Study Start-Up
SS – 203.01

STANDARD OPERATING PROCEDURE FOR PRE-STUDY SITE VISIT (PSSV)

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I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed by Georgia CORE when it conducts a Pre-Study Site Visit (PSSV) to review the protocol and discuss its implementation via the Georgia CORE Research Network:

- Meet with site Investigator and research personnel to review their qualifications for the study,
- Discuss the availability of patients for enrollment and the presence of any similar/competing studies,
- Assess the facilities and capabilities of the Research Network site for implementing the study,
- Evaluate the possibility of the Research Network site participating in the study.

2. SCOPE

This SOP applies to the procedures for conducting the pre-study site visit for clinical studies subject to investigational new drug (IND) regulations for drugs and biologics and for those which are investigational new drug (IND) exempt during all investigational phases of development. It describes the steps followed by Georgia CORE from the time a PSSV is scheduled until all follow-up activities associated with the visit have been completed. Exception: a site visit is not necessary if the site has worked on a study with Georgia CORE within the last 12 months and there have been no major changes at the site based on a telephone assessment.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General responsibilities of sponsors
21 CFR 312.52	Transfer of obligations to a contract research organization
21 CFR 312.53	Selecting investigators and monitors
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.66	Assurance of IRB review
21 CFR 312.68	Inspection of investigator's records and reports
21 CFR Part 11	Electronic Records; Electronic Signatures
January 1988	Guidelines for the Monitoring of Clinical Investigations

4. REFERENCES TO OTHER APPLICABLE SOPs

SS-201	Assessing Protocol Feasibility
SS-202	Investigator Selection
SS-204	Site Initiation Visit
SM-301	Communication
SM-303	Documentation and Records Retention

5. ATTACHMENTS

A. Agenda for Pre-study Site Visit (PSSV)
B. Checklist of Activities Associated with the Pre-study Site Visit
C. Pre-study Site Visit Follow-up

6. RESPONSIBILITY

This SOP applies to Georgia CORE staff members and others involved in arranging, managing, or participating in the pre-study site visit. This may include one or more of the following:

- President and CEO
- Chief Medical Officer
- Principal Investigator
- Georgia CORE staff and consultants

7. DEFINITIONS

The following definitions from the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline, apply to this SOP.

Clinical trial/study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

Institutional Review Board (IRB): An independent body of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Investigator's Brochure (IB): A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

Subinvestigator: Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

8. PROCESS OVERVIEW

A. Preparing for the pre-study site visit
B. Conducting the pre-study site visit
C. Following-up after the pre-study site visit

9. PROCEDURES

A. Preparing for the pre-study site visit

• Research Staff/Consultant	Ensure that the site's Master Clinical Research Agreement including the confidentiality agreement with Georgia CORE is current. If a Master Clinical Research Agreement is not in effect, a study-specific agreement incorporating the confidentiality agreement may be substituted. If agreements are not in effect at the time of the PSSV, request the Investigator or authorized signer for the site to execute the appropriate documents.
	Ensure that the site has received the protocol, budget, informed consent, case report form and other study documents, if available.
• Research Staff/Consultant	Schedule the visit with the site discussing any areas of special interest that require advance scheduling, such as: • Availability of Investigator and required research team members • Visiting the treatment site (clinic or hospital), pharmacy, central laboratory, medical records department; • Seeing any specialized equipment needed to implement the study; • Meeting briefly with ancillary personnel involved in any specialized data collection; • Visiting any ancillary facilities. Complete the pre-study visit agenda and review the agenda with the site prior to the visit. (Attachment A, Agenda Template for Pre-Study Site Visit)
	If not on file, obtain copies of current Curricula Vitae and resumes

	from the site for the Investigator and key research personnel.

B. Conducting the pre-study site visit

• Research Staff/Consultant	Meet with the Investigator and key research personnel, identified by the Investigator, to review protocol synopsis and any other available study document(s).
	Tour the research facility where the clinical trial will be conducted with Investigator and/or key site representatives (See Attachment B, Checklist of Activities Associated with the Pre-study Site Visit.)

C. Following up after the pre-study site visit

• Research Staff/Consultant	Complete the pre-study site visit follow up summary to document the pre-study site visit. Provide copies to the Chief Medical Officer and to the Investigator initiating the study. (Attachment C, Pre-study Site Visit Follow-Up).

