PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

CIP
CERTIFIED IRB PROFESSIONAL

CIP® Exam
Body of Knowledge/Content Outline

Domain	Exam Section	Percentage of Exam
1	**Human Subjects Protection** A. Historical Background B. Research Ethics 1. Belmont Principles 2. International Codes and Standards (i.e., Nuremburg, Helsinki, ICH GCP-E6) C. Regulatory Applicability 1. Common Rule 2. FDA (e.g., human subjects, drugs/biologics, devices) 3. Other FDA (e.g., HUD, expanded access, emergency use) 4. Agency Differences (e.g., DOD, DOJ, NIH)	29%
2	**IRB Responsibilities** A. IRB Membership and Authority B. Levels of Review C. Regulatory Criteria for Approval D. Informed Consent E. Privacy and Confidentiality Considerations (e.g., HIPAA, CoC) F. Vulnerable Populations G. Monitoring and Review of Reportable Events (e.g., unanticipated problems, noncompliance, research misconduct) H. Meeting Minutes	54%
3	**Institutional Responsibilities** A. Cooperative Research (e.g., reliance, local context, sIRB) B. Policies, Procedures, and IRB Records C. Conflict of Interest (e.g., IRB, researchers, institutional) D. Regulatory Reporting Obligations E. Document Management and Retention F. Educational Programs	17%