

MODELS OF BIOETHICS AND UNIVERSITY GOVERNANCE IN LATIN AMERICA: IMPLICATIONS FOR RESEARCH OVERSIGHT AND INSTITUTIONAL POLICY

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ABSTRACT

Universities in Latin America mediate the translation of bioethical theory into governance practices that regulate research, training and institutional accountability. This paper examines the principal bioethical models present in Latin American higher education — principlism, communitarian/social bioethics and the bioethics of intervention — and analyzes how these frameworks shape university governance of research ethics across Brazil, Mexico, Argentina, Colombia and selected Central American countries. Using a documentary mixed-method approach that combines peer-reviewed literature, official regulatory documents and regional studies, the paper constructs a comparative portrait of national and institutional ethics systems and interprets real indicators of ethics-committee distribution and regulatory development. Informant excerpts from UNESCO Redbioética, Volnei Garrafa and the GoEtiCA/Canario Guzmán et al. study are incorporated to ground conceptual claims. Findings indicate that Brazil's consolidated CEP/CONEP system offers a model of centralized governance and continuing quality-improvement, while other countries reveal heterogeneous, often fragmented arrangements that produced vulnerabilities during the COVID-19 emergency. The paper concludes that universities should strengthen training, embed community-oriented review practices consistent with regional bioethical models, and engage in regional networks to improve resilience and ethical consistency.

1. INTRODUCTION

Bioethical thought in Latin America has evolved through encounters with Anglo-American principlism while simultaneously producing conceptions that foreground social determinants, collective rights and structural injustice. The four principles of autonomy, beneficence, nonmaleficence and justice remain central to clinical training and individual protections in institutional review processes, but regionally rooted approaches such as communitarian bioethics and the so-called bioethics of intervention argue that ethical reflection must emphasize social contexts, power asymmetries and public goods (Garcia, Fernandes, & Goldim, 2019; Garrafa & Porto, 2003). Universities function as pivotal arenas where conceptual commitments become governance instruments: ethics committees, institutional policies, curricular priorities and community-engagement mechanisms are shaped by the bioethical models that academic leadership and disciplinary cultures endorse. This paper investigates which bioethical models predominate in university governance across selected Latin American countries, how those models are reflected in national and institutional arrangements for research ethics, and what concrete governance gaps were exposed during the COVID-19 pandemic.

2. METHOD

The study adopts a documentary mixed-method design that integrates bibliographic mapping, policy review and targeted use of public datasets and peer-reviewed accounts describing the structure and distribution of research ethics committees (RECs) or their national equivalents. The literature search prioritized peer-reviewed syntheses on bioethics in Latin America, national-level regulatory summaries, and qualitative regional studies assessing ethics governance during health emergencies. Sources included a 2019 mapping of bioethics scholarship in the region (Garcia et al., 2019), a 2022 qualitative policy study of Central America and the Dominican Republic (Canario Guzmán et al., 2022), and a 2024 quality-improvement evaluation of Brazil's CEP/CONEP system (Castro et al., 2024). Where possible I used official regulatory descriptions compiled by ClinRegs and national agency documents to corroborate system features for Mexico, Argentina and Colombia. To complement quantitative indicators, I selected short published excerpts from regional actors — UNESCO Redbioética statements and Garrafa's formulation of bioethics of intervention — as documented in open documents and editorial texts, noting when excerpts are taken from published material rather than interviews. The comparative table below synthesizes published counts and descriptive indicators; each table cell cites its supporting source.

3. RESULTS

The documentary evidence shows a markedly heterogeneous landscape. Brazil's national system, managed through institutional CEPs coordinated by CONEP (the National Research Ethics Commission), is the most consolidated model and has been the subject of recent quality-improvement efforts that documented approximately 770–870 active CEPs in national counts reported between 2021 and 2023 (Castro et al., 2024; CONEP reporting summarized in national analyses). Mexico's governance rests on COFEPRIS oversight for clinical trials and a distributed network of institutional RECs registered through national mechanisms such as CONBIOÉTICA, with mapping studies identifying dozens of institutional committees but no single centralized subsystem comparable to Brazil's CEP/CONEP structure (ClinRegs; Domínguez-Esponda et al., 2020). Argentina requires independent ethics committees for regulated clinical trials and relies on ANMAT rules in combination with institutional committees within universities and research centres (ANMAT regulatory summaries). Colombia has issued minimum national guidelines in recent years (2019 onward) that seek to standardize REC formation and operation while universities operate institutional RECs; regional mapping exercises indicate a smaller but growing number of active committees as standardization proceeds. Central American countries and the Dominican Republic present the greatest variation: many lack comprehensive national registration or accreditation frameworks and were shown in the GoEtiCA/Canario Guzmán et al. study to have limited coordination, variable training of committee membership, and weak surge capacity during the pandemic. Table 1 summarizes these indicators with their sources.

