This checklist should be used as a tool to assist you with a Pre-study/Site Qualification Visit

1. Before the visit

Request from the sponsor several potential meeting dates and times to accommodate as many key personnel as possible.

Ensure that these team members will be available and have allocated sufficient time for the PSSV meeting date established with the sponsor.

Ensure that key site personnel receive copies of the protocol, investigator’s brochure, and other available documents, as appropriate, for review and comment.

Ensure that the appointment with the sponsor is confirmed. Provide clinical site information packet that may include, site directions, hotels, restaurants, etc.

Prepare information on:

- Dates of regulatory meetings, such as the IRB, for the next 3-6 months
- An overview of the protocol review process at the site (if it is not straightforward)
- Grants and contracts office, if applicable
- 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, such as:

- Current organizational chart and proposed management of the study
- List of previous 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 participants
- Proposed patient identification and recruitment strategies
2. **During the visit**

Ensure that sponsor’s representatives have the opportunity to tour the facilities, such as:

- Exam rooms for subject evaluation and treatment
- Laboratory area
- Any special testing areas
- Pharmacy (satellite pharmacy, if appropriate)
- Hospital unit
- Work areas for research staff
- Storage areas for study drug
- Storage areas for supplies
- Data entry area, if appropriate

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.

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

- Sponsor responsibilities
- Monitoring plan
- Overview of data management

Discuss the following potential concerns:

- The benefits of the investigational product for the site's patient 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
Request from the sponsor:

- Information on the anticipated time line for the study
- Information on key dates, such as:
  - Investigators’ meeting and/or
  - Study initiation meeting
  - Study drug 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.

Discuss timeline at the site for IRB review and contract and indemnification agreement review and signoff.

3. **After the visit**

Once the protocol is finalized, prepare the following:

- The site-specific informed consent form
- The IRB submission
- The final budget

Submit the electronic clinical trial agreement to the Grants and Contracts Administrator.

Track documents identified above at the site/within the institution.

Plan for the site initiation meeting.