Operation of research ethics committees in Colombia, Costa Rica, Guatemala, and Mexico: Mesoamerican Project

Angélica Ángeles-Llerenas, PhD, MSc,[1] James F Thrasher, PhD, MA, MS,[2] Rosalinda Domínguez-Esponda, MSc,[1] Ruy López-Ridaura, PhD, MD,[3,4] Ruth Macklin, PhD.[5]

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Abstract

Objective. To attain a better understanding of the structure and processes of Research Ethics Committees (REC) in the low-and middle-income countries of the Mesoamerican region. The objectives are knowing the operational practices of the RECs regarding project evaluation, training needs, and infrastructure. **Materials and methods.** The REC training and needs assessment involved an online survey of all the RECs (n=55) identified in Colombia (n=11), Costa Rica (n=5), Guatemala (n=5), and Mexico (n=34). **Results.** Participants reported inadequate infrastructure for its proper operation (only 49.1 %, or 27/55, have an exclusive office to safeguard files); insufficient administrative staff (47.3%, 26/55), or financial resources to conduct active site monitoring (85.6%, 47/55) to ensure the protection of rights and welfare of study participants. **Conclusions.** Investments in REC member training and infrastructure are needed to ensure compliance of REC evaluations with the standards for ethical conduct of research.

Keywords: research ethics committee; training; infrastructure

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Resumen

Objetivo. Comprender la estructura y procesos de los Comités de Ética en Investigación (CEI) en países mesoamericanos de ingresos bajos y medios. Conocer las prácticas operativas en evaluación de proyectos, necesidades de capacitación e infraestructura. **Material y métodos.** Encuesta en línea para evaluar necesidades de capacitación de los CEI (n=55) identificados en Colombia (n=11), Costa Rica (n=5), Guatemala (n=5) y México (n=34). **Resultados.** Los participantes reportaron una infraestructura inadecuada para su correcto funcionamiento (oficina exclusiva para archivos 49.1%, 27/55); personal administrativo insuficiente (47.3%, 26/55), recursos financieros insuficientes para monitoreo del sitio (85.6%, 47/55), para garantizar protección de derechos y bienestar de los participantes. **Conclusiones.** Se necesita invertir en capacitación de los miembros e infraestructura del CEI, para garantizar la conducción ética de la investigación.

Palabras clave: capacitación; comités de ética en investigación; infraestructura

(1) Comité de Ética de Investigación, Instituto Nacional de Salud Pública. Cuernavaca, Morelos, Mexico.
(2) Health Promotion, Education, and Behavior Arnold School of Public Health, University of South Carolina. Columbia, South Carolina, USA.
(3) Centro Nacional de Programas Preventivos y Control de Enfermedades. Mexico City, Mexico.
(4) Centro de Investigación en Salud Poblacional, Instituto Nacional de Salud Pública. Cuernavaca, Morelos, Mexico.
(5) Distinguished University Professor Emerita, Department of Epidemiology and Population Health, Albert Einstein College of Medicine. New York, USA.

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Corresponding author: Rosalinda Domínguez-Esponda. Comité de Ética de Investigación, Instituto Nacional de Salud Pública. Av. Universidad 655, col. Santa María Ahuacatitlán. 62100, Cuernavaca, Morelos, México.
email: rdominguez@insp.mx

Globally, there is a great need to promote and provide high-quality health research and to make certain that this is conducted in an ethical manner. Research ethics committees (RECs) help to ensure ethical conduct in biomedical and behavioral studies involving human subjects by seeking to protect the rights and welfare of research participants. RECs are responsible for reviewing, approving, and continually monitoring all research projects involving human subjects. International guidelines specify staffing requirements, resources, membership composition, and procedures that adhere to regulatory frameworks. However, low- and middle-income countries (LMICs) often lack the capacity and resources to guarantee that these guidelines are met. The study described here aimed to improve the understanding of the structure and processes of RECs in the LMIC region of Mesoamerica, which extends from Mexico in the north, through the Central American isthmus, to Colombia in South America.

