Harmonizing Research Ethics Review Frameworks in the East African Community

Novat Twungubumwe¹, Fabian Mashauri¹, Ethel Makila², Yolanda Moyo²

Institutes: ¹East African Health Research Commission (EAHRC), ²IAVI

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Why Ethics Review?

1. Expedited ethics review of clinical trials is central to ensuring quicker access to proven new health technologies.

2. Increasing complexity of inter-disciplinary, multi-partner, cross-border health research in East Africa and globally.

3. Robust ethics national and regional review systems necessary to increase science quality and outputs in the region and protect the general public through compliance to high ethical standards in research.

4. Streamlined approaches, standards, tools and guidelines as well as, capacity create expanded pool of human, infrastructural and financial resources for regional research.
From research to public health solutions

IAVI nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges

- Supportive environment for research critical to accelerate the translation of scientific discoveries into affordable, accessible public health solutions.

- Partner with national, regional and global policymakers, and regulatory institutions to translate research findings to policies and practice.
The EAHRC-IAVI partnership

_Strengthening ethics and regulatory systems that can regulate across health areas and technologies_

- EAHRC and IAVI are working with East African Community partner states to create an environment for a harmonized framework for health research ethics review processes.

- Identifying opportunities to facilitate timely and efficient clinical trials reviews particularly for multi site, multi country clinical trials.

- Proposing strategies and key interventions for ethics review capacity strengthening and harmonization in EAC region.
Rationale for Harmonization

• **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.
Assessment and methodology

Baseline assessment of health research ethics review capacity in five EAC countries.

Capacity gaps identified and priority interventions to fill them recommended.

Optimum requirements for National RECs and IRBs were proposed.

National stakeholder workshops conducted to propose strategies to domesticate the harmonization process.
Legislation of RECs varies substantially across the region.

There are no universally applied international standards.

Insufficient or absence of a ring-fenced budget for REC operations.

Need for clarification on the roles of the national regulatory authority.

Limited investment in modern online review platforms that could support research ethics reviews and continuing education.

**Key Findings**

- Proportion of ERCs with dedicated budget allocation:
  - Kenya: 28%
  - Uganda: 25%
  - Tanzania: 15%
  - Rwanda: 12%
  - Burundi: 16%

- No of accredited ERCs:

- Level of ERC Operations within the EAC Partner States:
  - National Level (NRECs): 43%
  - Institutional Level (NRECs):
    - Hospitals (60%)
    - Universities (40%)
    - Affiliates (57%)

- Methods of Protocol Submission to ERCs:
  - Online: 1
  - Hard and Soft Copies: 24
  - Hard copies: 64
Main Strengths

- Existence of national policies and frameworks
- Potential for cross-regional joint review committee through existing online review platforms
- Ability to monitor IRECs and accredit new and existing RECs by national ethics regulatory bodies
- Increased momentum for harmonization & standardization of processes and capacity within the EAC and African Union
Next Steps

The marked differences within and across members states in governance and capacity of RECs have important implications on the quality, cost, and efficiency of ethics review in the region. Harmonization would encourage increased support for bigger multi-site research programs both from internal and external sources.

- Develop and implement national roadmaps to fill the capacity gaps.
- Ethics review processes should be harmonized at country level.
- Review operational and financial models to provide ring-fenced budgets for RECs.
- Adopt harmonized digitization and online systems.
- Constitute a representative ethics review board with representation from all EAC member states under the leadership of EAHRC.
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Thank you