

Harvard University Faculty of Medicine Committee on Human Studies
Electronic Training Book*

1. Ethical Guidelines
 - Nuremburg Code
 - Declaration of Helsinki
 - Belmont Report
 - CIOMS – International Ethical Guidelines for Research involving Human Subjects

2. IRB Regulations
 - DHHS 45 CFR 46
 - FDA 21 CFR 50
 - FDA 21 CFR 56
 - International Compilation of Human Subject Research Protections

3. OHRP Guidance
 - Engagement of Institutions in Research
 - Human Subject Regulations Decision Charts
 - IRB Review of (grant) Applications for HHS Support
 - Knowledge of the Local Research Context
 - Informed Consent Checklist
 - Exemption Categories
 - Use of Expedited Review Procedures
 - Expedited Review Categories
 - Research Involving Coded Private Information or Biological Specimens
 - Research Use of Stored Data or Tissues
 - Research Involving Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles
 - Guidance on the Genetic Information Nondiscrimination Act
 - Special Protections for Children as Research Subjects
 - Involvement of Prisoners in Research
 - Continuing Review
 - Approval of Research with Conditions
 - Reviewing and Reporting Unanticipated Problems and Adverse Events

4. Terms of the Federalwide Assurance for the Protection of Human Subjects

* All items listed are hyperlinks to information available on the internet.