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 to 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 UH Clinical Research Center Office of Research Compliance, Education & Outreach

University Hospitals
Clinical Research Center

WWW.UHHOSPITALS.ORG/CLINICAL-RESEARCH

Table of Contents

I. Getting Started..... Page 2
1. Resources to Help you Get Started
2. Research & IRB Policies, and Research SOPs
3. Department Level Training
4. Research Training
5. Identify a Faculty Scientific Mentor
6. Vetting a Research Idea or Industry Sponsored Trial & Study Feasibility
7. Design your Study

II. Required Reviews and Approvals..... Page 5
1. When is IRB Review Required?
2. Accessing PHI for Research & Data Security
3. UH Systems for Research
4. Conflict of Interest (COI) Disclosure
5. Department Review Committee & Additional Required Review
6. Contracts and Agreements
7. Coverage Analysis
8. Submit to FDA
9. Submit your Research to the IRB

III. Study Start-up..... Page 9
1. Source Documentation & Tools
2. Essential Regulatory Documents & Regulatory Binder
3. Protocol Training & Site Initiation
4. Recruitment, Screening & Enrollment, plus Privacy Issues
5. Informed Consent & Subject Eligibility
6. Grant Account Set-Up & Award Management
7. Research Billing
8. ClinicalTrials.gov

IV. Study Conduct..... Page 13
1. Investigator Responsibilities & PI Oversight
2. Protocol Compliance
3. Protocol & Consent Changes
4. Record Keeping & Good Documentation Practices
5. Adverse Events, Unanticipated Problems, & Protocol Deviations
6. Data Management, Collection & Reconciliation
7. Grant Accounting & Study Financial Management
8. Quality Assurance (QA) & Monitoring
9. IRB Continuing Review & Other Annual Reports

V. Study Completion & Close-out..... Page 17
1. Financial Data Analysis
2. Manuscript & Publishing
3. Study Closure
4. Report Study Findings
5. Document Retention & Archive
6. Post Award Grants Close Out

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 the academic medical center in Cleveland, in one of our community hospitals, or outpatients 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. 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.

4. RESEARCH TRAINING

The CRC offers a catalog of courses available to anyone working with UH. Courses are offered in a live classroom setting 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 your team typically gathers.

Read:

- ☐ The Code of Federal Regulations
  - o 45 CFR Part 46 - Applies to all human subjects research
  - o FDA Regulations -Applies to FDA regulated research
- ☐ Good Clinical Practices Guidelines: GCP E6 R2
- ☐ IRB Policy, *Training Necessary to Conduct Human Subject Research*

Back to Table of Contents

📖 Attend:

- ☐ CITI Training: Collaborative Institutional Training Initiative grants Human Subjects Protections Certification which is an IRB requirement.
- ☐ Investigator Training: required for principal investigators with less than one year of experience 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

🗁 Refer to:

- ☐ UH Research Education & Training Website

5. IDENTIFY A FACULTY SCIENTIFIC MENTOR

Contact the Department Chair, Administrator or Academic Coordinator can help match mentors to mentees and typically has a contact list.

6. 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 strategy, subject screening plan and work through overall study logistics.

🗎 Read:

- ☐ UH Research SOP *SP 201: Protocol Feasibility Assessment*

☎ Contact:

- ☐ ResearchIT@UHhospitals.org 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. Research IT Request Form can be found here.
- ☐ CRC Research Support Core to request statistical support for your research.

7. 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. Meet with the study team and get feedback and consult with other departments that may provide services.

Determine if your study needs to be reviewed by the FDA by contacting the Research Support Core.

Back to Table of Contents

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 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. Determine if your study needs to be reviewed by the FDA.

