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  IRB, Human Subjects, Special Protections
(Subparts A, B, C, D)
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)

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


Periodicals

Human Research Report. Omaha, NE. The Deem Corp. deemcorp.com/human_research.html