

Research Ethics Committees in Africa and Latin America

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ABSTRACT

Background: Research Ethics Committees (REC) play a crucial function in ensuring the review, commentary, guidance, and approval of research involving humans or animals to protect the dignity, rights, safety, and well-being of study participants. Many Low and Middle Income Countries (LMIC) focused considerable attention on developing REC. To date, there is a lack of information on the structure and operating modalities of REC in LMIC. This study describes the functioning of REC in Latin America and Africa and compares the situation between the different LMIC under study.

Methods: HR Web platform was used to get a general idea of the existing REC, to collect available information, as well as to identify contacts of existing REC. A questionnaire describing modalities of functioning was then sent to the different contacts identified on the website and other personal contacts.

Results: Results found on HR Web showed that among the 54 African countries listed, 176 REC were representing 36 countries. In Latin America, 1009 REC in 16 different countries were mapped. For most REC, little information was available on the website. While the questionnaire was sent to 79 countries, 52 mapped on the site and 27 other committees that are not mapped on HRWeb, but when knows their existence according to experts and having an accessible contact. Only 38 REC responded and were included in the study, representing 20 countries from both regions.

Interpretation: This was the first survey conducted on the description of REC in Africa and Latin America, providing a clear vision of their missions, composition, functioning, and the challenges encountered. This study found that there are still many challenges facing research ethics committees in Latin America and Africa. These include insufficient training in research ethics for ethics committee members, low funding for ethics committees, and lack of oversight of approved projects.

Keywords: Research ethics committee; Low and middle income countries; Latin America; Africa

INTRODUCTION

Since ethics review is an important pillar of the oversight and governance framework, Research Ethics Committees (REC) have become an indispensable element of any research involving humans or animals [1,2]. The importance of ethics committee review of research protocols involving human subjects has been well described in the Declaration of Helsinki [3], the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS) [4], and the World Health Organization (WHO) "operational standards and guidelines

for the ethical review of Health Research Involving Human Participants" (HRIHP) [5]. This REC provides review, commentary, guidance, and approval of research protocols before the inception of a study to protect the dignity, rights, safety, and well-being of study participants. The main mission of ethics review of research protocols is to ensure that they comply with three fundamental principles: respect for persons, beneficence, and justice in the conduct of research [6]. Although all REC around the world has the same primary mandate to provide ethics review of human research protocols to ensure ethical

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principles, the organization of research ethics varies from country to country, or from one ethics committee to another within the same country. Indeed, social, cultural, political, and legal contexts in Low and Middle Income Countries (LMIC) are different from the ones in high-income countries [7]. Research involving human subjects has experienced a phenomenal increase in various lower income regions. Hence in the field of biomedical research [8], many LMIC have begun focusing more attention on the development and/or strengthening of REC.

Basic constitution of an REC has not been clearly defined [2] and the modalities of operation not precisely defined. Evaluation of these committees in relation to the qualities required from them is not often discussed [9]. Many people question the functioning of REC in Latin American and African LMIC as well as their capacity and accountability to ensure the well being of research participants and the protection of their rights [10]. The main objective of this study was to describe the functioning of REC in Latin American and African LMIC. A secondary objective was to compare the situation between the different LMIC studied.

MATERIALS AND METHODS

Data collection

The Health Research Web Platform (HR Web) is a global platform for information on the structure, organization, funding, and prioritization of health research in low and middle income countries. HR Web enabled us to identify contacts of the mapped REC in the regions of interest and provided a general vision on the number of committees, their distribution and basic information on their functioning.

An online questionnaire was sent to REC identified through HR Web. This questionnaire was also sent directly to researchers, committee leaders, committee members, country researchers, professors, etc. identified through our networks and on social media. This targeted questionnaire designed to assess most of the operational characteristics of research ethics committees was based on the Council of Europe's Guide for Members of Research Ethics

Table 1: General information about the 179 RECS in 36 African countries (HRWeb).

