**CHECKLIST FOR SITE QUALIFICATION VISIT**

1. **Prior to the Site Qualification Visit**

Request from the sponsor, PI and study personnel several potential meeting dates and times to determine the best meeting date and time for all parties involved.

Ensure that delegated research team members have allocated sufficient time for the site qualification meeting date established with the sponsor.

Ensure that research team members receive a copy of the protocol, Investigator’s Brochure (is applicable), Lab Manual, and CRFs for review and comment prior to the meeting date.

Ensure that the appointment with the sponsor is confirmed. Provide directions to the investigative site. Offer to provide suggestions for hotels and restaurants nearby.

Prepare information on:

* Dates of regulatory meetings, such as the IRB
* An overview of the protocol review process at the site
* An overview of the grants and contracts office
* Names of key contacts, telephone numbers, and e‑mail addresses (if available) for individuals at the site involved in contract review and signoff

Prepare supporting documentation (for example):

* Current organizational chart and proposed management of the study
* List of generic clinical trials (overall and completed recently)
* Copies of any publications by research staff relevant to clinical study under consideration
* Copies of current medical licenses and laboratory certification (if applicable)
* Sample source documentation of subject participation in a clinical study
* Estimate of the number of potential study subjects
* Proposed recruitment strategy, including primary and secondary resources
1. **During the Site Qualification Visit**

 Ensure that sponsor’s representatives have the opportunity to tour the facilities (which may include):

* Exam rooms for subject evaluation and treatment
* Laboratory area
* Any special testing areas
* Pharmacy
* Hospital unit
* Work areas for research staff
* Storage areas for study drug
* Storage areas for supplies

Be prepared to discuss the following:

* Comments from site personnel's review of the protocol
* Any requests for site-specific modifications to the protocol
* Laboratory (central or local)
* Provision for any specialized procedures
* Any specialized data entry procedures
* Storage space required for study drug, specialized equipment, computers, etc.
* The benefits of the investigational product for the site's subject population
* Publication policy if the investigative site is interested in publishing the results of the study
* Availability of qualified, experienced and sufficient site personnel to conduct this study
* After study initiation, the site training plan for ancillary research and facility personnel involved in the study
* Timeline at the site for IRB review
* Timeline for contract and indemnification agreement review and signoff

Request that the sponsor/CRO provide an overview of the management process for the study at this site including:

* Sponsor/CRO responsibilities
* Monitoring plan
* Overview of data management or SOP on data management
* Information on the anticipated time line for the study
* Information on key dates, such as:

Investigators’ meeting and/or

Study initiation meeting

Investigational product availability

Indemnification agreement

Draft contract for review

Sponsor/CRO chain of command and communication plan

* Determine if there is any other information that the sponsor requires.
1. **After the Site Qualification Visit**

Request that the sponsor notify the site in writing if selected to participate in the clinical trial.

Once the protocol is finalized and if selected as a site, prepare the following:

* The site-specific informed consent form
* The IRB submission
* The final budget
* Submit the clinical trial agreement for signoff
* Track documents identified above at the site/within the institution
* Plan for the site initiation meeting