SS 401

INVESTIGATOR SELECTION AND QUALIFICATION

1. POLICY

Investigator selection is based on the training, experience and educational qualifications of the Investigator. Additional considerations include his/her ability to enroll an expected number of subjects in a reasonable period of time and the commitment to conduct the study according to the protocol, other <<Sponsor >> stipulations and applicable regulatory requirements.

Investigators will be qualified by <<Sponsor Designee>>. An initial feasibility questionnaire will be sent to a potential site to obtain information about its interest, qualifications and abilities to conduct a specific study. The feasibility questionnaire may be sent prior to the execution of a confidentiality disclosure form, or CDA, but the protocol-specific details must be blinded if a CDA has not been executed.

A qualification telephone screening process and/or pre-study site visit will be used, following collection of feasibility information on each site, to review the appropriateness of the Investigator, his/her staff, the facility and resources, and to gauge the understanding of applicable regulatory requirements of the Investigator and his/her key research staff. The purpose of the Qualification Visit is to ensure that the Investigator and his/her staff understand and accept the:

- ☐ Investigational nature of the study and the investigational product
- ☐ Expectations for access to an appropriate subject population
- ☐ Variances from Standard of Care (SOC) (if applicable)
- ☐ Roles and obligations as defined in the study contract and protocol
- ☐ Applicable regulatory requirements
- ☐ Responsibilities to the IRB/EC
- ☐ Content, maintenance and retention of source documents, records and Investigational Product.

The person conducting the Qualification Visit will be assessing and verifying that the Investigator:

- ☐ Meets experience and eligibility requirements
- ☐ Has sufficient time to complete the study
- ☐ Can meet subject accrual and subject population requirements
- ☐ Can complete subject information requirements for study documentation
- ☐ Has support staff with the necessary training, experience and credentials
- ☐ Has facilities suitable to conduct the study.

2. SCOPE

These policies and procedures apply to <<Sponsor >>, its employees, subcontractors and others who manage, oversee and conduct research regulated by the FDA.

Specifically, they apply to those conducting an assessment for selecting qualified potential Investigators.

3. RESPONSIBILITY

<<Sponsor Designee>> is responsible for identifying, qualifying and recruiting Investigators.

The monitor is responsible for assisting <<Sponsor Designee>> by conducting the assessment needed to determine an Investigator's suitability to conduct the clinical study.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General Responsibilities of Sponsors
21 CFR 312.53	Selecting Investigators and Monitors
21 CFR 312.70	Disqualification of a Clinical Investigator
Guidance for Industry	Oversight of Clinical Investigations- A Risk-Based Approach to Monitoring, August 2013
Guidance for Industry	Electronic Source Data in Clinical Investigations, September 2013
Guidance for Industry	Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors Clinical Investigator Administrative Actions- Disqualification, May 2010
ICH E6, 2.7	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.6	Investigator Selection
ICH E6, 5.7	Allocation of Responsibilities
ICH E6, 5.8	Compensation to Subjects and Investigators
ICH E6, 5.9	Financing

