OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Study Management
	SUBJECT	Pre-Study Protocol Evaluation
	SOP #	2.3
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	January 3, 2018

OBJECTIVE

Describe the steps entailed in evaluating the necessary protocol components for clinical research trials. 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 56	Institutional Review Boards
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions

REFERENCES TO RELATED SOPs

SOP 2.1

ATTACHMENTS

Sample Protocol Evaluation Checklist

1) The sample protocol evaluation checklist may be used to evaluate the protocol, Investigator's Brochure, and Clinical Trial Agreement to ensure that the appropriate information is available (if applicable) to the study. Evaluating the protocol will enhance the probability of timely and successful completion of the clinical research trial.

2) Notify the sponsor if the protocol does not meet minimum standards and cannot be executed as written. Collaborate with the sponsor to institute necessary changes.

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

SAMPLE PROTOCOL EVALUATION CHECKLIST

STANDARD	ELEMENT	YES	NO	N/A
General Information	**Is (are) there:**			
	A draft or final version designation			
	A title, protocol identifying number, and date			
	The name and address of the sponsor and monitor available			
	The name, title, address, and phone number of the sponsor's medical expert			
	The names and addresses of sponsor assigned ancillary central departments			
Background information	**Is (are) there:**			
	A name and description of the investigational product			
	The phase of the study indicated			
	An Investigational New Drug (IND) number or Investigational Device Exemption (IDE) number			
	A summary of findings from non-clinical studies present			
	A summary of relevant prior clinical trials			
	A summary of known and potential risks/benefits			
	A summary of relevant prior clinical trials			
	A summary of known and potential risks/benefits			
	Description and justification for the route of administration, dosage, dosage regimen, treatment periods (drug), description and justification for implantation and treatment periods (device)			
	A statement that the trial will be conducted in compliance with the protocol, Good Clinical Practices, and applicable regulatory requirements			
	A description of the population to be studied			
	Relevant literature references			
Objectives and purpose	**Is (are) there:**			
	A detailed description of the objectives			
	A detailed description of the purpose			
Design	**Is (are) there:**			
	Primary and secondary endpoints to be measured			
	A description of the trial design			
	A schematic design of the trial			
	A description of the dosage form or device, packaging, and investigational product labeling			
	Accountability procedures for the investigational product			
	Expected duration of subject participation, including follow-up			
	Stopping rules for subjects, portions of the trial, entire trial			
	Maintenance of randomization codes			
	Procedures for breaking randomization codes			

SAMPLE PROTOCOL EVALUATION CHECKLIST

STANDARD	ELEMENT	YES	NO	N/A
Subject selection and withdrawal	**Is (are) there:**			
	Inclusion criteria			
	Exclusion criteria			
	Subject withdrawal criteria			
	Subject withdrawal procedures			
Subject treatment	**Is (are) there:**			
	Subject risks minimized			
	Subject benefits maximized			
	Treatments and treatment periods listed, including the name of all products used			
	Plans to use procedures already being performed for diagnostic and/or treatment purposes			
	Medications permitted/not permitted before and during the trial			
	Medication washout procedures			
	Procedures for monitoring subject compliance			
Efficacy assessments	**Is (are) there:**			
	Efficacy parameters			
	Methods and timing sequences for assessing, recording, and analyzing efficacy parameters			
Safety assessments	**Is (are) there:**			
	Safety parameters			
	Methods and timing sequences for assessing, recording, and analyzing safety parameters			
	Procedures for acquiring and reporting adverse event reports by the site and the sponsor			
	Procedures for recording and reporting adverse events and concurrent illnesses			
	Description of follow-up after adverse events			
Scientific merit	**Is (are) there:**			
	Scientific merit of the study is valid			
	Planned statistical methods, including interim analysis(es)			
	Number of subjects to be enrolled			
	Power of the trial and level of significance			
	Patient population to be included in the analyses			
	A description of the Data and Safety Monitoring Board			
Ethics	**Is (are) there:**			
	A description of the ethical considerations relating to the trial			
Miscellaneous	**Is (are) there:**			
	Specifications that the investigator and institution will permit trial-related monitoring, audits, IRB review, and regulatory inspections by providing direct access to source documents			
	Descriptions of quality control and quality assurance measures			
	A statement of compliance with HIPAA			