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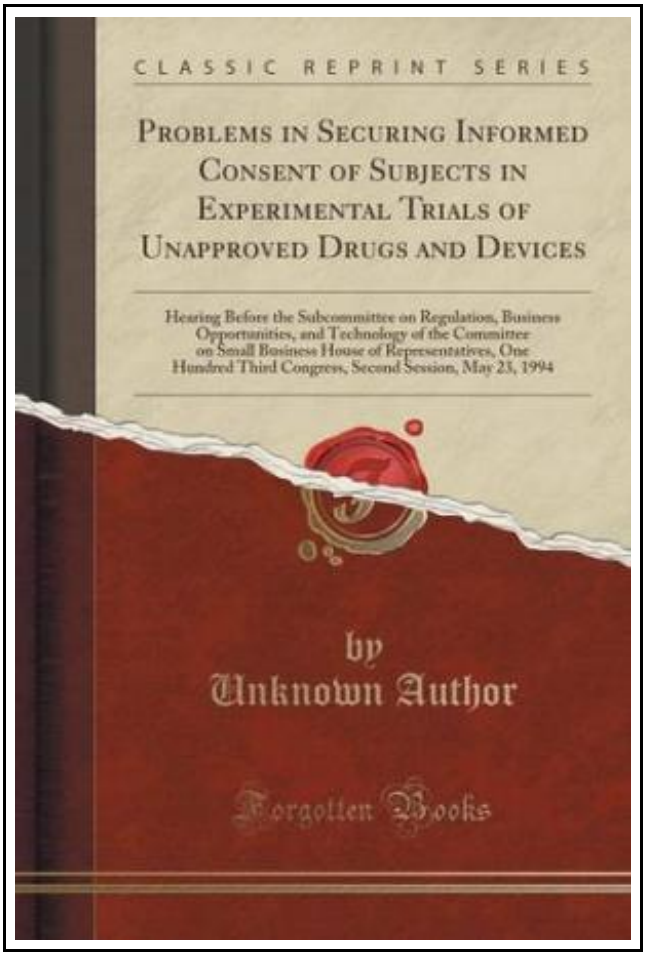

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Forgotten Books, United States, 2015. Paperback. Book Condition: New. 229 x 152 mm. Language: English . Brand New Book ***** Print on Demand *****.Excerpt from Problems in Securing Informed Consent of Subjects in Experimental Trials of Unapproved Drugs and Devices: Hearing Before the Subcommittee on Regulation, Business Opportunities, and Technology of the Committee on Small Business House of Representatives, One Hundred Third Congress, Second Session, May 23, 1994 The subcommittee met, pursuant to notice, at 10:10 a.m., in room 2359-A, Rayburn House Office Building, Hon. Ron Wyden (chairman of the subcommittee) presiding. Chairman Wyden. The subcommittee will come to order. Today the Subcommittee on Regulation, Business Opportunities and Technology examines the protection of our fellow citizens involved in clinical trials of unapproved drugs and medical devices. We are especially concerned with the effectiveness of both public and private institutions, and individual researchers, charged with the supervision of persons who may become test subjects. The key ingredient in this process is the provision of informed consent; the demand that test candidates be fully informed of the risks and objectives of any unapproved drug or device test prior to giving their consent to be included in trials. Most in medical science view this as a fundamental patient right. In this country, even in life or death situations, competent individuals have a basic right to refuse treatment. This right is especially important in decisions involving unapproved products. In practice, however, the provision of informed consent is inconsistently applied. Turf protecting Federal agencies have produced contradictory and confusing policies, which put vulnerable Americans at risk, frustrate drug and device companies, and stymie medical research. This issue is terribly complex. Our society demands that potentially life saving new drugs and devices are tested for safety and effectiveness, and are brought to market quickly with as...

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