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IMPORTANT

The time allowed for this exam is 3 hours.

Total marks: 200

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Section A: Multiple-Choice Questions

Question 1. For the following multiple-choice questions, fill in the circle of the letter that identifies the most correct answer.

Example: Ⓐ Ⓑ ● Ⓒ

DO NOT MARK THE ANSWERS ON THESE PAGES.

USE THE FIRST PAGE OF YOUR ANSWER BOOK.

1. Which of the following is one of the standard additional perils that may be added to the Basic Fire Policy?
- (A) Insurrection
 - (B) Rebellion
 - (C) Revolution
 - (D) Riot

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Marcel A. Müller



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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 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 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 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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