one package for registration</li> <li>• Minister for Health names the members of the NER</li> </ul>	
<b>Burundi</b>	<ul style="list-style-type: none"> <li>• Ministry of Public Health govern the conduct of health research</li> <li>• Institutional framework for health research coordination developed in 2012.</li> <li>• Action Plan and strategy for Implementation of the National Policy of the Scientific and Technological Innovation Research 2014-2018 available.</li> <li>• National Policy of the Scientific and Technological Innovation act was not accessed</li> </ul>	<ul style="list-style-type: none"> <li>• Health Research Coordination Framework mandated to coordinate all research through the Health Research Coordination Framework Secretariat</li> <li>• Key activities stipulated in the National Health Policy of Burundi</li> </ul>	<ul style="list-style-type: none"> <li>• Implementation Plan of the National Health Policy identifies ways of strengthening medicine development</li> </ul>

Country	Medicine Regulation	Ethics Review	Research Finance
<b>South Sudan</b>	<ul style="list-style-type: none"> <li>• Ministry of Health, Government of South Sudan registers protocols for clinical trials for new medicines</li> <li>• Establish guidelines for clinical trials involving human subjects</li> <li>• Grant approval of new investigational medicines after scientific and ethical considerations</li> </ul>	<ul style="list-style-type: none"> <li>• Overall responsibility for health research falls under the Division of Research, Monitoring and Evaluation, under the remit of the Directorate of Planning and Coordination in the Ministry of Health</li> <li>• MOH provides leadership and support for health research</li> <li>• Research hub, ethical committees and research secretariats are responsible for research</li> <li>• Research Ethics Committee ensure that research is conducted according to internationally accepted norms</li> <li>• South Sudan Research Ethics Committee (SSREC) develops guidelines on conducting research in South Sudan</li> </ul>	

## Annex 2. Interview – schedule of questions and requests for information

<b>Contact Information</b>	
Name of committee	
Name of an affiliate organization	
Name of chairperson	
Office administrator's name	
Telephone/mobile number	
Physical Address	
Postal address	
Country	
Website address	
<b>Organizational operations</b>	
Institutional affiliation of the organization? (University, Hospital etc.)	
Level of operation (e.g. institutional, national)	
Does your organization have a dedicated budget?	
Are your members compensated/remunerated for their work?	
Which year was the NREC/IREC established?	
Which year was NREC/IREC registered?	
Which institution registered/accredited the NREC/IREC?	
Sources of Revenue – details of charges, if any	
<b>National policies/framework</b>	
Are there any national laws or regulations in the country regarding the ethical conduct of research?	
How many registered IREC are there in the country?	
Which institution has the overall mandate to govern ethical conduct of research in the country?	
What is the process of accrediting IREC in the country?	
What are the key IREC strengths in the country	
What are the key IREC challenges in the country	
What should be done to increase the efficiency of ethics review in the country	
Appeal procedures – institutionally / nationally	
Provide copies of all relevant documents	
<b>NREC/IREC resources</b>	
How many members belong to the NREC/IREC?	Male [ ] and Female [ ] Total [ ]
How many members are community representatives?	Male [ ] and Female [ ] Total [ ]
How many staff are employed by the NREC/IREC?	Male [ ] and Female [ ] Total [ ]
What is the age of the youngest and oldest member	Youngest [ ]; Oldest [ ]
If possible: ages of all members	
What is the term of office for members?	
Is the term of office renewable?	
What is the professional backgrounds of members?	

