Institutional Review Board
DukeHealth

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 Guidance Documents
- 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 directives homepage
- Department of Defense Instruction (DoDI) 3216.02 - Updated APR 15, 2020 - Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research

- **For Department of the Navy-supported research: SECNAV Instruction 3900.39E CH-1 (issued May 29, 2018) - DoN Human Research Protection Program**
- **Department of the Navy may have additional training certification requirements for Extramural Performers of DoN-supported research**