Table 1. Selected indicators of national and institutional research-ethics governance in Latin America (published sources)

Country / Region	Principal regulatory feature (published description)	Published indicator / source	Interpretation
Brazil	CEP/CONEP national system with registration and accreditation mechanisms; Q-CEP quality improvement initiative.	National reports and BMC Medical Ethics Q-CEP evaluation: approximately 779–871 registered CEPs reported in national counts (data summarized in Castro et al., 2024; CONEP reports 2022). (BioMed Central)	Consolidated, centralized network enabling coordinated policy and quality-improvement actions.
Mexico	COFEPRIS oversight for clinical trials; institutional RECs registered through national mechanisms such as CONBIOÉTICA; ClinRegs overview of regulatory framework.	ClinRegs country profile and Mesoamerican REC mapping report showing dozens of institutional RECs and recent 2023 updates to submission and review guidance. (clinregs.niaid.nih.gov)	Regulatory framework exists but oversight is distributed and registration is heterogeneous.
Argentina	ANMAT regulation for clinical trials and independent ethics committees; universities maintain RECs.	ANMAT dispositions and legal summaries requiring independent ethics-committee approval (ANMAT dispositions; Baker McKenzie handbook). (anmat.gob.ar)	Formal rules for clinical research exist; institutional implementation varies across universities.
Colombia	Ministry guidance and institutional RECs; national standardization since 2019.	Ministry guidelines and regional mapping (Domínguez-Esponda et al.; national reports). (PubMed)	Progress toward standardized practices with ongoing capacity-building needs.
Central America & Dominican Republic	Wide variation; several countries lack centralized registration or accreditation frameworks.	Canario Guzmán et al., 2022 qualitative study documenting fragmentation and limited coordination during COVID-19. (BioMed Central)	Fragmentation and limited surge capacity exposed by public-health emergencies.

All numeric and descriptive data in Table 1 are drawn from the sources cited in the third column; where national registries reported different counts across years, I cite the most recent peer-reviewed synthesis or official report available. The sources consistently emphasize that registries and reporting practices differ across countries, which constrains granular cross-country comparison but does not detract from the broader pattern of Brazil’s relative centralization and the fragmentation elsewhere.

Qualitative material and published informant reflections reinforce how theoretical commitments shape governance choices. Volnei Garrafa’s argument that a bioethics attentive to peripheral countries must prioritize structural injustice and social determinants remains frequently cited in Latin American debates and has been used to justify governance measures that incorporate community interests and social impact into ethics review criteria (Garrafa & Porto, 2003). UNESCO Redbioética explicitly frames regional bioethics as an instrument to support human rights and to encourage networked capacity-

building among universities and ethics actors, stating that the Redbioética network is “engaged on the growth of a bioethic that supports human rights in the Latin America and the Caribbean region” (UNESCO, 2020). Published participants in the GoEtiCA study described how pandemic pressures exposed coordination weaknesses: one workshop summary observed that “there has been lack of coordination, which was exacerbated during the pandemic with the increase in demand for COVID-19-related reviews” (Canario Guzmán et al., 2022). These published excerpts show that regional actors link normative concerns about equity and social justice to concrete governance reforms and capacity-building priorities. ([Redbioética/UNESCO](#))

4. DISCUSSION

Interpreting the documentary results through the lens of bioethical models clarifies several patterns. Principlism continues to inform the technical architecture of review processes in university settings, especially where institutional RECs focus on informed consent, individual risk–benefit calculus and privacy protections. Yet the prevalence of communitarian and interventionist approaches in Latin American scholarship and policy networks shapes governance choices that go beyond individual protections to prioritize beneficence at the community and population level, equity in research agendas and participatory mechanisms in review. Brazil’s CEP/CONEP model demonstrates that a coordinated national system can institutionalize both technical standards and capacity-building mechanisms; the Q-CEP initiative documented in recent evaluations serves as an example of how systemic quality improvement can be organized at scale (Castro et al., 2024). Where national coordination is weaker, as in several Central American states, universities and ethics committees often shoulder the burden of locally adapting standards, which may yield inconsistent review quality and diminished surge capacity in emergencies. The COVID-19 pandemic functioned as a stress test that highlighted the governance consequences of these conceptual and organizational differences: institutions embedded in more coordinated national systems were generally better equipped to process high volumes of expedited reviews while maintaining documented standards, whereas fragmented systems experienced backlogs, ad hoc procedures and uneven protections (Canario Guzmán et al., 2022; ClinRegs summaries).

The implications for university governance are substantive. Embedding community engagement into review criteria and institutional research strategies can align procedures with regionally salient bioethical commitments to social justice. Institutional investment in formal training programs for REC members, implementation of digital submission and tracking systems, and the development of contingency protocols for public-health emergencies will improve resilience and ethical consistency. Participation in regional networks such as UNESCO Redbioética and Central American REC collaboration initiatives can facilitate knowledge transfer and harmonization of standards without erasing local contexts. Strengthening governance does not require abandoning principled protections for individuals; rather, it requires integrating individual-focused safeguards into broader institutional commitments to collective wellbeing and equity.

5. CONCLUSION

The bioethical landscape that informs university governance in Latin America is plural and dynamic. While principlism remains a foundational reference for research ethics committees, the region’s distinct orientation toward communitarian perspectives and the bioethics of intervention has pushed institutional governance to account for social determinants and justice-oriented priorities. Brazil’s CEP/CONEP system constitutes a relatively mature model of national coordination and quality improvement, whereas Mexico, Argentina, Colombia and many Central American countries show mixed arrangements marked by varying degrees of fragmentation and capacity constraints. The COVID-19 pandemic underscored the practical significance of these differences and catalyzed renewed calls for capacity-building, harmonization and regional collaboration. Universities seeking to align governance with Latin American bioethical models should strengthen REC training and infrastructure, institutionalize community-engagement practices in review, and participate in transnational networks to share standards, tools and emergency protocols.

6. REFERENCES

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