PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

CIP
CERTIFIED IRB PROFESSIONAL

CIP® Exam References and Resources

Regulations	
21 CFR 50/56	Informed Consent, Protection of Human Subjects, IRB
21 CFR 312	Investigational Drugs
21 CFR 361	Radioactive Drugs for Research Purposes
21 CFR 600	Biologics
21 CFR 812	Investigational Devices
34 CFR 98	PPRA – Protection of Pupil Rights Amendment
34 CFR 99	FERPA – Family Educational Rights and Privacy
45 CFR 46 (Subparts A, B, C, D)	IRB, Human Subjects, Special Protections
45 CFR 160/164	HIPAA
21 CFR 814 (Subpart H)	Humanitarian Use Devices
Ethical Codes	
Belmont Report	Ethical Principles and Guidelines for the Protection of Human Subjects of Research
CIOMS	International Ethical Guidelines for Biomedical Research
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Good Clinical Practice (E6)
Declaration of Helsinki	
Nuremberg Code	
Training Modules	
OHRP Protection Foundational Training	
Guidance	
FDA Information Sheets for Institutional Review Boards and Clinical Investigators	
OHRP Policy Guidance	

Note: Some of the above files are webpages, and others are documents that will appear in your downloads folder.

The CIP Council has prepared the list below as an example to assist candidates in preparing for the Certification Examination for IRB Professionals. These references, which are listed alphabetically, contain journals and textbooks which include information of significance to human research protection programs practice. Inclusion of references on this list does not constitute an endorsement by the CIP Council or PRIM&R of specific professional literature or educational materials. Note: The CIP examination does not test on additional institutional policies and procedures developed by individual IRBs.

Books
Bankert, E. & Gordon, B. Institutional Review Board: Management and Function, Third Edition. Sudbury, MA: Jones and Bartlett Learning, 2021.
Citro, C., Ilgen, R. & Marrett, C. Protecting Participants and Facilitating Social and Behavioral Sciences Research. National Academies Press, 2003.
Dunn, C. & Chadwick, G. Protecting Study Volunteers in Research: A Manual for Investigative Sites. (4th ed.). Boston: Center Watch, 2012.

Periodicals
Human Research Report. Omaha, NE. The Deem Corp. deemcorp.com/human_research.html
IRB: A Review of Human Subjects Research. Briarcliff Manor, NY. The Hastings Center

Common Research-Related Acronyms	
3Rs	Replacement, Reduction, and Refinement
AAHRPP	Association for the Accreditation of Human Research Protection Programs, Inc.
AE	Adverse Event
APHIS, AC	Animal and Plant Health Inspection Service, Animal Care (USDA)
AV	Attending Veterinarian
AVMA	American Veterinary Medical Association
AWA	Animal Welfare Act
AWAR/AWR	Animal Welfare Act Regulations
AWIC	Animal Welfare Information Center (USDA)
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CER	Comparative Effectiveness Research
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
COC	Certificate of Confidentiality
COI	Conflict of Interest
DEA	Drug Enforcement Agency
DHHS	Department of Health and Human Services
DMC	Data Monitoring Committee
DMR	Designated Member Review
DOD	Department of Defense
DOEd	Department of Education
DOJ	Department of Justice
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
EPA	Environmental Protection Agency
ESCRO	Embryonic Stem Cell Research Oversight Committee
FCR	Full Committee Review
FDA	Food and Drug Administration
FERPA	Family Educational Rights and Privacy Act
FFP	Fabrication, Falsification, and Plagiarism
FOIA	Freedom of Information Act
FWA	Federalwide Assurance
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GINA	Genetic Information Nondiscrimination Act
GLP	Good Laboratory Practice
GWAS	Genome-Wide Association Studies
HDE	Humanitarian Device Exemption
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HPA	Horse Protection Act

HRPP	Human Research Protections Program
HUD	Humanitarian Use Device
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
ICF	Individual Consent Form/Informed Consent Form
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
ILAR	Institute for Laboratory Animal Research
IND	Investigational New Drug
IO	Institutional Official
IRB	Institutional Review Board
IVD	In Vitro Diagnostics
LAR	Legally Authorized Representative
NCI	National Cancer Institute
NDA	New Drug Application
NHP	Nonhuman Primate
NIH	National Institutes of Health
NSF	National Science Foundation
NSR	Non-Significant Risk
OEHS	Occupational and Environmental Health and Safety
OHRP	Office of Human Research Protections (HHS)
OIG	Office of Inspector General
OLAW	Office of Laboratory Animal Welfare (NIH)
ORI	Office of Research Integrity
OSHA	Occupational Safety and Health Administration
PAM	Post-Approval Monitoring
PCOR	Patient-Centered Outcomes Research
PHI	Protected Health Information
PHS	Public Health Service
PI	Principal Investigator
PPRA	Protection of Pupil Rights Amendment
QA	Quality Assurance
QI	Quality Improvement
QRP	Questionable Research Practices
RCR	Responsible Conduct of Research
RIO	Research Integrity Officer
RM	Research Misconduct
SACHRP	Secretary’s Advisory Committee on Human Research Protections
SAE	Serious Adverse Event
SBER	Social, Behavioral, and Educational Research
SOP	Standard Operating Procedure
SR	Significant Risk
USDA	United States Department of Agriculture
VA	Department of Veterans Affairs
VMO	Veterinary Medical Officer
VVC	Veterinary Verification and Consultation
WHO	World Health Organization