OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH		
	CATEGORY	**Clinical Research: Study Management**
	SUBJECT	**Study Start-Up**
	SOP #	**2.7**
	EFFECTIVE DATE	**August 6, 2008**
	REVISION DATE	**August 27, 2018**

OBJECTIVE

Provide the common steps for reviewing the preparations for study start-up when participating in clinical research trials. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46	Protection of Human Subjects
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions

REFERENCES TO RELATED SOPs

SOP 2.1
SOP 2.2
SOP 2.5
SOP 3.1

ATTACHMENTS

Sample Delegation of Authority Form

1) The PI is responsible for, or may delegate study start up procedures. These include, but are not limited to:
   a) Ensure that all duties of the study have been delegated and that all individuals are knowledgeable about their responsibilities. Fill out a Delegation of Authority Form
   b) Verify that all personnel have completed required training
   c) Ensure that all pre-study activities required by other ancillary service providers have been completed
   d) Order any needed supplies not directly provided by the sponsor. Contact Supply Chain Management at 612-873-6598
   e) Ensure that reserved space for conducting trial visits, storage of study related materials, and equipment is prepared
   f) Develop (or utilize sponsor-generated) worksheets, checklists, and flow sheets to assist study personnel to conduct the study
   g) Confirm that the contract has been fully executed (talk with the appropriate Grant Administrator)
   h) Review study procedures with assigned study staff.
   i) Assure that any applicable HCMC employees are apprised and knowledgeable about the study. If an HCMC employee is working on the study <u>independent of their standard duties</u> ensure their names have been provided to the appropriate Grant Administrator. A service agreement between HCMC and HHRI may need to be completed for each HCMC employee. Notify manager/supervisor of appropriate department(s). Items to discuss with manager/supervisor and involved staff include, but are not limited to:
      i) Name of the study
      ii) Rationale for the study

iii) Responsibilities to be performed by HCMC staff
iv) Prohibited medications or other interventions outlined by the protocol
v) Potential adverse events to monitor participant for
vi) Name and number of PI
vii) Name and number of research coordinator

2) Ensure that all regulatory documents are complete, up-to-date, and in the regulatory binder.

3) Evaluate the trial to assess the need to register it with clinicaltrails.gov according to guidelines of the International Committee of Medical Journal Editors (ICMJE). ICMJE member journals require, as a condition of consideration for publication, registration in a public trials registry. The ICMJE defines a clinical trial as:
"Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-or-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator will not require registration".

4) Federal agencies including the FDA and NIH also have registration policies. See http://clinicaltrials.gov/ct2/manage-recs for further information.

5) Contact the Office of Education and Quality in Clinical Research (OEQCR) at 612-873-6341 if the trial qualifies to begin the registration process.
   a) PI or research staff is responsible for entering and updating information in the registry.
   b) Notify the OEQCR if the investigator is the holder of an IND.
   c) Sponsor/CROs usually have already registered their study. Check www.clinicaltrials.gov to assess if they are registered. Notify sponsor/CRO personnel if the study is not listed.

SAMPLE DELEGATION OF AUTHORITY FORM

Principal Investigator_____ Protocol Title and HSRC #_____

Name (Print)	Signature	Initials	Role in Study (sub-investigator, coordinator, etc.)	Authorized Functions* (List all that apply)	Start Date	End Date	PI Initials
			Principal Investigator				

**

1. Screening	9. Study drug/device accountability	16. Other (specify)
2. Verify inclusion/exclusion criteria	10. Assess AEs/SAEs	17. Other (specify)
3. Obtain informed consent	11. Reporting SAEs	18. Other (specify)
4. Randomization	12. HSRC communication	
5. Physical exam and history	13. Sponsor communication	
6. Study drug/device dispensation	14. CRF completion	
7. Subject study instructions	15. Query resolution	
8. Follow-up visits	16. Regulatory documents maintenance	