Despite the remarkable growth in research ethics education throughout the region in the past two decades, the participation of Latin American and Caribbean countries in global discussions of research ethics has generally been minimal.[1] The Fogarty International Center of the U.S. National Institutes of Health (NIH) has introduced training programs in research ethics beginning in 2000.[2] Training programs currently operating in the region are the Caribbean Research Ethics Education Initiative (CREEI), which has both a Spanish- and English-speaking component depending on the language of the country; a regional Training Program in research Ethics in the Americas headquartered in the *Facultad Latinoamericana de Ciencias Sociales* (Flacso) in Argentina and open to all eligible countries in Latin America, and Building Local Capacities in Ethics Training and IRB Review in Guatemala. Other bioethics educational programs in Latin America are sponsored by the United Nations Educational, Scientific and Cultural Organization (UNESCO) through *redbioética*, a regional network with programs in bioethics and ethics in the sciences.[3] Although these training programs have been implemented throughout the region, little information exists regarding the training REC members receive on research ethics and good clinical practice, courses taught in their institutions. The effects of these training courses on REC practices have not been evaluated.

Prior research indicates that RECs often operate at different levels of quality and efficiency.[4-6] First, decision making by RECs is not always in accordance with the regulatory guidelines.[7] Second, RECs' procedures can be idiosyncratic, as the same research proposal submitted to RECs from multiple sites often results in different conclusions regarding the type of review required (*e.g.*, expedited, exempt, or other).[8,9] Third, waiting times for approval of the same study protocol can vary substantially and are often extensive, without clear reasons why.[7,10] Fourth, RECs may lack sufficient infrastructure and funding to carry out activities.[11] On the other hand, reasonable concerns have been raised that regulations may impose cumbersome bureaucratic procedures having little to do with the protection of research participants, even though they require substantial funding and resources.[12] These barriers are likely to be frustrating for researchers when their studies carry only minimal risk to participants or involve only minor changes to the consent document, resulting in a delay in implementing the research protocol.

Based on the shortcomings and unknowns described above, the objective of the present study was to characterize the RECs of the Mesoamerican region by 1) identifying the qualifications of the REC members who received training in research ethics; 2) describing the infrastructure of RECs, and 3) determining the compliance of RECs with the standards set by the World Health Organization (WHO) in its operational guide for the ethical review of health-related research with human participants.

Materials and methods

Study design and data collection

The study was a quantitative and descriptive study based on an online survey in Colombia, Costa Rica, Guatemala, and Mexico, from February 2017 to October 2018. First, we sought RECs in National Institutes of Public Health in the four countries, because in these institutions' RECs review protocols that include chronic diseases. Second, we sought the Ministry of Health registry in each country in order to identify those RECs and invite them to participate. Third, when we received a reply from the Chairs, we asked if they knew about other RECs. RECs' members were invited via email and provided with a link to the study, an ID and a password. An e-Consent was used to complete the anonymous questionnaire. If the questionnaire was not completed within seven working days, a reminder was sent. No follow-up was given for those that had declined to participate in the study or did not answer. For our study population, we targeted those who held a position such as REC Chair or Director of the Research Ethics Committee, technical secretary, administrative coordinator, or any member of the Committee. Due to the nature of this study, the Research Ethics Committee of the National Institute of Public Health of Mexico

(*Instituto Nacional de Salud Pública*, INSP) approved the delivery of the questionnaire by email as constituting the participants' consent to participate (Approval number 1431, January 2018).

Survey. After the INSP´s REC approval, researchers from this institution and the University of South Carolina developed an online tool to identify and analyze training needs that decision makers could use to improve the protocol evaluation process, as well as to enhance knowledge of regulatory aspects and infrastructure needs. The questionnaire was created in line with the Research Ethics Committee Assessment Toolkit (RECAT)[13,14] developed by Johns Hopkins University researchers and reviewed by experts from INSP, and was tested for comprehension in a pilot study.

The questionnaire included six sections with a total of 71 items:

- Section I: Characteristics of study participants and theirs RECs: age, gender, profession, country, position and membership as REC member, years of REC operation in that institution.
- Section II: Adherence to policies and regulations: at international, national and/or institutional level, and Federal Wide Assurance registry.
- Section III: Membership and training needs: gender balance, designation of REC members, area of expertise and length of time as REC member and training in bioethics.
- Section IV: Operating procedures: procedures for protocol review, mechanism to communicate the decision, perceived quality of protocol evaluation during the meetings, expedited review, and continuing review procedures.
- Section V: Committee deliberations: meeting processes, verification of quorum, meeting attendance by researchers who submit protocols, and aspects on which the committees focus during the meeting discussion.
- Section VI: Staff, Infrastructure & Financial Resources: administrative staff, financial support and potential conflict of interest of institutional authorities.