5. REFERENCES TO OTHER APPLICABLE SOPS

GA 101 Sponsor Responsibility and Delegation of Responsibility

GA 103 Sponsor Research Team Training

GA 105 Vendor Selection and Agreements

PD 301 Clinical Protocol Development

SS 402 Initiation Visit and Site Training

CO 505 Study Closeout Visit

6. ATTACHMENTS

SS 401-A: Investigator Feasibility Evaluation and Qualification Visit Report

SS 401-B: Qualification Visit Checklist

7. PROCESS OVERVIEW

A. Investigator Qualification

B. Investigator Agreements

C. Disqualified Investigators

8. SPECIFIC PROCEDURES

A. Investigator Qualification

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	<<Sponsor Designee>>	Use multiple sources to identify potential Investigators.[1]		
2.		To assess general interest and qualifications, the initial contact with a potential Investigator may be made by telephone and/or a blinded (general request for information) feasibility questionnaire sent to the site.	SS 401-A: Feasibility Evaluation and Qualification Visit Report	
3.		Before discussing the study details, a Confidentiality Disclosure Agreement (CDA) must be sent to the prospective Investigator, signed by him/her and returned to <<Sponsor Designee>>.	GA 105-E Confidentiality Agreement Template	GA 105
4.		Once the signed Confidentiality Agreement has been returned, a complete protocol-specific feasibility questionnaire can be sent to the site. After return and review of the questionnaires, if the site meets minimal expectations follow up with an appointment for a detailed telephone assessment of the potential Investigator's interest and qualifications.	SS 401-A: Investigator Telephone Qualification	
5.		Determine whether the potential Investigator is a likely candidate.		
6.		If the investigative site meets the criteria to conduct the study, send a copy of the protocol along with other information about the study to the Investigator.		
7.		If the site is new to <<Sponsor>> or if the site has been used in the past but has not been qualified in the last <<_____ months/years>>, or has not conducted a study for <<Sponsor>> in the last <<_____ months/years>> or has moved locations since conduct of the last study with <<Sponsor>>, arrange for a qualification visit to confirm the potential Investigator's qualifications and the site's ability to conduct the study.[2]		
8.		Conduct the qualification visit and document the results of the assessment.	SS 401-B: Qualification Visit Checklist	
9.		Based upon the data gathered by telephone and verified by site visit, select Investigators best suited to conduct the study.		

Note:

[1] Sources include: network of researchers known and recommended by colleagues or previous Investigators; medical consultants and physician referrals; professional contacts from previous research programs, medical conferences, scientific symposia and professional meetings; literature review to identify opinion leaders and other published investigators; and member lists and directories in the relevant scientific specialty. The clinicaltrials.gov web site also may be searched for Investigators conducting studies in similar indications.

[2] If an Investigator has participated in a study for <<Sponsor >> within the past (_#_) year(s), a full Qualification Visit may not be necessary. In that case, a detailed and updated telephone qualification may be conducted.

B. Investigator Agreements

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	<<Sponsor Designee>>	Prepare an investigator contract that delineates all applicable requirements.[1] A detailed budget template should be developed in conjunction with the protocol. A draft budget should be provided by <<Sponsor>> for site consideration. Each activity should include a line item for direct and indirect costs. Direct cost line items should include the cost of procedures conducted at each visit, including time for the informed consent process, pre-screening activities, a pre-determined amount for screen failures, time for CRF/eCRF completion, query resolution and consideration of a start-up fee.	GA 105-F: Investigator Contract Template	GA 102 GA 105
2.		The contract negotiations may proceed during the study start-up and document collection process. However, Investigational Product cannot be shipped until the Investigator has signed and returned the contract and completed and signed Form FDA 1572 for an IND study meeting qualifications, Form FDA 3454 or 3455, evidence of IRB approval and any other required documents.	GA 101-C:Form FDA 1572 GA 104-A: Form FDA 3454 / GA 104-B: Form FDA 3455	
3.		Upon completion of these preliminary steps, provide the selected Investigator the final clinical protocol, Informed Consent form template, the IB and other study-related documents.		
4.		Arrange for a Site Initiation Visit (SIV).		SS 402

Note:

[1] Requirements may include but are not limited to the following: proposed dates for conducting the study; budget, reimbursement for direct and indirect costs; publication and presentation of study data; Investigator's responsibilities (e.g., compliance with GCP, HIPAA); a statement that the Investigator has read the protocol and will comply with its requirements; and other agreements that <<Sponsor>>'s counsel believes necessary.

C. Disqualified Investigators

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	<<Sponsor Designee>>	Check the FDA web site to ascertain whether a potential Investigator has received an FDA Warning Letter, been debarred or otherwise sanctioned.	RA 201-B: Accessing FDA Documents and Guidance Online	RA 201
2.		If an Investigator is being considered or selected and subsequently found to be disqualified, notify the Investigator in writing that he or she is not eligible to participate in the study.		
3.		Once selected and participating in a study, if an Investigator repeatedly fails to comply with <<Sponsor>>'s requirements, take actions as described in SOP 506.[1]	CO 506-B: Determination of Actions to Ensure Investigator Compliance	CO 506

Note:

[1] All investigational products should be collected from the Investigator as soon as possible and his/her termination should be reported as soon as possible to all required parties.