MERCY HEALTH

Institutional Policy and Procedure
Date of Original P & P: 07/01/2009
Revision No: 2
Effective Date: 03/31/2015

Title	Investigative Site – Project Management
	PM 301 Assessing Feasibility
Originator	Institutional Official
Approval	J Gallens MD

1. Policy

Feasibility assessment should be conducted for all potential studies presented to a research site. Feasibility assessment consists of a careful evaluation of whether a study is a good "fit" for the study site. This assessment should be conducted as soon as study details are presented to a site by a sponsor. Careful evaluation and consideration will include a compilation of information including, but not limited to, a site's facilities, equipment, experience, interest, staff and subject recruitment and retention capabilities. The site must carefully evaluate the scientific, ethical and financial merits of conducting the study in order to ensure that the study meets both the necessary requirements of the site and the sponsor. The sponsor may request the study site complete a feasibility evaluation form providing site specifics; however, the site also must complete an internal feasibility evaluation to consider whether it is interested in being considered for, and selected, for the study in question. This SOP describes the steps for assessing the feasibility of conducting a successful study.

2. Scope

This SOP applies to the processes involved in assessing and evaluating protocols for studies conducted at this investigative site.

3. Responsibility

Responsibilities for implementing this SOP are indicated as follows:

General administration: See Attachment GA 101-A: List of Key Personnel and Responsibilities at Mercy Health.

Specific studies: See Attachment GA 101-B: Delegation of Authority Protocol

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4. Applicable Regulations and Guidelines

FDA 21 CFR 312.60—General responsibilities of investigators

21 CFR 812.110—Specific responsibilities of investigators

21 CFR Part 11—Electronic Records, Electronic Signatures

ICH E6: Harmonized Tripartite Guideline for GCP

4.1 Investigator's Qualifications and Agreements

4.2 Adequate Resources

5. SOP Attachments

MHSM Feasibility Tool

6. Process Overview

A. Protocol Review and Assessment

B. Study Budget Development

C. Pre-Study Site Qualification Visit

7. Specific Procedures

A. Protocol Review and Assessment

#	*Who*	*Task*	*Attachments*	*Related SOPs*
A-1	Executive Director	Prior to agreeing to review a protocol, execute the confidentiality agreement. Decide if there is enough information available to make an informed decision regarding feasibility of the study (is there a final protocol? is the CRF design available?).	GA 104-B PM 301-A	GA 104
A-2		Determine who, in addition to the PI, should assess the study.	GA 101-A, B	GA 101
A-3		Review the protocol and complete an Assessment Checklist. Items for consideration include: 1. Interest in the study 2. Therapeutic Area and application to site population 3. Competing studies 4. Availability of staff resources 5. Standard of care 6. Ability to enroll a specified number of study subjects 7. Study timelines		
A-4		If possible, contact the sponsor for more information on the estimated site budget and let the sponsor know of any specific budget requirements that are anticipated (percent overhead, set start-up fees, hourly rate for PI and Coordinator(s), etc.) to ensure that the sponsor will be able to accommodate specific budget requirements.	GA 105-B	
A-5		If it is required that your site use a local IRB to conduct the study, submission, review and approval timelines		

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		should be evaluated in comparison with the study timelines and expected start-up and enrollment window. (If a local IRB must be used and the approval process will take an extended period of time, it is important to confirm that there still will be adequate time for enrollment following approval.)		
A-6		An enrollment potential validation should be completed to assess whether there is access to the protocol-specific patient population. Careful evaluation of overall numbers and percentages of potentially qualified subjects should be made to ensure that an enrollment commitment can be met for a specified number of subjects.		
A-7		Notify the sponsor regarding the decision to be further considered for, or of agreement to conduct, the study. If it is determined that the protocol is not a good fit for the site, or the potential budget cannot meet site requirements, the sponsor should be provided with the rationale for the decision. The protocol and other supporting materials must be disposed of as specified by the sponsor. If the site is interested in conducting the study, proceed to schedule the Pre-Study Site Qualification Visit or the Initiation Visit.	PM 301-F, G PM 302-A - C	PM 302
NOTE: It is important to inquire if there is a protocol revision forthcoming, as study procedures and timeline expectations change and acceptance of the study should be reconsidered depending on changes made.				

