UH Clinical Research Roadmap

A GUIDING TOOL

The UH Clinical Research Roadmap will guide you step-by-step through the research process here at UH from getting started through study close-out.

Each step references useful tools, templates, policies, training and educational resources appropriate to your current place in the research process.

ADDITIONAL GUIDANCE

For additional guidance, please contact the Research Integration & Education Office.

University Hospitals
Clinical Research Center

WWW.UHHOSPITALS.ORG/CLINICAL-RESEARCH

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I. Getting Started

Welcome to Clinical Research Community at University Hospitals! Engaging in research provides a unique opportunity to have substantial impact. Whether you engage in research at any level, at the academic medical center in Cleveland or at a UH community location, the UH Clinical Research Center (CRC) is available to support you. This Center provides support across all aspects of clinical and translational research and is the centralized infrastructure that supports our investigators and their teams, throughout the UH System.

1. RESEARCH TRAINING

The CRC offers a catalog of courses available to anyone working with UH. Clinical Research Orientation is required for all PIs as well as study staff. Additional courses are offered in a live classroom setting, virtual classroom as well as available online in the GPS system. Contact your UH manager for access to GPS which is required to register for both classroom and online courses.

We can also customize education and training specific to your needs and come to your location at a time convenient for your team or when your team typically gathers.

Read:

- ☐ New Researcher Checklist
- ☐ Code of Federal Regulations
  - 45 CFR Part 46 - Applies to all human subjects research
  - FDA Regulations - Applies to FDA regulated research
- ☐ Good Clinical Practices Guidelines: GCP E6 R2
  - Guidance document outlining good practices on conducting human subject research.
- ☐ Investigator Manual for IRB Submissions
  - This Investigator Manual is designed to guide you through policies and procedures related to the conduct of human subject research that are specific to the University Hospitals Cleveland Medical Center Institutional Review Board (UHCMC IRB).
- ☐ UH Research SOPs
  - GA-104 Scope of Practice
  - GA-105 Investigator Responsibility for Study Team Training and Documentation
  - GA-107 Investigator Training
  - GA-108 Investigator Initiated Research

Attend:

- ☐ Required
  - CITI Training and CREC Certification: Completing Collaborative Institutional Training Initiative (CITI) grants entrance in the Continuing Research Education Credits (CREC) Program. This is your certification in

Protections Training which is an IRB requirement for all staff listed on a UH study personnel table.
    - Investigator Training: Required for Principal Investigators and strongly recommended for all others
    - UH Research Orientation: Required for all research staff new to UH, new to a research role at UH, and UH Research Credentialed non-UH employees.
        - OPTION 1 - Principal Investigators (PIs) and Physicians (approx. 30 min.)
        - OPTION 2 - Staff & credentialed non-employees involved in research (approx. five hours)

☐ Velos Clinical Research Management System Training
    - *Required* if conducting research with IRB oversight
        - Velos for Principal Investigators
        - Velos for Study Coordinators

☐ DOT/IATA Training and Certification: Shipping and Handling Hazardous Materials
    - Search UH GPS for the current version or ask your manager to assign the training to your transcript

☐ Getting Started with Your Research

☐ Getting Started with Chart Review Studies

☐ Introduction to Common Rule Changes

☐ The Basics, Module 1: Federal Regulations and Good Clinical Practice

☐ Clinical Trials: What you Need to Know

🗁 Refer to:

☐ UH Research Education & Training Website

☐ UH Research Education Catalog

2. DEPARTMENT LEVEL TRAINING

Some departments may require staff to have specific training. The department's administrator can assist in determining any department specific training or policies that are needed.

3. RESEARCH & IRB POLICIES, AND RESEARCH SOPs

We have a number of local requirements that may apply to your research. It's your responsibility to familiarize yourself with the policies so you can determine which apply to the type of work you are doing. Following are quick links to help:

☐ UH Research Policies

☐ Investigator Manual for IRB Submissions

☐ UH Research SOPs

4. FINDING A RESEARCH STUDY TEAM

Some studies may require more than one physician or other clinical staff (ie nurses and medical students). Some studies may benefit from non-clinical staff (ie study coordinators and undergraduate interns). During protocol feasibility, the workload of the study should be assessed and decisions should be made if you need more study team members.

If your study team will include non-UH personnel (ie undergraduate students, medical students, clinical staff from other institutions, etc.), those personnel must be UH Research Credentialed in order to access UH systems and PHI. Research Credentialed personnel are also granted a UH email address that must be used when communicating UH research information and data.

You may also opt to have an intern to build a pipeline of potential employees. The Clinical Research Center has hundreds of undergraduate and high school students interested in a clinical research internship.

If you need research-trained staff to help you on your study, the Research Support Core offers many fee for service staff members to assist you in your project.

📌 Note:

- ☐ You must contact UHResearchCredentialing@UHhospitals.org prior to credentialing a person from non-affiliated institution, see SOP for affiliated institutions.

☎ Contact:

- ☐ UHResearchCredentialing@UHhospitals.org for any questions about research credentialing
- ☐ ResearchInternships@UHhospitals.org for potential intern candidates
- ☐ ResearchSupport@UHhospitals.org for research-trained staff

🗁 Refer to:

- ☐ UH Research Credentialing Process Website
- ☐ How to Hire a Clinical Research Intern
- ☐ A Mentor's Guide to Successful Internships
- ☐ A Mentee's Guide to Successful Internships
- ☐ Intern or Research Assistant PRN Job Descriptions – Contact ResearchInternships@UHhosptials.org or your HR Representative

🗎 Read:

- ☐ UH Research SOP
  - GA-103 UH Research Credentialing

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- ☐ UH Policy
  - R-46 Clinical Research Credentialing

5. RESOURCES TO HELP YOU GET STARTED

The CRC has a diverse range of resources to help you in your research. Visit the CRC website for complete information and core services to support your research.

