

CIP Exam Resources and References

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 Assurance Training Online \(HHS\)](#)

Guidance

[FDA Information Sheets for Institutional Review Boards and Clinical Investigators](#)

[OHRP Policy Guidance](#)

References

The CCIP has prepared the reference 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 CCIP 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. & Amdur, R. Institutional Review Board: Management and Function, Second Edition. Sudbury, MA: Jones and Bartlett Learning, 2006.

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