How many members have had formal training in research ethics?	Male [____] and Female [____] Total [____]
What is the total annual budget of the NREC/IREC?	
What are the sources of income of the NREC/IREC?	
What proportion of your income comes from the different sources (probe for the sources identified above)	
Total revenue / income of NREC/IREC annually?	
How much does the NREC/IREC charge for reviewing protocols, e.g. new, expedited, exceptions	New [____]; Expedited [____] Exceptions [____]; Renewal [____]
What external institutions collaborate with the NREC/IREC – if any?	
Does the NREC/IREC get any external financial support?	
What proportion of your financial support comes from external support?	
Does the NREC/IREC have a budget for office operations?	
Does the NREC/IREC own/have reliable access to facilities/equipment for ethics review such as computers, review software?	
Does the NREC/IREC have access to the internet	
Does the NREC/IREC have an office/room to meet?	
<b>NREC/IREC meeting coordination and reviews</b>	
How often does the NREC/IREC meet (full committee) to consider protocols?	
How long in advance should the protocol be submitted to be considered at the next meeting?	
How many protocols does the committee review annually?	
What is the average number of protocols reviewed by each member annually?	
What kind of studies does the NREC/IREC review?	
Do you review clinical trials?	
Do you review international research?	
What is the average turn round time for reviewing different protocols (prompt on categories identified above)	
How are the records stored?	
Does the NREC/IREC keep minutes for every meeting?	
Does the NREC/IREC have guidelines on meeting coordination?	
How are the minutes stored	
How are the minutes shared to members?	
Describe the NREC/IREC policy on decision making	
Does the REC have a policy for communicating a decision?	
Does the NREC/IREC have guidelines on benefits sharing and study feedback?	
Does the NREC/IREC have guidelines on data sharing	
What are the procedures for monitoring approved research?	
What are the procedures for ending a study?	
What is your preferred method of receiving protocols (Hard copy by mail or by hand)	

<b>NREC/IREC governance</b>	
What written policies, SOPs and guidelines does the NREC/IREC use?	
Does the NREC/IREC have any Standard Operating Procedures	
What templates has the NREC/IREC developed for use by IRECs/ applicants	
Does the NREC/IREC have a checklist to support applications?	
What is the process of selecting the chair of the NREC/IREC?	
What is the process of selecting members of the NREC/IREC?	
What is the process of selecting lay people to the NREC/IREC?	
Describe the qualifications of the chairperson	
Does the NREC/IREC have a policy on how to review protocols?	
Are the following areas included in the protocol review policy?	
Expedited review	
Waiver of review	[ ]
Vulnerable population	[ ]
Children participants	[ ]
Participants selection/enrolment	[ ]
Informed consent and assent	[ ]
Risk/Benefits	[ ]
Subjects compensation (financial or material incentives)	[ ]
Subjects protection and welfare	[ ]
Participants privacy and confidentiality	[ ]
	[ ]
In your experience, how can you described the political will of the governments to harmonize ethics review with the EAC?	
<b>NREC/IREC capacity</b>	
Does the NREC/IREC have a clear capacity building programme requiring members to be trained?	
Is there a requirement for continuous education in research ethics?	
When was the last refresher course on ethics given to members?	
Approximately how many members are supported for any type of educational opportunities in research ethics annually	Male [ ] and Female [ ] Total [ ]
Approximately how many members of the NREC/IREC are trained on	
a) Bioethics	Male [ ] and Female [ ] Total [ ]
b) Health research	Male [ ] and Female [ ] Total [ ]
c) Ethics review process	Male [ ] and Female [ ] Total [ ]
d) Human subjects' protection	Male [ ] and Female [ ] Total [ ]
What specific area of expertise is lacking in the NREC/IREC?	
What type of potential professional training is required by the NREC/IREC members?	

## Annex 3. Qualitative interview questionnaire

### Stakeholders views and opinions regarding on the harmonization of ethics review frameworks in the East Africa partner states

#### 1. Introduction

As you are aware, The East Africa Health Research Commission (EAHRC); an institution of the East African Community (EAC) established as a mechanism for making available to the community, advice upon all matters of health and health related research and findings necessary for knowledge generation, technological development, policy formulations, practices and related matters, is in the process of carrying out baseline assessment of ethics review frameworks in health research for the purpose of harmonization of the frameworks in the East Africa Community (EAC) partner states. In order to do this, the EAHRC has contracted the Councils on Health Research for Development (COHRED), which is a global independent, non-profit and non-governmental organization with offices in Geneva (Switzerland), Pietermaritzburg (South Africa), Gaborone (Botswana), Bangkok (Thailand) and Belo Horizonte (Brazil that aims at maximizing the potential of research and innovation to deliver sustainable solutions to health and development problems through empowerment of Low and Middle Income Countries (LMIC) to find sustainable solutions for their health challenges(<http://cohred.org>).

