

CIP EXAM STUDY GUIDE

COMPANION VOLUME TO THE CIP EXAM WORKBOOK

**INSTITUTIONAL REVIEW BOARD (IRB) RELATED CERTIFICATION
DHHS AND FDA REGULATIONS REVIEW
OHRP AND FDA GUIDANCE REVIEW**

FOR

- **IRB ADMINISTRATORS**
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PRAMOD M.LAD Ph.D., CIP, CCRP

FIRST EDITION

Cip Study Guide

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and responsibilities of the IRB have grown increasingly complex. This complex environment demands that the IRB be staffed and managed by professionals. As a part of affirming the professionalism of IRB staff administrators and directors, the Public Responsibility in Research and Medicine (PRIM R) provides an important forum for education and affirmation of ethical standards for the performance and management of clinical research. An important component of this program is the certification exam known as the CIP Certified IRB Professional. This examination, which is offered twice a year, covers a wide range of regulatory topics. The book addresses the key issues in federal regulations outlined in statutes including Title 45 part 4 Protection of Human Subjects, Title 21 part 50 Protection of Human Subjects, Title 21 part 56 Institutional review Boards, Title 21 part 54 Financial Disclosures by Clinical Investigators. Also addressed are key FDA statutes involved in the regulation of clinical trials, Title 21 part 312 Investigational New Drug Application, Title 21 part 812 Investigational Device Exemptions, and Title 21 part 11 Electronic Records and Electronic Signatures. The CIP exam covers material based not only on these regulations but also on guidances issued by OHRP and the FDA. Special attention has been devoted to material covered in these guidances. Also addressed are interactions of the IRB with other committees in the institutional environment.

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