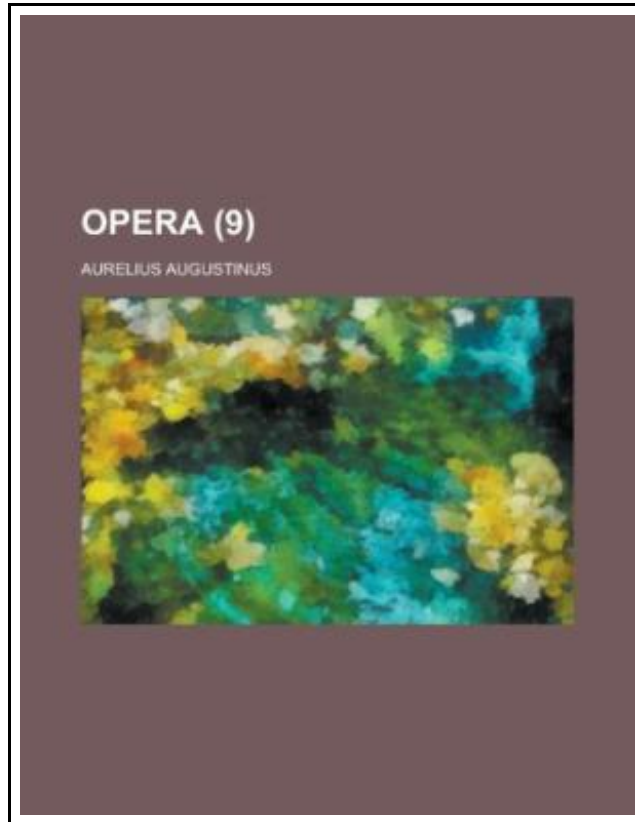


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RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 64 pages. Original publisher: Washington, D. C. (P. O. Box 37050, Washington 20013) : The Office, 2000 OCLC Number: (OCoLC)45482215 Subject: Human experimentation in medicine -- United States -- Evaluation. Excerpt: . . . B-283287 IRBs in our sample that were run by universities. In particular, we observed fewer problems with IRB membership, staff, space, and documentation at university-run IRBs than at VA-run IRBs. University-run IRBs were also more likely to conduct thorough and timely continuing reviews than VA-run IRBs. University-run IRBs we visited were not without problems, however. We found that some IRB-approved consent forms at each site omitted required information and some investigators used nonapproved consent forms. We found problems with the content or use of informed consent forms at Informed Consent all of the medical centers we visited. We found that some informed consent documents that had been approved for use by IRBs provided incomplete or unclear information. In addition, we found some studies in which the investigators used nonapproved consent forms when enrolling subjects. We also found one instance in which research was conducted without consent. Informed consent is a primary ethical requirement of research with human subjects and reflects the principle of respect for persons. The ability of competent subjects to make informed decisions about whether to participate in research and the ability of legally authorized representatives to protect those who are unable to provide consent because they are incapacitated are undermined when IRBs fail to ensure that all required information is included in consent forms or when investigators fail to obtain consent using approved procedures. We found that 60 percent of the 138 IRB-approved consent forms that we Information in IRB-Approved randomly sampled from lists of active projects provided incomplete or Consent...



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