

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**
- **IRB STAFF**
- **CLINICAL RESEARCH PROFESSIONALS**
- **CLINICAL RESEARCH COORDINATORS**
- **NURSING RESEARCH PROFESSIONALS**
- **HEALTH CARE RESEARCH**
- **PROFESSIONALS**

PRAMOD M.LAD Ph.D., CIP, CCRP

FIRST EDITION

Cip Study Guide

CL Gary

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Pramod Lad, 2018-09-02 **PRODUCT DESCRIPTION** The Institutional Review Board (IRB) is responsible for the review of a wide variety of clinical research. As the complexity of clinical research has grown over the years, the duties 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.

This workbook provides one tool for the preparation and study for the CIP examination. The book addresses the key issues in federal regulations outlined in statutes including Title 45 part 46 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. Some of the material also covers ICH guidelines for clinical trial management. The workbook is organized in distinct chapters each of which covers one aspect of the regulations or guidances. The multiple choice questions are deliberately designed to instruct on core materials rather than offering linguistically ingenious choices. An answer key is provided. The workbook is therefore designed not only to prepare for the CIP examination but also to educate IRB professionals on matters which arise frequently in IRB administration.

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Table of Contents Cip Study Guide

1. Understanding the eBook Cip Study Guide
 - The Rise of Digital Reading Cip Study Guide
 - Advantages of eBooks Over Traditional Books
2. Identifying Cip Study Guide
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Cip Study Guide
 - User-Friendly Interface
4. Exploring eBook Recommendations from Cip Study Guide
 - Personalized Recommendations
 - Cip Study Guide User Reviews and Ratings
 - Cip Study Guide and Bestseller Lists
5. Accessing Cip Study Guide Free and Paid eBooks
 - Cip Study Guide Public Domain eBooks
 - Cip Study Guide eBook Subscription Services
 - Cip Study Guide Budget-Friendly Options

6. Navigating Cip Study Guide eBook Formats
 - ePub, PDF, MOBI, and More
 - Cip Study Guide Compatibility with Devices
 - Cip Study Guide Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Cip Study Guide
 - Highlighting and Note-Taking Cip Study Guide
 - Interactive Elements Cip Study Guide
8. Staying Engaged with Cip Study Guide
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Cip Study Guide
9. Balancing eBooks and Physical Books Cip Study Guide
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Cip Study Guide
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Cip Study Guide
 - Setting Reading Goals Cip Study Guide
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Cip Study Guide
 - Fact-Checking eBook Content of Cip Study Guide
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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