

Scoping review: Strengthening ethics committees for health-related research in sub-Saharan Africa

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Objectives of the review

Identify and examine literature on strengthening health-related Research Ethics Committees (RECs) in sub-Saharan Africa.

With a focus on:

1. Regulatory governance and leadership
2. Strategies to develop technical expertise of REC members
3. Administrative and financial capacity of RECs



Methods and analysis

Six-stage methodological framework

(Arksey and O'Malley 2005; Levac et al. 2010; Joanna Briggs Institute)

1. Research question

2. Identifying relevant studies

- Databases: BioOne, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase (via Ovid), Education Abstracts, Global Health, Google Scholar, Jstor, OpenEdition (French), Philosopher's Index, PsycINFO, PubMed, Science Citation and Expanded Index (Web of Science).
- Websites: Commission on Health Research for Development (COHRD), WHO Africa, Pan Africa Bioethics Initiative (PANBIN), Mapping Africa Research Capacity (MARC)

3. Study selection

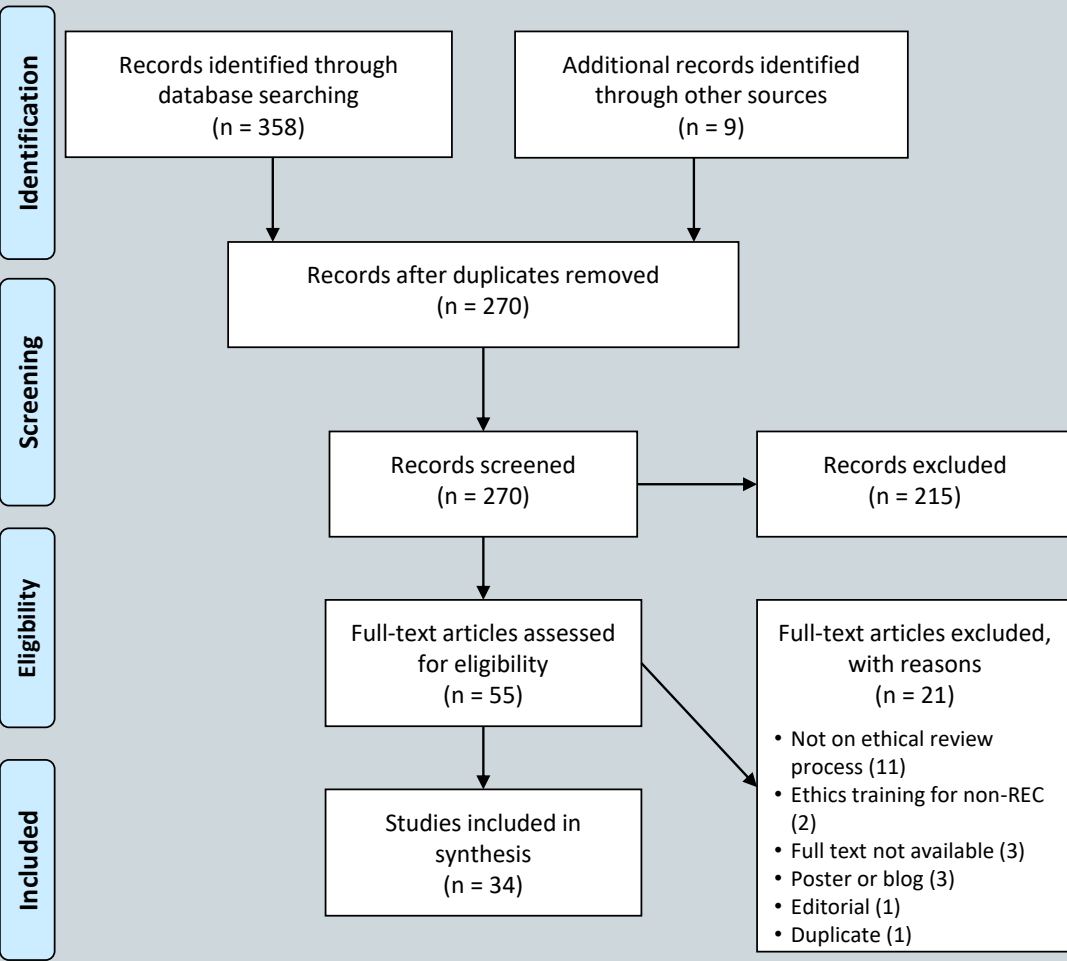
4. Charting the data

5. Collating, summarizing and reporting results

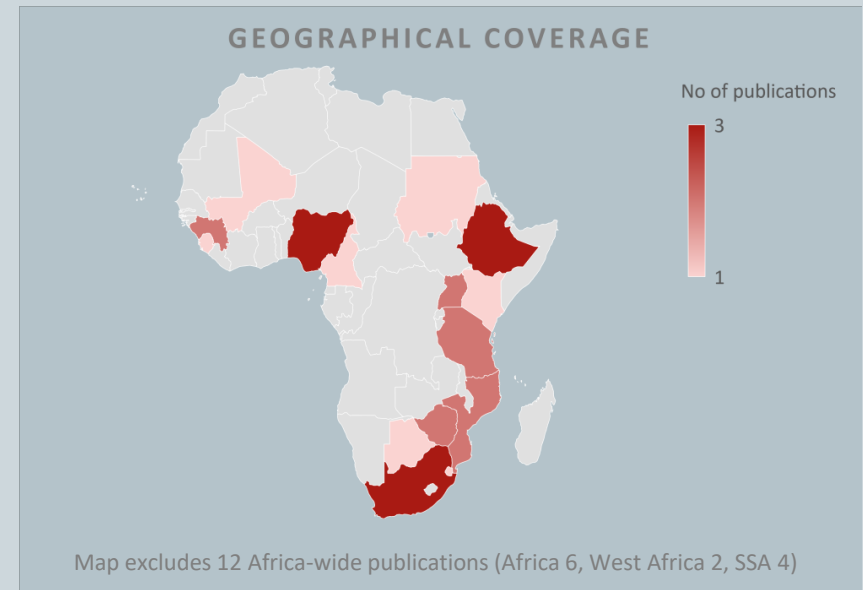
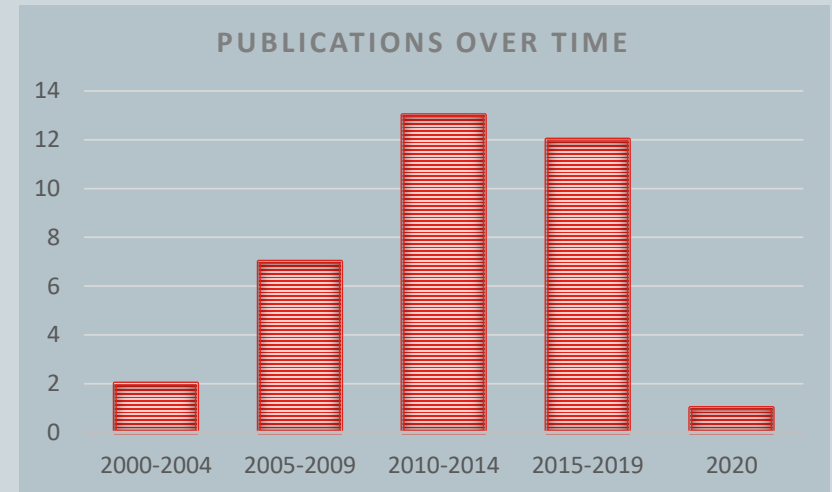
6. Consultation

	Inclusion	Exclusion
P - Population	RECs for health-related research in sub-Saharan African countries.	RECs not focusing on health-related research and RECs outside SSA.
C - Concept	Studies exploring the leadership and governance structures of RECs, administrative and financial capacity and technical capacity of REC members to conduct the review.	Studies not focusing on the structure and capacity of RECs but focusing on the implementation of ethical practices in research such as informed consent and data storage as well as papers focussing on the ethics of individual research studies.
C – Context	Studies focusing only on SSA	Studies outside SSA
Type of publications	Publications using empirical data.	Publications not using empirical data such as opinion pieces.
Language	English, French, Portuguese or Swahili.	Other than English, French, Portuguese or Swahili.
Time period	Jan 2000 to Dec 2020	Pre-2000 and 2021