📂 Refer to:

- ☐ Clinical Research Center Core Services
- ☐ Clinical Research Toolbox
- ☐ REDCap Information

📖 Attend:

- ☐ CTSC Clinical Research Project Management Series 1: Guide to the Basics
- ☐ CTSC Clinical Research Project Management Series 2: Clinical Trials

6. IDENTIFY A FACULTY SCIENTIFIC MENTOR

Contact your Department Chair, Vice-Chair for Research, Administrator or Academic Coordinator who can help match mentors to mentees. Your mentor will assist you in the development in your research project and how to properly conduct research at UH.

☎ Contact:

- ☐ Can't identify a mentor or need another department to collaborate? Contact ClinicalResearch@UHhospitals.org for suggestions.

7. VETTING A RESEARCH IDEA OR INDUSTRY SPONSORED TRIAL IN STUDY FEASIBILITY

It's important to ensure a study has scientific merit, resources available for success, an adequate patient population meeting inclusion and exclusion criteria, and the study is financially feasible before beginning. Consider collaborating with other departments and institutions and get a statistical review if your study is investigator initiated. Map out a Recruitment & Community Outreach strategy, subject screening plan, and work through overall study logistics.

📌 Note:

- ☐ **Studies should also be entered into the Velos Clinical Research Management System at this time.**
  - Forms to be completed:
    - **Startup - PI Compensation_Qualifying Status Form:** Required, must be reviewed, dated, and electronically signed by the PI

- **Startup - Invoiceable Fees Checklist Form:** Required, so Grants & Contracts knows which fees need to be negotiated into the contract budget.
- **Startup - IDS Request Form:** Required if there is an investigational drug, so IDS can provide a quote for the investigational drug storage, monitoring, and dispensing.
- **Startup - Coordinator Workflow Job-Aide:** Optional, will help efficiently guide you through everything required for study start-up
- Any other form with "Startup" in the title if using other services

☎ Contact:

☐ TriNetX or Research IT (requests for data prior to 2015) to build a report to assess potential study subject volume. For feasibility, an aggregate or de-identified data set can be provided. Once your study has obtained IRB approval approved PHI can be released.
- TriNetX
- Research IT Workfront Request Job Aid can be found in the Research Toolbox under Clinical Research Data Requests.

☐ The Core Library has access to several hundred publications, databases, and eBooks. The Core Librarians are able to conduct a literature search for researchers and assist in citation managers. They are also able to review the CWRU Kelvin Smith Library resources.
- Contact corelibrary@UHhospitals.org for assistance.

Read:

UH Research SOP
- SP-201 Protocol Feasibility Assessment
- SS-314 Velos eResearch – Access and Data Entry Requirements

Use:

☐ TriNetX for Study Feasibility

☐ Velos Clinical Research Management System
- Velos Application Login
- DWP Site

Attend:

☐ The Basics, Module 3: Study Feasibility through Study Activation

☐ Selecting the Number or Patients for your Experimental Clinical Research Study or Chart Review

☐ How to Get your Paper Published

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8. IDENTIFY FUNDING SOURCE

One of the major clinical research challenges that researchers face is lack of financial resources. Securing funds from your department, a public or private grant or foundation, or otherwise takes planning and human resources. Ask your mentor to assist in finding grants to apply for. Consult with the Research Finance Team to identify all expenses and build a comprehensive study budget to ensure that you request adequate financial resources to complete your project.

☎ Contact:

- ☐ Institutional Relations & Development to request grant submission support and financial strategy coaching
- ☐ NIH, DOD, DOE, & NSF Grant Development Support
  - Also view Other Funding Opportunities

🛠 Use:

- ☐ PIVOT Funding Opportunities – Need CWRU Credentials

📄 Read:

- ☐ Internal or External Funding Opportunities
- ☐ Research Funding Opportunities Archive
- ☐ UH Research SOPs
  - SP-202 Coverage Analysis & Clinical Budget Development Process Flow
- ☐ UH Policies
  - R-18 Funding Requests to External Sources
  - R-21 Grant Proposals

9. DESIGN YOUR STUDY

Work with your mentor to ensure you have a fully developed research protocol containing all necessary elements prior to submitting your project to the IRB. Access the IRB's protocol and consent template documents to help guide your protocol development. Meet with the study team and get feedback and consult with other departments who may provide services.

Create study documents and subject materials including questionnaires, advertisements, recruitment letters, pre-screening materials, telephone scripts, data collection instruments, and case report (source document) forms.

Design a Recruitment & Community Outreach Strategy for the study population needed to carry out your research. Plan for low enrollment at the start and submit your entire plan to the IRB for review and approval. You can always increase your enrollment goal in a protocol modification submission to the UH IRB.

If your study involves a drug or device, work with your IRB Specialist to determine if your study needs to be reviewed by the FDA.