Category	Details	Numbers of REC	Percentage in HRWeb (N=179)
Rules of Procedure	Available	29	16.00%
	Not Available	147	82.00%
Meeting	Every 2 weeks	8	4.50%
	Monthly	75	43.00%
	Every 2 months	8	4.50%
	Quarterly	27	15.30%
	Biannually	2	1.10%

Committees [11], the International Ethical Guidelines for Health Research Involving Human Participants developed by CIOMS and WHO in 2016 [12], and the Operational Guidelines for Ethics Committees Reviewing Biomedical Research developed by WHO in 2003 [5]. The questionnaire was administered using Google Forms. The questionnaire has been translated into two languages, English and Spanish; it includes 47 questions that are general questions in addition to more specific items assessing different aspects of REC performance and effectiveness. The questionnaire is divided into five parts: General information on the ethics committee, missions, composition, functioning, and research project evaluation.

Statistical analysis

This is a descriptive quantitative study. General information and responses to questions were analyzed using descriptive statistics: frequency and percentage, or arithmetic mean and standard deviation. Analyses of our data were performed using IBM SPSS Statistics version 21 software.

RESULTS

HR Web

Of the 54 African countries listed on the platform, 176 REC in 36 countries were mapped (Figure 1). According to HR Web, there is no REC in the following African countries: Cape Verde, South Sudan, Somalia, Comoros, Angola, Equatorial Guinea, Djibouti, Sao Tome and Principe, and Eswatini (formerly Swaziland). In Burundi, an ethics committee has been appointed in June 2019, but it is not yet mapped on the site (information provided through the Committee Director). General information available on HR Web for some African REC is presented in (Table 1).

	On request	4	2.20%
	Other	35	19.80%
	No data	17	9.60%
Continuing education	Yes	80	45.40%
	No	6	3.40%
	No data	90	51.10%
Initial training	Yes	77	43.70%
	No	14	7.90%
	No data	85	48.30%
Remuneration of members	Yes	33	18.70%
	No	60	34.10%
	No data	83	47.10%
Community Representatives	Only one representative	35	19.80%
	2-6 representatives	29	16.40%
	6-10 representatives	4	2.30%
	10-15 representatives	1	0.60%
	15>representatives	2	1.10%
	No data	105	59.70%
Sex of the REC member	1-5 women	49	27.80%
	5-10 women	33	18.70%
	10-15 women	7	3.90%
	15-20 women	0	0.00%
	20>women	1	0.60%
	No data	86	48.80%

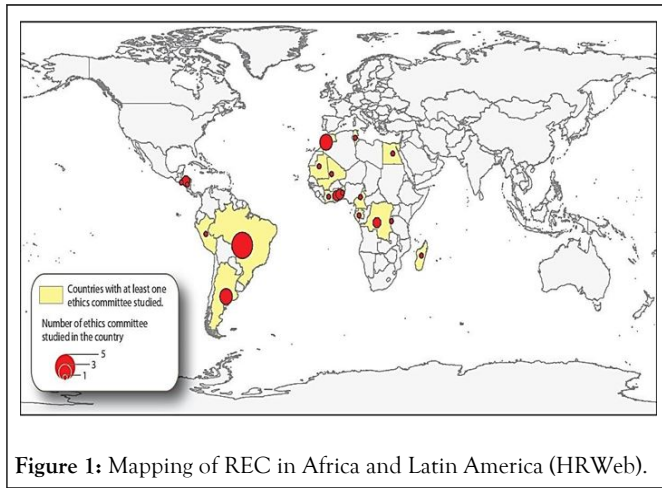


Figure 1: Mapping of REC in Africa and Latin America (HRWeb).

In Latin America, 1009 REC in 16 different countries were mapped, Figure 2 shows their geographic distribution and general information available on HR Web is summarized in Table 2 REC mapped is national, institutional, private, or other. Figure 3 shows the percentage of each type of REC in Latin America and in Africa.

