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

Iqra Chaudhry,1 Val Thurtle,2 Edward Foday,3 Andrew J M Leather,2 Mohamed Samai,4 Haja Wurie,4 Divya Parmar1,2

ABSTRACT

Objective Health-related research in sub-Saharan Africa (SSA) has grown over the years. However, concerns have been raised about the state of research ethics committees (RECs). This scoping review examines the literature on RECs for health-related research in SSA and identifies strategies that have been applied to strengthen the RECs. It focuses on three aspects of RECs: regulatory governance and leadership, administrative and financial capacity and technical capacity of members.

Design A scoping review of published literature, including grey literature, was conducted using the Joanna Briggs Institute approach.

Data sources BioOne, 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), reference lists of included studies and specific grey literature sources.

Eligibility criteria We included empirical studies on RECs for health-related research in SSA, covering topics on REC leadership and governance, administrative and financial capacity and the technical capacity of REC members. We included studies published between 01 January 2000 and 18 February 2022 and written in English, French, Portuguese or Swahili.

Data extraction and synthesis Two independent reviewers screened the records. Data were extracted by one reviewer and cross-checked by another. Owing to the heterogeneity of included studies, thematic analysis was used.

Results We included 54 studies. The findings show that most RECs in SSA work under significant administrative and financial constraints, with few opportunities for capacity building for committee members. This has an impact on the quality of reviews and the overall performance of RECs. Although most countries have national governance systems for RECs, they lack regulations on accountability, transparency and monitoring of RECs.

Conclusions This review provides a comprehensive overview of the literature on RECs for health-related research in SSA and contributes to our understanding of how RECs can be strengthened.

INTRODUCTION

Health research in low-income and middle-income countries, which shoulders the greatest burden of disease, is critical to combat health inequity.1 Recognition of this burden in sub-Saharan Africa (SSA) has led to a growth in international collaborative research implemented in SSA funded mainly by the USA, UK, Germany and Japan. This has been crucial in establishing research governance in SSA.2 However, significant challenges remain3: international collaboration and external funding can skew priorities, external investigators may lack knowledge of the local context and local researchers may have limited exposure to research methodology and ethics training.4 In addition to these, sometimes gross ethical misconduct can occur.5–7 New and complex challenges are also emerging, such as research involving genetic and genomic analyses and the use of artificial intelligence in healthcare.8 9 These challenges are more serious in SSA, where research participants are likely to be vulnerable and less aware of their rights. Previous literature has identified the difficulty in adequately explaining complex genomic research methods, the risk of diagnostic misconception when recruiting healthy and unhealthy populations and the administration of informed consent in the context of low health and research literacy in African countries.7 10 Further to this, a recent survey on regulatory activities and ethical review in Africa in April 2020 found seven countries (Niger, Burkina Faso, Comoros, Togo, Guinea
Bissau, Tanzania and Cote d’Ivoire) indicated that they do not have ethics review boards at universities or research institutes and most national regulatory authorities face resource constraints resulting in the lack of capacity for adequate review and approval of research. All these issues highlight the importance of strong research ethical review governance structures for health-related research in SSA, now more than ever, with the global impact of the pandemic resulting in outbreaks of several infectious diseases in SSA, making research into disease prevention and management crucial.11 Ethical reviews are conducted by boards commonly referred to as Institutional Review Boards, Research Ethics Committees (RECs) or Ethics Review Committees.12 The Declaration of Helsinki emphasises the importance of an independent and appropriately constituted REC that must have the authority to monitor ongoing studies, including any serious adverse events.13 Further, the review process should ensure that the interests of human participants are protected and that the research is ethically sound and relevant. While ethical and regulatory bodies in SSA are best placed to understand their local context and advise on how to conduct reviews, their capacity to do so may be limited by several factors. These factors include a lack of infrastructure (eg, information technology and office space), limited financial and administrative support, a small pool of REC members and regulators, a lack of theoretical training in ethics and regulatory affairs and weak governance structures.14 The concerns about ethical and regulatory issues, and the state of RECs in SSA, have persisted, despite various efforts to strengthen them. One example of this effort is the African Vaccine Regulatory Forum (AVAREF) which was established in 2006 by the WHO to serve as an informal capacity-building network to enhance the ethics and regulatory oversight of interventional clinical trials undertaken in Africa. Despite the AVAREF having demonstrated its value in strengthening regulatory and ethics reviews through promoting standards and approaches as well as accelerating the review of priority public health vaccines, literature has continued to identify constraints faced by RECs.15

