Compliance and Accreditation

Part 11 Compliance

FDA regulations related to electronic records and electronic signatures are located at 21 CFR Part 11. An Institutional statement regarding Part 11 has been developed to assist study teams in responding to inquiries from sponsors and CROs.

Click Here for the Institutional Statement Regarding Part 11 and Duke Health's Notification to FDA of the Intent to Use Electronic Signatures. (SCROLL TO THE BOTTOM OF THE PAGE)

Compliance Statement

The Duke University Health System IRB (DUHS IRB) complies with all U.S. regulatory requirements related to the protection of human research participants.

Click Here for Compliance Statement

AAHRPP Accreditation

Duke Health's Human Research Protection Program has been fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since March 2009.

AAHRPP accreditation uses a set of objective standards to evaluate the quality and level of protection that an organization provides research participants. Through accreditation, an organization can demonstrate the overall excellence of its research program by providing the most comprehensive protections for research participants. The process is based on self assessment, peer assessment, and continuous quality improvement.

Accreditation benefits research participants and organizations in many ways. Each time a new organization becomes accredited, the global benchmark for human research protection in science is raised.

The goals of AAHRPP accreditation are to:

- Improve the systems that protect the rights and welfare of individuals who participate in research.
- Communicate to the public the strength of Duke Health's commitment to the protection of human research participants.