POLICY BRIEF

May 2018

The Path towards Harmonization of Ethics Review Frameworks in East Africa

Context

Ethics review is central to health research activity in the context of timely discoveries and enhanced access to new technologies and interventions. The rapid increase and complexity of inter-disciplinary, multi-partner, cross-border health research currently taking place in East Africa lends urgency to building and strengthening capacity for competent Research Ethics Committees (RECs) in the EAC region. The availability of robust ethics review systems both nationally and regionally is necessary for the efficient application of up-to-date regulatory and ethical frameworks and to increase science quality and outputs in the region. This is particularly vital if East Africa is to benefit from research that addresses its burden of existing and emerging health and health care challenges.

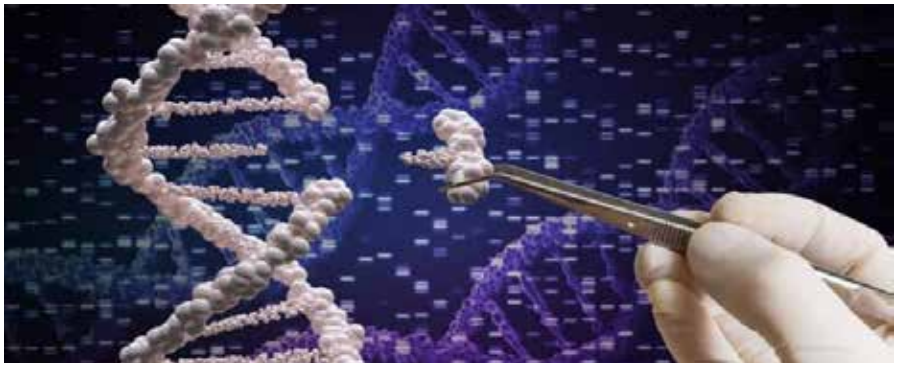
Key Findings

Results

- Sixty-nine accredited RECs were mapped.
- All 5 EAC countries had national ethics guidelines and National Research Regulatory Authority (NRRA) , however their mandates varied across countries.
- 57% of RECs reviewed local and international research, 43% reviewed local studies only.
- On average, 91 protocols were reviewed annually across all RECs (range 15 to 200).
- Membership ranged from 6 to 22 members per REC with age range of 29 to 75 years.
- Annual budget allocation ranged from $3.000 to $2.9 millions financed through review fees (84%) or/and institutional budget (14%).
- 71% of RECs had education policy but only 41% had members with training in ethics.
- Review turn-around time ranged from 14 to 90 days.
- All RECs supported harmonization and attributed it to improved efficiency, quality and standardized costs.

Key recommendations for harmonization

1) Harmonization of policy frameworks and tools;
2) institutionalization of regional joint review mechanisms;
3) standardization of training and capacity strengthening; and
4) review of the REC operational and financing models.



Assessment and methodology

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.

A desktop review of documentation (national and institutional guidelines, policies and SOPs) was conducted in five EAC countries. Semi-structured questionnaires were used to collect data from key informants. Qualitative interviews were used to collect views on stakeholders' perception of benefits, opportunities and challenges of harmonization.

The harmonisation framework for ethics review in health research involves the process of streamlining the approaches, standards, tools and guidelines as well as, capacity-strengthening, training and resource mobilisation across the EAC partner states.

Why harmonisation?

Harmonisation will:

- **Reduce the time required to approve protocols**
  Cross-border research and clinical trials took inordinately long periods of time to be approved due to the process of securing approval for each of the countries involved particularly for multi-centre and multi-country research.
- **Increase performance and promote better utilization and cost** of doing of research through harmonisation and training on the use of standard tools—reducing the current discrepancies between countries
- **Promote the efficiency of the ethics review committees** in the EAC. It would also discourage researches from moving from one REC to another after receiving unfavourable reviews
- **Facilitate an integrated electronic/digital database accessible in real-time by all RECs**, providing stakeholders with timely information and progress status of the various research projects in the region
- **Attract funding from researchers and funding agencies** willing to support large, cross-border research creating bigger opportunities for research capacity development in the EAC