Table 2: General information about the REC of 16 Latin American countries (HR Web).

Category	Details	Number of REC	Percentage in HR Web (N=1009)
Rules of Procedure	Available	1	0.10%
	Not Available	1008	99.90%
Meeting	Every 2 weeks	3	0.30%
	Monthly	2	0.20%
	Every 2 months	0	0.00%
	Quarterly	0	0.00%
	Biannually	0	0.00%
	On request	0	0.00%
	Other	0	0.00%
	No data	1004	99.50%
Continuing education	Yes	4	0.40%
	No	1	0.10%
	No data	1004	99.50%
Initial training	Yes	5	0.50%
	No	0	0.00%
	No data	1004	99.50%
Remuneration of members	Yes	2	0.20%
	No	3	0.30%
	No data	1004	99.50%
Community Representatives	Only one representative	2	0.20%
	2-6 representatives	2	0.20%
	6-10 representatives	0	0.00%

	10-15 representatives	0	0.00%
	15>representatives	0	0.00%
	No data	1005	99.60%
Expert woman	1-5 women	2	0.20%
	5-10 women	2	0.20%
	10-15 women	0	0.00%
	15-20 women	0	0.00%
	20>women	0	0.00%
	No data	1005	99.60%
	Deadline for submission of the protocol	<1 month	6
1 month		0	0.00%
2 months		0	0.00%
Other		0	0.00%
No data		1004	99.50%

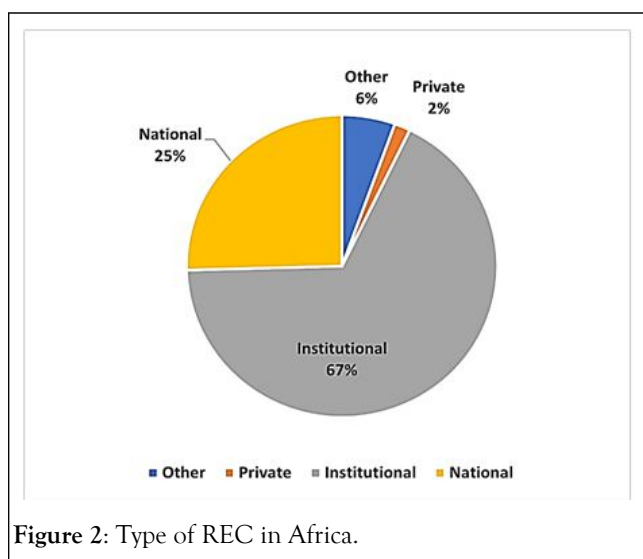


Figure 2: Type of REC in Africa.

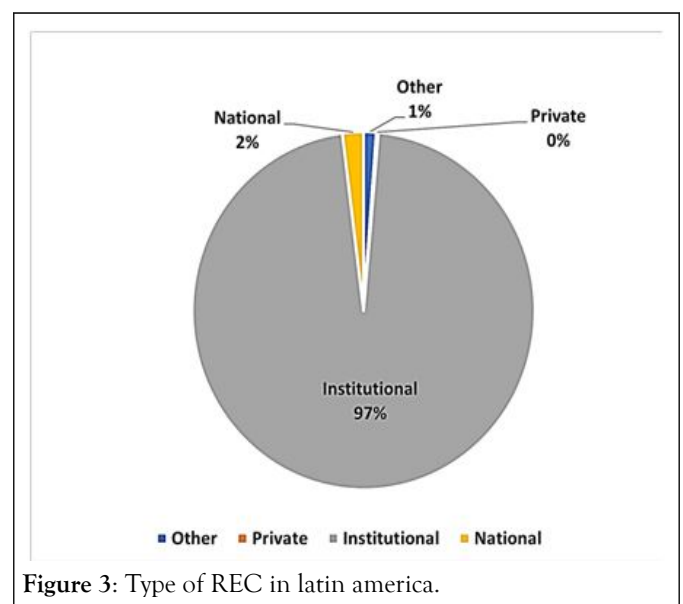


Figure 3: Type of REC in Latin America.