A more detailed description of the topics addressed in the questionnaire can be found in the appendix A. Instrument Sections.[15]

Analysis

We analyzed the survey information and stratified it by section and country. We conducted statistical tests (two-tailed Fisher's Exact Test) to determine whether the participants' responses to the scenarios varied by individual or institutional characteristics.

Results

Section I. Characteristics of study participants

Of the 55 study participants, 27/ 49% belong to Universities (Mexico 14/39.4%, Colombia 8/72.7%, Costa Rica 2/40%, Guatemala 3/60%); 19/35% work for National Institutes of Health (Mexico 12/36.4%, Colombia 2/18.2%, Costa Rica 3/60%,Guatemala 2/40%), and 9/16% are from hospitals (Mexico 8/24.2%, Colombia 1/9.1%). Out of the 55 participants (70% response rate), most were women (74.6%), older than 40 (73.7%) and with professional experience in health sciences (72.7%). Most participants said that they have been REC members for 5 to 10 years (45.5 %), and their current position was Chair of the Ethics Committee (96.4%), although half of them also hold an administrative position in their REC (52.7%, 29/55). Half of these committees have existed for more than 10 years in their institution (50.9%, 28/55) (table I).

Section II. Adherence to policies and regulations

Most participants reported that their institutions not only have a REC but also a Bioethics Hospital Committee, a Biosecurity Committee, and a scientific committee. Most participants mentioned that they follow the international framework of health research review--The Council for International Organizations and Medical Sciences (CIOMS) Guidelines and the Declaration of Helsinki (89.1%), as well as national (81.2%) and institutional (45.5%) guidelines. When we analyzed how the Federal Wide Assurance (FWA) registry was distributed by country, we found that nine RECs in Mexico, four in Guatemala, and three in Colombia had been registered (table I).

Section III. Membership and training needs

Only 40% (22/55) RECs abide by the WHO 50/50 gender balance regulations. We found that institutional officials (directors or managerial staff) designated the great majority of the REC members (56.4%, 31/55). When we explored the REC members' area of expertise, most REC participants mentioned that their committee's members belonged mostly to medical and social sciences. We also found that study participants from Colombia were, in addition to medical and social scientists, mostly

Table I
SOCIODEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS AND REGULATORY POLICIES IN RECs. MESOAMERICAN STUDY, 2018

Section I. Characteristics	*n*	%*
Age		
< 40	15	27.3
≥ 40	40	73.7
Sex		
Women	41	74.6
Men	14	25.6
Profession		
Health Sciences	40	72.7
Social Sciences	9	16.4
Other (lawyer, administrator, etc.)	6	10.9
Country (Institutions)‡		
Mexico	34	61.8
Colombia	11	20.0
Guatemala	5	9.1
Costa Rica	5	9.1
Period of time being member of the REC		
< 5 years	25	45.5
5 to <10 years	25	45.5
≥ 10 years	5	9.0
Respondent position at the REC		
Chair/Director		
Yes	53	96.4
No	2	3.6
Assistant Chair/Technical secretary		
Yes	47	85.5
No	8	14.5
Active member		
Yes	20	36.4
No	35	63.6
Administrative coordinator		
Yes	29	52.7
No	26	47.3
Number of years of the REC in their institution		
Less than 5 years	11	20.0
5 to 10 years	16	29.1
More than 10 years	28	50.9
Section II. Policies and regulations		
Types of Committees in their institution		
Research ethics committee		
Yes	50	90.1
No	5	9.1
Hospital ethics committee		
Yes	21	38.2
No	34	61.8
Scientific committee		
Yes	40	72.7
No	15	27.3
Biosequrity committee		
Yes	26	52.7
No	29	47.3
Animal research committee		
Yes	19	65.5
No	36	34.5

