Getting Started with Clinical Research

So you’ve got a great research idea. Now what? Use this checklist for guidance on how to:

1. Design Your Study
2. Initiate Your Study
3. Conduct Your Study
4. Close Out Your Study


1. **DESIGN YOUR STUDY**

   - **Develop Your Study Idea**
     Utilize the institutional resources available, including:
     - The [Biomedical, Epidemiology, and Research Design (BERD) Program](https://www.clinicalandtranslational.wfu.edu/berd) provides statistical consultations and support.
     - The [Human Research Protection Program](https://www.clinicalandtranslational.wfu.edu/hrpp) offers guidance on regulatory and consent requirements.
     - The [Study Coordinator Resources Forum (SCARF)](https://www.clinicalandtranslational.wfu.edu/scarf) is a valuable resource for planning a successful study.
     - The [Institutional Data and Safety Monitoring Board (I-DSMB)](https://www.clinicalandtranslational.wfu.edu/idsmb) provides oversight of human research.

   - **Apply For Funding**
     The CTSI website provides information on [featured funding opportunities](https://www.clinicalandtranslational.wfu.edu/funding) and [additional resources](https://www.clinicalandtranslational.wfu.edu/resources).
     - Once you are ready to apply, review the [Proposal Development A-Z](https://www.clinicalandtranslational.wfu.edu/proposal-development) resource for guidance.
     - All funding must be routed to the CTSI’s Office of Sponsored Programs through [InfoEd](https://www.clinicalandtranslational.wfu.edu/infoed) for institutional approval.

   *More About InfoEd:*
   - Final proposals should be submitted to InfoEd **3 days prior** to the sponsor deadline (review the [WFSM Proposal Deadline Policy](https://www.clinicalandtranslational.wfu.edu/policy)).
   - Required routing documents differ by type of award.
   - There may be someone in your department who helps with InfoEd, or you may need to submit to InfoEd yourself.

Wake Forest Clinical and Translational Science Institute: Your partner in research.

For more information, please visit the [CTSI website](https://www.clinicalandtranslational.wfu.edu).
Complete CITI Training

In order to conduct clinical trials and/or human research, you will need to complete CITI Training for Biomedical Investigators.

- Find instructions for how to complete the required training on the CTSI website.

Request eIRB Access

All human research must be submitted through the eIRB.

- The eIRB is a web-based, electronic method to submit, track, and review Human Subjects Applications, including continuing reviews, safety events, and amendments.
- To request eIRB user access, please contact the IRB at 336-716-4542. You will then be able to log into the system with your Medical Center ID and password.
- Learn more in the eIRB User Guide.

OTHER THINGS TO CONSIDER WHEN DESIGNING YOUR STUDY

Plan for Publishing

It will be helpful to begin considering your manuscript from the initiation of your research process. You can get a lot of the initial writing done while designing your project.

- The CTSI offers Manuscript Editing Services to aid in publishing scientific findings.

Find Collaborators

Find collaborators or established researchers to consult.

- Profiles Research Networking Software is a web-based networking tool designed to identify connections and expertise among researchers.
- Research Studios promote multi-disciplinary team formation to provide feedback and translate innovations to specific plans.
- Learn about available mentoring programs focused on research on the Faculty Development website.

Assess Study Feasibility

- The Translational Data Warehouse (TDW) and i2b2 platform allow investigators to query clinical data for cohort identification and pull detailed data for research projects.
  - Prior to IRB approval, i2b2 can be used to pull aggregate numbers and assess the feasibility of a clinical study.
- The Research Toolbox provides information about CTSI resources and answers to other feasibility questions that may be asked by potential sponsors.

Wake Forest Clinical and Translational Science Institute: Your Partner in Research

For more information, please visit the CTSI website.
Learn About Available Resources

- The Study Coordinator Pool provides investigators with research staff to assist in clinical research studies.
- The Clinical Research Unit provides bionutrition, laboratory, and patient care services for approved studies.
- A wide variety of Centers, Cores, and Shared Resources are available for use by research studies.
- The Veterans Affairs Medical Center (VAMC) provides possible research opportunities for Wake Forest faculty.
- The Research Toolbox provides information about institutional resources for research.

