Researchers

Navigating the IRB review process and complying with federal regulations and institutional policy relating to human subject protection can be challenging. The DUHS IRB reminds researchers that their primary responsibility is to safeguard the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research. Below you will find useful links and answers to common questions.

Training & Education

Getting Started

FAQs

PI/Study Team Checklists

For your convenience, we have attached the PI/Study Team Checklists from the "Forms" page here:

- Humanitarian Use Device Checklist
- IDE Checklist
- IND Checklist
- Research Involving Cognitively Impaired Persons Checklist

IRB Meeting Dates and IRB Rosters

- Click Here for IRB Meeting Dates
- Click Here for IRB Rosters
Tools Available to PI/Research Teams

Here are links to some of the main pages on this website and other tools/guides:

- Duke HRPP Policies
- Standard Language for Consent Forms (with links to Translation Services)
  - English Standard Language
  - Spanish Standard Language
- Locate the Forms You Need
- IVD Regulatory Assessment Guide (should be used to help determine when an In Vitro Diagnostic Device is subject to 21 CFR 812, the FDA’s IDE regulations)
- Links to the Federal Regulations and Guidance
- Federal Wide Assurance Information
- Fees
- Compliance and Accreditation
- IRB Metrics

Other Helpful Websites:

- DOCR Website
- OHRP Guidance by Topic
- OHRP FAQs

Common Consent Form Errors

Click Here for Common Consent Form Errors