Operational criteria related to biobank research practices: Mesoamerican Project

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Abstract

Objective. To investigate the implementation of international ethics guidelines in Research ethics committees (RECs) to address ethical considerations in biobank research in Mesoamerican countries, given the importance of biobank research and the role of RECs in its evaluation. **Materials and methods.** Based on a 2018 study that used an online survey to assess training needs of RECs in Colombia, Costa Rica, Guatemala, and Mexico, this paper describes information on RECs operating procedures related to biobank research reported by 55 participants. **Results.** More than 70% of participants reported frequently requesting key components of biobank research. Specifying the time and location of sample and data storage was the least reported. 43.6% used a specific consent form, while 41.8% identified gaps in knowledge regarding the inclusion of residual samples. Recontact policies varied across countries and were limited by sample anonymity. **Conclusión.** RECs in Mesoamerican countries lack clear policies on biobanks and have deficiencies in informed consent and governance. Regulatory advances and ongoing training are needed to protect participants' rights.

Keywords: governance; biobank; research ethics committees; informed consent

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Resumen

Objetivo. Investigar la implementación de lineamientos éticos internacionales en los Comités de ética en investigación (CEI) para abordar consideraciones éticas en la investigación con biobancos en países mesoamericanos, dada la importancia de la investigación con biobancos y el rol de los CEI en su evaluación. **Material y métodos.** Con base en un estudio de 2018 en donde se utilizó una encuesta en línea para evaluar necesidades de capacitación de los CEI en Colombia, Costa Rica, Guatemala y México, se describe la información sobre los procedimientos operativos de los CEI en relación con la investigación con biobancos, reportada por 55 participantes. **Resultados.** Más de 70% de los participantes reportaron solicitar frecuentemente componentes clave en la investigación con biobancos. La especificación de tiempo y lugar de almacenamiento de muestras y datos fue la menos reportada; 43.6% usó un formato de consentimiento específico, mientras que 41.8% identificó lagunas en el conocimiento sobre la inclusión de muestras residuales. Las políticas de recontacto variaron entre países y se limitaron por el anonimato de las muestras. **Conclusión.** Los CEI en países mesoamericanos carecen de políticas claras sobre biobancos y presentan deficiencias en consentimiento informado y gobernanza. Se requieren avances regulatorios y capacitación continua para proteger los derechos de los participantes.

Palabras clave: gobernanza; biobanco; comités de ética en investigación; consentimiento informado

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Scientific health research has been transformed by the rise of biobanks, which are essential for studying diseases, personalize therapies, and identifying biomarkers. Biobanks store biological samples, such as blood, tissue and DNA, alongside clinical and epidemiological data, providing researchers with invaluable resources for innovative research.[1] Their rapid growth, diversity of models, networking and data sharing capabilities have driven significant advances in understanding complex diseases, identifying new therapeutic targets, and developing more precise and effective medications.[2]

However, this progress brings ethical and legal challenges, particularly around informed consent, privacy, and data confidentiality. In a globalized and technology-driven landscape with continuous new opportunities and challenges,[3] addressing these concerns is crucial to protect individual rights and maintain research integrity. Issues like intellectual property and data access rights further complicate biobank research governance,[4] highlighting the need for clear regulations on donors' informed consent, personal data protection, research benefits' fair distribution, transparency in sample collection, storage, and use in order to build public trust and maintaining system integrity.[5]

Research ethics committees (RECs) play a fundamental role in the governance of biobank research. RECs evaluate the ethical implications of studies involving biobanks, safeguarding participant rights, privacy, dignity and scientific integrity.[6] Nevertheless, ongoing debate persists regarding the scope of REC attributions in biobank research, as they must balance the encouragement of innovative research with prudent safeguards to ensure ethical research.[7]

The growing international interest in biobank research has led to the development of ethical guidelines to address its specific challenges. Key documents include the revised 2024 Helsinki declaration,[8] the 2016 Taipei declaration on ethical considerations regarding health databases and biobanks,[9] the 2016 International ethical guidelines for health-related research involving humans published by the Council for International Organizations of Medical Sciences (CIOMS),[10] the 2023 international guidelines on good governance practice for research institutions,[11] and region-specific initiatives, such as the 2010 OECD guidelines on human biobanks and genetic research databases.[12] These documents highlight the importance of informed consent, confidentiality, and privacy protection in biobank research, promoting respect for individual autonomy and participant welfare, fostering trust and integrity in research involving human biological materials.