2. INITIATE YOUR STUDY

Submit eIRB Application

- The eIRB can be accessed by any computer with internet connectivity.
- You can find detailed instructions in the eIRB User Guide.
- For additional questions, please contact the IRB at 336-716-4542.

Set up Research Budget in CRMS

All clinical research studies must set up their research budget in the Clinical Research Management System (CRMS).

- The CRMS is an electronic application designed for budget development, financial, and overall management of clinical studies.
- Application includes participant tracking, regulatory reporting, and document management.
- CRMS training is available through the CTSI Service Request Form.

Register on ClinicalTrials.gov

The FDA requires mandatory registration and results reporting for certain clinical trials of drugs, biologics, and devices.

- To comply with all regulations, we strongly recommend registering your trial prior to any enrollment of participants.
- Find resources for navigating ClinicalTrials.gov on the CTSI website.

Build Data Collection Forms

You may choose to use REDCap for data collection and management.
- REDCap is a free, secure, web-based application for building and managing online surveys and databases.
- REDCap surveys and databases are HIPAA compliant and include audit trails while data is backed up twice daily.
- Find upcoming REDCap training on the CTSI Event Calendar.
- Learn more about REDCap on the CTSI website.

**Recruit Participants**
- The CTSI’s Participant Identification and Recruitment Unit are available to assess and assist with recruitment goals for clinical trials.
- The Integrating Special Populations Program helps reach underrepresented groups.
- The Recruitment Toolbox provides a variety of resources to assist in recruiting research participants, including Be Involved.

**OTHER THINGS TO CONSIDER WHEN INITIATING YOUR STUDY**

**Consult with EH&S**
Environmental Health and Safety (EH&S) provides broad expertise, assistance, regulatory guidance and practical information to the Medical Center community.
- This includes issues related to biosafety; chemical safety; emergency management and response; environmental management; fire and life safety; industrial hygiene; occupational safety; and radiation safety.
- Learn more on the EH&S website.

**Train Personnel**
- CITI Training is required for all human research study staff personnel.
- CRMS Training is required for clinical study budget management.
- REDCap Training may be required if you plan on using REDCap for data management.
- Clinical Study Staff Orientation Modules are available online for fundamental areas of clinical research studies.

**Apply for Certificates of Confidentiality**
Certificates of Confidentiality (CoCs) allow researchers to refuse to disclose names or other identifying characteristics of research subjects in response to legal demands.
Certificates are issued by NIH and other Department of Health and Human Services (HHS) agencies to researchers to help protect the privacy of human subjects enrolled in sensitive, health-related research.

- Learn more on the NIH website.

***Report INDs/IDEs***

Regulatory support and assistance navigating FDA regulations for Investigational New Drug (IND) and Investigational Device Exemption (IDE) applications is available from the CTSI.

- Learn more about the guidance and service available on the CTSI website.

### 3. CONDUCT YOUR STUDY

#### Conduct Participant Visits

- The Study Coordinator Pool provides investigators with research staff to assist in clinical research studies.
- The Clinical Research Unit provides bionutrition, laboratory, and patient care services for approved studies.
- The CTSI offers Research Navigation and Project Management services for medical center studies.
- A wide variety of Centers, Cores, and Shared Resources are available for use in research studies.
- Check the Research Toolbox for more information about institutional resources.

#### Manage Budgeting and Billing

Find specific information on managing clinical trial budgets, both industry and federal, through the CTSI's Office of Sponsored Programs.

- The CTSI offers guidance on navigating the Clinical Research Management System (CRMS).
- There are also courses offered specializing in specific budget areas. See the CTSI Educational Offerings for available sessions.
- The CTSI’s Grant Management Core provides investigators with reliable, experiences administrative support to assist in all facets of grant management.

#### Submit an IRB Continuing Review

DHHS and FDA regulations requires the IRB to continually review ongoing research at various intervals and, at least, annually.

- Some human research studies may be granted Exempt registration.
To request continuing review of a protocol, the principal investigator or designee should complete an appropriate request via eIRB.

Instructions for this process can be found on page 68 of the HRPP/IRB Policies and Procedures.

