

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

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ABSTRACT

Introduction Health research in low-income and middle-income countries, which face the greatest burden of disease, is a vital component of efforts to combat global health inequality. With increased research, there has also been concern about ethical and regulatory issues and the state of research ethics committees, with various attempts to strengthen them. This scoping review examines the literature on ethics committees for health-related research in sub-Saharan Africa, with a focus on regulatory governance and leadership, administrative and financial capacity, and conduct of ethical reviews.

Methods and analysis We will use the methodological approach proposed by Arksey and O'Malley and adapted by Levac *et al* and the Joanna Briggs Institute. Inclusion and exclusion criteria are based on the 'Population–Concept–Context' framework. Literature (from January 2000 to December 2020) will be searched in multiple databases including Embase and PubMed and websites of relevant organisations. All records will be screened by applying the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Review flowchart: two reviewers will independently screen titles and abstracts, and full text of included records. Using an inductive approach, we will synthesise the literature, identify best practice and gaps in evidence on strengthening research ethics committees.

Ethics and dissemination Ethical approval is not required as the review will include only published literature. The findings will be published in a peer-reviewed journal and presented at stakeholder meetings and conferences.

INTRODUCTION

Health research in low-income and middle-income countries (LMICs), which face the greatest burden of disease, is a vital component of efforts to combat global health inequity.¹ The benefit of increased research is accompanied by major challenges for research governance.^{2–3} International collaboration and external funding can skew priorities; external investigators may lack knowledge of the local context and local researchers may have had limited exposure to research methodology and ethics training.⁴ Gross ethical

Strengths and limitations of this study

- The review focuses on ethics committees for health-related research in sub-Saharan Africa, which is largely understudied.
- A comprehensive search strategy will be followed to identify peer-reviewed papers and grey literature.
- The review will be limited to literature published between 2000 and Dec 2020 and in English, French, Portuguese or Swahili.
- There is a possibility that we will find insufficient literature to address all the objectives of the review.

misconduct has occurred in sub-Saharan Africa (SSA), such as not obtaining informed consent from meningitis vaccine participants or giving placebos to HIV-infected pregnant women despite evidence of the beneficial effect of antiretroviral therapy on mother-to-child transmission.^{5–6} Many less blatant challenges to ethical research exist. These can be because participants in SSA are more likely to be vulnerable and questions have been raised on the nature of 'informed consent' for such participants.⁷ Further, new and complex challenges are also emerging. These are observed when urgent measures such as during the Ebola outbreak were implemented or resulting from research involving genetic and genomic analyses, and the use of artificial intelligence in healthcare.^{8–10}

A key component of health research governance involving human participants includes ethical review by a Research Ethics Committee (REC). RECs may also be called an Institutional Review Board or an Ethics Review Committee. RECs set out to protect human participants by conducting ethical reviews of health-related research. The Declaration of Helsinki¹¹ highlights the need for ethical review by an independent and appropriately constituted REC. The committee must be transparent in its functioning, must be independent of the researcher, the sponsor and

any other undue influence, and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards. The committee must have the right to monitor ongoing studies including information about any serious adverse events. At the end of the study, a final report should be submitted to the committee including the study's findings and conclusions.

While ethical and regulatory bodies in LMICs and SSA are best placed to understand their local context and advise on challenges to informed consent, vulnerable populations, cultural beliefs and the way care is delivered, their capacity to do so may be limited by a range of factors. These include a lack of infrastructure (eg, Information Technology (IT) resources, meeting and storage space, transport to trial sites); limited financial and administrative support; a small pool of REC members and regulators; lack of theoretical training in ethics and regulatory affairs; and a lack of comprehensive governance structures.¹²

There has been ongoing concern about ethical and regulatory issues and the state of RECs in SSA, with various attempts to strengthen them. In 2007, a mapping of ethical review committee activity in western and central Africa reported little available information on existing committee structures.¹³ Subsequent workshops followed that led to the creation of national structures in many countries. As health research initiatives in SSA grew in scope and complexity, increased research activity resulted in the need for sound ethical review structures and functions in the form of REC. A large-scale survey of research ethics policies and practices in SSA concluded that there are extensive gaps in the capacity of health research institutions in Africa to undertake ethical reviews of studies.¹⁴ The Mapping African Research Ethics Capacity (MARC) project started in 2009. It has created an interactive wiki-type platform and tools, which can be found on the Council on Health Research for Development's Health Research website.¹⁵ The platform was to understand the capacity of the research institutions that were part of the network, to help to facilitate the flow of information between the centres and provide a public space where researchers could provide each other with technical and strategic support for health research. Tools were designed for strengthening ethical review and regulation of health research in Africa.^{16 17} There was a need to identify existing capacity and funding and demonstrate the areas where this needed to be developed. In 2012, this was seen to be lagging in requirements, often because of poor resource availability and lack of capacity.¹⁶ MARC went on to develop an interactive map of health research ethics review capacity and drug regulatory capacity in Africa.¹⁵ Since then, studies focussing on different aspects of national research systems of different countries have identified weaknesses and in some countries, have recommended extensive work to strengthen the ethical and regulatory systems.^{10 18 19} A 2015 systematic review,

