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"Clinical Trials in Latin America: Where Ethics and Business Clash"

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Review by Norman M. Goldfarb

"Clinical Trials in Latin America: Where Ethics and Business Clash" addresses the issue of human subjects protection in an environment where economic incentives are often high, the population is often vulnerable, and the protective infrastructure is often weak. The book focuses on five countries in Latin America, where 80% of Latin American studies are conducted.

In theory, a country could interrupt clinical research until strong protections are in place, but, as India has demonstrated recently, the existing infrastructure cannot sustain itself for long. And, it is probably not practical to develop the infrastructure in the absence of ongoing research. The question, thus, is what research should be allowed while the protective infrastructure evolves? In the absence of a suitable, properly enforced policy by the country, the burden is on study sponsors and investigators to decide which studies can be ethically conducted in that country, what limitations should be placed on them, and what oversight should be provided. Ethical research can certainly be conducted in the absence of highly effective regulatory authorities and ethics committees, but *someone* has to take responsibility.

Capable, well-intentioned people are working to build up Latin America's protective infrastructures, but resources are limited and progress is incremental. (For perspective, consider the current, halting efforts in the U.S. to update only a tiny fraction of the Common Rule.) The issue is not just about ethics, but about the quality of the data collected when investigators perceive they will not be held to high standards. The international clinical research community should decide what, if any, carrots and sticks it should use to accelerate progress, and not just in Latin America. If conducting a study in Brazil, for example, is X% cheaper than conducting it in the United States, how much of that savings should be applied to developing Brazil's clinical research infrastructure?

The following passage illlustrates the challenges that Latin America faces:

> **3.4.2 Ethics Committees**
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> There have been functional problems with ethics committees in most countries. Some countries have a registry of ethics committees; very few have an accreditation system; and none have a formal performance evaluation. Brazil has disabled ethics committees that did not meet minimum requirements, and the Peruvian regulatory authority has also banned one committee. The regulations often specify that ethics committee members must be independent of the administration of the institutions in which they are based and must include community representation and experts in clinical research and in bioethics. In practice, this does not always happen.
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> Rivera and Ezcurra (2001) studied 22 Latin American ethics committees and found that 80% of their members were contracted by the institution where the committee was operating. In most cases (16 of the 22), members had been nominated by the Directors, and only six committees elected their members. Physicians were heavily represented in most committees, and there was little community representation. Other researchers have found similar situations. Valdez-Martinez et al. (2004. 2005, 2006. 2008) studied the ethics committees of the Mexican Social Security Institute (IMSS) and found that most lacked experts in clinical research and bioethics, fewer

than half kept minutes of the meetings, more than 50% of the members had roles as Directors in the IMSS institutions, and the refusal rate for research projects was less than one per thousand. Brazil is considered to have the most advanced and best organized system for the ethical review of research protocols involving humans (Novaes et al. 2008), but it still has problems (Freitas 2006). In several countries of the region, if one ethics committee rejects a project, the researcher can seek the approval of other committees until approval is obtained.

While there are well-functioning ethics committees, there are many that do not sufficiently protect study participants, either because they lack the technical capacity to do so or because they respond to the interests of the researchers, study sponsors, or the institutions where the clinical trial will take place (Clarin 2002; Fuentes and Revilla 2007). Moreover, various regional experts have affirmed that committee members who ask too many questions and stimulate controversy during the process of protocol review are dismissed from the committees.

The book includes 13 chapters:

- Introduction
- A Review and Critique of International Ethical Principles
- Globalization and Clinical Research in Latin America
- The Regulatory Framework and Case Studies from Argentina
- Politics and Clinical Trials in the Province of Cordoba
- Brazil: The System for the Protection of Voluntary Participants in Research
- Progress and Challenges of Clinical Research with New Medications in Brazi
- A Small Country forBig Pharma: Costa Rica
- Cervical Cancer and Development of HPV Vaccines in Guanacaste, Costa Rica
- Ethical Guidelines for Clinical Trials in Mexico: Theory and Practice
- Who Decides? Informed Consent for Cancer Patients in Mexico
- A View from Inside: Regulation and Ethical Conflicts in Peru
- Conclusion

The book is available in bookstores.

Reviewer

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