OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Study Management
	SUBJECT	Study Initiation Visit
	SOP #	2.8
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	January 3, 2018

OBJECTIVE
Provide the common steps for participating in a study initiation visit for clinical research personnel performing 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 2.6

ATTACHMENTS
None

1) Ensure that all documentation and materials associated with the study are provided to assigned personnel.

2) 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.

3) Prepare for and meet with the Clinical Research Associate (Monitor). S/he will want to:
   a) Conduct a final protocol review.
   b) Ascertain that the study team is familiar with the protocol.
   c) Ensure that staffing and the physical environment is the same as documented during the pre-study site evaluation.
   d) Ensure that study procedures are compatible with site routines or that special plans have been made to accommodate the protocol.
   e) Ensure that the study team is comfortable with the process to fill the case report forms.
   f) Confirm that the study team understands and is willing to follow all regulatory obligations.
   g) Verify that all needed supplies are present and ready.
   h) Familiarize the study team with the monitoring plan.

4) The study team should:

a) Obtain answers to any final questions.
b) Clarify communication procedures with the sponsor/CRO.
c) Discuss process and requirements for monitor/CRA onboarding and EPIC access

5) If all preparatory activities are complete, the sponsor/CRO will issue a written official notification that the PI is free to begin the study. The study and administration of the test article should not begin until this is received.