Study Start-Up
SS – 202.00

STANDARD OPERATING PROCEDURE FOR
Investigator Selection

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(Signature and Date)

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30 May 2017
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I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed by Georgia CORE when it identifies and qualifies potential Investigators for clinical studies at contracted research network sites.

2. SCOPE

This SOP applies to the procedures for identifying and qualifying potential investigators for clinical studies subject to investigational new drug (IND) regulations for drugs and biologics and those which are IND exempt during all investigational phases of development. It describes the steps followed by Georgia CORE from the time a list of potential Investigators is created to the completion of a list of Investigators qualifying for a pre-study visit (PSSV) or to be in the study 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 as assessed by telephone.

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
January 1988	Guidelines for the Monitoring of Clinical Investigations

4. REFERENCES TO OTHER APPLICABLE SOPs

SS-201	Assessing Protocol Feasibility
SS 203	Pre-Study Site Visit (PSSV)
SM-301	Communication
SM-303	Documentation and Records Retention

5. ATTACHMENTS

A. FDA Debarred or Disqualified Investigator or Organization, FDA Warning Letters, and Federal Health Care Programs Exclusions
B. Georgia CORE Site Solicitation Feedback form
C. Potential Investigator Assessment form

6. RESPONSIBILITY

This SOP applies to those Georgia CORE staff members involved in identifying, qualifying and recommending potential investigators for clinical studies. This may include one or more of the following:

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

7. DEFINITIONS

The following definitions from the International Conference on Harmonisation, 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.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. The investigator is responsible for compliance with NCI, OHRP, FDA, IHC and GCP guidelines. 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.

NCORP Lead Investigator: A physician who assumes full responsibility for the conduct of NCORP protocols approved by the CIRB and selected to be open at the members' site. Responsibilities include oversight of regulatory requirements, data management, pharmacy accountability, staff supervision and in most cases long term follow up beyond the period of actual treatment.

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. Identify potential investigators
B. Screen potential investigators
C. Create a list of investigators for potential PSSVs

9. PROCEDURES

Identify potential investigators

Responsible staff:	**Procedure:**
• Designee	Identify potential investigators to participate in the study under consideration. Study investigators will: • Meet the experience and eligibility requirements to conduct the study • Have sufficient time to complete the study in the required timeframe • Meet subject accrual and study population requirements • Complete all participant information requirements for study documentation • Have adequate support personnel with necessary training, experience and credentials • Have facilities that are suitable to conduct the study Confer with the Chief Medical Officer, the Investigator initiating the study and/or the Sponsor for advice on potential Investigators and on conducting assessments of a potential Investigator's suitability. The following sources may be used to identify potential investigators: • The Georgia CORE network • Board certified oncologists listed in the Georgia CORE Directory of oncologists • Investigators associated with American College of Surgeons Commission on Cancer Approved Cancer Programs

• Designee	• Referrals from other investigators Prior to contacting a potential Investigator, ascertain whether a potential Investigator has been debarred or otherwise disqualified from participating in FDA-regulated activities, and /or whether the potential Investigator has received any FDA Warning letters in the recent past. In addition, check if the potential Investigator has been excluded from any federal health care program, including Medicare and Medicaid. (Resources listed in Attachment A) If the potential Investigator is on the debarred, disqualified and/or federal health care exclusion list, share this information with the President and CEO and the Chief Medical Officer and do not proceed with the potential investigator. If the potential Investigator has received FDA Warning letters, share the findings with the Chief Medical Officer to determine how to proceed.

Screen potential investigators

• Designee	To assess general interest and qualifications, the initial contact with an Investigator site may be made by telephone or e-mail. Before disclosing the study details to the Investigator, the Investigator must sign the confidentiality agreement for the clinical study or be covered by the site's Master Clinical Research Agreement which incorporates the confidentiality agreement. In this case, the Investigator is to be reminded of and concur with the contractual confidentiality provision. Once the appropriate confidentiality agreement is in place, the clinical protocol or summary may be sent to the potential Investigator. The potential Investigator will review the documents and complete the Georgia CORE Site Solicitation Feedback Form. (Attachment B)

Create a list of potential investigators for pre-study visits

• Designee	Complete the Potential Investigator Qualification Form (Attachment C), via telephone, to identify the potential investigators best qualified to conduct the study. Review findings of the site assessments, when there are questions, with the Chief Medical Officer or Sponsor representative to determine what sites qualify for a Pre-Study Visit or qualify for the study and are exempt from the Pre-Study Visit.