Questionnaire

Two mailings were conducted with the goal of maximizing participation rates. Out of 709 questionnaires sent out, we received 38 completed questionnaires, representing an overall response rate of 5.3%.

General information: REC could be national committees (28.9%), or institutional with a predominance of these committees at the hospital and faculty level (65.8%), so they could be private (2.6%), provincial (5.3%), or regional (7.9%) committees.

The majority of REC were newly established (REC in Burundi created in 2019 and in 2017 in the Democratic Republic of Congo), while others were older (like REC for Bioethics in Casablanca (Morocco) created in 1989, followed by the REC in Peru created in 1995).

Missions: The "Commission Nacional de Bioetica" of El Salvador and the "Institutional Ethics Committee CHU Razi" in Tunisia played several roles at the same time: evaluation of research projects and monitoring of these projects, participation in reflection on ethics teaching, guidance, and counseling in the ethical aspects of public health, scientific advances, and the environment.

Almost half of the REC reviewed all types of research involving humans and animals (47.4%), while other REC reviewed only research involving humans only (81.6%), while other REC reviewed only research involving humans. Others reviewed research in emergency situations, such as the National Ethics REC for Life Sciences and Health (CNESVS) in Côte d'Ivoire and the REC of the University Hospital of the Federal University of Rio de Janeiro in Brazil, while others were not involved in this task.

Composition: Total number of REC members ranged from five to a maximum of 37 (13.3 ± 6.9) with the number of female members ranged from one member to a maximum of 16 (4.9 ± 3.1), while male members ranged from two to 34 (8.3 ± 6.5) (mean sex ratio of 1.7).

Quorum was held by half plus 1 of the members in most REC (7.2 ± 3.7). The term of office for ethics committee members ranged from a minimum of two years to a maximum of ten years (3.7 ± 1.8), noting that for a REC the term was automatically renewed until the member's resignation.

The multidisciplinary diversity is important (ethics, epidemiology, economics, sociology, medicine, biology, psychology, religious sciences, philosophy, management, political and legal sciences, demography, etc.). Most RECs had community representatives among their members, but their role differed from one committee to another (65.8%).

The multidisciplinary aspect sometimes corresponds to an opening up to outside members: independent consultants are invited in an advisory capacity and can provide additional information in 92.1% of REC. These consultants are either fixed or identified by a list in 20% of cases or vary according to the theme developed by the research being evaluated.

Some REC had collaborations with bodies of other institutions involved in the review, authorization and monitoring of research projects (68.4%).

For institutional REC, some members of these committees were affiliated with the institution with the presence of non-affiliated members in 86.2% of cases, while for other committees; all members were affiliated with the institution.

Functioning: The number of meetings scheduled by the committee during the year ranged from one to a maximum of 48 meetings during the year (14 ± 12). These meetings were either held regularly (71.1%), or as requested (57.9%), or both.

Initial training was required for 68.4% of REC, while continuing education was required for 81.6% of REC, with the number of sessions during the year of initial training varying from one session to 12 sessions (2.6 ± 2.9). External audits were conducted in 64.7% of REC and external audits were conducted in 41.7% of REC. An annual activity report was completed by 86.1% of REC.

The majority of REC had a technical means of archiving the documents reviewed (94.4%), either by paper archiving within the institution (61.1%), or by electronic archiving (63.9%), or by specific archiving dedicated to the REC (30.6%). A website has been set up for 52.6% of REC, also 97.4% of REC had rules of procedure. These rules were either public, available to the entire population concerned for 67.6% of the REC, or private, available only to the members of the board of directors. REC was divided into two types according to whether the decision was advisory (63.2%), decision-making (*in vitro*, legally binding) (57.9%), or advisory and decision-making.