Read:

☐ IRB Policies
- *Submission of New Human Subjects to the IRB*
- *Completion of a Protocol Template Document*
- *Writing a Consent Document*
- *General Consent Requirements*
- *Electronic Consent*
- *Consent Documentation*
- *Use of Placebos*
- *Use of Washout*
- *Investigational Drugs or Biologics Used in Research*
- *Investigational Devices Used in Research*
- *Research Conducted Internationally by U.S. Investigators*
- *Inclusion of Minors in Human Subjects Research*
- *Inclusion of Decisionally Impaired Subjects*
- *Inclusion of Pregnant Women*
- *Inclusion of Neonates*
- *Inclusion of Prisoners*
- *Inclusion of Non-English Speaking Participants*
- *What Other Vulnerable Populations can be included in my study?*
- *Approvals Needed Before Submission*
- *IRB requirements for use of data collected from the "PopEx" system*

Use:

☐ IRB Forms and Templates
- *Protocol Templates*
- *Templates for Consent Documents*

Contact:

☐ Consult with other departments that may provide services and consider CRC support:
- Research Support Core - Service Request Form (or 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.)
- Dahms CRU - Dahms CRU Service Request Form
- Investigational Drug Services (IDS) - IDS Services Form
- Lab Services - Requisition Form
- Radiology Form

Back to Table of Contents

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:

☐ IRB Policies
- *Quality Improvement Activities*
- *Case Reports*
- *Chart Review and Discarded Tissue Studies*
- *IRB requirements for use of data collected from the "PopEx" system*
- *Decisions Made By The IRB*
- *Regulatory Classifications for Research*
- *Expanded Access / Compassionate Use*

Back to Table of Contents

📖 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 SOP *GA 102: Use and Disclosure of Protected Health Information Preparatory to Research*

📖 Attend:

☐ *Everything You Need to Know About HIPAA and 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:

☐ E-security requests are completed by a UH Manager. May also need S:Drive, physician portal, community record, Soarian, UHCare, FoxPro, REDCap, etc.

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
- o *CE-8: Conflicts of Interest*
- o *R-43: Research & Development: Conflicts of Interest*

Back to Table of Contents

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:

- ☐ IRB Policies
  - o *Approvals Needed before Submission*
  - o *Appendix A-10 Departmental Review of Protocols*
  - o *Appendix A-11 Additional Required Reviews*

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 CCC, 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
  - o *R-16: Development of Clinical Trials Budgets*
  - o *GM-69: Contracts*
  - o *GOV-7: Transaction Approval and Authorization*

Refer to:

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

Back to Table of Contents

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
  - o *R-2: Patient Billing Under Research Grants*
  - o *R-16: Development of Clinical Trials Budgets*
- ☐ UH Research SOPs
  - o *SP 202: Coverage Analysis & Clinical Budget Development Process Flow*
  - o *SS 306: Investigational Pharmacy Fee Waiver*
- ☐ IRB Policy, *Remuneration of Subjects*

Attend:

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

Refer to:

- ☐ UH CRC Forms
  - o *Research Billing - Qualifying Status Form*
  - o *Research Billing - Device or Drug Detail Form*
  - o *Research Billing - Service Catalog Request (Devices or Drugs)*
  - o *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

Attend:

- ☐ *FDA Education Series*

9. SUBMIT YOUR RESEARCH TO THE IRB

The UH IRB is the primary IRB for Biomedical research done 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

- ☐ IRB: 216-844-1529
- ☐ 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 art 11 compliance is required for your study.

📖 Attend:

- ☐ *The Basics, Module 7: Good Documentation Practices & Clinical Data Management*
- ☐ *REDCap 101: An Introduction*

🗁 Refer to:

- ☐ REDCap Introduction Handout
- ☐ FDA 21 CFR Part 11

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 SOP *SS 301: Maintenance of Research Regulatory Documents*
- ☐ GCP E6 R2 Guidelines, section 8 for details

📖 Attend:

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

Back to Table of Contents

🛠 Use:

- ☐ Regulatory Binder Files Index

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
  - o *GA 104: Scope of Practice*
  - o *GA 105 Investigator Responsibility for Study Team Training*
  - o *SS 303: Site Initiation Visit &* associated checklist

📂 Refer to:

- ☐ UH Research Education Catalog for courses to fill any training gaps identified.

