1. PURPOSE:
This Standard Operating Procedure (SOP) describes the standards for conducting investigator initiated research at University Hospitals (UH) and the requirements for ensuring the necessary oversight and compliance measures for an investigator initiated protocol at UH. The UH Clinical Research Center (UHCRC) has resources available, on a fee-for-service basis, to support Sponsor-Investigator research.

2. SCOPE:
This SOP provides instruction and sets minimum standards regarding the process for an investigator who is implementing an investigator initiated research protocol at UH. This SOP is not intended to supersede federal regulations set forth by the code of federal regulations but is intended to set a minimum standard for all investigators who wish to conduct investigator initiated research.

3. RESPONSIBLE INDIVIDUALS:
This SOP applies to all investigators engaging in investigator initiated research including those studies that are regulated by the Food and Drug Administration Code of Federal Regulations (FDA CFR) under an Investigational New Drug (IND- 21 CFR Part 312) or Investigational Device Exemption (IDE- 21 CFR Part 812) at University Hospitals. The Department Review Committee and/or Department Chair or designee is charged with ensuring that this review is complete and thorough. It is encouraged that other senior research members within the department be available as a mentor for anyone conducting investigator initiated research within a particular department.

4. DEFINITIONS:
Please reference the Clinical Research Center (CRC) Standard Operating Procedures Glossary for complete definitions of terms found in this SOP.

5. POLICY STATEMENT:
All research protocols must be reviewed for scientific merit and ethical standards consistent with local, state and federal requirements and must be consistent with UH IRB Policy, Department Review of Protocols.

6. PROCEDURES:

6.1 Mentoring young investigators
If the investigator is not experienced in the conduct of clinical research at UH, the Department Chair or designee will identify a mentor in the applicable field; preferably during the study design phase.
6.2 Project Feasibility Assessment
Before beginning a new research proposal at UH, investigators must complete a protocol feasibility assessment to ensure that there are adequate resources and potential participants to successfully conduct and complete the study. See UH Research SOP 201 Feasibility Process.

6.3 Protocol Oversight/Sponsorship
The Sponsor-Investigator of an investigator initiated study that is regulated by the FDA under an IND (21 CFR Part 312) or IDE (21 CFR Part 812) must be a UH attending physician (MD/PhD; MD; DO; OD). The FDA regulated trial that is held by the sponsor must be within the sponsor-investigator’s scope of practice. In addition, the acting Sponsor-Investigator must not delegate the primary responsibly of oversight, project implementation, and treatment oversight to a trainee or anyone else who is not an attending physician (MD/PhD; MD; DO; OD).

The oversight and sponsorship of a clinical trial is critical to the successful outcome of a research study and the engagement and experience of the principal investigator is necessary.

6.4 Project Design/Protocol Creation
Sponsor-Investigator creation of a protocol includes creation of: (1) a project design that will meet scientific and ethical review, (2) informed consent form describing potential research volunteer risks and benefits, and (3) corresponding study budget and coverage analysis to ensure adequate funding to complete the study. Templates including all necessary elements for both protocols and consent forms are available on the UHCRC website and should be used prior to submitting for review by the local institutional review board and the Food and Drug Administration, if applicable. UH Research SOP SP 202 describes the Coverage Analysis & Clinical Budget Development Process Flow. Certain investigational products must be added to the hospital charge master to assure compliant billing. The investigator must engage the Research Finance Specialist core to assist in this process.

The Sponsor-Investigator should also consult with a statistician to verify their statistical outcomes and ensure endpoints can be met based on the proposed patient number. Statistical services may be requested by contacting the Regulatory & FDA Guidance Core.

6.5 Investigational Products
If the investigator initiated research proposal includes the use of a drug, device, and/or biologic and the investigator is unsure if it’s approved for use by the FDA for the study’s therapeutic target, the investigator should contact the Regulatory & FDA Guidance Core for assistance in helping to determine if the protocol needs to be reviewed by the FDA. Refer to the IRB Policy Investigational Developed by the UH Clinical Research Center SOP Committee.
Drugs or Biologics Used in Research for additional information regarding instruction requirements. This includes the required use of Investigational Drug Services.

6.6 Study Funding
The Sponsor-Investigator must identify external funding or sufficient non-operating internal funding to support the research plan, in accordance with UH Policy R-41.

6.7 Data Management
The FDA mandates that any study regulated under the Code of Federal Regulations must adhere to FDA 21 CFR Part 11 Compliance, or the electronic storage and entry of clinical research information. For more information, contact the Regulatory & FDA Guidance Core. See UH IRB Policy, Research Involving Human Data or Specimens. Research that is not regulated by the FDA is not held to this standard, however, every measure should be taken to ensure all research information and data is stored in a secure location to minimize the risk.

6.8 Study Implementation and Oversight
Investigator initiated research requires an increased level of regulatory and clinical coordination support. Each investigator should ensure that they have experienced regulatory and clinical support to help conduct the research study and maintain compliance throughout the course of the study.

The Clinical Research Center strongly recommends that the individual responsible for the regulatory and clinical coordination duties is not a fellow, resident, or medical student, unless these trainees have undergone the necessary credentialing and training, including the completion of UH Investigator Training. If personnel are not available within a department to assist with an investigator initiated research study, the Clinical Research Center has fee for service support available that can assist with any regulatory and clinical coordination duties.

6.9 Federal and Local Compliance
The Code of Federal Regulations (21 CFR Part 312 and 812) mandates that the sponsor of a drug, device, or biologic research trial provide independent monitoring of the information relating to their research trial (this is independent from the function of a Data Safety Monitoring Board or a Medical Monitor). The FDA acknowledges the responsibility of the placement of a monitor to be with sponsor-investigator.

Regular monitoring of Sponsor- Investigator research studies is expected. Fee for service monitoring services are available through the Clinical Research Center, Regulatory & FDA Support upon request. All studies at UH are subject to audit by the Office of Research Compliance, FDA or

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other Regulatory bodies and those studies without an established monitoring oversight plan will be subject to mandatory audits. Contact the Office of Research Compliance for additional details.

7. REFERENCES
FDA 21 CFR Part 312 Investigational New Drug Application
FDA 21 CFR Part 812 Investigational Device Exemption
FDA 21 CFR Part 11 Electronic Records; Electronic Signatures – Scope and Application
UH Research SOP GA 106 Transfer of Protocols out of UH
UH Research SOP SP 201 Study Feasibility Process
UH Research SOP SP 202 Coverage Analysis & Clinical Budget Development Process Flow
UH IRB Policy, Research Involving Human Data or Specimens
UH IRB Policy, Protocol Submission Requirements
UH IRB Policy, Investigational Drugs or Biologics Used in Research
Informed Consent Template
UH Investigator Training

8. FORMS OR ATTACHMENTS

APPROVALS

Approved by Dr. Grace McComsey, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center– March 7, 2018

Developed by the UH Clinical Research Center SOP Committee