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## "Clinical Trial Compliance in Underdeveloped Countries"

**FDAnews, 2006, 114 pages, $295.00**

**Review by Norman M. Goldfarb**

"Clinical Trial Compliance in Underdeveloped Countries" presents compliance as a balancing act between home-country regulations, international guidelines, and local rules and customs. In a 25-page essay, the authors discuss important considerations and provide eye-opening examples. The essay includes many words-to-the-wise, such as:

- HIPAA regulations apply if a U.S. institution (that qualifies as a HIPAA Covered Entity) conducts research overseas or receives foreign data that includes protected health information.
- According to the current version of the Declaration of Helsinki, the protocol should describe post-trial access by study subjects to medical care, e.g., the study drug.
- In many developing countries, the ministry of health expects to participate in the selection of study sites.
- In some developing countries, the ministry of health wants the right to veto publication of study results from that country.
- Some developing countries, e.g., Zimbabwe, have research regulations that are more stringent than in the U.S.
- In some developing countries, medical records consist of index cards completed by the physician (never the nurse) and taken home by the patient between visits.
- U.S. and local regulations may conflict. For example, U.S. regulations require gender balance on IRBs, a problem in patriarchic cultures.

The essay is accompanied by two must-read documents: a Department of Health & Human Services (HHS) report on the globalization of clinical trials and a National Bioethics Advisory Committee (NBAC) report on equivalent protections for human subjects in different countries.

The book is available at http://www.fdanews.com

### Reviewer

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