SOP#: ADCR-1	**Sponsor Site Qualification Activities**
Version #: 1.0	**Next Review Date: 01/2026**
Approved Date: 01/2024	**Review Interval Period: Biennial**
NCI Clinical Director Signature/ Effective Date:	James Gulley, M.D., Ph.D. Digitally signed by James Gulley, M.D., Ph.D. Date: 2024.01.08 15:02:22 -05'00'

POLICY

Sponsors may assess sites for staff experience, facilities, and other operational needs necessary to perform a clinical trial. This is often done when a sponsor has not yet worked with a site and may include a site qualification questionnaire (sometimes called a "Feasibility Questionnaire") and/or an on-site assessment of the facility.

The site questionnaire usually will request information about the investigator and study staff, as well as information on laboratory facilities, patient care units, pharmacy, source documentation, and regulatory processes. Since input from multiple groups is needed, the Protocol Support Office (PSO) will coordinate the completion of the questionnaire and if requested, will also provide appropriate policies and procedures. The Office of Education and Compliance (OEC) will assist if needed.

The on-site qualification visit includes meeting with the study staff, touring the pharmacy, clinical areas, research laboratories, and other areas where research activities may take place. The PSO and OEC teams must be notified when an on-site qualification visit is requested.

PURPOSE

To centralize the completion of site qualification questionnaire with other requested information and to harmonize the process of an on-site qualification visit if requested.

RESOURCES

NIH HRPP Policy & Guidelines

CCR Policies/Standard Operating Procedures

PROCEDURES

Questionnaire Completion

STEP 1: PI/Team Receive Questionnaire from Sponsor

- Typically, the PI will receive a site qualification (feasibility) questionnaire from the sponsor (or sponsor's designee – e.g., CRO). PI must send this questionnaire to their PSO Manager to facilitate accurate completion if the PSO manager is not included in the sponsor's email.

STEP 2: PSO will Facilitate Completion of Questionnaire

- PSO staff will facilitate the completion of the questionnaire with the research team and appropriate departments with the help of the research team (e.g., pharmacy, DTM).
- PI or Clinical Research Coordinator (CRC) will complete the components of the questionnaire applicable to the research team (e.g., number of staff) and protocol (e.g., enrollment).
- For questions about policies and SOPs, please refer the sponsor to both the NIH HRPP Policy & Guidelines website and the CCR Policies/Standard Operating Procedures website. Both websites are open for public viewing.
- PSO and/or CRC will inform OEC when a site qualification questionnaire has been requested for a certain PI and request assistance as needed.
    - OEC and/or PSO Director will inform OCD leadership as needed

IMPORTANT: If the questionnaire requests information about previous FDA inspections, please consult with OEC.

STEP 3: Submission of Completed Questionnaire to Sponsor

- PI/CRC or PSO Manager will submit the completed questionnaire to sponsor.
- Completed questionnaire will be saved by PSO Manager as applicable.

On-Site Qualification Visit

STEP 1: PI/team is Contacted by Sponsor with request for On-site Visit

- PI/Team must clarify with sponsor:
    - Anticipated length of visit (should be no more than one day)
    - Specifically what areas they want to visit (pharmacy, outpatient clinic, day hospital, research labs, etc.)
    - How many sponsor staff are going to attend the meeting? (will affect meeting room size)
    - What CCR/study staff need to be present for the meeting?
    - Can the meeting be hybrid for those staff that cannot attend in person?

STEP 2: Secure a Meeting Room for the Visit

- As soon as the request is made by the sponsor for an on-site visit, CRC will contact OEC (NCI CCR OEC in Global) with the following information:
    - Three dates that PI and study staff are available
    - Other information from sponsor specified in Step 1
- OEC will secure a meeting room for three possible dates/times that can be given to the sponsor for on-site availability.

STEP 3: Contact Areas that Sponsor Requests to Visit

- CRC will contact areas that the sponsor wants to visit to assess the availability of those areas during the proposed day of the visit. OEC will assist as needed. See Contact List attached below this SOP.
- CRC will keep an agenda for visit and times that other areas can see the sponsor representative.

  Note: Some areas (intensive care, inpatient units) may not allow nonpatient visitors.

STEP 4: Visit Preparation and Day of Visit

- CRC will send sponsor representative NIH campus access information.
- CRC will send all people involved in the visit the final meeting agenda when available.
- CRC should plan to meet the sponsor representative on the morning of the visit to escort them to the meeting room and be available for the entire visit to escort to different areas of the Clinical Center.
- OEC staff will attend the meeting if available.

STEP 5: After the Visit

- PI, CRC and/or PSO Manager will send any requested additional information to the sponsor representative. OEC will assist as needed.
- PSO Manager will save any related correspondence.