

CIP EXAM STUDY GUIDE

COMPANION VOLUME TO THE CIP EXAM WORKBOOK

INSTITUTIONAL REVIEW BOARD (IRB) RELATED CERTIFICATION

DHHS AND FDA REGULATIONS REVIEW

OHHRP 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

Pramod Lad

Cip Study Guide:

Cip Exam Study Guide Pramod M. Lad, 2019-02-03 PRODUCT DESCRIPTION This study guide provides one tool for the preparation and study for the CIP examination. It is a companion book to the CIP Exam Workbook. The sequence of chapters in the study guide follows the same sequence as in the CIP exam workbook and the flow of ideas in each chapter is concordant with the sequence of questions in the workbook. It is recommended that the two books be studied together for the most effective exam preparation. The study guide is organized in distinct chapters each of which covers one aspect of the regulations or guidances. The study material is designed to instruct on core information relevant to the examination. However, it is hoped that the study guide can also function as an IRB Handbook. The study guide is therefore designed not only to prepare for the CIP examination but also to educate IRB professionals and Clinical Research Coordinators on matters which arise frequently in IRB administration. 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. 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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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 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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