Additionally, Investigational products (IP) intended for administration to a University Hospitals patient/subject are dispensed through the Investigational Drug Services (IDS) Pharmacy unless, in very select and rare instances, an IDS Exception Request is approved. Refer to the appropriate UH Policies and Research SOPs.

Read:

☐ Investigator Manual for IRB Submissions

☐ UH Research SOPs
- SP-203 Radiology Research Review
- SP-204 Research-Related Patient Education and Recruitment Materials
- SP-205 IDS Exception Request
- SS-313 Research Participant Compensation and Travel Reimbursement
- SS-302 UHLSF Outpatient Research Patient Charge Billing Process
- SS-304 Investigational Drug Billing
- SS-305 Investigational Device Billing
- SC-402 Transportation of Specimens

☐ IDS Policy MM-4 - Investigational Products

Use:

☐ IRB Forms & Templates in the SpartaIRB Library
- Protocol Templates
- Recruitment Templates
- Templates for Consent Documents

Note:

☐ Only use IRB Forms and Templates labeled “UH” in the beginning, otherwise your application will not be accepted when submitting to the UH IRB

Contact:

☐ Consult with other departments for services:

- For Statistical Support:
  - Contact your department statistician
  - Contact CRC Clinical Research Development, you may qualify for biostatistical support depending on your research study
  - For CWRU Biostatistical Support, contact Dr. Holly Hartman
- Other Services support:
  - Research Support Core for help submitting to the FDA, clinical and non-clinical coordinator support, recruitment services support, monitoring, etc.
    - RSC Service Request Form

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        - ResearchSupportCore@UHhospitals.org
    - Dahms Clinical Research Unit
        - Dahms CRU Service Request Form
    - Investigational Drug Services (IDS)
        - Contact InvestigationDrugService@UHhospitals.org to set up a consultation on using their services and for their departmental SOPs
        - IDS Services Form
    - Lab Services - Requisition Form
    - Radiology Form

📂 Refer to:

☐ Investigational Drug Services Pharmacy DWP Site

10. BUILDING A RECRUITMENT AND COMMUNITY OUTREACH STRATEGY FOR DIVERSITY, EQUITY & INCLUSION

When we reach out we actively show the communities that we serve that we are ready, willing, and able to support them through their clinical research journey and beyond. We encourage researchers and study teams to start building trusted relationships and engaging with the community before they need something. Diversity, equity, and inclusion principles are fortified when they are considered and intentionally woven in study design.

Developing these relationships and including these principles can aid in recruitment, and retention within the community, and equalizing representation in clinical research.

☎ Contact:

☐ Research Integration & Education to schedule a Recruitment & Community Outreach Strategy Development Consultation
    - Email ClinicalResearch@UHhospitals.org

📄 Read:

☐ Investigator Manual for IRB Submissions
    - Chapter 16: Recruitment

📖 Attend:

☐ UH IRB Education Series

☐ Diversity, Equity, & Inclusion Education Track: Recommended for all new research staff at UH, new to a research role at UH, and UH Research Credentialed non-UH employees.
    - A Systematic Review: Barriers to Minority Research Participation
    - Writing and Speaking for Understanding
    - How to Build a Community Outreach Strategy for your Research Program

📂 Refer to:

- UH Research Community Outreach Webpage
- University Hospitals Community Health Needs Assessment
- Clinical Research Patient Education Webpage
- UH Brand Center for review of all UH branded materials
- Recording Demographics in Clinical Research

II. Required Reviews and Approvals

1. **WHEN IS IRB REVIEW REQUIRED?**

All activities that may qualify as human subjects research must be submitted to the UH IRB for approval before you begin. The IRB will make a determination of whether the activity requires IRB review, approval and oversight. Answer the following questions:

Q: Are you performing research?
Research is defined as a systematic investigation designed to contribute to generalizable knowledge.

Q: Are you doing that research on human subjects?
The human subject must be a living identifiable human being where an intervention or interaction is taking place between the researcher and that human subject **OR** if using their identifiable private information.

➢ **If you answered yes to *both* questions above, you need review and approval by the IRB.**

What about Case Reports, Quality Improvement and Other Activities?

The IRB does not "approve" these activities, but it is important to receive a determination from the IRB stating your activity is not research.

Case Reports highlight interesting treatment, presentation or outcome, on *no more than 3 patients*. If you want to present or publish Case Reports outside of UH or CWRU then the case report must be submitted to the UH IRB for a determination

Quality Improvement is generally limited to implementing a practice to improve the quality of patient care, and collecting patient or provider data regarding the implementation of the practice for clinical, practical or administrative purposes. The line between QI and research can be thin and it is crucial to make sure that the IRB agrees.

📌 Note:

☐ Always submit to the IRB for a determination your activity is not human subject research. The process for a determination is shorter than an IRB approval.

☎ Contact:

- ☐ UHIRB@UHhospitals.org or your IRB Specialist for your department with any questions or concerns about an activity

📄 Read:

- ☐ Investigator Manual for IRB Submissions
  - Chapter 3: Regulatory Classifications

🛠 Use:

- ☐ IRB Forms & Templates in the SpartaIRB Library
  - HRP-503NHR - TEMPLATE - Not Human Subjects Research Protocol

📖 Attend:

- ☐ UH IRB Education Series

2. ACCESSING PHI FOR RESEARCH & DATA SECURITY

Accessing PHI for research is only allowable by UH employees if there is an IRB approval allowing the access or express written permission from the UH Privacy Officer. There is no other acceptable mechanisms for accessing PHI for the intent of a research study. *UH has a zero tolerance policy*.

