Policies and Regulations

Policies

Current policies related to the Duke Health IRB and Human Research Protection Program (HRPP) are located here. Click the tab to the left, and you can search for policies in the following categories:

- Compliance
- Conduct of Research
- Conflict of Interest (COI)
- Consent
- Database, Repository, & Retrospective Research
- Drugs, Devices, & Biologics
- Recruitment
- Reporting to the IRB
- Review by the IRB
- State Law Considerations
- Telephone, Mail, E-Mail, or Web-Based Research
- Vulnerable Populations


Regulations

The Duke Health HRPP complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45 CFR 46, 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812, and 45 CFR 164.508-514. The ethical and regulatory requirements of the HRPP apply to all research involving human participants conducted on behalf of Duke Health (regardless of funding or lack thereof) and to all individuals and components of the institution. Find direct links to federal regulations and guidance by clicking the tab to the left.