Each REC adopted a specific method for making decisions, either by systematic consensus (60.5%), systematic voting (23.7%), or voting only when necessary (47.4%). For those that adopted systematic consensus, in the event of disagreement by one or more members, various procedures were retrieved, but for the majority, a vote was organized. For those who adopted systematic voting, and in the event of a tie vote, other procedures were adopted, but the chair had the casting vote in most REC. Final decisions taken by most committees were as follows: project rejected but could be re-submitted (84.2%), definitively rejected (73.7%), accepted subject to modifications (89.5%), or accepted without reservation (81.6%). The number of research projects reviewed by ethics committees last year varied very remarkably from one REC to another (71.5 ± 110) with a minimum of two projects reviewed and a maximum of 458 projects for the REC of the Federal University Hospital of Rio de Janeiro in Brazil.

Actions taken in response to a conflict of interest varied: in 63.9% of REC the person was excluded from the room and did not participate in the discussion and decision making, and in 26.3% of REC the person remained in the room but did not participate in the discussion and decision-making, while for 5.3% of REC no action was taken, with a simple declaration of the conflict. Self-assessments were conducted in 60.52% of the REC and external audits were conducted in 39.4% of the REC.

Research project evaluation: Each REC had a specific method for reviewing a research project (Figure 4). The majority of REC used a project-reading grid (84.8%). Payment modalities varied between REC but also between and within countries; 52.6% of REC evaluated research projects for free while 34.2% requested a lump sum and 13.2% of REC requested a percentage of the amount allocated to the project. The average time to process a submission ranged from a minimum of eight hours to a maximum of 12 weeks. Expedited review and functioning procedures existed for 80.6% of REC. In each country, there were numerous rules and guidelines that REC should or could use to guide their work. Most REC used common international guidelines for the review of research projects such as the Nuremberg Code (44.7%), the World Medical Association

Declaration of Helsinki (73.7%), the World Health Organization (WHO) International Guidelines for Good Clinical Practice (68.4%), the International Ethical Guidelines for Biomedical Research of the Council for International Organizations of Medical Sciences (CIOMS) (63.2%), the Universal Declaration on Bioethics and Human Rights (UNESCO) (50.0%), and the Convention on Human Rights and Biomedicine (Oviedo Convention) (34.2%). Others adopted national lines in addition to international lines like the Constitution of the Republic of Benin of December 11, 1990, and the African Charter on Human and Peoples' Rights in Benin.

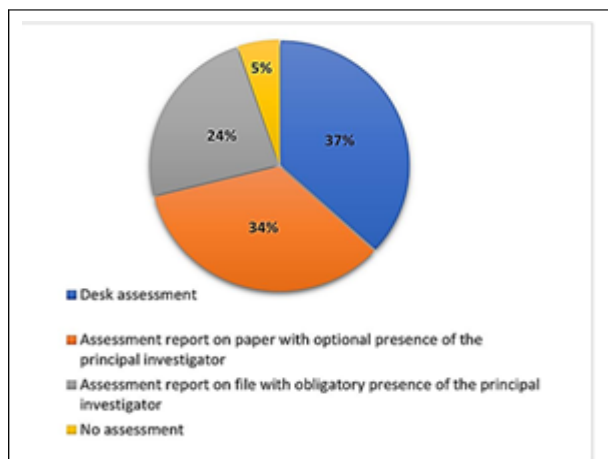


Figure 4: Methodology for evaluating research projects.

The elements evaluated by most REC in a research project were as follows: relevance was evaluated by 86.8%, feasibility of the protocol by 78.9%, consent by 92.1% (with a different consent requirement either written and signed, or oral if the project did not allow written.

Consent), scientific validity by 84.2%, risk-benefit ratio by 92.1%, and finally confidentiality by 89.5% of the REC. Ethical follow-up after validation of the protocol was carried out through different strategies (Figure 5).