A 2007 mapping of REC activity in Western and Central Africa reported limited information on existing committee structures.16–20 In 2009, the Mapping African Research Ethics Capacity (MARC) project was launched to understand the capacity of the network’s research institutions, to aid in the flow of information between the centres and to provide a public space for technical and strategic support for health research.21,22 There was a need to identify existing capacity, funding and areas where additional development would be beneficial. In 2012, this was seen to be lagging in terms of requirements, often due to a lack of resources and capacity.23 A 2015 systematic review focusing on the structure, functioning and outcomes of biomedical RECs in SSA found several factors impeding RECs’ work, including a lack of diversity in membership, limited resources, insufficient member training and a lack of national ethics guidelines and accreditation.24

This review builds on these previous efforts by applying a scoping review approach that provides an overview of the literature on health-related RECs in SSA and identifies strategies that have been applied to strengthen the RECs. We focus on three aspects of the RECs: the technical capacity of members, administrative and financial capacity and leadership and governance.

## METHODS

### Search strategy

We applied the methodological approach proposed by the Joanna Briggs Institute on how to extract, analyse and present results.25 This approach also aligns with the Preferred Reporting Items for Systematic Review and Meta-Analysis extension for scoping reviews (PRISMA-ScR).26 We initially conducted a preliminary search to refine the scope of the review, eligibility criteria for selecting the literature (table 1) and relevant online databases. The review included studies published from 01 January 2000. This start date was based on our preliminary search because most of the initiatives to improve RECs in SSA were after 2000. We included publications

### Table 1  Inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Inclusion</th>
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<tr>
<td><strong>P—population</strong></td>
<td>Research ethics committees (RECs) for health-related research in sub-Saharan African (SSA) countries.</td>
</tr>
<tr>
<td><strong>C—concept</strong></td>
<td>Studies exploring the leadership and governance structures of RECs, the administrative and financial capacity; and the technical capacity of REC members to conduct ethical reviews.</td>
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<td><strong>C—context</strong></td>
<td>Studies focusing on SSA.</td>
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<tr>
<td><strong>Type of publication</strong></td>
<td>Publications using empirical data such as peer-reviewed journals, reports, discussions, theory papers, case studies, editorials and commentaries.</td>
</tr>
<tr>
<td><strong>Language</strong></td>
<td>Publications written in English, French, Portuguese or Swahili.</td>
</tr>
<tr>
<td><strong>Time period</strong></td>
<td>Published between 01 January 2000 and 18 February 2022.</td>
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written in English, French, Portuguese or Swahili as these are some of the official languages in SSA and those that the authors were familiar with.

We conducted structured searches of online health research-focused databases: PubMed, Web of Science, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase, Education Abstracts, Global Health, Google Scholar, Jstor, OpenEdition (French), Philosopher’s Index, PsycINFO and BioOne. Search terms were combined using Boolean and proximity operators and database subject headings such as Medical Subject Headings (MeSH), were used: For example, the search string for PubMed was: ((ethic* committee* (title/abstract)) OR (ethics guidance (title/abstract)) OR (ethics review committee* (title/abstract)) OR (ethics regulation (title/abstract)) OR (research regulation (title/abstract)) OR (institutional review boards (title/abstract)) AND ((capacity development (title/abstract)) OR (capacity (title/abstract)) OR (governance (title/abstract)) OR (leadership (title/abstract)) AND (health OR medical (title/abstract)) AND (sub Saharan Africa (MeSH Terms)) AND ((English (Language) OR French (Language) OR Portuguese (Language) OR Swahili (Language)) AND ((‘2000’ (Date—Publication): ‘2022’ (Date—Publication)))). Search strings for all databases are available in the supplementary file, online supplemental appendix A. We also hand-searched websites of relevant organisations to identify grey literature: the Council on Health Research for Development (https://www.cohered.org), WHO Regional Office for Africa/Integrated African Health Observatory (https://aho.afro.who.int), Pan African Bioethics Initiative (PANBIN) (http://www.who.int/sidcer/fora/pabin/en) and MARC (https://ahrecs.com/resources/mapping-africa-research-ethics-capacity-marc). The end date of the search was 18 February 2022.