Key Requirements for Harmonization of Ethics and Regulatory Frameworks in East Africa

Few, if any internationally agreed upon standards for research ethics review systems and performance exist. In the EAC region, there are substantial differences between countries. In the absence of a universal set of indicators to guide the EAHRC, the following set of performance measurements were proposed by the expert technical working group from ministries of health and of education, science and technology from partner states:

- Stakeholder engagement and buy-in with possible indicators to include establishment and maintenance of an up-to-date list of stakeholders; activities and standard operating procedures
- Communication of information on harmonisation through newsletters, meetings and dedicated internet platforms
- An agenda of activities and reports on each indicating response rates, agreements and issues that need to be addressed. Monitor progress over time.
- Digitisation of RECs to acceptable standards of ethics review administration and management – with possible indicators to include number of RECs adopting online systems; measurement of review times and workloads of protocols; regional, national and local budgets
- Standardised quality and efficiency of regional and national ethics review – Harmonised adherence to common standards, SOPs and guidelines
- Harmonization and standardization of review fees and allocation of budget to REC by responsible ministries
- Establishment of joint reviews and monitoring mechanisms

Strengths and gaps – ethics review capacities in health research in EAC

Strengths:

- **Existence of national policies and frameworks** this will make the process of harmonization and standardization of policies, review fees and allocation of budget to REC by responsible ministries much more efficient.
- **Increased potential for cross-regional research within the EAC** – Online submissions of protocols will be possible— a common ethics review platform has the advantage of allowing online submission of protocols, screening by administrators and onward distribution within the region.
- **Ability to monitor** institutional RECs and accredit new and existing RECs by national regulators.
- **Real-time actualisation of a joint review committee** without members having to travel away from their stations.
- **Increased momentum for harmonization and standardization of trainings within the EAC and African Union**—Access to existing and future training courses through digitising research ethics review thereby improving the research ethics expertise of the REC membership and researchers.
- **Strengthened capacity**— Countries with excellent track records could be leveraged to strengthen capacity of countries with limited capacity under the leadership of the East African Health Research Commission.

Gaps:

- **Insufficient or absence of a ring-fenced budget for REC operations—**leading to lack of autonomy as well as inability to undertake some of the critical functions required by RECs including monitoring approved studies.
- **Limited investment in modern online review platforms** that could support research ethics reviews and continuing education.

There is also need for:

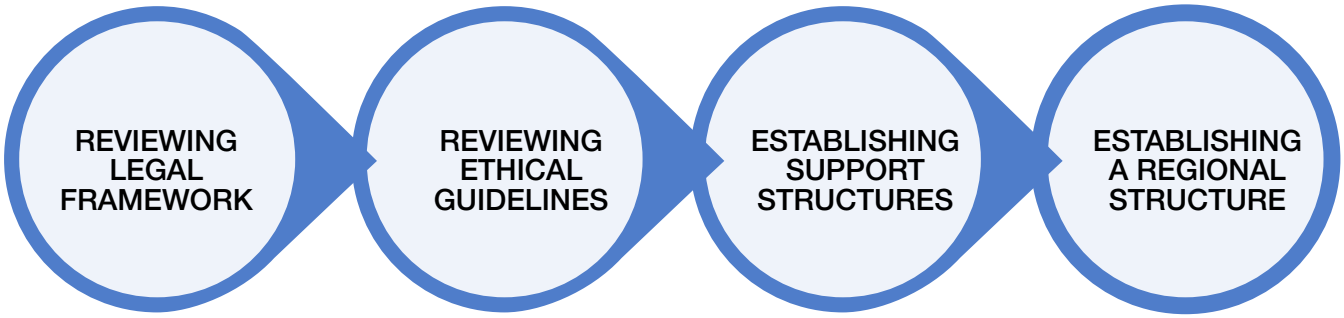
- Clarification on the of the national regulatory authority roles;
- allocation of adequate resources to the entities involved;
- harmonisation of fees charged for the review of protocols across institutions and countries in the region as well as budgetary support from their parent institutions;
- a regional guideline of costing of REC operations supported by adequate budget and resource provisions by governments and parent institutions;
- RECs to diversify their sources of income – necessitating appropriate skills mix and finding interested partners for REC capacity building; and
- investment in attracting and retaining professionals to ensure efficiency, stability, continuity and professionalism within REC secretariats.