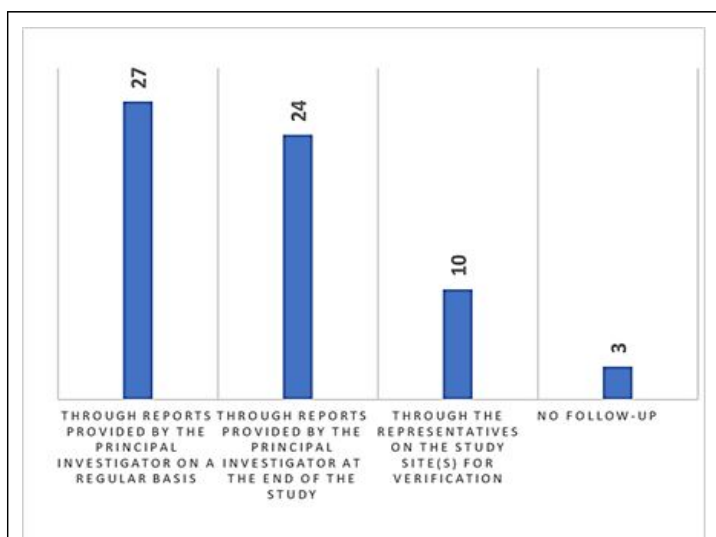


Figure 5: Strategies of ethical monitoring after validation of the protocol.

DISCUSSION

This study provided useful insights into how REC operates in low and middle-income countries in Latin America and Africa. REC plays a crucial role in the evaluation of research projects in LMIC. It is clear that there is a great deal of diversity in the composition, functioning and their method of ethical and scientific review.

In terms of the composition of the REC we note a lack of parity between women and men, with a higher proportion of men within the REC members.

The same results were revealed by a first review in sub-Saharan Africa, on the structure and functioning of African REC, where they reported that female members are under-represented [13].

This lack of parity is explained by the potentially more difficult access of women to higher-level positions and careers that are represented on committees. It should also be noted that this phenomenon is still found in high income countries in some areas.

To review protocols effectively, REC should be composed of members from diverse backgrounds: many of the REC interviewed met the requirements of multidisciplinary. A survey conducted in 2017, presenting the state of the art of the institutional framework for research in sub-Saharan Africa, particularly in Benin, Cameroon, and Nigeria, also revealed that the constitution of most REC met the requirements of multidisciplinary [14].

The absence of community representatives was noted for a few RECS, whereas their presence must be applied by all REC to ensure that the interests of the communities targeted by the research project to be examined are considered and thus reflect the views of the public and patients. Patient and Public Involvement (PPI) is where members of the public are actively involved in research projects and research organizations. REC should develop appropriate contacts and exchange information with other bodies that promote the harmonization of the ethics review system, both in terms of ethical standards and procedures.

The study found that most REC had collaboration with other bodies but perhaps not close enough. Where members of the public are actively involved in research projects and research organizations.

For a few REC, the members were all affiliated with the institution, a survey of 31 ethics committees (REC) across sub-Saharan Africa had shown that the members of 10 institutional committees were all affiliated with the institution. While a REC composed of members of the institution hosting it, without external members, faces a high risk of bias in its work. It is therefore imperative that REC attract members from outside the parent institution. Training of members before or after joining a REC will help orient them in terms of the standard operating procedures in place and the ethical review procedure of the relevant committee. The study had revealed a need for training of REC (14.4% of REC without continuing training and 31.3% without initial training). These results were somewhat like the ones from a previous survey conducted in sub-Saharan Africa, which showed that 38% of REC members had not received any form of training. Conflicts of interest management was not considered for some REC despite its potential impact.

