

## CIP Exam Resources and References

### Regulations

<a href="#">21 CFR 50/56</a>	Informed Consent/Protection of Human subjects, IRB
<a href="#">21 CFR 312</a>	Investigational Drugs
<a href="#">21 CFR 361</a>	Radioactive Drugs for Research Purposes
<a href="#">21 CFR 600</a>	Biologics
<a href="#">21 CFR 812</a>	Investigational Devices
<a href="#">34 CFR 98</a>	PPRA—Protection of Pupil Rights Amendment
<a href="#">34 CFR 99</a>	FERPA—Family Educational Rights and Privacy
<a href="#">45 CFR 46</a> (Subparts A, B, C, D)	IRB, Human Subjects, Special Protections
<a href="#">45 CFR 160/164</a>	HIPAA
<a href="#">21 CFR 814 (Subpart H)</a>	Humanitarian Use Devices

### Ethical Codes

<a href="#">Belmont Report</a>	Ethical Principles and Guidelines for the Protection of Human Subjects of Research
<a href="#">CIOMS</a>	International Ethical Guidelines for Biomedical Research
<a href="#">ICH</a>	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Good Clinical Practice (E6)
<a href="#">Declaration of Helsinki</a>	
<a href="#">Nuremberg Code</a>	

### Training Modules

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

*Note: Depending on your browser settings, some of these documents might download directly to your downloads folder instead of opening in a browser window.*

## 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

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