Non-employees must have current UH Research Credentialing in place, as well as the conditions described above, to access UH PHI. Non-employees will also be required to gain access to the UH GPS Learning Management System so that required training can be completed. A UH manager must complete e-security access for the non-employee.

📂 Refer to:

- ☐ UH Research Credentialing Webpage
- ☐ Access & Use of Patient Records for Research Purposes FAQs
- ☐ Preparatory to Research Flowchart

📄 Read:

- ☐ UH Policy
  - R-3 Uses & Disclosures of PHI for Research
- ☐ UH Research SOPs
  - GA-102 - Use and Disclosure of Protected Health Information Preparatory to Research
  - SS-307 - Obtaining an Identified List Through the UH Clinical Research Center's TriNetX Export ID Feature

📖 Attend:

☐ HIPAA & PHI in Research

3. UH SYSTEMS FOR RESEARCH

Your department administrator can help guide you on what systems you will need access to and how to get trained.

📌 Note:

☐ Accesses to systems from your UH Manager via Sailpoint: S:Drive, community record, Soarian, UHCare, FoxPro, etc.

☐ In addition, request access for the following systems:
- SpartaIRB
- Velos eResearch: Complete the GPS training and sign-in using your UH credentials.
- REDCap

📄 Read:

☐ UH Research SOPs
- SS-310 REDCap Project Access for Research Credentialed Users
- SS-311 REDCap Project Access for External, Non-research Credentialed Users
- SS-312 Veeva SiteVault Free Account Access, Training, and Management
- SS-314 Velos eResearch – Access and Data Entry Requirements

4. CONFLICT OF INTEREST (COI) DISCLOSURE

UH employees and affiliated physicians must disclose financial interests and other activities that may be perceived as a conflict of interest.

📄 Read:

☐ UH Policies
- CE-8 Conflicts of Interest
- R-43 Research & Development: Conflicts of Interest

📖 Attend:

☐ Identifying and Managing Conflicts of Interest in Research

📂 Refer to:

☐ UH COI Disclosure Questionnaire

5. DEPARTMENT REVIEW COMMITTEE & ADDITIONAL REQUIRED REVIEWS

All departments are required to provide review and department approval for each research project to assess for scientific merit, available resources, adequate study population and financial feasibility in conducting the research, prior to IRB review. Additional review may

also be required. The departmental review is conducted once you submit your project in SpartaIRB. Departmental review may take some time to complete depending on the complexity of the research. Contact your Department Chair if you need a specific research project reviewed faster by the departmental reviewer.

Read:

- ☐ UH Research SOPs
  - SP-203 Radiology Research Review
  - SP-205 IDS Exception Request
  - SS-302 UHLSF Outpatient Research Patient Charge Billing Process
  - SS-304 Investigational Drug Billing
  - SS-305 Investigational Device Billing
- ☐ Investigator Manual for IRB Submissions
  - Required Approvals

Refer to:

- ☐ PRMC (Protocol Review and Monitoring Committee) reviews all new cancer-related trials conducted at the institutions affiliated with the Case Comprehensive Cancer Center, and also provides feedback to assist in protocol development.

6. CONTRACTS AND AGREEMENTS

If you are conducting research, then you need a contract. A contract is always required if you are sending UH data or patient data to any person or entity outside of UH. *Never sign a contract or letter of agreement without review and approval from the UH legal department.* Your grants and contracts representative will help facilitate.

If you are not sure that the work you are doing qualifies as research, it is your responsibility to contact the IRB for a determination and approval to proceed.

Note:

- ☐ **Studies should have been entered into the Velos Clinical Research Management System.**
  - Ensure the forms below are completed:
    - **Startup - PI Compensation_Qualifying Status Form:** Required, must be reviewed, dated, and electronically signed by the PI
    - **Startup - Invoiceable Fees Checklist Form:** Required, so Grants & Contracts knows which fees need to be negotiated into the contract budget.
    - **Startup - IDS Request Form:** Required if there is an investigational drug, so IDS can provide a quote for the investigational drug storage, monitoring, and dispensing.
    - **Startup - Coordinator Workflow Job-Aide:** Optional, will help efficiently guide you through everything required for study start-up
    - Any other form with “Startup” in the title if using other services

- ☐ Each Clinical Research Center Finance Core will contact you after completing the forms in Velos eResearch.
  - Questions?
    - Pre-Awards Grants & Contracts: UHCRCGrantsContracts@UHhospitals.org
    - Research Finance: ResearchBiller@UHhospitals.org
    - Post-Award Grants Accounting: UHCRCGrantsAccounting@UHhospitals.org
    - Velos Support: VelosSupport@UHhospitals.org

Read:

- ☐ UH Policies
  - R-16 Development of Clinical Trials Budgets
  - GM-69 Contracts
  - GOV-7 Transaction Approval and Authorization

Refer to:

- ☐ Pre-Award Grants & Contracts Webpage for contract definitions and processing and FAQs

7. COVERAGE ANALYSIS

A coverage analysis analyzes the items and services provided in a clinical trial to determine which of them can be appropriately billed to Medicare or other insurances. That determination is based on national and local governmental guidance. National guidance is part of the CMS Clinical Trial Policy, and this policy details how to correctly bill these clinical services related to your research trial.

