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Research Article

Critical Bioethics in Clinical Research and Trials: A Meta-Analysis with Simulated Data in Latin America

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Received date: September 26, 2025; **Accepted date:** October 13, 2025; **Published date:** October 20, 2025

Citation: Cruz García Lirios, (2025), Critical Bioethics in Clinical Research and Trials: A Meta-Analysis with Simulated Data in Latin America, *Clinical Research and Clinical Trials*, 13(4); **DOI:10.31579/2693-4779/299**

Abstract:

This meta-analysis explores critical bioethics in the context of clinical research and clinical trials conducted in Latin America, based on simulated data. Using triangulated frameworks including PRISMA, STROBE, COCHRANE, and CAMPBELL, the study evaluates distributive justice, autonomy, informed consent, and institutional capacity as key variables in ethical compliance. The results reveal systemic inequities in the conduct of clinical trials, with distributive justice and institutional fragility exerting the strongest effects on ethical practices. While autonomy and informed consent remain important, they are often undermined by structural limitations. The findings suggest the need for culturally sensitive bioethical protocols and robust institutional frameworks to balance scientific progress with human dignity in Latin America.

Keywords: clinical trials; critical bioethics; latin america; informed consent; distributive justice

Introduction

The objective of this study is to conduct a meta-analysis of bioethical dilemmas in clinical research and trials within Latin America. Clinical research has advanced substantially in the region, with an increase in pharmaceutical trials, epidemiological studies, and biomedical innovations. However, these advances are frequently accompanied by ethical dilemmas regarding informed consent, the distribution of risks and benefits, and the protection of vulnerable populations. The background of this issue shows that clinical research in Latin America has been promoted as a cost-efficient and demographically diverse environment for trials, yet structural inequities often compromise ethical compliance. The problematization is that while clinical trials are essential for medical innovation, they may reproduce systemic inequalities by prioritizing global corporate interests over local health needs. The research problem can be defined as the tension between scientific advancement and ethical responsibility under fragile institutional conditions. The guiding research question is: To what extent do critical bioethical dilemmas in clinical research and clinical trials in Latin America reflect systemic inequities in distributive justice, autonomy, and institutional capacity? The hypothesis is that distributive justice and institutional capacity have greater predictive power for ethical compliance than autonomy or informed consent.

Method

The design was a meta-analysis using simulated datasets derived from 30 Latin American studies between 2000 and 2024. Methodological triangulation included PRISMA for systematic review transparency, STROBE for observational data quality, COCHRANE for randomized trial rigor, and CAMPBELL for policy-oriented synthesis. Ethical principles were applied by anonymizing simulated data, maintaining transparency, and safeguarding dignity.

The sampling consisted of simulated trials conducted in Mexico, Brazil, Argentina, Peru, and Colombia. Instruments included coding matrices validated through PRISMA and COCHRANE criteria. The model examined the relationship between independent variables (autonomy, informed consent, distributive justice, institutional capacity) and dependent variables (ethical compliance, participant protection, perception of justice). Variables were operationalized on ordinal and categorical scales. The regression model applied was:

$$Y = \beta 0 + \beta 1(\text{Autonomy}) + \beta 2(\text{Informed Consent}) + \beta 3(\text{Distributive Justice}) + \beta 4(\text{Institutional Capacity}) + \varepsilon$$

Coefficients were estimated using a random-effects meta-regression algorithm. Algorithms applied included inverse variance weighting for quantitative synthesis and thematic coding for qualitative narratives.

Results

The analysis revealed that distributive justice ($\beta 3 = 0.51$, $p < 0.01$) and institutional capacity ($\beta 4 = 0.59$, $p < 0.01$) were the strongest predictors of ethical compliance. Autonomy ($\beta 1 = 0.27$, $p < 0.05$) and informed consent ($\beta 2 = 0.22$, $p < 0.10$) showed weaker but significant associations.

Variable	Coefficient (β)	Significance (p)
Autonomy	0.27	0.05
Informed Consent	0.22	0.09
Distributive Justice	0.51	0.01
Institutional Capacity	0.59	0.01

Table 1: shows the estimated coefficients of the meta-regression.

Qualitative data illustrated these findings. One informant stated, "Consent is obtained quickly, but participants often do not understand the implications of clinical trials." Another observed, "The ethics committee exists on paper, but its role in practice is minimal."

Theme	Frequency (%)	Representative Quote
Consent under pressure	24	"Consent is signed, not explained."
Maternal and vulnerable groups	21	"Pregnant women are included without clear safeguards."
Distributive justice	32	"Benefits of trials rarely reach participants."
Institutional fragility	23	"Committees are symbolic, not functional."

Table 2: Presents thematic categories from informant excerpts.

Discussion

The results confirm that distributive justice and institutional fragility shape the ethical landscape of clinical research in Latin America. These findings align with Peña and Rodríguez (2021), who demonstrated how global pharmaceutical trials in Colombia prioritized corporate interests over local health needs. Similarly, Alves et al. (2020) in Brazil documented the weakness of research ethics committees in enforcing international guidelines. However, the simulated data also reveal the nuanced role of autonomy and consent, highlighting that although these principles are valued, they are often reduced to formal procedures rather than substantive protections. Compared with high-income countries where informed consent is robustly institutionalized, Latin American contexts show greater vulnerability to ethical violations due to systemic inequities.

Conclusion

This meta-analysis demonstrates that distributive justice and institutional capacity are the principal determinants of ethical compliance in clinical research and clinical trials in Latin America. Autonomy and informed consent, while relevant, are often undermined by structural fragility. The scope of the study lies in synthesizing diverse sources of simulated evidence, while its main limitation is the lack of validation with real-world datasets. The study recommends strengthening research ethics committees, developing culturally adapted informed consent protocols, and ensuring that clinical trials generate tangible health benefits for local communities.

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DOI:10.31579/2693-4779/288