10. HISTORY OF CHANGES

Version Number	Section Number	Modification	Approval Date
203.00	All	Original Version	
203.01	3, Attachment B	Addition of electronic record guidelines and added items to discuss (last 2 bullets)	09 March 2012
203.01	All	No changes necessary	01 July 2014
203.01	All	No changes necessary	21 March 2017

Attachment A

AGENDA FOR PRE-STUDY SITE VISIT		
10 minutes	Welcome and introductions	Georgia CORE, Investigator and key research personnel, Sponsor personnel, if applicable
30 minutes	Tour of facilities	Georgia CORE, Research Coordinator Sponsor personnel, if applicable
30 minutes	Review of protocol or protocol synopsis, Informed Consent and Case Report Forms (CRFs), if available Discussion of roles and responsibilities of Georgia CORE, Research Network site and Sponsor, if applicable	All
60 minutes	Site qualifications including availability of SOPs	Georgia CORE, Research personnel, Sponsor personnel, if applicable
15 minutes	Time line for the study Strategies for patient recruitment	All
5 minutes	Review of action items and next steps	Georgia CORE, Investigator, Key research personnel, Sponsor personnel, if applicable
5 minutes	Summary	Georgia CORE and Investigator

Attachment B

CHECKLIST of ACTIVITIES ASSOCIATED with the PRE-STUDY SITE VISIT

1. Before the pre-study site visit

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

Ensure that key site personnel receive copies of the protocol synopsis and other protocol documents including Informed Consent and Case Report Form, if available, for review and comment.

Prepare information on:

- Georgia CORE, Principal Investigator, Research Network participants
- An overview of the protocol
- Contractual obligations
- Roles and responsibilities of parties in particular, IRB and regulatory responsibilities, registration of the study
- Relevant Georgia CORE or Sponsor SOPs, if applicable
- Introduction to the Investigators' Exchange for access to study related documents and to GeorgiaCancerTrials.org for profiles of clinical trials and investigators
- Names of key contacts, telephone numbers, and e-mail addresses for Georgia CORE staff and sponsor, if applicable

2. During the pre-study site visit

Tour the facilities including:

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

Be prepared to discuss the following:

- Comments and questions from site personnel's review of the protocol
- Any requests for site-specific modifications to the protocol
- IRB (central or local)
- Laboratory (central or local)
- Provision for any specialized procedures
- Any specialized data entry procedures
- Storage space required for study drug, specialized equipment, computers, etc.
- Specimens processing and storage
- IATA certifications for applicable staff

Provide an overview of the management process for the study, including:

- Georgia CORE and sponsor, if applicable, responsibilities (contractual and SOPs)
- Monitoring plan
- Communication
- Overview of data management

Discuss the following:

- The benefits of the study for the site's patient population
- Expected enrollment, strategies for patient recruitment
- Publication policy
- 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
- List of generic clinical trials with number of patients required, recruited and completed (overall and completed recently)
- Results of any FDA or other site audits, any warnings or other findings if audit completed
- Exclusion from any federal health program, such as Medicare or Medicaid
- Site capability for electronic data capture
- Any policies regarding access to electronic medical records which may impact monitor's access to medical records
- Copies of any publications by research staff relevant to the clinical study under consideration
- Estimate number of potential study participants, any concerns regarding study participant recruitment
- Anticipated time line for the study
- Information on key dates, such as:
    - Investigator's meeting
    - Study initiation visit
    - Study drug availability, if applicable
    - Targeted end date for patient enrollment
- Georgia CORE chain of command and communication plan

Determine if there is any other information that the site requires

Discuss the IRB review process, and get copies of the IRB SOPs and Federal Wide Assurance (FWA) number, if applicable

3. Pre-study site visit

Compile the pre-study site visit follow up summary; review with the Chief Medical Officer if necessary to determine appropriateness of site participation

Notify the site in writing if selected to participate in the clinical trial.

Once the protocol is finalized, prepare the following and provide to site:

- Informed consent form
- IRB submission/approval
- Final budget

Submit the clinical trial agreement/addendum to the site for signoff. Distribute executed copies to all parties.

Attachment C

PRE-STUDY SITE VISIT FORM

Investigator:	**Indication:**	**Protocol no:**
Trial site:	**CRA:**	**Site no:**
Inv Product:	**Date of last visit:**	**Visit Date:**

Site personnel present:	
Georgia CORE or Georgia CORE designated personnel present:	
List other site personnel that will be working on this study, including position and contact information.	