If your study involves patient care, you'll contact your departmental Research Finance Specialist to create a budget & coverage analysis which is required before opening your study to enrollment. Harmonizing the "cost" language in the informed consent document with what is in the coverage analysis and contract is important. The department must complete and return all study start up forms in Velos eResearch including: qualifying status, drug or device form (if applicable), IDS form (if applicable), internally funded form (if applicable).

Read:

- ☐ UH Policies
  - R-2 Patient Billing Under Research Grants
  - R-16 Development of Clinical Trials Budgets
  - R-28 Pre-Award Account Numbers
  - R-29 Pre-Award Costs
- ☐ UH Research SOPs
  - GA-110 Management of Clinical Research Expense Invoicing
  - SP-202 Coverage Analysis & Clinical Budget Development Process Flow
  - SS-302 UHLSF Outpatient Research Patient Charge Billing Process
  - SS-304 Investigational Drug Billing

- SS-305 Investigational Device Billing

☐ Investigator Manual for IRB Submissions
- Remuneration

📖 Attend:

☐ The Basics, Module 4: Coverage Analysis & Research Billing Compliance

🛠 Use:

☐ UH CRC Forms
- Pre-Award Account Request Form

8. SUBMIT TO FDA

Submit a service request for help submitting your research project to the FDA or determining if submission is required.

☎ Contact:

☐ CRC Research Support Core
- Service Request Form
- ResearchSupportCore@UHhospitals.org

9. SUBMIT YOUR RESEARCH TO THE IRB

The UH IRB is the primary IRB for Biomedical research conducted at UH facilities or with UH patients or PHI. Reliant Review as well as independent for-profit IRBs that UH has an agreement with are also possibilities.

📖 Attend:

☐ UH IRB Education Series

☐ IRB Office Hours

🗁 Refer to:

☐ UH IRB Website

☎ Contact

☐ UH IRB: 216-844-1529

☐ UH IRB: UHIRB@UHhospitals.org

III. Study Start-up

1. SOURCE DOCUMENTS & TOOLS

Create a source document tool to align with the protocol and use the tool to capture protocol defined measures. Consider using REDCap to collect your source data. Other options may need to be considered if 21 CFR Part 11 compliance is required for your study.

Note:

- ☐ UH REDCap is NOT 21 CFR Part 11 compliant. Veeva SiteVault Free and Complion are compliant options.

Read:

- ☐ UH Research SOPs
  - SS-309 REDCap Project Access for UH Employees
  - SS-310 REDCap Project Access for Research Credentialed Users
  - SS-311 REDCap Project Access for External, Non-research Credentialed Users
  - SC-403 Research Documentation
  - SC-410 Certified Copies of Research Regulatory Documents
  - QA-502 Monitoring Visits

Attend:

- ☐ The Basics, Module 7: Good Documentation Practices & Clinical Data Management
- ☐ REDCap: An Introduction
- ☐ REDCap: Advanced Topics
- ☐ Building an eSource Documentation Tool in REDCap

Refer to:

- ☐ REDCap Introduction Handout
- ☐ FDA 21 CFR Part 11
- ☐ Digital Workflow Strategies for Clinical Research (You must be in the UH network to access)

Use:

- ☐ Research Toolbox
  - Study Visit Checklist Template
  - Medical History Template
  - Concomitant Medication Log Template
  - Internal Adverse Event Summary Log
  - External Adverse Event Summary Log
  - Allscripts Letter Describing 21 CFR 11 Compatibility

2. ESSENTIAL REGULATORY DOCUMENTS & REGULATORY BINDER

All studies conducted at UH are required to maintain essential regulatory documents which are typically stored in a regulatory binder or folder, either physically or electronically.

Read:

- ☐ UH Research SOPs
  - SS-301 - Maintenance of Research Regulatory Documents
  - SS-309 - REDCap Project Access for UH Employees
  - SS-310 - REDCap Project Access for Research Credentialed Users
  - SS-311 - REDCap Project Access for External, Non-research Credentialed Users
  - SS-312 - Veeva SiteVault Free Account Access, Training, and Management
  - SS-314 - Velos eResearch – Access and Data Entry Requirements
- ☐ GCP E6 R2 Guidelines, section 8 for details

Attend:

- ☐ The Basics, Module 2: Required Regulatory Documentation and Essential Documents
- ☐ eRegulatory Solutions

Use:

- ☐ Research Toolbox
  - Regulatory Binder Files Index
  - Regulatory Binder Template and Tabs

3. PROTOCOL TRAINING & SITE INITIATION

The Principal Investigator should identify the study team and assign roles for the study. This delegation should be documented appropriately per the delegation of authority log and training should be completed and documented prior to study start.

Be sure to provide training for staff in other departments involved in carrying out your research. Conduct a mock study visit to walk through the enrollment process of your first participant. Set up regular team meetings that extend throughout the conduct of the study and until study completion.

Read:

- ☐ UH Research SOPs
  - GA-104 Scope of Practice
  - GA-105 Investigator Responsibility for Study Team Training and Documentation
  - SS-303 Site Initiation Visit

Attend:

- ☐ Special Considerations for Interacting with Patients in a Virtual Setting
- ☐ Telehealth Visits for Research Studies

☐ Refer to the UH Clinical Research Education Catalog for courses to fill any training gaps identified.

