UH Clinical Research Roadmap

NAVIGATION GUIDE

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 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, in one of our community hospitals, or outpatient clinics, 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. 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.

2. 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

3. RESEARCH CREDENTIALING

If your study team will include non-UH personnel, 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.

📂 Refer to:

- ☐ UH Research Credentialing Process Website

📄 Read:

- ☐ UH Research SOP GA-103 – UH Research Credentialing
- ☐ UH Policy R-46: UH Research Credentialing

4. 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.

5. 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
- ☐ The 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
- ☐ Investigator Manual for IRB Submissions
  - Required Training Necessary to Conduct Human Subject Research
- ☐ UH Research SOPs
  - GA-107 Investigator Training
  - GA-105 Investigator Responsibility for Study Team Training and Documentation

Attend:

- ☐ Required
  - CITI Training and CREC Certification: Collaborative Institutional Training Initiative grants Continuing Research Education Credits (CREC) Program Certification in Human Subjects Protections which is an IRB requirement for all staff listed on a UH study personnel table.
  - Investigator Training: Required for principal investigators and 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. Email ClinicalResearch@UHhospitals.org to schedule.
    - 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
  - For Principal Investigators
  - Velos for 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
- ☐ Clinical Research Certification Crash Course

📂 Refer to:

- ☐ UH Research Education & Training Website
- ☐ UH Research Education Catalog

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 and typically has a contact list. Your mentor can

📄 Read:

- ☐ UH Research SOPs
  - o GA-108 - Investigator Initiated Research

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

It's important to ensure that a study has scientific merit, resources available to ensure success, an adequate patient population that meet inclusion and exclusion criteria and that 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.

Studies should also be entered into the Velos Clinical Research Management System at this time.

☎ 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.
  - o TriNetX
  - o Research IT Workfront Request Job Aid can be found in the Research Toolbox under Clinical Research Data Requests.

Read:

UH Research SOP

- SP-201 - Protocol Feasibility Assessment

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

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. The Institutional Relations & Development department is happy to support you if you are seeking internal or external funding support for your research. 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 writing support
- ☐ Internal or External Funding Opportunities
- ☐ ClinicalResearch@UHhospitals.org to request a complimentary Research Recruitment & Community Outreach Strategy Consultation.

Read:

- ☐ 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 that 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 forms.

Prepare a Recruitment & Community Outreach Strategy for the study population needed to carry out your research. Plan for low enrollment by preparing for best and worst case at the start and submit your entire plan to the IRB for review and approval.

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. If you need support with the FDA Submission, contact the Research Support Core.

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
- 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

Contact:

☐ Consult with other departments that may provide services and consider

- For Statistical Support:
  - First, contact your department statistician
  - CRC Research Support Core Biostatistical Support
- CRC support:

- Research Support Core for help determining if the study product/design will need to be submitted to the FDA prior to IRB, coordinator support, recruitment support, biostatistical support, monitoring, etc.
  - RSC Service Request Form
  - ResearchSupportCore@UHhospitals.org
- Dahms Clinical Research Unit
  - Dahms CRU Service Request Form
- Investigational Drug Services (IDS)
  - IDS Services Form
  - InvestigationDrugService@UHhospitals.org
- Lab Services - Requisition Form
- Radiology Form

📂 Refer to:

☐ Investigational Drug Services Pharmacy DWP Site

📖 Attend:

☐ IRB Forms & Templates

10. RECRUITMENT; COMMUNITY OUTREACH & ENGAGEMENT; and 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 and schedule a Recruitment & Community Outreach Strategy Development Consultation

& 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 through Research Results Dissemination

Refer to:
- UH Research Community Outreach Webpage

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 that the IRB agrees 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.

Read:

- ☐ Investigator Manual for IRB Submissions
  - Regulatory Classifications
    - Quality Improvement Activities
    - Case Reports
    - Chart Review and Discarded Tissue Studies
    - IRB requirements for use of data collected from the "PopEx" system

- Regulatory Classifications for Research
- Expanded Access / Compassionate Use

& 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

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:

☐ Sailpoint requests are completed by a UH Manager. You may also need access to the S:Drive, physician portal, community record, Soarian, UHCare, FoxPro, etc.

☐ In addition, you should request access for the following systems:

- SpartaIRB
- Velos eResearch: Complete the GPS training and you will be sent login 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
- QA-504 - Requesting Remote EMR Access for Monitors and Auditors

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.

Read:

☐ Investigator Manual for IRB Submissions
- Required Approvals

Refer to:

☐ UH Brand Center for review of all UH branded materials

☐ 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.

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 including: qualifying status, drug or device form, 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

🗁 Refer to:

☐ UH CRC Forms
- Research Billing - Qualifying Status Form
- Research Billing - Device or Drug Detail Form
- Research Billing - Service Catalog Request (Devices or Drugs)
- Pre-Award Account Request Form (DWP Link, must be on the UH network)

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

📖 Attend:

☐ FDA Education Series

1. 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.

📖 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 (DWP site, you must be in the UH network to access)

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.