Despite these guidelines' existence, their implementation remains uneven, particularly in low-and-middle-income countries. RECs in these regions often face significant challenges, including limited resources, insufficient training, and lack of staff[13,14] hindering their ability to align their processes with international guidelines for biobanks research. Therefore, it's essential to examine how RECs in the Mesoamerican region are applying these guidelines. This understanding is essential to assess whether ethical challenges in biobank research are being properly addressed and to ensure that RECs are equipped to protect participants' rights and promote responsible research practices.

Materials and methods

Study background

The *Instituto Nacional de Salud Pública* (INSP, by its Spanish acronym) in México, in collaboration with the University of South Carolina, developed a research project to characterize the RECs of Mesoamerican countries (Colombia, Costa Rica, Guatemala, and Mexico) during 2017 and 2018. A detailed description of the project can be found elsewhere.[14]

Methodology

This article reports findings from a 2018 study on REC compliance with then-current ethical guidelines. A quantitative and descriptive study was performed by sending online questionnaires to REC members in the four countries. RECs were identified by contacting National Institutes of Health, Ministries of Health records, and references from REC Chairpersons who responded the call. The members' email addresses were obtained to send the questionnaire invitation, which included link, ID, and password. Invitations were addressed to any Committee member, including the chair/director, technical secretary, or administrative coordinator.

An e-consent was obtained, ensuring anonymity of participation. If the questionnaire was not completed, a single reminder was sent within seven working days. No further communication occurred for non-respondents or those who declined participation.

Instrument

For the original research project, a 71-items questionnaire was created, based on the Research Ethics Committee Assessment Toolkit (RECAT)[15] and areas of

interest from the research team (biobanks governance and stewardship). The final questionnaire was reviewed by INSP experts[16] and pre-tested in a pilot study. Data included in this article focuses on 15 questions from the instrument´s fourth section "Operating procedures", addressing three thematic areas:

1) *Informed consent characteristics requested by RECs for biobank research*, including consent for future use of samples; biological samples storage location and duration; specification of people and institutions accessing data and samples; option to withdraw samples from a study; appropriate informed consent type for research on biological material; and appropriate consent procedure for including residual samples in biobanks.

2) *REC´s policies for recontacting participants who reach adulthood in biobanks*, including biobank doesn't initiate recontact, but participants can withdraw their samples; participants are recontacted and may withdraw. If not removed, samples and data may be used according to prior parental permission; participants are contacted and their consent is requested. If they don't respond or cannot be located, samples and data may be used according to parental prior permission; participants are contacted and their consent is requested. If they don't respond or are not located, samples and data are destroyed; and participants are not recontacted because the samples are anonymized.

c) *RECs role in the formation of research biobanks*, including to train and advice to biobanks and researchers on how (and why) to implement consent; to verify that biobank research proposals comply with the country's current policy, and to monitor the implementation of the approval procedure in practice

Analysis

A univariate descriptive analysis was conducted to present the country's characteristics. Due to low observation numbers in some countries, the informed consent characteristics variable was recategorized into two groups: "Always and almost always" and "Other", while the countries variable was grouped into "Mexico" and "Other countries". Therefore, while the tables present data for each country, the statistical tests results are provided for Mexico and other countries. Despite this reorganization, cell counts remained low, therefore Fisher's exact test was used to explore the association between the two aforementioned variables.

Results

Participant characteristics

A total of 55 subjects responded to the questionnaire. Most (49%) worked at University RECs, 35% at National Institutes of Health RECs, and 16% at hospital RECs. The majority were women (74.5%), over 40 years old (72.7%), and had a health sciences background (63.6%). Most participants had been in the REC for less than five years or between five and nine years (table I).

Informed consent characteristics requested by RECs for biobanks research

Participants reported high frequencies requesting four key components (always and almost always) in biobank research (above 70%) (table II). The first component, requiring consent to store samples for future studies and specifying the location, had the lowest value in Mexico (76.5%). In Colombia, the remaining three components were also the lowest, with 54.5% for sample storage time, 72.7% for specifying persons and/or institutions with access to data and biological samples, and 72.7% for giving the option to withdraw samples from the study.

Most participants (43.6%) reported a specific consent form as appropriate for research with biological material, while 38.2% reported the partially restricted consent, and only 14.5% favored broad consent. Regarding the most appropriate procedure for the inclusion of residual samples in biobanks, 41.8% of participants did not know the appropriate procedure, 18.2% selected the option where researcher is in contact with the participants and the committee required consent obtained, 29.1% considered appropriate to always require consent, and 10.9% selected the option of no contact and no request got. In Mexico and Colombia, the highest percentage of participants declared "not knowing" (41.2 and 63.6%, respectively), while Guatemala and Costa Rica reported higher percentages of participants favoring that committees always request consent (60%).