Results (provisional)



PREFERRED REPORTING ITEMS FOR SYSTEMATIC REVIEWS AND META-ANALYSES (PRISMA) FLOWCHART



1. Regulatory governance and leadership

- Review (Barchi 2016): Twenty-nine (60%) of the countries in SSA had some national ethics guidance, either in the form of laws, regulations, codes, guidelines, or standard operating procedures.
- Many countries lack basic national legal or ethical guidance, or the guidance is old.
- Many have no guidance on TORs for IRBs, processes for scientists to dispute IRB decisions, biobanks and export of human samples, compensation to research participants, oversight of continuing studies
- Lack of transparency and inconsistency across IRBs and poor monitoring of IRBs (Uganda: IRB members reported when application is rejected or recommend major amendments, researchers go to another IRB)
- Challenging to apply international guidance

Good examples

- Guinea: Double ethical review beneficial for externally sponsored trials (contradictions/disagreements)
- Tanzania: Joint IRB meetings by videoconferencing (US and Tanzania). Included live interactions and discussions of protocols. Each session included some training (drawbacks: costs, logistics, time)

Membership of IRBs

- Many countries either have no clear national guidance or do not monitor membership of IRBs

Composition

- Africa-wide survey (Nyika 2009): 33% female, wide variation in size (3-19 members), limited participation of external members (32% no external members) – community members, NGOs, civic organisations, professional associations etc.
- MARC Africa (Ijsselmuiden 2012): insufficient representation by discipline, gender and age.
- SA (Moodley 2007): Predominantly male and white, community representation only 8%
- Nigeria survey (Yakubu 2017): Average of 12 members, more men, 14 IRBs (56%) reported at least one layperson/community member, 16 (64%) a lawyer, 7 (28%) a bioethicist, only 3 (12%) had both a Muslim and a Christian clergyperson. All IRBs reported at least one physician.

Membership benefits

- Many receive no financial incentives or compensation for attending meetings, academic prestige or acknowledge, training,

Good examples

- Ethiopia: Members represent different parts of the faculty/college and membership is governed by (national?) SOPs and include community representatives.

2. Strategies to develop technical expertise of REC members

- Lack of training on research ethics, determining risks and benefits of research, research methods, complex studies including clinical trials, national and international regulatory guidance etc.
- Limited training opportunities for new members or refresher training for current members
- Responsibility for training varies across RECs and countries – National REC, IRBs, universities, international/externally funded training

Good examples

- Botswana: Training requirements for new members and continued professional development opportunities for current members (e.g., biomedical research, regulatory guidance, use of biospecimens)
- Ethiopia: Mentoring programme and 'learning by doing' approach.
- Nigeria: 10/16 RECs require members to receive refresher training once a year
- MARC project – mapping ethical review activity and identifying developing needs.

3. Administrative and financial capacity

- Lack of administrative support (office space, infrastructure, secretarial resources)
- Inadequate financial resources – may charge a fee but concerns about conflict of interest,
- Poor review management systems, record keeping, monitoring and archiving system.
- Lack or unclear administrative processes (SOPs)
- Time to review varies across and within countries (10 days to 12 weeks)

Good examples

- Ethiopia: Follow-up mechanisms, hard-copy and electronic archiving system
- Uganda: Accreditation involves assessment of facilities for the REC's operation such as office space, meeting space, documents available to REC.

Conclusions

Evidence

- We found only 34 publications since 2000
- More evidence on gaps and challenges and less evidence on what works well

Regulatory governance and leadership

- Countries should have up-to-date and clear national ethical, legal and management guidance
- National regulatory body needs to monitor IRBs to ensure transparency and consistency of review process and adherence to membership requirements and training (accreditation)

Strategies to develop technical expertise

- Training for new members; refresher courses and continued professional development for current members
- Membership benefits: financial and non-financial.

Administrative and financial capacity

- IRBs need administration and financial support including adequate infrastructure, human resources, and record and archiving systems

Thank you



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