📄 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:

- ☐ Tools and Templates
  - Study Staff Delegation log
  - Training Log
  - Training Signature Sheet
  - 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
  - o Recruitment
  - o Remuneration of subjects
- ☐ UH Research SOPs
  - o SP-204 - Research-Related Patient Education and Recruitment Materials
  - o SS-313 - Research Participant Compensation and Travel Reimbursement
  - o GA-102 - Use and Disclosure of Protected Health Information Preparatory to Research

📖 Attend:

- ☐ The Basics, Module 5 - Prescreening Eligibility & Enrollment Process
- ☐ Study Recruitment Workshop
- ☐ ResearchMatch Workshop

📂 Refer to:

- ☐ ResearchMatch.org
- ☐ Online clinical trials listing
  - o Cancer Trials
  - o Non-Cancer Trials

🛠 Use:

- ☐ Tools and Templates
  - o UH Research Recruitment Toolkit
  - o Screening Log
- ☐ IRB Recruitment Templates
- ☐ UH Brand Center for additional flyer templates

☎ Contact

- ☐ Research Integration & Education for Recruitment & Outreach Strategy Consultation
- ☐ Research Support Core for Recruitment Specialist Support:
  - o Service Request Form
  - o 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
  - o Decisionally Impaired Subjects
  - o 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:

- ☐ Tools and Templates
  - o Enrollment Log
  - o Informed Consent Documentation Checklist
  - o Eligibility Checklist
  - o Dotphrases for Clinical Research

6. GRANT ACCOUNT SET-UP & AWARD MANAGEMENT

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

📖 Attend:

- ☐ UH Grants Accounting Training, FoxPro Training, Patient Study Reimbursement System Training

🗁 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 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 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

8. 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:

☐ UH Research SOP
- SC-401 - Registration of Clinical Trials in ClinicalTrials.gov
- SC-406 - Results Reporting of Clinical Trials in ClinicalTrials.gov

IV. Study Conduct

1. 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
  - o Research Staff Responsibilities
- ☐ UH Research SOP
  - o GA-105 - Investigator Responsibilities for Study Team Training and Documentation
  - o SC-409 - UH IRB SOP CC IRB Approved CCCC Protocols

📖 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

2. 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
  - o Research Compliance Monitoring
- ☐ UH Research SOP
  - o QA-501 - FDA Inspections of Investigators
  - o QA-502 - Monitoring Visits
  - o QA-503 - Corrective and Preventative Action

📖 Attend:

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

🛠 Use:

- ☐ Adverse Event and Protocol Deviation Log

3. 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
  - o IRB Submission Components
- ☐ UH Research SOP
  - o GA-105 - Investigator Responsibilities for Study Team Training and Documentation.

🛠 Use:

- ☐ Training Log

4. 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
  - o SS-301 - Maintenance of Research Regulatory Documents
  - o SC-403 - Research Documentation
  - o SC-405 - Records Retention, Archive and Storage
  - o SS-312 - Veeva SiteVault Free Account Access, Training and Management

📖 Attend:

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

🛠 Use:

- ☐ ALCOA+C Tip Sheet and In-service
- ☐ Drug/Device Accountability Log

5. 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
  - o SC-403 - Research Documentation
- ☐ Investigator Manual for IRB Submissions
  - o Compliance and Monitoring

📖 Attend:

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

🛠 Use:

☐ Tools and Templates
- o Adverse Event Log
- o Protocol Deviation Log

6. 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

7. 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

☐ Clinical Research Toolbox

📖 Attend:

☐ Grants Accounting Training

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

8. 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
- GA-106 - Transfer Sponsor Investigator Initiated Protocols
- GA-109 - Departing Investigators

- ☐ Investigator Manual for IRB Submissions
  - o Compliance and Monitoring

📖 Attend:

- ☐ A Practical Guide to Remote Monitoring

🛠 Use:

- ☐ Internal QA checklist - Participant
- ☐ Internal QA checklist - Regulatory

9. 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.

📄 Read:

- ☐ Investigator Manual for Manual Submissions
  - o 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, and update listing on clincialtrials.gov.

Read:

- ☐ Investigators Manual for IRB Submissions
  - o IRB Submission Components
- ☐ UH Research SOP
  - o 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-405 - Results Reporting of Clinical Trials in ClinicalTrials.gov

Refer to:

- ☐ CRC Community Outreach Website

Attend:

- ☐ How to Build a Community Outreach Strategy through Research Results Dissemination

5. DOCUMENT RETENTION & ARCHIVE

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

Read:

- ☐ UH Policies
  - o GM-1: Records Management
  - o R-11: Archiving Grants Historical Data (Post 4/1/03)

R-23: Labor Distribution: Archiving Historical Data

- ☐ UH Research SOPs
  - o SC-405 - Records Retention, Archive and Storage
  - o SC-410 - Certified Copies of Research Regulatory Documents
- ☐ 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.

📂 Refer to:

- ☐ UH Policy R-34: Award Close Out

☎ Contact:

- ☐ Grants Accounting Team
- ☐ Research Finance Team