* Some percentages do not reach 100% due to missing values
‡ Institutions: Colombia: Clínica Oftalmológica del Caribe, Universidad del Norte, Comité de Ética en Investigación Fundación Universitaria Sanitas, Universidad de La Sabana, Universidad de Antioquia, Universidad del Norte, Pontificia Universidad Javeriana, Instituto Nacional de Cancerología and Instituto Nacional de Salud; Costa Rica: Instituto Costarricense de Investigaciones Clínicas (CEC-ICIC), Universidad de Ciencias Médicas and Caja Costarricense de Seguro Social; Mexico: Instituto Nacional de Salud Pública, Instituto Nacional de Cancerología, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Instituto Nacional de Pediatría, Instituto Nacional de Perinatología, Instituto Nacional de Enfermedades Respiratorias and Instituto Nacional Neurología y Neurocirugía; Guatemala: Instituto de Nutrición de Centro América y Panamá and Universidad del Valle de Guatemala, Centro de Estudios en Salud.
REC: Research ethics committees

bioethicists (p=0.01) and, 67.3% (37/55) reported that their REC does not include community representatives, with no statistically significant differences across countries (p=0.11). In addition, participants reported that, according to their REC regulations, the length of membership on the REC is 1 to 3 years (38.2%). Mexican regulations stipulate that membership should last three years (47.1%) with the possibility to renew it for another three years. Participants from Colombia mentioned that membership lasted less than a year (72.7%). These characteristics were statistical different across countries (p=0.04) (supplementary table II).[16]

Training

Approximately half of the participants (50.9%, 27/55) mentioned having attended a face-to-face course (50.9%) and/or an online course (63.7%). Of the latter, the most

frequently reported was Good Clinical Practices (GCP) (30.9). The Collaborative Institutional Training Initiative (CITI program) and National Institute of Health (NIH) online courses were also mentioned, but with a lower frequency (16.4%). Others reported that they had attended seminars, elective courses, conferences, and other meetings (43.6%). Nevertheless, some participants expressed the view that one of the reasons why they find it difficult to evaluate a protocol is their lack of knowledge of topics in research ethics (14.6%), along with the fact that protocol review is based 62100rather on methodology than on ethical aspects (20%) (supplementary table II).[16]

Section IV. Operating procedures

The protocol submission process to RECs is mainly electronic (58.2%, 32/55) or on paper (45.5%, 25/55), but the distribution of protocols to reviewers is mostly electronic (76.4%, 42/55). REC decisions are communicated to researchers mainly through printed letters (72.7%, 40/55); this method of submission entails a relatively heavy workload for the committees and an extra expense for paper. Most RECs members reported that their committees review different types of protocols, for example: clinical research/clinical trials (87.3%, 48/55), social and behavioral studies (74.5%, 41/55), basic biomedical research (74.5%, 41/55), documentary research studies (56.4%, 31/55), and animal research (36.4%, 20/55) (supplementary table II).[16]

We also explored the participants' perceptions of the efficiency of the process of protocol evaluation from submission to the final approval. Reasons for a potentially deficient evaluation of a protocol included lack of time due to the patients' workload 41.8% (23/55), and 14.6% (8/55) lack of knowledge in research ethics topics. In the opinion of 7.3% (4/55) of the participants, there are pressures on the REC; only 1.8% said that there are conflicts of interest. Study participants mentioned that expedited reviews in RECs (in which the REC chair assigns protocols with minimum risk *to one or two reviewers* for timely evaluation and approval) were infrequent (69.1%, 38/55). Only a few committee members across the countries (30.9%, 17/55) said that committees use this type of review *always* or *sometimes*. According to Mexican regulations —by the National Bioethics Commission (*Comisión Nacional de Bioética*, Conbioetica)—, only administrative addenda can be evaluated by expedited review. This happens even though the CIOMS guideline No. 23 makes provision for this type of protocol review. Few committees mentioned that expedited review was sometimes used for clinical trials. We assumed that such clinical trials were minimal risk research (12.7%, 7/55). In Mexico, 32.4% (11/34) of the participants reported that they do not carry out an annual project review, whereas participants in Colombia (45.4%, 5/11), Costa Rica, and Guatemala (40 %, 4/10) reported that their RECs comply with this practice (p=0.14). In those cases where annual reviews are carried out, participants said they are performed through an annual or biannual report sent by the researchers (61.8%, 34/55). This practice is used mainly in Colombia (81.8%, 9/11), Costa Rica, and Guatemala (90%, 9/10). Only very rarely do representatives of the REC visit the research site (14.6%, 8/55) ($p<0.001$ among countries), which may represent a concern for clinical trials and other types of research with more than minimal risk (supplementary table II).[16]