🛠 Use:

- ☐ Tools and Templates
  - o *Study Staff Delegation log*
  - o *Training Log*
  - o *Training Signature Sheet*

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:

- ☐ IRB Policies
  - o *How to Recruit Research Participants*
  - o *Remuneration of subjects*

📖 Attend:

- ☐ *Study Recruitment Workshop*

Back to Table of Contents

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 Letter Template

5. INFORMED CONSENT & SUBJECT 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*
- ☐ IRB Policies
  - o *General consent requirements*
  - o *Consent Documentation*
  - o *Inclusion of Minors in Human Subjects Research*
  - o *Inclusion of Decisionally Impaired Subjects*
  - o *Inclusion of Pregnant Women*
  - o *Inclusion of Neonates*
  - o *Inclusion of Prisoners*
  - o *Inclusion of Non-English Speaking Participants*
  - o *What Other Vulnerable Populations can be included in my study?*

Attend:

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

Use:

- ☐ Tools and Templates
  - o *Enrollment Log*
  - o *Informed Consent Documentation Checklist*
  - o *Eligibility Checklist*

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*

Back to Table of Contents

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 subjects receiving compensation.
- Complete REDCap enrollment tracking.

Read:

- ☐ UH Policy R-2: *Patient Billing Under Research Grants*
- ☐ UH Research SOPs
  - o *SS 302: UHLSF Outpatient Research Patient Charge Billing Process*
  - o *SS 304: Investigational Drug Billing*
  - o *SS 305: Investigational Device Billing*
  - o *SS 306: Investigational Pharmacy Fee Waiver*

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 subject and for reporting results per requirements.

Read:

- ☐ UH Research SOP *SC 401: Registration 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-40: *Research Misconduct*
- ☐ IRB Policies
  - *Responsibilities of the Principal Investigator*
  - *Appendix A-9, IRB-1 Investigator Responsibilities*
- ☐ UH Research SOP *GA 105: Investigator Responsibilities for Study Team Training and Documentation.*

Attend:

- ☐ *Investigator & Study Team Responsibilities*

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:

- ☐ IRB Policy
  - *Research Compliance Monitoring*
    - *IRB Compliance Determinations and Reporting Guidelines*
- ☐ UH Research SOP *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 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:

- ☐ IRB Policy, *Study Modifications*
- ☐ UH Research SOP *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.

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:

- ☐ IRB Policy,
  - o *Research Compliance Monitoring*
    - ▪ *IRB Compliance Determinations and Reporting Guidelines*

Attend:

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

Back to Table of Contents

🛠 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 Grants Accounting system which is part of Oracle eBusiness financial application. 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 subjects receiving compensation.
- Complete REDCap enrollment tracking.

Read:

- ☐ UH Policies
  - o *R-14: Grants Accounting: Charging Direct and Indirect Costs*
  - o *R-30: Grants Accounting*
  - o *R-33: Grants Accounting Distribution of Facility and Administration*
  - o *R-41: Internally Funded Research Projects*

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 ResearchCompliance@uhhospitals.org.

Read:

- ☐ Research SOPs
  - o *QA 502: Monitoring Visits*
  - o *QA 501: FDA Inspections of Investigators*

- ☐ IRB Policies
  - o *Research Compliance Monitoring*
  - o *Allegations of Non-Compliance*
  - o *Suspension or Termination of a Study*

Use:

- ☐ Internal QA checklist

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:

- ☐ IRB Policy, *Continuing Reviews*

Attend:

- ☐ *UH IRB Education Series*

Back to Table of Contents

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.

2. MANUSCRIPT & PUBLISHING

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

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:

- ☐ IRB Policy, *Study Closure*
- ☐ 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.

5. DOCUMENT RETENTION & ARCHIVE

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

Read:

- ☐ UH Policy GM-1: *Records Management*
- ☐ UH Research SOP *SC 405: Records Retention, Archive and 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

Back to Table of Contents