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], research is defined as:

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The following activities are deemed not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

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

A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
**Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject.

**Private information** includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

**Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

**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.

- 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) 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 for 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 Sharon Ellison, 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 iRIS when you submit a study, and can be read by clicking here.

Additional responsibilities are taken on when the PI is also a sponsor. The Sponsor/Investigator policy can be found by clicking here.

What is the Required Training for Duke Health Researchers?

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 submit in iRIS:

- The set of CITI modules (human subject protection training) required for Duke Health researchers are described on the DOCR CITI Training Support Page
  - Click here for the DOCR CITI Training Support Page

After you have completed these above items, you should be able to log into iRIS using your Duke netID and password.

For help with iRIS:
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 iRIS there are 5 protocol application types. In the "Protocol Application Type" section 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 Research, Not Human Subject Research, & Not Research.
- **External IRB Application**: Any study using an external IRB as the IRB-of-Record.
- **Trainee Research While Away from Duke**: Research conducted by medical students overseen by the Office of Curriculum & other student/trainee research away from Duke.
Individual Patient Expanded Access, Including Emergency Use - Use of an investigational product under expanded access, including emergency use of an investigational drug or biologic or emergency use of an unapproved device.

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

Expedited Reviews:

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

Exempt Reviews:

- 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

Expanded Access/Emergency Use of a Test Article:

- HRPP Policy: Click here for Expanded Access/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 iRIS User Guides and Tips?

Please visit the DOCR iMedRIS Support Page to find training resources for the iRIS system.
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 FDA-regulated research, and all greater than minimal risk 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]
- **Study Closure**: Studies should be closed in accordance with the HRPP Closure Guidelines:
  - [Clinical Research Closeout Policy from DOCR - 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]