**Screening and data extraction**

As per the PRISMA-ScR guidelines, we first screened the titles and abstracts of papers identified by the search (excluding duplicates) and then the full texts of papers that met the eligibility criteria. Two authors (VT and DP) conducted the screening independently. When there were disagreements, another author (AJML) was involved. We also searched the references of the included papers. Abstracts and full texts of additional papers identified were screened in the same manner. We identified 54 papers that were included in the review (figure 1).

We extracted data from the included papers on publication type, country, study objectives, study design, methods and findings on RECs (technical capacity, administrative and financial capacity and leadership and governance). Lastly, owing to the heterogeneity of the included papers in terms of study designs and methods, we used thematic analysis.27 Papers were imported into NVivo V.12, software for analysis of qualitative and mixed-method studies. The data from these papers were coded according to the REC themes stated above. The coding was done by one author (IC) and reviewed by another author (DP), and all authors contributed to identifying the subthemes. The scoping review protocol has been peer-reviewed and published.28 We extended the time period to 18 February 2022; in the protocol, it was October 2020. Additionally, we included studies that examined international collaborations with SSA countries and multicountry studies if the findings were relevant to SSA. This was not clearly explained in the protocol. All data relevant to the study are included in the article or uploaded as online supplemental information.

**Patient and public involvement**

None.

**RESULTS**

We identified four key themes (figure 2). The most common theme was technical capacity, examined by 43 papers, while financial capacity was examined by only 19 papers. The included papers are summarised in the supplementary file (online supplemental appendix B).

**Technical capacity of RECs**

The quality of reviews depended on the technical capacity of reviewers, that is, the expertise of REC members and strategies used to improve their technical capacity.

**Expertise of members**

Across studies at national and institutional levels, there are attempts at recruiting members with a high level of education or expertise in health research. Most SSA countries employ members such as scientists, physicians and statisticians.14 29–33 Some additionally involve other professionals such as lawyers and legal advisers,14 30 32 and a few also include lay members to ‘represent the cultural and moral values of the community’52 and who serve as
‘community gatekeepers and shape community attitudes towards research’.34 Two countries (South Africa and Nigeria) also include consumer groups or faith-based organisations.14 29

The capacity of RECs to conduct reviews also depends on the overall number of members in RECs. The average number of members per committee differed within and between countries. For example, in Nigeria, the number of members of the Health Research Ethics Committee (HREC) ranged from 9 to 15.35 Similarly, in South Africa, the University of Witwatersrand’s REC had only three members, whereas the University of Pretoria, Medical University of South Africa, had nine members.33 36

Challenges of recruiting and retaining members included high workloads, especially as REC activities are considered additional duties and there is a lack of compensation for attending REC meetings and for conducting reviews.22 37–41 Further, there are no rewards, incentives or academic acknowledgements for committee members participating in REC meetings and training.38–42 Only one study from Ethiopia identified benefits for academic staff working in institutional RECs, who could ‘theoretically’ request ‘research leave’ of up to 4 months to conduct their research in lieu of REC work.31 These challenges in recruiting and retaining members were also found to impact the quality of reviews which were reported as poor in most SSA. The primary reasons were related to poor administrative capacity, but ‘lack of adequate time and attention devoted to review tasks’ was also identified as a problem.40

Strategies used to improve technical capacity
Some studies blamed the poor quality of reviews on the REC governance that ‘did not train their staff in study related aspects’, therefore, some staff ‘had very little knowledge of research ethics and ignorance particularly about the…National Guidelines’.39 Most studies identified the training and education of members as critical to improving the technical capacity to conduct reviews.43–48 Understanding research ethics regulations and the ability to evaluate reviews were identified as two areas where training was required. Benefits of training such as better quality of reviews and reduced review processing times were commonly seen at the institutional RECs that implement strategies such as ethics workshops or trainings.23 33 34 49–53 Despite recognising the need for training, the quality of training and the number of training opportunities were largely ‘inconsistent’ across and within RECs.37 44 49 A study in Guinea also recommended that multiple ethical reviews, where a study is reviewed by the RECs in the countries where the study is being carried out and in the countries of the sponsor and research partners, should be routinely implemented for externally-funded trials to improve the quality of reviews.54

Financial capacity of RECs
Many RECs have inadequate financial resources, with institutional RECs facing greater financial challenges as they are considered a low priority within institutions.35 46 55 Many institutional RECs rely on fees charged for reviewing research protocols,29–31 33 35 36 50 56–58 but this is not adequate. One review across nine SSA countries found that ‘three out of twelve REC had no operating funds whatsoever’.37 In contrast, many national RECs receive funding from the government, non-governmental organisations (NGOs) or foreign agencies.37 51 59 60 However, many studies also reported that receiving funding from different sources, national and international, has challenges and can raise concerns about conflict of interest. ‘Many reviewers are not aware of more subtle conflicts—they could be influenced by the prospect of more international recognition of a participating institution, the arrival of world-renowned experts and other indirect benefits’61