Section V. Committee deliberations

Once the researcher has submitted the protocol, the REC administrative staff assigns it to a reviewer. The reviewer may be a board member and/or a subject-matter expert. In the case of studies with more than minimal risk (like many clinical trials), most study participants reported that Health Sciences protocols were reviewed by two REC members (69.1%, 38/55). We also found that some studies with minimal or no risk are reviewed by two REC members: social sciences (43.6%, 24/55), basic research (50.9%, 28/55), and literature reviews (21.8%, 12/55). Regarding the final decision a committee can take, a great proportion of participants (85.5%, 47/55) reported that their RECs do not have an "exempt" option for risk-free protocols (supplementary table III).[16]

With respect to the process for reaching a final decision with regard to a protocol, most participants (70.9%, 39/55) from every country said that consensus was a more frequent practice than voting. Finally, participants reported that the Chair or Co-Chair is usually the one responsible for preparing the meeting minutes (56.4%, 31/55). As for the evaluation of protocols, almost all study participants said that REC members are concerned about the potential risks of harm to research subjects (94.6%, 52/55). The great majority said that, during the meetings, REC members focus on both methodological (81.8%, 45/55) and ethical aspects (100%, 55/55) of a protocol (supplementary table III).[16]

Section VI. REC Staff and Infrastructure, Financial Resources, and Independence from Institutional Authorities

In relation to REC staff, not all committees have administrative staff, which almost certainly results in work overloads and delays in protocol evaluation and com-

munication of results (minutes, protocol submission, etc.). As to the available personnel at the REC, 94.5% (52/55) of the respondents said there are a director/chair and a technical secretary (83.6%, 46/55), with statistically significant differences found across countries (p=.001). Nevertheless, most RECs participants mentioned there was neither a coordinator who performs administrative functions (65.5%, 36/55) nor administrative staff (47.3%, 26/55) who can do these tasks. With regard to infrastructure and resources, nearly half of the participants said that their committees do not have an exclusive office to safeguard files (49.1%, 27/55). Nearly a third of the participants (30.9%, 17/55) reported that they do not have a website to publicize the membership roster or the regulations under which the committee operates (14.5%, 8/55). In relation to independence and to any pressure that may be exerted on the REC, 83.4% (46/55) of the participants mentioned that they always make decisions in an independent way, whereas 24.2% (9/34) of Mexico REC participants said that they "usually" do so. Participants said that they sometimes (14.6%, 8/55) or rarely (20.0%, 11/55) receive pressure from institutional authorities to make a favorable final decision on a protocol. It is important to note that 23.6% (13/55) of the participants reported that the Chair of the REC has a managerial position within the institution.

A large proportion of the participants 67.3% (37/55) mentioned that their institutions do not provide any amount of money for the proper operation of the REC; this is primarily the case in the RECs in Mexico (84.8%, 29/34). Overall, the RECs do not charge for reviewing protocols of their institution (94.5%, 52/55), and only a few charge for reviewing external protocols (34.5%, 19/55). Additionally, participants reported that REC members do not receive any compensation for their work on the REC (63.6%, 35/55), and some (20.0%, 11/55) reported they receive some other type of support (through scholarships, gift vouchers, proof of participation) (supplementary table III).[16]

Discussion

Adherence to ethics guidelines

This study provides a quantitative description of RECs in four Latin American LMICs, focusing on the adherence to international guidelines, infrastructure and operational procedures. The answers of the 55 REC members who completed the online survey indicated that their RECs adhere to the international framework of health research review —the CIOMS International Ethical Guidelines and the Declaration of Helsinki— as well as to national and institutional guidelines. Nevertheless, almost all participants reported that they do not have the FWA registration with the Office for Human Research Protections (OHRP) of the U.S. Department of Health & Human Services (DHHS). When an institution becomes engaged in research to which the U.S. FWA applies, the institution and REC need to comply with at least one of the following research ethics guidelines: CIOMS, the Declaration of Helsinki, GCP, among others. In recent years, research has increased in the developing world.[17] As of 2021, Center Watch reports there are around 516 clinical trials taking place in Mexico, 183 in Colombia and 37 in Guatemala.[18] According to the clinicaltrials.gov website, the number of intervention studies financed with NIH funds or US Federal Funds that are taking place in these countries are 42 in Mexico, 20 in Colombia, 12 in Guatemala, and three in Costa Rica.[19] This means that, in order to be competitive at international level, the RECs of the Mesoamerican region need to comply with the FWA requirement of the DHHS.

