Getting Started

As you prepare to submit a study to the DUHS IRB, or if you are wondering whether you have to submit your project to the IRB at all, here are the basic keys to getting started. Familiarizing yourself with these fundamental points will save you time and reduce effort down the road. The IRB is here to assist you at each step in the process.

DUHS IRB Oversight vs. Duke University Campus IRB Oversight?

All research involving human subjects must be reviewed by the DUHS IRB prior to initiation of the research when it:

- is sponsored by DUHS, including all of its institutional components; OR
- is conducted by or under the direction of any employee or agent of DUHS (including a student, resident or fellow) in connection with his/her institutional responsibilities, regardless of funding source (or lack thereof), and regardless of the performance site; OR
- is conducted by or under the direction of any employee or agent of DUHS using any DUHS property or facility; OR
- utilizes DUHS non-public information (e.g., medical records) to identify or contact human subjects.

The Duke University campus IRB maintains a separate Federal Wide Assurance and has responsibility for the oversight and review of human research conducted by Duke University faculty and students. The DUHS IRB and Duke University Campus IRB maintain reciprocal authorization agreements, allowing the DUHS IRB to review biomedical research involving human subjects, conducted by Duke campus researchers, and any FDA-regulated research conducted by campus researchers.

Click Here for the Campus Human Subjects Protections Program Website
How Do I Know if I am Conducting Research with Human Participants?

Research involving human subjects means any activity that either:

- Meets the DHHS definitions of "research" involving a "human subject" or
- Meets the FDA definitions of "clinical investigation" ("research") involving a "human subject".

**DHHS Definitions:**

According to (DHHS) [45 CFR 46.102(d)], research is defined as:

- a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Please note: Activities which meet this definition constitute research per the regulations, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

According to (DHHS) [45 CFR 46.102(f)], a human subject is defined as:

- a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
  - "Intervention" as defined by DHHS regulations means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (for example, providing stimuli to gauge a reaction and response).
  - "Interaction" as defined by DHHS regulations means communication or interpersonal contact between investigator and subject (for example, surveys and interviews).
  - "Private information" as defined by DHHS regulations means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
  - "Identifiable information" as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

**FDA Definitions:**
Clinical Investigation (FDA) [21 CFR 56.102(c)] - any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.

- Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]
- Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]
- Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]

Human Subject (FDA) [21 CFR 56.102(e); 21 CFR 812.3(p)] - an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research that evaluates the safety or effectiveness of a device, the definition includes a human on whom or on whose specimen an investigational device is used. A subject may be in normal health or may have a medical condition or disease.

Note that the Privacy Rule (HIPAA), including its research provisions, applies to both living and dead people, and the research provisions apply when the DHHS definition of research (45 CFR 46.102(d)) is met.

For additional guidance on what types of projects are likely or not likely to be research involving human subjects, click here for the following policy, ?Research for Which Review by the Duke University Health System Human Research Protection Program is Required?. We also suggest looking at OHRP’s Decision Chart of Human Subject Research. If you are still unsure if your project meets the definition of research involving human subjects, please consult with an IRB Chair who can provide guidance in making this determination. Click Here for Contact Information on IRB Staff and Chairs

What Are the Eligibility Requirements for a Principal Investigator?

It is Duke University policy that only those with whom the University has or intends to have an ongoing employment or contractual relationship may serve as Principal Investigator (PI) on research projects submitted to the DUHS IRB. In practice, this means that only regular-rank faculty members may serve in the PI or co-PI roles.

Click Here for the Policy Regarding Who May Serve as Principal Investigator (PI) at Duke
Please note occasional exceptions are made with a personal request (email) from your Department Chairperson or CRU director, sent to Jody Power, the Executive Director of the DUHS IRB.

- Click Here for an Example of the Text that Should Be in the Email
- Click Here for the Spreadsheet Showing the List of Job Codes that Are Required for a Person Serving in the Role of PI.

As a PI, you assume the responsibility of the whole of your research study, including any responsibility delegated to study coordinators and research teams. The full scope of PI responsibilities is described in the Investigator’s Agreement which you electronically sign in eIRB when you submit a study, and can be read by clicking here.

Additional responsibilities are taken on when the PI is also a sponsor. These can be found by clicking here.

What is the Required Training for Duke Health Researchers, & How Do I Gain Access to the eIRB?

All Duke Health researchers must complete the following required training before they are placed on a protocol submitted to the Duke Health IRB, and before they can gain access to eIRB:

- The set of CITI modules (human subject protection training) required for Duke Health researchers, available on the CITI website
  - Click here for directions

After you have completed these above items, your Duke netID will be automatically loaded into the eIRB system within 2 to 3 business days. Then you should be able to log into the eIRB using your Duke netID and password. If you cannot log into the eIRB after 3 business days have passed since you completed the above required items, please email eIRB technical support: eirb@dm.duke.edu

What Are My Responsibilities/Expectations?