focusing on the structure, functioning and outcomes of biomedical RECs in SSA, found several factors that hinder the work of RECs including lack of membership diversity, scarcity of resources, insufficient training of members, inadequate capacity to review and monitor studies, and lack of national ethics guidelines and accreditation.¹⁹ Further, studies have conducted assessments of needs in different countries,²⁰ sometimes as part of developmental programmes^{21 22} while other studies have conducted only partial evaluations looking at certain aspects of research development.²³ The overall evidence on health-related RECs in SSA is growing but is largely fragmented. This review will provide a more comprehensive understanding of the health-related RECs in SSA.

A scoping review is considered to be the most suitable approach to establish the current situation, rather than a systematic review and meta-analysis.²⁴ A scoping review provides an overview of a broad field.²⁵ This review will identify and examine current literature to understand how ethics committees for health-related research operate and ways of developing them in SSA. The evidence about RECs is likely to be from disparate or heterogeneous sources which a scoping review can bring together. Scoping reviews provide a map of the existing literature. These reviews do not normally assess the quality of evidence as the main purpose is to identify and map the evidence itself. While scoping reviews may inform future systematic reviews, they are also useful for policy-makers and practitioners.²⁶

The objectives of the review were formulated from the issues outlined above and the preliminary literature search. They are to identify and analyse literature on leadership and governance, strategies to develop the technical ability of ethical committees, and the administrative and financial capacity of health-related RECs in SSA.

METHODS AND ANALYSIS

A preliminary search for existing scoping reviews on the topic was conducted using PubMed and Global Health databases to check that a similar review had not been undertaken. A scoping review of empirical research relating to quality and effectiveness of research ethics review published in 2015 sought to find research assessing ethics review processes but reported no work related to Africa.²⁷ At a similar time, Silaigwana and Wassenaar¹⁹ conducted a collective review of empirical studies examining the structure, functioning and review outcomes of African RECs. We will build on their work by examining wider issues related to RECs. The protocol is registered with the Center for Open Science (OSF) and is funded by the European and Developing Countries Clinical Trials Partnership (EDCTP) grant number CSA2018ERC-2330.

This scoping review will use the six-stage methodological framework proposed by Arksey and O'Malley,²⁴ as well as the amendments made to this framework by Levac *et al*²⁸ and by the Joanna Briggs Institute.²⁹ We used the Preferred Reporting Items for Systematic Reviews and

Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) to draft this protocol³⁰ to ensure key aspects were included.

Identifying the research question

Arksey and O'Malley²⁴ suggest a scoping review framework is not dependent on set words or study types; rather it is an iterative process, developing one or more questions to be addressed. Scoping searches were carried out at the start of the project to give an overview of the extent and types of studies on strengthening ethics committees for health-related research in SSA. These indicated there was an abundance of material related to ethics, review boards and institutional reviews in SSA on which we will draw.

Based on the preliminary search, we identified the following research questions for the scoping review: How can ethics committees for health-related research in SSA be further strengthened?

We will examine the literature on three aspects of RECs

- ▶ Leadership and governance.
- ▶ Administrative and financial capacity.
- ▶ Strategies to develop the technical ability of ethical reviewers and regulators.

Identifying relevant studies

The electronic literature search strategy will follow the three-step process: identification, screening and eligibility as in PRISMA-ScR and recommended by the Joanna Briggs Institute.²⁹ Based on the first step, the preliminary search, a comprehensive search strategy was developed to identify relevant literature, underpinned by key inclusion and exclusion criteria (see [table 1](#)). These are based on 'Population–Concept–Context'.

In the second step, after reviewing the titles and abstracts of pertinent papers, we identified the following search string which will be adapted for different databases: (Ethics committees OR ethics guidance OR ethics review committees OR ethics regulation OR research regulation OR institutional review boards) AND (capacity development OR capacity OR governance OR leadership) AND (health OR medical) AND (SSA OR <individual countries in SSA>) AND Language (English OR French OR Portuguese OR Swahili) AND Publication date (2000 to December 2020).