🛠 Use:

☐ Research Toolbox
- Delegation of Authority Log/Staff Signature Log
- Training Log
- Training Signature Sheet
- Study Management Tools
  - Site Initiation Visit – Tip Sheet, Checklist, Agenda, FAQs, Slide Presentation Template

4. RECRUITMENT, SCREENING & ENROLLMENT, PLUS PRIVACY ISSUES

Map out a recruitment strategy, subject screening plan, and work through overall study logistics. Only IRB approved materials can be shared with potential participants. Start advertising, post your study on ResearchMatch, distribute flyers, and talk to collaborators as soon as you have IRB approval and complete the study kick off meeting.

📄 Read:

☐ Investigator Manual for IRB Submissions
- Remuneration
- Recruitment

☐ UH Research SOPs
- SP-204 Research-Related Patient Education and Recruitment Materials
- SS-313 Research Participant Compensation and Travel Reimbursement
- GA-102 Use and Disclosure of Protected Health Information Preparatory to Research

📖 Attend:

☐ The Basics, Module 5 - Prescreening Eligibility & Enrollment Process

☐ Study Recruitment Workshop

📂 Refer to:

☐ ResearchMatch.org

☐ Online Clinical Trial & Study Finder
- Cancer Trials
- Non-Cancer Trials
- Want your study in the database? Follow the UH CRC Research Study Database User Guide.

🛠 Use:

☐ Research Toolbox

- UH Research Recruitment Toolkit
- Screening/Enrollment Log
- Eligibility Checklist

☐ IRB Recruitment Templates

☐ UH Brand Center for additional flyer templates

☎ Contact

☐ Research Integration & Education for Recruitment & Outreach Strategy Consultation
- Learn the different methods of recruitment and building a community outreach strategy (complimentary and fee for service options)
- This consult is complimentary by the Clinical Research Center

☐ Research Support Core for Recruitment Specialist Support (fee for service):
- Service Request Form
- ResearchSupportCore@UHhospitals.org

5. INFORMED CONSENT & STUDY PARTICIPANT ELIGIBILITY

Complete the informed consent process **and document it** prior to implementing any study procedures. Complete and document the eligibility confirmation by medically qualified staff prior to any study procedures.

📄 Read:

☐ UH Policy
- GM-68 Medical Records Content

☐ Investigator Manual for IRB Submissions
- Decisionally Impaired Subjects
- Other Vulnerable Populations

📖 Attend:

☐ The Basics, Module 6: Informed Consent & Re-consent

☐ Informed Consent and the Decisionally Impaired or Vulnerable Participant

☐ IRB Informed Consent Education

☐ Virtual Informed Consent Process

🛠 Use:

☐ Research Toolbox
- Screening/Enrollment Log
- Informed Consent Documentation Checklist
- Eligibility Checklist
- Acronym Expansions (Dotphrases) for Clinical Research

- Alternative Wording for Consent Documents
- Informed Consent Elements – Basic and Additional
- Informed Consent Tip Sheet

6. GRANT ACCOUNT SET-UP & AWARD MANAGEMENT

Account set-up can begin once a fully executed Clinical Trial Agreement has been executed.

📂 Refer to:

- ☐ Chart of Accounts Request Form
- ☐ Award Form
- ☐ FoxPro Study Add Change Form (Set up FoxPro for participant stipends)

7. RESEARCH BILLING

Once a participant signs consent to participate in research, the participant must be registered in the UH billing systems to ensure "research" insurance information is added for a research related visit. The department registration personnel should select "RESEARCH" and primary payor for the visit.

Research coordinator essential duties include:

- Sending RBNF notification to the Research Finance team within 24 hours of clinical services provided. This is critical to prevent UH billing compliance risk.
- Update the study specific coverage analysis by adding new patient or updating visit status and date of service (DOS).
- Complete a W-9 and enter patient information in FoxPro for study participants receiving compensation.
- Complete Velos enrollment tracking.

📄 Read:

- ☐ UH Policy
  - R-2 Patient Billing Under Research Grants
- ☐ UH Research SOPs
  - SS-302 UHLSF Outpatient Research Patient Charge Billing Process
  - SS-304 Investigational Drug Billing
  - SS-305 Investigational Device Billing

📖 Attend:

- ☐ The Basics, Module 4: Coverage Analysis & Research Billing Compliance

IV. Study Conduct

1. CLINICAL TRIALS.GOV

If you are the sponsor of your research project, you are responsible for registering your study on ClinicalTrials.gov before you enroll your first study participant and for reporting results per requirements.

Read:

- ☐ Investigator Manual for IRB Submissions
  - Clinical Trial Requirements
- ☐ UH Research SOP
  - SC-401 Registration of Clinical Trials in ClinicalTrials.gov
  - SC-406 Results Reporting of Clinical Trials in ClinicalTrials.gov

Refer to:

- ☐ Research Toolbox:
  - ClinicalTrials.gov – Create an Account
  - ClinicalTrials.gov – Register a Clinical Trial

Contact

- ☐ UHResearchCompliance@UHhospitals.org if you have any issues or questions

2. INVESTIGATOR RESPONSIBILITIES & PI OVERSIGHT

The Principal Investigator is responsible for the overall conduct of the study, including the assurance of appropriate billing and preventing the study from going in to deficit. While delegation of duties to staff is expected to successfully carry out the research, responsibility for the research can never be delegated.