Principal Investigator:

- Selection of qualified individuals for roles on study team
- Complete knowledge of protocol, investigator’s brochure(s) and consent form(s)
- Process for oversight of study team
- Process for monitoring subject safety and data collection
- Understanding of reporting obligations to funding sources, FDA, and IRB
- Understanding of scope of responsibility for multi-site studies, PI-initiated studies, federally funded studies
- Understanding of federal, IRB and institutional policies and regulations applicable to the research
- Compliance with the DUHS PI Agreement.
Study Team:

- Understanding of federal, IRB, and institutional regulations and policies applicable to the research
- Appropriate knowledge (according to role) of the study’s purpose(s), activities, risks and benefits
- Thorough understanding of individual role on the study and its relation to regulations and policies
- Understanding of reporting obligations to the PI, IRB, and institution.

How Do I Select and Prepare the Correct IRB Application?

In the eIRB there are 5 protocol application types. In Section 03 of your IRB application, select the correct application type for your study:

- **Regular Study Application**: Most common. The IRB will determine if the study is eligible for expedited review or requires full board review upon submission.
- **Application for Exemption from IRB Review**: Includes Exempt (45 CFR 46.101 (b)), Not Human Subject Research (45 CFR 46.102 (f)), & Not Research (45 CFR 46.102 (d)).
- **External IRB Application**: Includes phase II, phase III, phase IV protocols that are industry sponsored multi-site studies, and includes selected DCRU phase I protocols.
- **Trainee Research While Away from Duke**: Research conducted by medical students overseen by the Office of Curriculum & other student/trainee research away from Duke.
- **Emergency Use of a Test Article**: Emergency use of an investigational drug or biologic, emergency use of an unapproved device.

Information, checklists and policies to help you choose the appropriate application type can be found here:

Expeditied Reviews:

- [Click Here for Checklist for Expedited Reviews (New Protocols)]
- HRPP Policy: [Click Here for Expedited Review]

Exempt Reviews:

- [Click Here for Checklist for Exemption or Relief from Further IRB Oversight]
- HRPP Policy: [Click Here for Research for Which Review by the DUHS HRPP is Required]
- OHRP’s Decision Chart for Human Subject Research

External IRB Application:

- HRPP Policy: [Click Here for Reliance on the IRB of Another Institution, Organization, or an Independent IRB (External IRB Policy)]
- [Click Here for Process for Reliance on an External IRB]
- [Click Here for Process for Reliance on the DUHS IRB by External Institutions or Individuals on Multi-site Studies]
Trainee Research While Away from Duke:

- **HRPP Policy:** [Click Here for Duke Trainees (Medical Students & Others) Engaged in Research Involving Subjects at a Site Other Than Within DUHS]

Emergency Use of a Test Article:

- **HRPP Policy:** [Click here for Emergency Use]

Other Considerations:

- [Click Here for the HRPP Policy: Case Reports]
- [Click Here for the Quality Improvement (QI) Activities vs. Research Policy and Checklist]
  - [Click Here for the QI Summary Template and Instructions]
  - [Click Here for OHRP's Decision Chart for Human Subject Research]
- [Click Here for the Education Research Projects-Summary Template and Instructions]

Are There eIRB User Guides and Tips?

The following are eIRB User Guides and tips for study teams:

- General Reference Guide
- Study Staff User Guide
- Students and Trainees Reference Guide
- Emergency Use Reference Guide
- Research Data Security Plan (RDSP) Reference Guide
- Amendments Reference Guide
- Safety Events and Correspondence Reference Guide
- Re-Open Reference Guide
- Tips for Formatting Complex Documents in Microsoft Word

What Are My Responsibilities After IRB Approval?

The PI/study team must conduct the study in accordance with the Duke IRB-approved protocol and DUHS IRB policies. Please be aware of reporting requirements post IRB approval. The following activities require further submission to the IRB:

- **Amendments:** Any modifications to the study must be approved by the IRB prior to implementation. [Click Here for HRPP Policy: Amendments to IRB-Approved Studies]
- **Continuing Review:** IRB review is required at least annually for all non-exempt research, unless a shorter approval period was determined by the IRB. [Click Here for the HRPP Policy: Continuing Review]
- **Reportable Events:** Serious Adverse Events, Unanticipated Problems, Protocol Deviations and other events must be reported as detailed in the following HRPP Policies:
  - [Click Here for Unanticipated Problems]
- Click Here for Protocol Deviations/Violations

- **Study Closure**: Studies should be closed in accordance with the HRPP Closure Guidelines:
  - Clinical Research Closeout Policy from DOCR that can be found [here](#)
  - Click Here for HRPP Policy: External Use of Duke Data by Former Students & Employees
  - Click Here For HRPP Policy: Retention of Records
  - Click Here For Re-Opening a Closed Study