OC - (8474) - ASSESSMENT OF ETHICS REVIEW FRAMEWORKS FOR HEALTH RESEARCH IN EAST AFRICA FOR PURPOSES OF HARMONIZATION

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Background

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 or protection of the research subjects requires assessment of review capacity.

The East African Health Research Commission commissioned a study to assess the capacity of Review Ethics Committees (RECs) in the EAC countries, as a step towards strengthening and harmonizing the regions’ capacity and review frameworks

Methodologies

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.

Results

Sixty-nine accredited RECs were mapped: All countries had national ethics guidelines and National Research Regulatory Authority whose 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 M. financed through review fees (84%) or/and institutional budget (14%). 71% of RECs had education policy but 41% had members with training in ethics. Review turn-around time ranged from 14to 90 days. All RECs supported harmonization and attributed it to improved efficiency, quality and standardized costs.

Conclusion and Recommendations

Similarities and dissimilarities were noted in the EAC countries’ ethics review frameworks. Harmonization should consider 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.