What Next?

There are marked differences within and across members states on the governance and regulation of health research that have important implications on the quality, cost, and efficiency of ethics review in the region.

Harmonisation would greatly encourage more science in EAC – both from internal and external sources – to the benefit of all. Below is a proposed harmonisation pipeline that offers important steps to be considered in realizing the harmonisation of ethics review frameworks within the EAC partner states.

Harmonisation process pipeline



Align existing national legal and ethical frameworks	Align national research policies, guidelines and SOPs	Develop SOP for multinational RECs accreditation system	Develop SOP for nominating REC members to a joint EAC REC
OUTPUT: Member states have similar structures, systems and processes		**OUTPUT: All RECs that review multinational research have similar infrastructure, resources, budget, technology and member skills/expertise etc.**	

References used/accessed

1. https://healthresearchweb.org/?action=download&file=GuidelinesfortheconductofClinicalTrialsinKenya.pdf accessed 3rd July 2017)
2. https://healthresearchweb.org/?action=download&file=GuidelinesfortheconductofClinicalTrialsinKenya.pdf (accessed 3rd July 2017)
3. https://healthresearchweb.org/?action=download&file=GuidelinesonEthicsforHealthResearchinTanzania_2009.pdf (accessed 3rd July 2017)
4. https://healthresearchweb.org/?action=download&file=Tanzania_TheNationalResearchDevelopmentPolicy_2010.pdf (accessed 3rd July 2017)
5. https://healthresearchweb.org/?action=download&file=Human_Subjects_Guidelines_March_27.pdf (accessed 3rd July 2017)
6. https://healthresearchweb.org/?action=download&file=Research_registration_UNCST_2007.pdf (accessed 3rd July 2017)
7. https://healthresearchweb.org/?action=download&file=Rwanda_HealthSectorResearchPolicy.pdf (accessed 3rd July 2017)
8. www.rhinnolabs.org
9. IJsselmuiden C, Marais D, Wassenaar D, Mokgotla-Moipolai B. *Mapping African ethical review committee activity onto capacity needs: the MARC initiative and HRWeb's interactive database of RECs in Africa.* Developing World Bioethics 2012; 12: 74-86. doi:10.1111/j.1471-8847.2012.00325.x
10. Villanueva EC, Ribeiro de Abreu D, Cuervo LG, Becerra-Posada F, Reveiz L, IJsselmuiden C. *HRWeb Americas: a tool to facilitate better research governance in Latin America and the Caribbean.*Cadernos de SaúdePública, Rio de Janeiro, 2012; 28: 2003-2008. http://dx.doi.org/10.1590/S0102-311X2012001000018
11. Kasule M, Wassenaar D, IJsselmuiden C, Mokgatla-Moipolai B. *Silent voices: current and future roles of African Research Ethics Committee Administrators.* IRB: Ethics and Human Research 2016; 38: 13-19.
12. Mokgatla B, Bahati P, IJsselmuiden C. *Enhancing the efficiency and quality of African research ethics review processes – through an automated review platform.* J AIDS Clin Res 2017; 8: 658. doi: 10.4172/2155-6113.1000658
13. Mokgatla B, IJsselmuiden C, Wassenaar D, Kasule M. *Mapping research ethics committees in Africa: evidence of the growth of ethics review of health research in Africa.* Developing World Bioeth. 2017;1–8. DOI: 10.1111/dewb.12146
14. Kombe F, Toohey J, IJsselmuiden C. *Research ethics capacity building for the next decade – 'beyond training' – RHInnOEthics as model to improve and accelerate ethics review of health research.* Brit Med J Glob Health 2017;2(Suppl 2):A1–A67. DOI: 10.1136/bmjgh-2016-000260.147

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