B. Study Budget Development

#	*Who*	*Task*	*Attachments*	*Related SOPs*
B-1	Executive Director/Financial Analyst	If it has been determined that the study is feasible for execution by the site, budget development and negotiations should begin. Using the protocol, CRF and Worksheets, develop a draft study budget.	PM 301-B - E	
B-1		Create a spreadsheet and itemize every study-related procedure at each visit. Consider the costs of activities that may not be itemized in the proposed budget. If needed, draft a budget for contingencies (ranked by most likely to least likely).		
B-2		Negotiate the budget if necessary. Be prepared to discuss the rationale for increases. (Always have an analysis of costs associated with staff duties.)		
B-3		Consider and include provisions to amend study budget based on protocol amendments.		
B-4		Include reimbursement for pre-screening activities and screen fails.		
B-5		Consider unscheduled subject visit time requirements.		
B-6		Determine if sponsor will provide specialized equipment.		

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B-7		Confirm if paper-based or electronic case report forms will be used, evaluate electronic data capture (EDC) system and consider time for data entry.		
B-8		Review monitoring expectations with sponsor/CRO. Confirm expected time on site for visits, number of monitoring visits and any impact for Risk-Based Monitoring implementation (i.e., expectation for source documents to be scanned in and faxed, remote access to subject information other than e-CRF records, remote monitoring visit teleconferences, need for internal quality control or assurance procedures, etc.)		
NOTE: It is important to consider that additional study procedures, visit windows, source document revisions, data entry requirements, data correction forms, etc. all require additional staff time and should always be anticipated when evaluating and negotiating a budget.				

C. Pre-Study Site Qualification Visit

#	Who	Task	Attachments	Related SOPs
C-1	Clinical Research Coordinator	Identify key clinical research personnel likely to be involved in conducting the study under consideration. Consider role of pharmacist, if the study requires separate blinded or unblinded staff, specific evaluator requirements, etc.		
C-1		Ensure that the sponsor's Confidentiality Agreement *(if applicable)* has been signed by the Principal Investigator and returned to the sponsor. (Some sponsors/CROs have a central Confidentiality Agreement available; inquire and request.)		
C-2		Schedule the Pre-Study Site Qualification Visit with the sponsor/CRO and key staff. Obtain a copy of the confirmation letter and request or develop an agenda.		
C-3		Prepare for the visit. Request a list of documents that will be needed; gather them and have them ready for the visit.	PM 301-F, G	
C-4		Prepare recruitment and retention plan and be prepared to explain how the site will meet enrollment goals.		
C-5		Determine if the sponsor has any areas of special interest that require advance scheduling, such as: — Visiting the treatment site (clinic or hospital), pharmacy, central laboratory or medical records department; — Seeing any specialized equipment needed to implement the study; — Meeting briefly with ancillary personnel involved in any specialized data collection; — Visiting any ancillary facilities.		
C-6		Meet with sponsor/CRO representatives to review protocol, investigator's brochure and communication plan for sponsor/CRO and clinical site.		

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C-8		Complete the checklist to document the Pre-Study Site Qualification Visit.		
C-9		Before signing a contract to conduct the study, make sure all concerns have been addressed and the schedule of payments is satisfactory.	GA 104-A, B	GA 104
C-10		Request an expected date for site selection letter.		
C-11		Confirm if a site initiation visit will occur or if an Investigator Meeting will serve as the site initiation visit and training. Confirm timelines for study start-up, Investigator Meeting and/or Site Initiation Visit.		
NOTE: It is important to ensure that all calibration records, maintenance records and temperature logs are current and copies of certificates are available for the visit. In addition, current CVs and licenses should be provided for all qualified and study-specific staff.				

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