RECs policies for recontacting participants who reach adulthood

The most reported policy for recontacting participants who reach adulthood in biobanks was that participants weren't re-contacted because their samples were anonymous (43.6%) (table III). The second most frequent policy was recontacting participants and asking

Table I
Sociodemographic characteristics of participants in Mexico, Colombia, Guatemala, and Costa Rica, 2018

	Overall	*Mexico*	*Colombia*	*Guatemala/Costa Rica*
	n (%)	*n (%)*	*n (%)*	*n (%)*
Age (years)				
<40	15 (27.3)	10 (29.4)	4 (36.4)	1 (10.0)
≥40	40 (72.7)	24 (70.6)	7 (63.6)	9 (90.0)
Sex				
Women	41 (74.5)	23 (67.6)	9 (81.8)	9 (90.0)
Men	14 (25.5)	11 (32.4)	2 (18.2)	1 (10.0)
Profession				
Health sciences	35 (63.6)	22 (64.7)	8 (72.7)	5 (50.0)
Social sciences	9 (16.4)	7 (20.6)	2 (18.2)	0
Other (lawyer, administrator, etc.)	11 (20.0)	5 (14.7)	1 (9.1)	5 (50.0)
Period of time being member of the REC (years)				
<5	25 (45.5)	16 (47.1)	7 (63.6)	2 (20.0)
5 to 9	25 (45.5)	16 (47.1)	3 (27.3)	6 (60.0)
≥10	5 (9.1)	2 (5.9)	1 (9.1)	2 (20.0)

REC: Research ethics committees

for consent, if participants could not be located or did not respond, samples and data were destroyed (23.6%). This pattern was repeated in Guatemala and Costa Rica (50% for both policies). In Colombia, the first policy was the most frequent (54.5%), followed by the option where participants are re-contacted and asked for consent. If they cannot be located or do not respond, samples and data may be used in accordance with the previous parental permission (27.3%). In Mexico, the first policy remains the most common (38.2%), with the second and third policies sharing equal frequency (20.6%).

RECs role in the formation of research biobanks

Table IV shows that the most frequent REC role in biobank formation was "Monitoring the implementation of the approval procedure in practice" (76.4%), followed by the other two roles (70.9%). In Guatemala and Costa Rica, the most common role was "To verify that biobank research proposals comply with the country's current policy" (90.0%), while in Colombia the most frequent role was "Monitoring the implementation of the approval procedure in practice" (81.8%). In Mexico, two roles shared equal frequency: "To train and advice to biobanks and researchers on how to implement consent" and "Monitoring the implementation of the approval procedure in practice" (76.5%). While all three roles are appropriate, the 2016 CIOMS Guidelines[10] describe several other RECs' roles, highlighting their importance in the biobank research management and governance.

Discussion

Compliance with ethical guidelines

This article presents findings from a 2018 study assessing compliance of RECs with the ethical guidelines applicable at the time and discusses them in light of updated international standards. A key finding was that most participants reported consistently including essential elements in informed consent for biobank research: biological samples storage time and location (70.9%), consent to store samples for future studies (81.8%), samples withdrawal options (81.8%), and identification of individuals/institutions with access to data and samples (85.5%). Notably, 81.8% of participants reported requiring consent to store samples for future studies, while 43.6% considered specific consent the most appropriate model, highlighting a divergence between knowledge and actual REC practices. Although general compliance with informed consent requirements in biobank research wasn't low, the critical importance of these standards calls for stronger adherence.

Table II
INFORMED CONSENT CHARACTERISTICS REQUESTED BY RECS FOR BIOBANK-RELATED RESEARCH IN MEXICO, COLOMBIA, GUATEMALA, AND COSTA RICA, 2018