Submit a Progress Report for Federal Sponsors
Clinical studies that are federally supported must submit a Research Performance Progress Reports (RPPR).

- These are required for research grant and cooperative agreement awards to standardize recipient reporting on federally-funded research projects.
- Resources and instructions for RPPR’s can be found on the CTSI website.

Collect and Assess Data
REDCap is available for data collection and management.

- REDCap is a free, secure, web-based application for building and managing surveys and databases.
- Learn more about REDCap on the CTSI website.

The Translational Data Warehouse (TDW) and i2b2 platform allow investigators to query clinical data and pull data.

- Once a study has received IRB approval, i2b2 can be used to pull personal health information.

OTHER THINGS TO CONSIDER WHEN CONDUCTING YOUR STUDY

Submit IRB Amendments
It may be necessary to submit amendments within the eIRB.

- The Human Research Protection Program (HRPP) will review submitted amendments and determine next steps.
- For instructions on submitting amendments, please see the eIRB User’s Guide.
- Be aware that there may be charges for IRB amendments to industry studies.

Access Available Expertise

- The Veterans Affairs Medical Center (VAMC) offers collaboration opportunities.
- The Biomedical, Epidemiology, and Research Design (BERD) Program offers statistical consultations and support.
- **Research Studios** are available to connect researchers with experts who can provide valuable feedback and advice.
- **Wake Forest Innovations** brings industry together with Wake Forest scientists and clinicians.
- Check the **Research Toolbox** for more information about institutional resources.

### Report AEs and Protocol Deviations

Research teams are required to promptly report AEs and protocol deviations to the IRB.

- An adverse event (AE) is an unanticipated occurrence that results in increased pain, distress, or health risk to a study participant.
- A protocol deviation is any departure from the procedures approved in the IRB protocol.
- Reporting AEs and protocol deviations assists in determining the cause and preventing re-occurrence.
- Find instructions for reporting on the [CTSI website](#).

### Apply for Supplemental or Diversity Funding

Requests for supplemental and diversity funding to an existing project are processed as proposals through the Office of Sponsored Programs (OSP).

- Find more information on these types of funding and the request process on the [CTSI website](#).

### Request Study Coordinators

The **Study Coordinator Pool** provides investigators with reliable, experienced research staff to assist in clinical research studies.

- Study Coordinators are a valuable resource to any study and can help with various steps in a research process.

### 4. CLOSE OUT YOUR STUDY

### Award Closeout

Closeout is the process of documenting and assuring the fulfillment of the terms and conditions of the award or contract and making final report of all study by-products.

- All technical, financial, and other reports must be submitted as required to the sponsoring agency.
- Learn more about the closeout procedure for each type of award on the [CTSI website](#).
Cite the CTSA
The number of attributed publications is a key measure of a program’s productivity and ability to obtain future funding.

- All publications, press releases, or other documents that result from the utilization of any Wake Forest CTSI resources, including data and images, are required to credit the CTSA grant.
- Find citation examples on the CTSI website.

Publish Your Manuscript
Publishing scientific findings is an essential component of success in academia.

- CTSI offers the Manuscript Editing Services for Wake Forest investigators.
- The results of federally funded studies must be made publicly available to comply with the NIH Public Access Policy through submission to PubMed Central.

OTHER THINGS TO CONSIDER WHEN CLOSING OUT YOUR STUDY

Get Help with Data Analysis
The Biomedical, Epidemiology, and Research Design (BERD) Program offers statistical consultations and analyses.

- Services are available through both informal open office hours and more formal support.

Close Out on ClinicalTrials.gov
The FDA requires mandatory registration and results reporting for certain clinical trials of drugs, biologics, and devices.

- To comply with all regulations, remember to close out your clinical study on ClinicalTrials.gov.
- Find resources for navigating ClinicalTrials.gov on the CTSI website.

Publicize Your Study
Now that all the hard work is done, get the word out there!

- Let us know about the results of your study, as well as any associated publications.
- The CTSI can help to publicize your accomplishments and connect you with other researchers in your area and new opportunities.
- Contact the CTSI at CTSI@wakehealth.edu.