Administrative capacity of RECs
The administrative capacity of RECs to follow and document ethical review processes depends on their workload, organisation and resources.
Institutions have largely established their own structures that three RECs reviewed 8–12 protocols per year, three varied substantially. Kass, covering nine SSA countries, found the number of study protocols reviewed in the meetings also support ethics reviews.42 70 For improving the functioning dedicated office spaces or resources to conduct meetings/


The leadership and governance of RECs are reflected in the national guidance and regulations and the structure of RECs.

National guidance and regulations

The majority (60%) of the countries have ‘some national ethics guidance, either in the form of laws, regulations, codes, guidelines or standard operating procedures’.71 Institutions have largely established their own structures despite following national guidance.42 64 72 73

Most countries also attempt to use international guidelines and regulations, namely, the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research involving Human Subjects and guidelines from the WHO.43 53 57 74 In Botswana, for example, the Human Resource Development Council (HRDC) is guided by principles articulated in the Helsinki Declaration and the International Ethical Guidelines for Biomedical Research involving Human Subjects (HBS) of the Council for International Organisations of Medical Sciences. Until recently, regulatory guidance on HBS was only available for clinical trials related to drug applications. The Ministry of Health issued Standard Operating Procedures in 2011 to guide the structure and operation of the HRDC and the review of research protocols at institutional and national levels.62 Similarly, in Nigeria, the National HREC, established in 2006, is empowered by regulations and the National Health Act, thereby having clear Terms of Reference that states its role in registering and auditing the work of institutional RECs.38

A survey exploring the training needs in research ethics evaluation among RECs in Camerooon, Mali and Tanzania found that ‘92.7% of respondents reported that they have no difficulty’ in applying ethics regulation guidance at national and institutional (local) levels, ‘whereas 47.3% reported having some difficulties concerning adaptation to local context, interpretation difficulties, difficulties applying to particular context and discrepancy with local regulations’64. Guidance documents that were reported to be followed were from the following regulations: Declaration of Helsinki, CIOMS Guidelines, The Nuremberg Code, The Belmont Report, Guidelines of the Medical Research Coordinating Committee, Tanzania, National constitutions, Universal Declaration of Human Rights, ‘Déclaration droit de malade’ and others.64 The survey also identified the need for developing laws and guidelines adapted to the local context to avoid discrepancies in international guidelines that do not fit in with local norms.75

Most countries have a national authority within the Ministry of Health that is responsible for setting up national guidance. However, the structure and mandate of the national authority vary across countries.21 57 61 Many are ‘not legally constituted hence lack official recognition and a legal framework to support the establishment’.21 Therefore, in cases of fraud or research misconduct, these authorities may lack the power to take legal action. One study highlighted the need for greater accountability, transparency and monitoring of RECs to mitigate the ‘unfortunate possibility of REC members becoming corrupted (bribed)’.61 Monitoring of RECs is also important for building trust, as a study reported that ‘some (scientists) believe that members of the committee will plagiarise their ideas during the review process’.76

Structure of RECs

There was less literature discussing the management structure of RECs, and most were limited to describing the expertise and designation of people who headed the committees, which greatly varies across countries. In most cases, RECs are ‘headed by a medical doctor’ or ‘scientist or health-related professional’, and they tend to have ‘some personal experience pertaining to the conduct of research’.59

DISCUSSION

We found that RECs in SSA work under significant administrative and financial constraints, with limited capacity-building opportunities and support available to committee members. This affects the quality of reviews
and the overall performance of RECs. There is little evidence on the impact of strategies used for improving their performance, whether through training REC members, using software to improve administrative efficiency or establishing clear standard operating protocols.

