

	<p style="text-align: center;"><b>Standard Operating Procedures</b></p>
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Procedure Category:	Pre-Study Activities
Procedure CLN-02-04:	Preparation for Sponsor/CRO Pre-Study Visit

**Procedure Overview**

This procedure describes the necessary activities performed by CACR personnel in preparing for and assisting in the pre-study visits carried out by the sponsor or clinical research organization (CRO). This procedure covers tasks necessary to ensure adequate staffing, facilities, patient population, understanding of the site responsibilities, obligations, and roles, review of study objectives, overall study design, specialized procedures, patient criteria, and initiation of financial arrangements related to the targeted protocol.


**Responsible Individuals**

Qualified CACR personnel (including, but not limited to, Study Coordinator and Research Assistant); Investigator; Laboratory Manager (if in-house lab is to be used); Pharmacy Manager; Director, CACR

**Procedure**

1. The pre-study visit by a sponsor or CRO is scheduled for a time agreed to by the sponsor and the CACR. This visit is designed to allow the sponsor to assess the ability to conduct the targeted study and to further establish communication between the CACR and the sponsor or CRO.
2. Upon the receipt of the request from the sponsor or CRO to schedule a pre-study visit, the assigned CACR personnel checks to make sure all necessary personnel are available to meet with the sponsor or CRO representative.
3. Every effort is made to select a day and time for the pre-study visit that is acceptable to all the necessary study personnel. If the necessary study personnel are not available to meet with the sponsor or CRO on the pre-selected day, if acceptable with the sponsor or CRO, a study back-up can be identified to attend the required visit meetings. The responsible individual must be familiar with the targeted protocol prior to the visit. This is accomplished by a review of the Investigator Brochure, the final protocol, and the case report forms, as applicable.
4. CACR personnel ask the sponsor or CRO for the meeting agenda and any relevant study documentation in advance of the meeting.
5. CACR personnel will schedule the visit and notify all necessary study personnel of the scheduled visit, at least two weeks in advance (if possible).

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Approval Signature, Date:	

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6. CACR personnel confirm the schedule for the pre-study visit one or two days in advance of the visit, either by phone, fax, or email.
7. CACR personnel ensure that appropriate space and equipment has been reserved for the sponsor or CRO to meet with the staff and review all relevant materials.
8. CACR personnel ensure all relevant materials requested by the sponsor or CRO are complete and available. These materials may include the Administrative Study Checklist (see Appendix 1), original Form 1572 (see Appendix 2), curriculum vitae(s) for staff listed on Form 1572, current lab certifications, lab value ranges, original signed protocol, IRB membership list, informed consent, Investigator Brochure, case report form notebook, subject population data, and budget information.

**Documentation**

Documentation for this procedure includes the Administrative Study Checklist, the meeting agenda, supporting study documentation, and sponsor and/or CRO communication documentation.

**Deviation Approval**

The Director, CACR or designee, must approve deviation(s) from this procedure. The Director, CACR or designee, must store documentation of the deviation approval in the appropriate study file.


**Relevant Definitions**

IRB – Institutional Review Board  
 Form 1572 – Statement of Investigator  
 CRA – Clinical Research Associate

**Appendices**

Appendix 1 Administrative Study Checklist  
 Appendix 2 Form 1572

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**Procedure Author**  
Manager, Research Support Core

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