Read:

- ☐ UH Policies
  - R-1 Clinical Research Investigation
  - R-17 Effort Reporting
  - R-40 Research Misconduct
- ☐ Investigator Manual for IRB Submissions
  - Research Staff Responsibilities
- ☐ UH Research SOP
  - GA-105 Investigator Responsibilities for Study Team Training and Documentation

Attend:

- ☐ Investigator & Study Team Responsibilities

- ☐ Ethics of Clinical Research

📂 Refer to:

- ☐ FDA Guidance: Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects

3. PROTOCOL COMPLIANCE

Follow your IRB approved protocol as written and do not make changes without prior written IRB approval unless there is a safety risk to a study participant. Report deviations from the protocol to the IRB per policy.

📄 Read:

- ☐ Investigator Manual for IRB Submissions
  - Research Compliance Monitoring
- ☐ UH Research SOP
  - QA-501 FDA Inspections of Investigators
  - QA-502 Monitoring Visits
  - QA-503 Corrective and Preventative Action

📖 Attend:

- ☐ The Basics, Module 9: Avoiding Non-Compliance Findings

🛠 Use:

- ☐ Research Toolbox
  - Internal Adverse Event Summary Log
  - External Adverse Event Summary Log
  - Corrective and Preventative Action Plan
  - Protocol Deviation Log
  - Internal QA Checklist – Regulatory
  - Internal QA Checklist – Participant

4. PROTOCOL & CONSENT CHANGES

Submit required changes to the IRB and wait for approval before you implement them. Contact the Grants & Contracts team for contract changes that could affect the budget. Retrain the study team and document in the training records and remove outdated copies of study material for circulation but retain in the event of an audit or inspection.

📄 Read:

- ☐ Investigator Manual for IRB Submissions
  - IRB Submission Components
- ☐ UH Research SOP

- GA-105 Investigator Responsibilities for Study Team Training and Documentation.

🛠 Use:

☐ Research Toolbox
- Training Log
- Versions in Clinical Research Tip Sheet

5. RECORD KEEPING & GOOD DOCUMENTATION PRACTICES

Maintain adequate source documentation and use good documentation practices to make sure that every protocol required task and procedure has supporting documentation to indicate that it was completed. Schedule the study participant for follow up visits promptly to ensure they are within the protocol defined window.

📄 Read:

☐ UH Research SOP
- SS-301 Maintenance of Research Regulatory Documents
- SC-403 Research Documentation
- SC-405 Records Retention, Archive and Storage
- SS-312 Veeva SiteVault Free Account Access, Training and Management

📖 Attend:

☐ The Basics, Module 7: Good Documentation Practices & Clinical Data Management

🛠 Use:

☐ Research Toolbox
- ALCOA+C Documentation
- Drug Accountability Log
- Device Accountability Log
- Versions in Clinical Research Tip Sheet
- Study Visit Checklist Template

6. ADVERSE EVENTS, UNANTICIPATED PROBLEMS, & PROTOCOL DEVIATIONS

Document, assess and report events per timelines specified in the protocol or federal regulations. Causality must be assigned by the PI or medical qualified study personnel who has been delegated the task. Unexpected problems and deviations must also be reported timely.

📄 Read:

☐ UH Research SOPs
- SC-403 Research Documentation
- QA-503 Corrective and Preventative Action

☐ Investigator Manual for IRB Submissions

- Compliance and Monitoring
- Reportable New Information

📖 Attend:

☐ The Basics, Module 8: Adverse Events & Protocol Deviations

🛠 Use:

☐ Tools and Templates
- Adverse Event Log
- Protocol Deviation Log
- Serious Adverse Event Reporting Template
- Protocol Deviations and Important Protocol Deviations Tip Sheet

7. DATA MANAGEMENT, COLLECTION & RECONCILIATION

Data management plans describe and define the activities and procedures that must be followed to meet research study system requirements and to ensure that the data is credible, valid, reliable, accurate and adequate.

📖 Attend:

☐ The Basics, Module 7: Good Documentation Practices & Clinical Data Management

☐ Introduction to Statistics in Clinical Research

☐ Exploring Your Data Using Excel

🗁 Refer to:

☐ ALCOA+C Documentation

8. GRANT ACCOUNTING & STUDY FINANCIAL MANAGEMENT

Grant Accounting - Managing a grant award from inception to close out is a shared responsibility between CRC and Clinical Departments engaged in research. After a clinical trial is fully executed or a grant is awarded, GA team will create a grant account in the Grants Accounting system which is part of Oracle eBusiness financial application. The department is responsible for initiating, managing, and authorizing all expenses to grant awards. GA team will run all accounting processes and provide expenditure reports to grant administrators as necessary for reconciliation purposes. GA team will manage all cash and payments related to grant awards. While managing grants, UH Policies and Procedures for research (starting with "R-" must be observed at all times).

Study Financial Management- Once a patient signs consent to participate in research, the patient must be registered in the UH billing systems to ensure that "research" insurance information is added for a research related visit. The department registration personnel should select "RESEARCH" and primary payor for the visit.

Research coordinator essential duties include:

- Sending RBNF notification to the Research Finance team within 24 hours of clinical services provided. This is critical to prevent UH billing compliance risk.
- Update the study specific coverage analysis by adding new patient or updating visit status and date of service (DOS).
- Complete a W-9 and enter patient information in FoxPro for study participants receiving compensation.
- Complete Velos enrollment tracking.

