OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Study Management
	SUBJECT	Pre-Study Feasibility Evaluation
	SOP #	2.4
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	January 11, 2018

OBJECTIVE

Describe the questions that should be asked when evaluating the feasibility of carrying out a clinical research protocol. This SOP may be used as a tool for investigators to evaluate Investigator Initiated protocols to ensure completeness and accuracy. 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 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions

REFERENCES TO RELATED SOPs

SOP 2.1
SOP 2.3
SOP 2.5

ATTACHMENTS

Sample Protocol Feasibility Checklist

1) The Sample Protocol Feasibility Checklist may be used to evaluate the feasibility of the site's ability to complete a study. Evaluating the feasibility of a protocol will enhance the probability of timely and successful completion of the clinical research trial.
   a) Notify the sponsor if the protocol cannot be executed as written.
   b) Collaborate with the sponsor to institute necessary changes.
   c) Collaborate with the appropriate Grant Administrator for budget needs, recommendations, and concerns.

2) The sample protocol feasibility checklist may be used as a template for Investigator Initiated studies. Consult the funding source for Investigator Initiated studies to obtain additional instructions, requirements, and templates for protocol development and evaluation.

SAMPLE PROTOCOL FEASIBILITY CHECKLIST

ELEMENT	YES	NO
Is the study plan feasible as written?		
Can the protocol be carried out as written		
Does the study rationale make sense?		
Planned assessments are appropriate for valid conclusions		
Is the study plan logical in light of prior research		
Are subject risks minimized?		
Can the study be carried out with available resources?		
Is there adequate space		
Is there adequate manpower		
Is there adequate equipment		
Will the patient population seen on campus support the protocol?		
Are there competing protocols that will reduce the subject pool		
Are there mechanisms to recruit subjects from other sources if needed		
Does the study plan require unfamiliar procedures?		
Is proper training available from the sponsor or other sources		
Does the study plan require unavailable tests or procedures?		
Will the sponsor allow appropriate substitutions		
Does the study plan require equipment not currently available?		
Is the equipment available from the sponsor		
Does the equipment require additional time and effort for in-servicing		
Will the sponsor provide in-servicing		
Is sufficient time available?		
Is there adequate time to recruit the assigned number of subjects		
Is there adequate time to fulfill regulatory obligations		
Is the time commitment for the whole study within reasonable proportions		
Is funding adequate?		