As a key stakeholder and a key informant in health research ethics and review, we would like to seek your consent to take part in an exercise that involves collecting views and opinions of stakeholders on their experiences, challenges, needs and recommendations that you may have in strengthening ethics review process and harmonization of ethics review frameworks in your institution and the East Africa Community partner states as a whole. Your name and contacts were given by the EAHRC because of the body of invaluable knowledge, expertise and experiences which you possess in the field being studied.

If you agree to contribute to this exercise, we would like you to spend 10 to 15 minutes to answer the questions below. Please note that the information that you share will be used for the purpose of this baseline assessment only. Information collected will be shared in summary form and will not contain individual

person's or institution's names or any identifiable information. The report generated from this assessment will provide a situational analysis of the views, opinions and recommendations of key stakeholders about this matter. This information will be important in informing the EAHRC on how best to support national and institutional RECs in order to strengthen ethics review process and will provide important insights on the potential for harmonization of ethics review frameworks in the East Africa Community partner states.

I hope this information will serve to help you make a more informed decision on whether or not to take part in this activity. Participation in the interview is voluntary. It is however important to note that your participation will contribute to an existing body of literature on the capacity, needs, challenges and experiences of research ethics stakeholders in the EAC and will provide invaluable insights in informing targeted intervention and support towards RECs in EAC and other similar settings.

#### 2. Questions

- 1) Describe your views on whether or not you think it is importance and necessary to have a harmonized framework for ethics reviews within East Africa.
- 2) If the East Africa Health Research Commission is to establish a harmonized framework for ethics review within the East Africa community, what issues must they put into consideration?
- 3) Describe any opportunities and challenges that might arise in the process of establish a harmonized framework for ethics review within the East Africa community.
- 4) If you foresee any potential challenges, how can they be addressed?
- 5) What recommendations do you have about the suggestion to establish a harmonized framework for ethics review within the East Africa community?

**Thank you for your contribution**

## Annex 4. Approach to Desk Top Reviews

National and local (institutional) guidelines were reviewed and analysed thematically based on the information obtained. Specifically, documents were reviewed for similarities and discrepancies in the following areas:

- Ethics governance processes, policies and organogram
- Regulation, registration and guidelines for accrediting institutional RECs
- Performance management of institutional RECs and monitoring of approved studies
- Members training in human subject protection, resources for training, expertise requirements, decision making SOPs
- Strengths, Weaknesses and Opportunities from existing policies and guidelines



## Annex 5. List of accredited RECs by country

### Burundi (1)

1. Burundi National Ethics Committee

### Kenya(28)

1. University of Kabianga
2. JaramogiOginga Odinga and Referral Hospital
3. The Nairobi Hospital
4. JaramogiOginga Odinga of Science and Technology
5. International Livestock Research Institute
6. United States International University
7. Mount Kenya University
8. Masinde Muliro University of Science & Technology
9. Egerton University
10. Pwani University College
11. Kenya Methodist University
12. Moi Teaching and Referral Hospital
13. Amref Kenya
14. Institute of Primate Research
15. The Aga Khan University Hospital
16. Chuka University
17. International Centre for Insect Physiology and Ecology
18. Kenyatta University
19. Maseno University
20. University of Eastern Africa of Baraton
21. Jomo Kenyatta University of Agriculture & Technology
22. Strathmore University
23. Kenyatta National Hospital - University of Nairobi
24. Kenya Medical Research Institute
25. Getrude's Children Home
26. Great Lakes University
27. AIC Kijabe Hospital
28. Daystar University

