PURPOSE: The purpose of this SOP is to outline the activities required to facilitate the clinical site selection process. The visit is conducted to determine if the site has the ability to conduct the research with adequate staff, training, education, experience and resources.

SCOPE: This SOP applies to all site personnel involved in the implementation and coordination of clinical research at the CRC.

RESPONSIBILITY: The qualified Investigator and Research Coordinator are responsible for providing the required information to the sponsor.

DEFINITIONS:

Feasibility Assessment: To evaluate the possibility to conduct a clinical trial in a proposed location based on a list of questions. The answers will allow the sponsor and qualified PI to make an informed decision regarding the feasibility of the study at his/her site.

Monitoring: The act of overseeing the progress of a clinical trial, and of ensuring that is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s)

Site Qualification Visit (SQV): A meeting with a representative from a sponsor representative to ensure the institution is fully capable and equipped to run a specific clinical trial. This visit may also be referred to as Site Selection Visit (SSV) or Pre-Study Qualification Visit (PSQV). The sponsor representative will usually request a tour of the facility and time to discuss the fundamentals of the protocol and how that relates to the feasibility of recruiting potential participants. Other topics of discussion during the SQV include:

- Investigator responsibilities
- Qualifications of investigator or other site personnel
- Study objectives, protocol-required procedures, eligibility criteria, and patient recruitment
- IRB (e.g., informed consent requirements)
- Adverse event reporting, source documentation, and record retention
- Space requirements, availability of a secure area to store investigational drug or devices, and availability of required equipment

Sponsor: An individual, company, institution, or organization that takes responsibility for and initiates a clinical research trial

PROCEDURE:

1. The Investigator or study coordinator will be contacted by the sponsor representative to schedule a SQV at the CRC. The study coordinator will consider sending a Site Qualification Letter to the Monitor (Appendix R)

2. The study coordinator will schedule the visit with the sponsor on a mutually agreed upon date during regular business hours to ensure that as many study members as possible can attend.

3. The study coordinator will complete a SQV Checklist (Appendix Q) once a scheduled date has been determined.

4. The study coordinator will request an agenda from the sponsor representative at least 2 weeks in advance of visit or creates one for the visit if not provided.

5. The study coordinator will ensure that all research staff attendees have copies of all research related materials prior to the visit (e.g.: agenda, protocol, if available).

6. The study coordinator will conduct the timely visit with the sponsor representative, reviews departmental procedures, and answers any questions the sponsor may have.

7. The study coordinator will provide the following information during the visit:

    6.1. Demonstrate the site's ability to recruit the appropriate number of subjects within the protocol-specified time frame.
    6.2. Current licensing or accreditation of local clinical laboratories (if applicable)
    6.3. Copy of local laboratories' director's CV signed within 2 years (if applicable)
    6.4. Current normal lab reference ranges (if applicable)
    6.5. Updated copies of research personnel's CVs, medical licenses, etc.

8. The study coordinator will take the representative on a tour of the CRC to view exam rooms, equipment, and sample preparation areas.

9. The Investigator may be present for the duration of the visit or meet with the sponsor representative briefly upon request.

10. If the tour will include the Clinical Investigational Research Pharmacy (CIRP), the research pharmacist and/or research technician will be notified in advance to schedule the tour.

11. The sponsor representative will discuss and review the items that need to be completed or addressed; usually documented on a qualification checklist provided by the sponsor representative.

12. The Principal Investigator and/or study coordinator will complete, sign and place a completed site qualification checklist in the site's files.

REFERENCES:	21 CFR 312 Subpart D: Selecting Investigators and Monitors May 1997 International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline (E6), Section 5.18 Monitoring;
RELATED POLICIES:	SOP# 102: Training Clinical Research Staff SOP#104: Clinical Study Conduct
APPENDICES:	Appendix Q: Site Qualification Visit (SQV) Checklist; Appendix R: Site Qualification Letter to Monitor

REVISION HISTORY: Keep a running history of all revision dates.

Approval Date	Effective Date	Review/Revision Date
01/01/2015	**06/01/2016**	