OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Study Management
	SUBJECT	Pre-Study Site Evaluation Visit
	SOP #	2.6
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	August 27, 2018

OBJECTIVE

Provide the common steps for participating in pre-study evaluation visit for 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

Hennepin Healthcare Research Institute Sponsored Project Administration: Guidance and Procedures

REFERENCES TO RELATED SOPs

SOP 2.1

ATTACHMENTS

None

1) Ensure that the sponsor's confidentiality agreement has been signed and returned (check with the appropriate Grant Administrator).

2) Review protocol materials to assess study protocol and feasibility of carrying out the protocol.

3) Identify personnel to be assigned to the study.

4) Ascertain whom the sponsor/CRO will want to meet with. Collaborate with the sponsor/CRO to schedule a mutually convenient date and time when all required parties can attend.

5) Prepare explanatory information for the sponsor/CRO. This may include, but not be limited to:
   a) Dates of HSRC meetings
   b) Dates of other regulatory meetings, e.g., HCMC Radiation Safety Committee
   c) Overview of the local protocol review process
   d) Overview of HHRI, Grants Administration, Accounting

6) Collect supporting documentation. These may include but not be limited to:
   a) Organizational Charts of HHRI and HCMC as appropriate
   b) Copies of medical licenses of PI and sub-investigator(s)
   c) Current signed and dated curriculum vitae for PI and sub-investigator(s)
   d) Copies of nursing licenses if required
   e) Staff curricula vitae if required

f) Copy of institutional laboratory certification(s)

7) Collaborate with all desired attendees and develop a schedule for the sponsor/CRO to meet personnel and tour the facility. Individuals and /or areas the sponsor/CRO may want to visit include:
   a) PI
   b) Sub-investigator(s)
   c) Pertinent research personnel
   d) Grant Administrator
   e) Research pharmacist
   f) Office areas of the research team
   g) Research pharmacy
   h) Clinical laboratory
   i) Radiology
   j) In-patient hospital areas or out-patient clinic areas
   k) Storage area for investigational drug if out-patient study
   l) Storage area(s) for investigational devices

8) Be prepared to discuss:
   a) The protocol
   b) Central facilities that will be used
   c) Grants Administration
   d) HSRC process
   e) Special needs the sponsor/CRO should be willing to supply (i.e., equipment, training)
   f) Anticipated study timeline
   g) Investigators' meeting and/or study initiation meeting
   h) Sponsor/CRO chain of command and communication plan

9) Determine if there is other information required by the sponsor/CRO.

10) Request that the sponsor/CRO notify the site in writing if selected to participate in the trial.