	Overall	*Mexico*	*Colombia*	*Guatemala/ Costa Rica*	*p value**
	n (%)	*n (%)*	*n (%)*	*n (%)*	
Frequency with which informed consent					
Requests consent to store samples for future studies					
Always / almost always	45 (81.8)	26 (76.5)	9 (81.8)	10 (100.0)	
Other option	10 (18.2)	8 (23.5)	2 (18.2)	0	0.29
Specifies location and time of storage of biological samples					
Always / almost always	39 (70.9)	23 (67.6)	6 (54.5)	10 (100.0)	
Other option	16 (29.1)	11 (32.4)	5 (45.5)	0	0.56
Specifies persons and/or institutions that will have access to data and biological samples					
Always / almost always	47 (85.5)	29 (85.3)	8 (72.7)	10 (100.0)	
Other option	8 (14.5)	5 (14.7)	3 (27.3)	0	1.00
Gives the option to withdraw their samples from the study and provide contacts to do so					
Always / almost always	45 (81.8)	28 (82.4)	8 (72.7)	9 (90.0)	
Other option	10 (18.2)	6 (17.6)	3 (27.3)	1 (10.0)	1.00
Additional informed consent characteristics related to biobank research					
Type of informed consent considered appropriate for research on biological material					
Broad consent	8 (14.5)	7 (20.6)	0	1 (10.0)	
Partially restricted	21 (38.2)	11 (32.4)	5 (45.5)	5 (50.0)	
Specific consent	24 (43.6)	15 (44.1)	5 (45.5)	4 (40.0)	
Doesn't know	2 (3.6)	1 (2.9)	1 (9.1)	0	
Appropriate consent procedure for the inclusion of residual samples in biobanks					
If the researcher is not in contact with participants, the committee does not request consent	6 (10.9)	6 (17.6)	0	0	
If the researcher is in contact with participants, the committee requests consent	10 (18.2)	7 (20.6)	1 (9.1)	2 (20.0)	
Regardless of contact with participants, the committee always requests consent	16 (29.1)	7 (20.6)	3 (27.3)	6 (60.0)	
Doesn't know	23 (41.8)	14 (41.2)	7 (63.6)	2 (20.0)	

RECs: Research ethics committees
* Fisher's Exact Test (two sided) was used, considering two comparison groups between countries: Mexico and other countries

Regarding informed consent models, specific consent was most commonly preferred (43.6%) for biobank research, followed by partially restricted consent (38.2%) and broad consent (14.5%). The limited adoption of broad consent may reflect insufficient governance or limited awareness of the guidelines supporting this option. Regarding this topic, a tiered consent approach, where participants decide the research type their samples may be used for, is also a valid option.[17] The 2016 CIOMS guidelines (guidelines 11-12)[10] and the 2023 CIOMS guidelines (chapter 4)[11] recommend specific consent for particular uses of data/samples, and broad consent when future, unspecified research is anticipated, provided there is robust governance to

Table III

RECs' policies on recontacting biobank participants upon reaching adulthood in Mexico, Colombia, Guatemala, and Costa Rica, 2018

	Overall n (%)	*Mexico* n (%)	*Colombia* n (%)	*Guatemala/Costa Rica* n (%)
Policy on whether children should be re-contacted in adulthood to obtain their permission for new biobank research				
Yes	19 (34.5)	12 (35.3)	3 (27.3)	4 (40.0)
No	13 (23.6)	5 (14.7)	4 (36.4)	4 (40.0)
I don't know	23 (41.8)	17 (50.0)	4 (36.4)	2 (20.0)
Re-contact policy for participants who reach adulthood in biobanks				
Biobank doesn't initiate re-contact, but participants can withdraw their samples and/or data				
Yes	8 (14.5)	6 (17.6)	1 (9.1)	1 (10.0)
Once children reach maturity, they are re-contacted and given the opportunity to withdraw. If they don´t withdraw, samples and/or data may be used in accordance with the permission previously given by their parents				
Yes	7 (12.7)	4 (11.8)	3 (27.3)	0
Participants are re-contacted and asked for consent. If they cannot be located or do not respond, samples and data may be used in accordance with the permission previously given by their parents				
Yes	10 (18.2)	7 (20.6)	2 (18.2)	1 (10.0)
Participants are re-contacted and asked for consent. If they cannot be located or do not respond, samples and data are destroyed				
Yes	13 (23.6)	7 (20.6)	1 (9.1)	5 (50.0)
They are not re-contacted because these are anonymous samples				
Yes	24 (43.6)	13 (38.2)	6 (54.5)	5 (50.0)

RECs: Research ethics committees

Table IV

RECs role in the formation of research biobanks in Mexico, Colombia, Guatemala, and Costa Rica, 2018

In relation to biobanks formation, the participation of the RECs is:	*Overall* *n (%)*	*Mexico* *n (%)*	*Colombia* *n (%)*	*Guatemala/Costa Rica* *n (%)*
To train and advice to biobanks and researchers on how (and why) to implement consent	39 (70.9)	26 (76.5)	8 (72.7)	5 (50.0)
To verify that biobank research proposals comply with the country's current policy	39 (70.9)	23 (67.6)	7 (63.6)	9 (90.0)
Monitor the implementation of the approval procedure in practice	42 (76.4)	26 (76.5)	9 (81.8)	7 (70.0)

RECs: Research ethics committees

uphold ethical standards. Given the increasing trend of data sharing between biobanks, RECs should promote training their members encouraging the use of broad consent to align with participants' wishes regarding their biological samples and associated data.