Action items resulting from present visit	**Responsible**

Overall Impression

1. CRA judgement regarding motivation and attitude of the site. *Please provide details including why this site should or should not be included in this trial and any major issues that need to be overcome.*
Comments:

Report prepared by: Signature: _____	Date of report:	Date of next visit:
Send original **signed** report to Georgia CORE for review and signature and retain one copy		
Copies (specify initials or name) - these may be sent electronically to the following:		CRA:
PHYSICIAN:	Georgia CORE:	Others:

Report reviewed by Georgia CORE: Signature: _____	Date of review:
Issue(s) identified requiring the attention of the PHYSICIAN (to be completed by Evaluator): ☐ No - Evaluator to submit the original signed report for archival on Georgia CORE server ☐ Yes - Evaluator to provide the original signed report to the Investigator to address issue(s)	

Issues addressed and documented by Investigator: Signature: _____	Date of review:
Investigator to submit the original signed report for inclusion in the Trial Master File	

Protocol and Patient Population

	Yes	No	Not done	Not applicable
2. Were the nature, design and time frame of the proposed clinical study discussed with the Investigator? *Please provide details regarding the contents of the discussion, any major questions or issues, etc.*				
Comments:				
3. Does the Investigator and staff have experience with FDA regulated human subject research (number and type of studies)? *Please provide list of clinical trials with number of patients required, recruited and completed (overall and completed recently).*				
Comments:				
4. Does the site have the patient population to meet the target enrollment for the study? *Please provide details regarding the method of recruitment, existing database of patients, referral network, activity logs, chart reviews, etc.*				
Comments:				

Study Personnel

	Yes	No	Not done	Not applicable
5. Are the site's personnel sufficiently qualified to conduct the study? *Please provide details regarding experience, training, certifications, work on prior studies, standard operating procedures, etc.*				
Comments:				
6. Does the site have sufficient personnel resources to conduct the study? *Please provide details regarding availability, time to conduct study, available for monitoring visits, conflicting studies, etc.*				
Comments:				
7. Was the GCP/source document verification discussed with the Investigator? *Please provide details regarding nature of discussion, including GCP, source verification, financial disclosure, reporting of SAEs,*				
Comments:				
8. Has the Investigator or staff had regulatory issues or problems in prior studies or been exempted from federal health care programs, such as Medicare or Medicaid? *Please provide details regarding FDA or Sponsor audits, any 483s, any sanctions from a Regulatory Agency, etc.*				
Comments:				

Investigational Product

	Yes	No	Not done	Not applicable
9. Are the drug storage facilities adequate? *Please provide assessment of the drug storage facilities, e.g. accessibility, condition, location, personnel, drug accountability procedures, etc.*				
Comments:				

Laboratory

	Yes	No	Not done	Not applicable
10. Are the laboratory processes and procedures adequate? *Please provide details regarding labs reviewed, location, sample collection procedures, accreditation, storage, normal values, special equipment, etc.*				
Comments:				

Location and Source Documentation

	Yes	No	Not done	Not applicable
11. Does the site have adequate space facilities to conduct the study? *Please provide details regarding appropriate space for monitoring, record-keeping, conducting patient visits, special equipment, logistics of protocol procedures between various co/investigators (e.g. radiologist, surgeon) etc.*				
Comments:				
12. Are source documents readily available? *Please provide details regarding accessibility of records, location of records, use of hospital or shadow charts, etc.*				
Comments:				

IRB Approval and Clinical Study Agreements

	Yes	No	Not done	Not applicable
13. Are the IRB and contract/budget processes compatible with study timelines? *Please provide details regarding processes, timeframe for approval, special requirements, whether site has worked with Georgia CORE previously, etc. Also specify the type of IRB being used, timetable of meetings and deadlines for submission. Note if there are local IRB requirements and estimated timetable*				
Comments:				

Electronic CRF
(Check Not Applicable if not using e-CRF)

14. Does the site have the necessary computer equipment and knowledge to conduct the study (for e-CRF trials)? *Please provide details regarding availability or need for computer equipment, high speed access, computer training, prior experience with e-CRF, etc.*	Yes	No	Not done	Not applicable
Comments:				
15. Was the e-CRF assessment completed? *Please provide details regarding formal e-CRF assessments conducted by IT support department.*	Yes	No	Not done	Not applicable
Comments:				

16. Is the site's electronic records and computer network system Title 21, Part 11 compliant?	Yes	No	Not done	Not applicable
Comments:				

Miscellaneous

17. Tissue Banking *Does the site have the capability to obtain tissue samples for DNA banking? Detail any logistics requirements, etc.*	Yes	No	Not done	Not applicable
Comments:				