REC composition

When we explored REC composition, we observed that RECs are made up mostly of women, which implies that they do not abide by WHO gender balance guidelines. In addition, according to WHO, Committees must be "large enough to ensure that multiple perspectives are brought into the discussion". In our study, we found a variety of professionals within the RECs, including bioethicists. International regulations recommend that, besides members with scientific expertise —including expertise in behavioral or social sciences—, RECs should have members with expertise in research ethics as well.[20]

The inclusion of non-affiliated or community members is an important feature of RECs, as they can be the voice of those who are going to take part in a research study. However, only one third of participants reported that community members are part of their REC, and, therefore, these fail to comply with the international guidelines. In order to comply with the quorum requirements, at least 51% of the members should be present to make decisions about the proposed research, including at least one lay member and one non-affiliated member.[20] This means that research protocols are approved without the inclusion of these members. Non-scientific members may identify certain types of risks that scientific members may fail to consider —for example, those related to social, legal or cultural issues—, offering a laypersons' perspective. In addition, an important function of these board members is to help avoid using scientific jargon in informed consent forms, which often contain overly technical descriptions of the research. Nevertheless, it is important to highlight that even though international

regulations do not emphasize this aspect, institutional RECs must include community members who are unaffiliated with the institution, and therefore it may be to compensate them for the time spent reviewing informed consent documents and attending the REC meetings. The lack of incentives may affect the dedication of these persons to their work or attendance at REC meetings. It may also be a reason why only a few RECs reported the inclusion of such members.

Another important aspect of the composition of the RECs is the period of time allowed for members to belong to a committee. While some participants informed up to three years, or even more than three years, others reported that their membership is less than a year. The frequent turnover of REC members is likely to affect the performance and decisions taken by the members, considering that the new members need ethics training and must gain expertise in their role in reviewing protocols. At the same time, this practice wastes the experience and training obtained by the outgoing members. Regulations in Mexico indicate that members can belong to the REC for a period of three years with the possibility to renew their membership for the same period. In the case of Colombia, for a long time the evaluation of scientific research lacked the requirement of an ethical perspective (Resolution 8430/93); therefore, the formation of the *Consejo Nacional de Bioética* in Colombia was established until 2010 (Law 1374/2010).[21] At the end of 2019, the *Minimum guidelines for the formation and operation of research ethics committees in Colombia* (CNB) were published; besides the international guidelines, these take into account regulations from other countries, such as those published in Mexico in 2018 by Conbioetica. Nevertheless, according to these new guidelines for RECs in Colombia, membership in a REC is only for two years - instead of the three years that Conbioetica requires.[22]

The appointment of REC members is another relevant aspect to consider since it is made by an institutional official, suggesting the possibility of conflicts of interest. In order to avoid any type of pressure in the evaluation of and decisions about a protocol, the institutions should establish clear, unbiased methods for choosing REC chairs and members. In Mexico, Conbioetica allows the institutional official to designate the REC Chair, and RECs in Colombia follow this practice as well. Nevertheless, the designation of the REC chair by an institutional official could involve a potential conflict of interest, e.g., by requesting the REC chair to review and approve with minor changes a protocol of the director´s working group, compromising the independence of the REC's decisions.

REC staff and infrastructure

The international guidelines require institutions to provide administrative staff "to enable the REC to carry out its technical and administrative responsibilities";[20] however, as reported by more than half of the participants, in the absence of administrative staff, the chair or the secretary will probably be in charge of the meeting minutes. This suggests that work overloads are likely and may explain delays in protocol evaluation, communication of the REC's decision to researchers, and, ultimately, the initiation of the studies. Apparently, this situation is common in the RECs of LMICs.[23]

In our study, we observed differences related to the administrative mechanisms for receiving the protocols (online or printed), and the way the RECs communicate the evaluation is mostly printed. This means that the RECs do not own an online platform for receiving and submitting documents, which might accelerate the evaluation process from protocol submission until its approval and make the whole process more efficient. This could be the reason that a considerable proportion of the participants perceived the quality of the review process as merely "efficient".

Financial support

International Guidelines stipulate that REC institutions should provide enough support for their proper operation and for their activities as REC members. However, participants in our study reported this does not occur. This fact is important, because they acknowledge that the evaluation of a protocol may be deficient due to their workload, which implies that they focus first on their regular activities, and afterwards, on their REC responsibilities. We believe that their commitment to their duties as REC members might be strengthened if there were any type of acknowledgment from their institution for the time that they devote to the institutional REC.

