Regulations

All Studies

- 45 CFR 46
- Categories of Research That May Be Reviewed by the IRB Through an Expedited Review Procedure
- Comparison of FDA and HHS Human Subject Protection Regulations
- OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events
- OHRP Guidance by Topic

Studies Using Investigational Drugs, Devices, or Biologics

- 21 CFR 50
- 21 CFR 56
- 21 CFR 312 (IND studies)
- 21 CFR 312.2(b) IND Exemption Criteria
- 21 CFR 812 (IDE studies)
- FDA Guidances, Information Sheets, and Notices
- FDA Device Advice - Comprehensive Regulatory Information Regarding Medical Devices
- FDA Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs -- Improving Human Subject Protection (Issued January 2009)
- FDA Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA/BE Studies (Issued December 2012)
- FDA Guidance for Sponsors, IRBs, Clinical Investigators, and FDA Staff: Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that Are Not Individually Identifiable (Issued April 2006)

HIPAA Regulations

- 45 CFR 160, 162, and 164 (combined regulation text)

DoD-Supported Research

- Department of Defense (DoD) policies and links to the DoD Components policies may be found at: http://www.dtic.mil/whs/directives/. See especially DoD Directive (DoDD) 3216.02 “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research.”
• Department of Defense Instruction - Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
• Department of the Navy (DON) Training and Education Guidance for DON-Supported Extramural Performers (2013)