University Hospitals Clinical Research Center

UH Investigator Training Modules

The following is an overview of the research process at UH. Contact the UH Clinical Research Center at ClinicalResearch@UHhospitals.org or visit UHhospitals.org/Clinical-Research for more information.

Module 1 – Getting Started

- Resources to Help You Get Started
- Institutional and IRB Policies, and Research SOPs
- Department Level Training
- Research Training
- Identify a Faculty Scientific Mentor
- Vetting a Research Idea or industry Sponsored Study & Study Feasibility
- Design Your Study

Module 2 – Required Reviews and Approvals

- When is IRB Review Required?
- Accessing PHI for Research & Data Security
- UH Systems for Research
- Conflict of Interest Disclosure & Management
- Department Review & Additional Required Reviews
- Contracts & Agreements
- Coverage Analysis
- Submit to FDA
- Submit Your Research to the Institutional Review Board

Module 3 – Study Start-Up

- Source Documents & Tools
- Essential Regulatory Documents & Regulatory Binder
- Protocol Training & Site Initiation Visit
- Recruitment, Subject Screening & Enrollment
- Informed Consent & Subject Eligibility Criteria
- Grant Account Set-up & Award Management
- Research Billing
- ClinicalTrials.gov

Module 4 – Study Conduct

- Investigator Responsibilities & PI Oversight
- Protocol Compliance
- Protocol & Consent changes
- Record Keeping & Good Documentation Practices
- Adverse Events, Unanticipated Problems & Protocol Deviations
- Data Management, Collection & Reconciliation
- Grant Accounting & Study Financial Management
- Quality Assurance & Monitoring
- IRB Continuing Review & Other Annual Reports

Module 5 – Study Completion and Close-out

- Final Data Analysis, Reconciliation & Final Study Report
- Manuscript & Publishing
- Study Closure
- Report Study Findings
- Document Retention & Archive
- Post Award Grants Close-out

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