A lack of quality control of REC was noted. This included a lack of self-assessment and an absence of external audit for most REC. Committees should put in place mechanisms to regularly assess the quality of their work, as well as their functioning, with a view to possible improvements. Conducting an independent audit of REC can play an important role in enhancing the quality of the ethical review process by encouraging the development of policies and procedures. Standardized procedures will help promote the consistent application of ethical principles and prove accountability. Paper-only review of research projects has been adopted by most REC, although it is desirable to invite the principal investigator to participate to allow an effective review and informed exchange.

Expedited review procedures were absent for some REC whereas they should be established by all REC. They should be prepared to timely and properly review protocols in the event of a public health disaster, without losing the quality of protocol review. REC that is well prepared for timely review of protocols remain ethical and scientific priorities, to better monitor and coordinate future major public health issues.

The lack of funding and weak support still characterized most REC in Latin American and African LMIC, with most of them receiving little or no support from their respective governments. These findings are fully consistent with the results of the survey that was conducted in 2017 on the 3 REC in Benin, Cameroon, and Nigeria. It revealed the need for the committees to have sufficient financial and material resources for their proper functioning [14]. In addition to the results of the review on the structure, and functioning of the African REC which had also shown that the functioning of the REC is hampered by the scarcity of financial resources, inadequate training of members to review and monitor studies [13]. Most of the REC assessed the following elements when evaluating the research project (relevance of the idea, feasibility, consent, scientific validity, confidentiality, risk/benefit ratio), but a failure to assess the scientific validity and feasibility of the protocol was noted for some REC. Meeting these six criteria is necessary and sufficient to ensure the ethical nature of a research project. Given the lack

of literature on previous studies on the functioning of a set of REC in Latin America, we did not find sufficient data to make a comparison with our study. The role of REC is critical after the validation of the protocol for ethical monitoring. However, most REC flavored follow-up through reports either at the end or on a regular basis and neglected the method of sending representatives to the site, which would allow more reliable follow-up.

Among the highlights of the study was that it was the first survey conducted on the description of REC in Africa and Latin America. The HR Web site was very useful. It is a platform that can be used by any other REC. In addition, the questionnaire sent to the REC was relatively clean, simple, and easy for the translation, filling it out did not exceed 20 min.

Alternatively, some limitations of the study should be noted, namely, the non-availability of general information for some REC on the HR Web platform, and a difficulty in finding the contacts of the REC (email addresses). Among the contacts identified, some email addresses were nonfunctional, which led to a rejection of many emails sent. In addition, some REC had difficulty understanding the questionnaire because of the language. Not forgetting, of course, that because of the difficult situation of the coronavirus pandemic, the following unfavorable response was received: "the REC is closed in this period of pandemic, and we cannot provide the information currently requested". It is likely that the lack of response from other REC could be due to the same reason. Note that it was intended to include Asian LMIC, but the unavailability of contacts to send the questionnaire, and the unavailability of information on the HR Website, led us to exclude Asian LMIC [15].

The overall analysis of the functioning of the REC has allowed us to propose some key recommendations to address the various difficulties that hinder the proper functioning of the REC:

- Improve public funding of REC to ensure proper coordination, training and monitoring of REC by establishing lines in the national budget for the operation of ethics committees.
- Mandatory and adequate training in research ethics for researchers
- Researchers and REC members could ensure confidence and appreciation of the utmost importance of ethical review.
- Establish a framework for dialogue and coordination mechanisms between the different committees and make regular meetings between them to harmonize protocol review and monitoring tools.
- Build research ethics capacity in these countries.

CONCLUSION

There are still many challenges faced by ethics committees in Latin American and African LMIC regarding the efficient implementation of ethics in health research. These include insufficient training in research ethics for committee members, low funding for ethics committees, and lack of supervision of approved projects. Ultimately, it would seem interesting and necessary to explore and compare the functioning of all REC in

LMIC through a descriptive study of REC also in LMIC in Asia, and Europe. Another perspective would be to compare the functioning of REC in LMIC with the functioning of REC in high-income countries.

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