Regarding this point, and the lack of clear legislation on research with biobanks, the INSP REC in Mexico[18] has developed a two-step broad consent strategy for biobank research with potentially vulnerable populations, used since the 2022 *Encuesta Nacional de Salud y Nutrición* (Ensanut, by its Spanish acronym) survey in Mexico. Firstly, this includes providing potential participants with an "Information Note" about donating samples for the biobank and future analyses, followed by a second visit two weeks later to confirm the participant's decision, facilitating a better understand-

ing of the study characteristics, its risks and benefits, enhancing an informed decision-making.

Other concern was the lack of clarity regarding the appropriate informed consent procedure for including residual samples in biobanks: 41.8% of participants were unaware of proper consent procedures, and only 29.1% reported consistently requesting it. According to 2016 CIOMS guidelines (guideline 11),[10] consent should always be sought for the inclusion of residual samples unless donors cannot be contacted, under which RECs may authorize their use. Therefore, to strengthen ethical compliance, broad informed consent should be implemented in accordance with the revised Helsinki Declaration,[8] alongside enhanced biobank governance.[19]

Another issue was the lack of recontact policies: 41.8% of participants were unaware of policies for re-contacting participants who reach adulthood for new biobanks research, and only 34.5% reported having a recontact policy. This contrasts with the 2023 CIOMS guidelines (chapter 4)[11] and the Taipei declaration[9] requiring procedures to obtain consent from minors once they reach adulthood. Thus, RECs should ensure that researchers propose and formalize mechanisms for obtaining consent when participants reach adulthood, using tools as the e-consent could allow a more dynamic consent, facilitating its process and compliance.[20,21]

Legislative context and local guidelines

Mesoamerican countries have made significant legislative progress in biobank research. Colombia's Law 2287 (2023)[22] established the National Biobank System regulating the use of human biological samples for research[23] by defining roles and obligations of biobanks actors, consent procedures, management of clinical, genetic, biological, and personal data, reinforcing ethical standards and biobank governance in biomedical research.

Costa Rica lacks specific biobank legislation, but has relevant provisions in the 2021 biomedical research regulations[24] and the 2011 personal data protection legal framework.[25] These could pave the way for future legislation taking into account current challenges.[26]

Guatemala's 2019 human clinical trials regulations[27] includes provisions on biological sample use; however they lack specific provisions for personal data protection, nonetheless, these regulations could serve as a foundation for developing a regulatory framework for biobank research.[28]

In Mexico, legislation for biobank research is still under development,[29] specially in comparison to advances in other regions.[30] The regulatory framework remains fragmented, without a unified approach. The *Comisión Nacional de Bioética* research ethics committee guidelines briefly refers to biobanks,[31] while the General Health Law also refers to biological material, and there is specific legal framework regarding personal data protection and sensitive genetic information.[32,33] Notably, biobanks, such as the Mexican Social Security Institute (IMSS, by its Spanish acronym) Biobank,[34] and the Mexican Biobank of Metabolic Diseases[35] have been established.

This study is the first to assess the compliance of biobank research policies across Mesoamerican RECs, revealing substantial gaps in the implementation of ethical guidelines and informed consent practices in biobank research, highlighting the need for clearer regulations and continuous training for REC members. Additionally, specific consent remains the preferred model among REC members, probably due to lack of experience in using and sharing data/samples. However, as biobanking research continues to expand globally, broad consent adoption becomes essential to prevent unapproved samples use.

Regarding existing regulations in the study countries, we highlight the legislative advances in Mesoamerican countries, such as Colombia's Law 2287, which establishes the National Biobank System, ensuring high ethical standards in biomedical and technological research.

Based on our results, we recommend that Mesoamerican countries promote specific legislation and clear regulations that strengthen RECs work in biobanks research. Key priorities include strengthening the use of broad consent, ensuring informed consent is obtained for residual samples, developing clear policies for re-contacting participants, promoting governance practices aligned with international guidelines, and encouraging the development of unified and specific legislation to regulate biobank research. In conclusion, it is imperative to establish a more robust and coherent regulation for biobank research in Mesoamerica, inspired by international ethical standards and adapted to local realities.

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