Many of the challenges faced by RECs have knock-on effects on other aspects.33 For example, reviewers’ workloads can compound administrative challenges relating to the regularity of REC meetings. However, administrative efficiency can be improved by using softwares as is done in most high-income countries (HICs), such as the Research for Health and Innovation Organiser (RHInnO Ethics), which serves as an information management and expert-decision support system for individual RECs. RHInnO Ethics is currently installed in 29 RECs in eight African countries and has been shown to improve review quality, efficiency and standardisation.13 A similar REC management tool is Research Electronic Data Capture (REDCap), which helps REC members to review projects anywhere online securely. REDCap has been found to increase the number of projects completed and reduce the time required for completion at the Faculty of Health Sciences, University of the Witwatersrand, where it was first used.77 This highlights the importance of encouraging RECs in SSA to invest in and use management systems to address current administrative challenges, particularly in institutional RECs.

The technical ability of REC members was also assessed across countries, and differences were observed in levels of training and experience. Overall, the technical ability of members was found to vary between national and institutional RECs. This could be the reason for the differences in the quality of reviews and the overall performance of national and institutional RECs. A 2015 review focusing on the structure, functioning and outcomes of biomedical RECs in SSA discovered several factors impeding REC work, including a lack of diversity in membership, a scarcity of resources, insufficient member training, insufficient capacity to review and monitor studies and a lack of national ethics guidelines and accreditation; supporting claims that the body of evidence on health-related RECs in SSA is still fragmented.20-22 24 78

RECs work under severe financial constraints. Most countries have inadequate financial resources at the institutional level, as they are considered low priority. This contrasts with funding available to the national RECs that receive funds from pre-allocated research budgets from the government, NGOs or other foreign funding agencies. This is similar to funding available in HICs such as in the UK where RECs such as the Royal College of Physicians, the Nuffield Trust and the unofficial Clinical Ethics Network receive financial support from the Department of Health of England.79 SSA countries’ lower Gross Domestic Product (GDP) growth rates are one of the primary reasons for the lower funding budgets and allocations received by RECs as compared with HICs.80 As a result, financial and resource support from HIC donors is needed to improve the resources and financial capacity of RECs in SSA. This may be through donations of old technical equipment, sponsoring training workshops or supporting the development of standard operating processes. A review has previously indicated that the US funding for biomedical RECs in SSA helped improve their structure, functioning and outcome.4 However, international collaboration and external funding can skew national priorities4 and cause a conflict of interest at national and institutional RECs.61 Furthermore, it is important to acknowledge that foreign funding is usually used for short-term support for RECs, highlighting the need for stronger governance and regulation of RECs with long-term sustainability.51

Leadership and governance for ethics and research were found to exist on two levels in most countries: institutional and national. Despite adhering to national guidelines, institutions were found to have largely established and maintained their own RECs. National RECs were also found to follow their own countries’ recommended guidelines. Many countries promote and implement international guidelines and regulations such as the Declaration of Helsinki. These guidelines emphasise the importance of independent and appropriately constituted RECs13 18 and that each committee’s operation must be transparent and independent of the researcher, the sponsor and any other undue influence. However, most countries still lack national guidance and regulations concerning accountability, transparency and monitoring of RECs.

RECs in SSA should consider using the World Medical Association’s Declaration of Helsinki (1964, updated in 2013) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2016) guidelines as recommended by the WHO. These guidelines are viewed as tools that promote ethical standards through appropriate systems of review for any course of research. By applying these guidelines, SSA’s RECs can promote research of the highest ethical standards.33 71

**Strengths and limitations of the review**

This review advances our understanding of how RECs can be strengthened in SSA, a topic that has not received much attention despite increased health-related research in SSA. We applied a comprehensive search strategy that included a broad range of studies. However, there are a few limitations. The review included studies from 01 January 2000 until 18 February 2022 and only those published in English, French, Portuguese or Swahili. We did not exclude studies because of poor quality. The findings on administrative capacity are primarily based on qualitative studies and self-reported responses, and many studies did not use validated tools to measure administrative outcomes. Furthermore, few studies evaluated the effectiveness of measures taken to improve the ethical review of health-related research.
CONCLUSION

Most RECs in SSA face considerable administrative and financial constraints, with limited opportunities for capacity building of their members. This has an impact on the quality of reviews and the overall performance of RECs. To support RECs in SSA, more research is needed on the type of applications reviewed by RECs. This will also help to understand the training gaps for REC members.

Contributors AJML, DP and VT were responsible for the study concept and design. AJML, DP, IC and VT identified the papers and conducted the thematic analysis, IC wrote the first draft, while all authors (AJML, DP, EF, HW, IC, MS, VT) contributed to identifying the themes and drafting the manuscript. DP is the guarantor of the study and attests that all listed authors meet the authorship criteria and have agreed to publish this paper.

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