The following databases will be searched: 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). In the third and final stage, reference lists of included studies will be hand-searched.

As an example, search string for PubMed: ((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

Table 1 Inclusion and exclusion criteria

	Inclusion	Exclusion
P—Population	RECs for health-related research in sub-Saharan African (SSA) countries	RECs not focusing on health-related research and RECs outside SSA. Papers and material focussing on the ethics of individual research studies, including consent for specific empirical studies
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 on SSA, including studies examining international collaborations with SSA countries. Studies across multiple countries including SSA countries if the findings were relevant for SSA.	Studies outside SSA
Type of publication	Publications using empirical data such as peer-reviewed journals, reports, discussion, theory papers, case studies, editorials and commentaries.	Publications not using empirical data such as opinion pieces.
Language	Publications written in English, French, Portuguese or Swahili	Studies available in a language other than English, French, Portuguese or Swahili
Time period	Published after 2000 until the end of December 2020	Pre-2000

REC, Research Ethics Committee.

[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]: “2020”[Date - Publication])). For grey literature, we will search websites of organisations that display a strong interest in National Ethical and Review Boards in SSA such as the Commission on Health Research for Development <https://www.cohred.org/>, WHO Regional Office for Africa <https://www.afro.who.int/> Integrated African Health Observatory <https://aho.afro.who.int/>, Pan African Bioethics Initiative (PANBIN) <http://www.who.int/sidcer/fora/pabin/en/> and Mapping Africa Research Capacity <https://ahrecscom/resources/mapping-africa-research-ethics-capacity-marc/>. Besides these websites, we will also search Google Scholar using terms such as ‘ethics’, ‘ethics committees’, ‘Institutional review board’ and ‘Africa’.

As scoping reviews use an interactive process, our research objectives might be refined, or new questions added, as familiarity with the literature is developed and different issues become important.

Study selection

Records identified in stage two will be exported to Excel. After removing duplicates, title and abstracts will be reviewed based on the inclusion and exclusion criteria. An iterative approach to selecting studies and extracting data will be undertaken²⁸ by two reviewers independently. The second part of the process will involve retrieving the full text of all potentially eligible material. Articles selected for full-text review in which the full text is unavailable will be documented. All records will be assessed based on our inclusion and exclusion criteria. Disagreements between the two reviewers will be discussed with a third reviewer. Following best practice, a flowchart detailing the stages of the search will be documented, adapted from the PRISMA checklist.

Charting the data

A draft charting form (see [box 1](#)) has been developed for the collection and sorting of key pieces of information from the selected articles to facilitate the synthesis and interpretation of qualitative data by sifting, charting and sorting material according to key issues and themes.²⁴

Box 1 Draft data charting form

Author and year of publication
 Type of publication
 Study country
 Title
 Aims/purpose of the study
 Study design
 Methods and data
 Findings on Leadership and governance of REC,
 Findings on Strategies to develop the technical ability of REC members
 Findings on Administrative and financial capacity of REC
 Funding source

The form and process will be tested in the early stages of searching and it will be refined during the full-text screening to capture detailed information on each study. Additional categories that may emerge during data extraction will be added.

Collating, summarising and reporting the results

Key characteristics extracted from included publications will be used to produce an annotated summary of the literature. We will conduct the scoping review following the PRISMA-ScR Checklist.³⁰ This descriptive summary will outline the nature of the current literature relevant to the strengthening of ethics committees for health-related research in SSA. Where possible, it will identify gaps and synthesise evidence related to leadership and governance, the technical capacity of reviewers and regulators, and the administrative and financial capacity of RECs.

Consultation exercise

The final stage refers to consultation with stakeholders. This has also been shown to be a knowledge translation activity and an important step in scoping reviews.³⁰ The project is part of an EDCTP funded project, and throughout the process of this review, we will use a participatory approach, involve key stakeholders from SSA, namely in Sierra Leone. This will ensure that individual and institutional expertise is maximised to ensure material from the literature are context-specific and application can be sustainable in the long term. We will be completing the scoping review by September 2021.

ETHICS AND DISSEMINATION

We have described a protocol for a scoping review to examine and map evidence on ethics committees for health-related research in SSA. Ethical approval is not required as the review will include only published literature. The findings will be published in a peer-reviewed journal and presented at stakeholder meetings and conferences.

Contributors All authors have made substantive intellectual contributions to the development of this protocol. AJML conceived the idea for the project. AJML, HW, EF and MS secured the funding. VT, AJML and DP led the development of the study design and research questions, which were reviewed and agreed upon by all authors. VT led the writing of the manuscript. All authors provided detailed comments on earlier drafts and approved the final protocol.

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