### Rwanda (2)

1. Rwanda National Ethics Committee (RNEC)
2. University of Rwanda, College of Medicine and Health Sciences

### Tanzania (15)

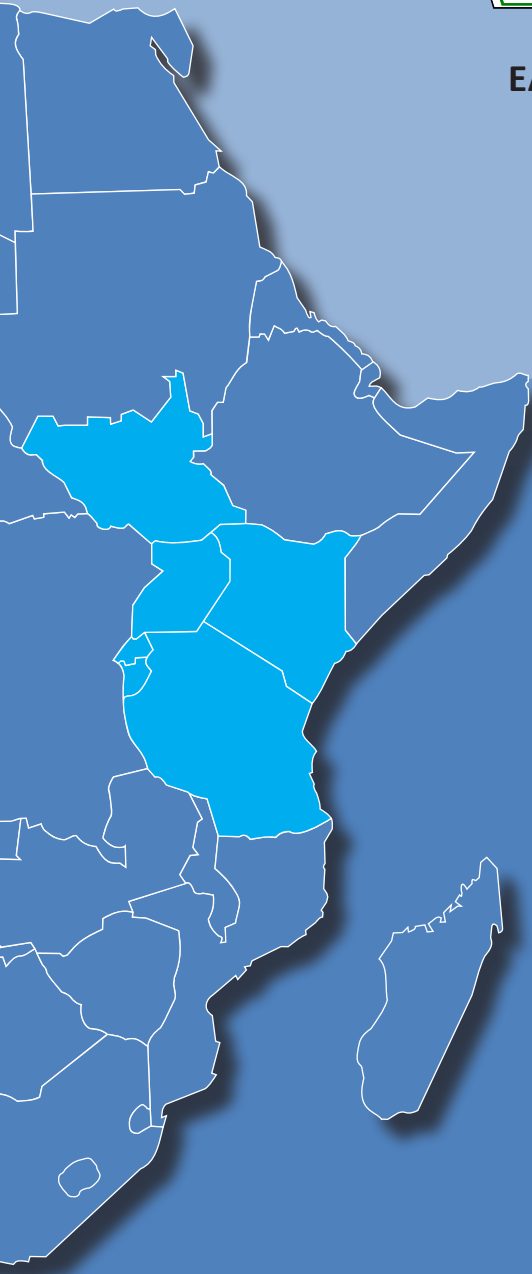
1. University of Dodoma
2. Kilimanjaro Christian Medical University College
3. Muhimbili National Hospital
4. Hubert Kairuki Memorial University
5. Ifakara Health Institute
6. National Institute for Medical Research (NIMR)
7. Mbeya Medical Research Centre
8. Muhimbili University of Health and Allied Sciences
9. Africa Medical Research Foundation (AMREF Health)
10. Open University of Tanzania
11. Sokoine University of Agriculture
12. Nelson Mandela African Institute for Science and Technology (2018)
13. St Johns University
14. Catholic University of Health and Allied Sciences
15. Aga Khan University

### Uganda (23)

1. National HIV/AIDS Research Committee
2. Makerere University School of Biomedical Sciences
3. Hospice Africa Uganda
4. Kampala International University
5. Makerere University School of Medicine
6. Makerere University School of Health Sciences
7. International Health Sciences University
8. Vector Control Division REC
9. Makerere University School of Social Sciences
10. Makerere University School of Public Health
11. Mild May Uganda
12. Uganda Cancer Institute
13. St Francis Hospital Nsambya
14. Joint Clinical Research Centre
15. Mbarara University of Science and Technology
16. Uganda Virus Research Institute
17. TASO
18. Mbale Regional Referral Hospital
19. Gulu University
20. THETA Uganda
21. Mulago Hospital
22. Mengo Hospital
23. St Mary's Hospital Lacor



## EAST AFRICAN HEALTH RESEARCH COMMISSION



### East African Health Research Commission (EAHRC)

The East African Community (EAC) is a regional intergovernmental organization whose mission is to widen and deepen economic, political, social and cultural integration in order to improve quality of life of the people of East Africa, through increased competitiveness, value added production, trade and investment. The countries that form EAC are the Republic of Burundi, Republic of Kenya, Republic of Rwanda, Republic of South Sudan, Republic of Uganda and the United Republic of Tanzania.

As the East African Regional Economic Community (REC), the EAC co-operates, negotiates, and collectively determines legislation and policy that are legally binding at national and regional level.

The vision of EAHRC is high quality health research for improvement of health and wellbeing of the people of East Africa. The mission of EAHRC is to coordinate, conduct, and promote the conduct of health research in the region, and source, gather and disseminate findings from research for policy formulation and practice.

“Health is Wealth”: EAHRC focuses on improving health of the citizens of EAC as a tangible approach towards poverty eradication.

[www.eac.int/institutions/eahrc](http://www.eac.int/institutions/eahrc)

