# PRE STUDY SITE / INVESTIGATOR QUALIFICATION

1. **PURPOSE**To define procedures to be followed during site selection for a specific clinical study conducted by <name of Sponsor/Investigator> and the required documentation associated with these activities.
2. **SCOPE**This SOP is required for all clinical studies conducted by <insert Sponsor/Investigator name> involving human subjects.
3. **BACKGROUND**
<Name of Sponsor/Investigator> shall select qualified investigators based on their training and experience to investigate the drug/device/biologics. 21 CFR 312 & 812.

Sponsor/Investigators are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, submitting an IND/IDE application to FDA, and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation.

If a coordinating committee and/or coordinating investigator(s) are to be utilized for multi-center clinical trials, their organization and selection are the Sponsor/Investigator’s responsibility. ICH E6 Section 5.6 Investigator Selection.

[Principal] investigator means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

1. **RESPONSIBILITIES**
<Name of Sponsor/Investigator > will be responsible for all prequalification activities for a specific clinical study. (S)he may delegate activities to selected personnel to assist in the selection of qualified investigators / suitable sites for a specific study.
2. **PROCEDURE**
	1. <Name of Sponsor/Investigator> is responsible for training all appropriate employees, contractors, designees and site investigators participating in trial conduct (if applicable) SOPs and their responsibilities. Such training will be documented on a training log.
	2. <Name of Sponsor/Investigator> will solicit potential investigators from a variety of methods including referrals, list of investigators from medical congresses, symposia, meetings within a specialty, internet searches, investigator databases, personal contacts, directories of medical societies, etc.
	3. Investigators will be qualified based on a review of the following:
		1. Investigator CV (knowledge, training and experience in the field of the proposed study, publications).
		2. Good Clinical Practice (GCP) training and experience in clinical trials.
		3. Certification as a principal investigator.
		4. Prior regulatory audit(s) history.
		5. Not being listed on the restricted / debarment list with FDA.
		6. Prior history of conducting trials with <name of Sponsor/Investigator>.
		7. Resources, time and staff to participate in and assume full responsibility for the conduct of the study.
		8. Knowledge of Good Clinical Practice.
		9. Review of site SOP manual.
		10. Facilities and equipment:

i. Protocol required testing equipment and associated manuals, records of maintenance, calibration / validation.

 ii. Suitable storage (locked, restricted access) for test article(s).

 iii. Proximity to investigators.

iv. Suitable laboratory equipment and storage areas as necessary for protocol requirements. All appropriate licenses, CLIA, CAP, current normal values and all forms submitted to Sponsor/Investigator.

v. Trained personnel necessary to complete protocol required tests.

vi. Adequate space / exam rooms for subject visits.

k. Access to an adequate number of potential subjects eligible for enrollment in the study.

l. Ability to work with an IRB that functions in compliance with all applicable regulations.

m. Regulatory audit (FDA or HHS) history of the reviewing IRB / accreditation status of the reviewing IRB.

n. No or limited number of conflicting studies.

o. Comprehension of and agreement to follow written approved protocol, regulatory and ethical requirements, monitoring and audit procedures and GCP.

p. Documentation of all communications with potential investigators will be documented and kept in the Sponsor/Investigator study files.

q. Selection of investigators will be based on information gathered concerning prequalification assessments. Sign off on investigator qualification will be done by <insert title>.

r. All potential investigators must sign a non-disclosure agreement prior to receiving any protocol summaries, protocol, budget or contract templates. Two original non-disclosure agreements will be obtained. One fully executed original will be filed in the Sponsor/Investigator study files and one will be retained by the investigator.

s. Once <name of Sponsor/Investigator> has selected a potential investigator, a site qualification monitoring visit will be scheduled. This visit may be done in conjunction with a site initiation visit if the Sponsor/Investigator has prior experience with the site.