REC monitoring

Most respondents reported that their RECs fail to meet the need for onsite monitoring throughout an approved research project as indicated by the international guidelines.[20] After a protocol has been approved, there is no comprehensive system in place to monitor research and ensure that the REC's recommendations are carried out.[24] Unfortunately, the lack of a sufficient workforce, the lack of training of REC members on how to conduct monitoring, and inadequate funds are cited as major

hurdles for conducting active site monitoring.[25] Most RECs focus on reviewing and approving protocols and also reserve some time for monitoring reports submitted by researchers, but site visits are not considered.[24] In our study, an annual report to the REC was the monitoring mechanism frequently used. Many RECs confine their monitoring to reviewing documents and reports of ongoing studies (*e.g.* clinical trials), which includes reviewing data such as Serious Adverse Event (SAE) reports[25] and protocol violations.[26] In order to protect human participants in research, policies and mechanisms for their protection have to be established and adhered to, whether the research is taking place in public or private institutions.[24] In order to obtain annual approval, researchers must present a report on the progress of their studies. Although this report should include any deviations from the protocol, not all researchers or committees comply with this requirement. This is the case for one third of RECs in México; participants reported that their committees do not require annual renewal, even though it is stipulated in the national guidelines of Conbioetica. Without annual renewal and/or on-site monitoring, protocol violations can rarely be detected, resulting in insufficient protection of the rights and welfare of study participants.

REC training

The importance of competent committees and comprehensive standards for REC functioning in LMICs has been highlighted in the literature.[7,27,28] As already mentioned, over the years, there have been a number of different training programs in Latin America sponsored by the Fogarty International Center of the US-NIH, such as Flacso, in Argentina, and CREEI, in Mexico and the Caribbean region.[29] Although a large proportion of the study participants reported they had taken research ethics courses, some expressed that one of the reasons why the evaluation of a protocol is difficult is their lack of knowledge of certain topics in research ethics. In order to enhance the capacity of REC members in evaluating protocols, national research ethics committees may require a minimum number of training hours in research ethics as a condition for membership in a REC. These institutions could provide different options to candidates, such as online or face-to-face certified courses, to fulfill this requirement. It is worth mentioning that efforts to improve knowledge and capabilities in conducting and reviewing research with human participants began at least 20 years ago and continue today.

Limitations of the study

The overall sample is not representative of the RECs in the countries that took part in the study or in the Mesoamerican region.

Conclusions

Some RECs of our study exhibited lack of compliance with international guidelines, for example: the gender balance requirement, the inclusion of a community member, and allowing that managerial personnel at the institution serve as chair of the REC. Expedited review of protocols having minimal risk is not a frequent practice, and neither is the exemption review for risk-free protocols. This could interfere with the efficiency of the RECs in the timely evaluation of protocols. Besides, RECs of the Mesoamerican region might be seen as less competitive at the international level, as they do not comply with the FWA requirement.

At the operational level, it was observed that REC Institutions do not use an electronic platform, which not only may result in low efficiency but also risks a breach of confidentiality that could potentially lead to a legal situation. In order to improve their efficiency and competitiveness in the evaluation of international protocols, RECs in this region might consider using the free web-based platform that the Pan-American Health Organization (PAHO) offers to all countries of the region; this would make it possible to monitor and enhance the entire protocol evaluation process, as well as to safeguard the confidentiality of the documents[30] and thus render them better qualified. Not all the RECs reported in the study receive appropriate support from their institutions, such as providing the necessary infrastructure for its proper operation and sufficient administrative staff. The lack of financial resources to conduct active site monitoring prevents ensuring not only the quality of the research process but also, in particular, the protection of rights and welfare of participants in clinical trials.[31] RECs do not charge for evaluating external protocols. Funds coming from this source could help address some of its needs. Finally, it was observed that in some cases, RECs are pressured by their institutional authorities to favor certain protocols, which jeopardizes their autonomy.

Recommendations

National and institutional regulations or guidelines should:

- Formulate new mechanisms for the designation of the REC chair instead of this being appointed by the institutional official.
- Consider allowing expedited review for initial protocols with minimal risk and not only for administrative addenda.
- Provide a compensation or other type of incentive to the community member, as well as an institutional acknowledgment to the scientific members in order to render participation an attractive activity for both groups.

National research ethics committees should:

- Specify a minimum number of training hours in certified research ethics courses (online or face-to-face) and promote these courses between RECs. Having qualified personnel in the RECs would ensure higher quality and greater professionalism in the evaluation of protocols.

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