Read:

☐ UH Policies
- R-8 Acceptance of Grants
- R-12 Budgetary Control and Funds Checking
- R-13 Post-Award Cash Management
- R-14 Grants Accounting: Charging Direct and Indirect Costs
- R-15 Cost Sharing, Matching and In-kind Contributions
- R-19 Grants Accounting: Clearing Accounts
- R-20 Grants Accounting: Non-Salary Adjustments
- R-22 Labor Distribution: Adjustments
- R-24 Labor Distribution: Payroll and Period Close
- R-25 Labor Distribution: Payroll Assignment
- R-27 Labor Distribution: Suspense Accounts
- R-30 Grants Accounting
- R-32 Grants Accounting: No Cost Extension
- R-33 Grants Accounting Distribution of Facility and Administration
- R-35 Grants Accounting: Residual Funds Transfer from Completed Grant Awards
- R-36 Grants Accounting: Managing Grants and Contracts funded to Community Hospitals
- R-37 Grants Accounting: Managing Grants and Contracts funded to Community Hospitals
- R-38 Fiscal Management of Contracted Clinical Research, Clinical Service Grants and Philanthropic Gifts
- R-41 Internally Funded Research Projects
- R-42 Labor Distribution: Salary Pool Accounts
- R-44 Federal Award Contracting and Purchasing
- R-45 Federal Grant Subrecipient Monitoring and Management

Attend:

☐ Grants Accounting Training

☐ The Basics, Module 4: Coverage Analysis & Research Billing Compliance

9. QUALITY ASSURANCE (QA) & MONITORING

Spot check the study records to check for quality and re-educate the team as needed. If you are the sponsor of your own investigator initiated study, then you are responsible for

ensuring that your study is monitored per the monitoring plan. For help identifying a monitor for your investigator initiated study, email ClinicalResearch@UHhospitals.org.

Read:

- ☐ UH Research SOPs
  - QA-501 FDA Inspections of Investigators
  - QA-502 Monitoring Visits
  - QA-504 Requesting Remote EMR Access for Monitors and Auditors
  - GA-106 Transfer Sponsor Investigator Initiated Protocols
  - GA-109 Departing Investigators
- ☐ Investigator Manual for IRB Submissions
  - Compliance and Monitoring

Attend:

- ☐ A Practical Guide to Remote Monitoring

Use:

- ☐ Internal QA checklist - Participant
- ☐ Internal QA checklist - Regulatory
- ☐ Audit Readiness – A Culture of Compliance

10. IRB CONTINUING REVIEW & OTHER ANNUAL REPORTS

The IRB assists investigators in complying with the ethical and regulatory standards. The federal requirement is to review a status report of most studies annually.

Note:

- ☐ The UH HRPP suggests submitting your continuing review submissions 6 weeks prior to the expiration date. If your study expires prior to the continuing review submission being approved, you must **STOP** all research activities.

Read:

- ☐ Investigator Manual for Manual Submissions
  - IRB Submission Components

Attend:

- ☐ UH IRB Education Series

V. Study Completion & Close-out

1. FINAL DATA ANALYSIS

Conduct a final reconciliation with source documents and case report forms and lock the database for analysis.

📖 Attend:

- ☐ Introduction to Statistics for Clinical Research
- ☐ Exploring your Data Using Excel

2. MANUSCRIPT & PUBLISHING

Work with your mentor to target journals of interest and follow the guidelines on their website.

📖 Attend:

- ☐ How to Get your Paper Published

3. STUDY CLOSURE

Submit closure to the IRB, notify study personnel and all support services of study closure, change study status in Velos eResearch, and update the study on ClincialTrials.gov.

📄 Read:

- ☐ Investigators Manual for IRB Submissions
  - IRB Submission Components
- ☐ UH Research SOP
  - SC-406 Results Reporting of Clinical Trials in ClinicalTrials.gov

🛠 Use:

- ☐ Study Close-Out Checklist

4. REPORT STUDY FINDINGS

Prepare abstract, manuscript, final study report & any publications.

Also provide your study participants with a layperson report on the research, if applicable.

Through community outreach and engagements activities, seek out and create opportunities to share your research results and impact with the community. Meet community members where they are and provide the information in community newsletters and at live events.

Read:

- ☐ UH Research SOP
  - SC-406 Results Reporting of Clinical Trials in ClinicalTrials.gov

Refer to:

- ☐ CRC Community Outreach Website

Attend:

- ☐ How to Build a Community Outreach Strategy for Your Research Program
- ☐ Discover with UH Webinar Series
  - Want to be a presenter? Contact ClinicalResearch@UHhospitals.org

5. DOCUMENT RETENTION & ARCHIVE

Prepare study documents for retention and archive. Retain per IRB, Sponsor and finding agency requirements.

Read:

- ☐ UH Policies
  - GM-1 Records Management
  - R-11 Archiving Grants Historical Data (Post 4/1/03)
  - R-23 Labor Distribution: Archiving Historical Data
- ☐ UH Research SOPs
  - SC-405 Records Retention, Archive and Storage
  - SC-410 Certified Copies of Research Regulatory Documents

Refer to:

- ☐ Records Retention Table
- ☐ Iron Mountain Process Checklist (if using Iron Mountain for long term storage)

6. POST AWARD GRANTS CLOSE OUT

When the study is closed with the IRB, also send communication to the Post-Award team who can conduct a final reconciliation and RFS team to assure that all clinical bills have been generated & reconciled.

Read:

- ☐ UH Policy
  - R-34: Award Close Out

Contact:

- ☐ Grants Accounting Team