10. History of Changes

Version Number	Section Number	Modification	Approval Date
202.00	All	Original Version	
202.00	All	No change was necessary	09 March 2012
202.00	All	No change was necessary	01 July 2014
202.00	All	No changes necessary	10 March 2017

Attachment A

FDA Debarred or Disqualified Investigator or Organization
FDA Warning Letters
Federal Health Care Programs Exclusions

To check if an investigator has been disqualified or restricted, go to the following web site:
http://www.fda.gov/ICECI/EnforcementActions/DisqualifiedRestrictedAssuranceList/ucm131681.htm

To check if an investigator or firm is debarred, go to the following web site:
http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/ucm2005408.htm

To see the Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) Letters, go to the following web site:
http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm092185.htm

To determine if an investigator or organization has received a warning letter (Form 483) from the FDA, go to the following web sites:
The first site gives you access to warning letters for investigators, IRBs, etc
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

The second site gives you access to warning letters for investigators and provides a mechanism for downloading the list if you want. There are additional links to such lists as the disqualified list at the bottom of the web page.
http://www.fda.gov/Drugs/InformationOnDrugs/ucm135198.htm

To determine if an investigator, practice staff or organization is excluded from Medicare and Medicaid go to the following web site:
http://exclusions.oig.hhs.gov/.

Attachment B

Site Solicitation Feedback Form

Date

(These variables would be populated from the Research Concept Design Form)
Study Name:
GA-CORE Protocol #
Study Phase
Site, Stage, Study endpoint

Investigator Name

Institution/practice

Contact information – address, email, phone, fax, etc.

Study participation level:

__Very interested ___Have competing protocols for this patient population

___Lukewarm ___No interest

__would serve as investigator and enter patients on the trial. Our practice sees ___# of patients per month who would qualify for the study trial

___would screen patients to the trial

___would refer patients to the trial

___would not recommend patients for the trial

Benefits of the trial (1-2 sentences)

Concerns/issues about the trial (1-2 sentences)

This form is available via the Investigators' Exchange on the web site and is designed to be completed electronically.

Attachment C

Potential Investigator Qualification Form

The purpose of this form is to:
1. Qualify potential investigators and their facilities as a clinical site and
2. Re-qualify previous investigators who have been qualified within the past year.

Potential Investigator: _____

Title/Department: _____

Site Name/Address: _____

_____

Telephone: _____ Fax: _____

E-mail: _____

Date of last qualification visit: ___/___/___ (Attach copy of previous Form)

As a result of that visit, was the potential Investigator selected to conduct a clinical study sponsored by (Name of Sponsor)? ___Yes ___No

If Yes, did the investigator meet the requirements of the previous study(s)? ___Yes ___No

If Not selected previously, why not? _____

Names/Titles of site personnel involved in that study: ___N/A
Name: _____ Title: _____

Name: _____ Title: _____

Name: _____ Title: _____

If the potential Investigator is unable to answer any of these questions, arrange to contact him/her at another time to complete the form.

Is the Investigator covered by an executed site Master Clinical Research Agreement? ___ Yes ___ No

Has the Investigator signed/returned the study specific Confidentiality Agreement? ___ ~~Yes~~ Yes ___ No ___ NA

If Yes, has the Investigator received and reviewed the protocol? __ Yes ___ No

If Yes, has the Investigator completed the Georgia CORE Site Solicitation Feedback Form? ____Yes ____No

Investigator's Experience with Federally Regulated Research	
• Prior clinical research experience	☐Yes ☐No
• Approx. number of clinical research studies	_____
• Experience in which phases (check all that apply)	☐ I ☐II ☐III ☐IV
• Have you ever held an IND or IDE	___IND ___IDE ___Other
Investigational Product	
• Prior Experience with this Investigational drug/device?	☐Yes ☐No
• If No, Prior Experience with similar drugs/devices?	☐Yes ☐No

Human Subject Protection		
• Have the Investigator ever been audited by the FDA?	☐Yes	☐No
○ If yes, were there any 483s issued?	☐Yes	☐No
• Has the Investigator ever been audited by a Sponsor?	☐Yes	☐No
• Has the Investigator ever been sanctioned by a Regulatory Agency?	☐Yes	☐No
Study Team		
• How many potential Sub-investigators?	_____	
• Does he/she have experience in this or other clinical studies?	☐Yes	☐No
• How many potential Sub-Investigators do not have any clinical research experience?	_____	
• How many potential clinical research coordinators?	_____	
• What is the distribution of studies per coordinator?	_____	
Protocol Requirements		
• The protocol requires (outline subject enrollment criteria and projected sample size and timeline for each site). Will the Investigator be able to enroll that many study subjects?	☐Yes	☐No
• Does the Investigator's patient population meet the study subject requirements?	☐Yes	☐No
• The protocol requires a certain number and type of monitoring visits (describe). Will the Investigator and study team be available for them?	☐Yes	☐No
Clinical Laboratory Accreditation		
• Clinical laboratory accrediting body?	_____	
• Date accreditation/certification expires?	_____	

Finance

- As PI, is he/she aware of all FDA financial disclosure requirements for investigators, and agree to comply? ☐Yes ☐No

Regulatory

PI understands and agrees to the following:

- Access to study and medical records ☐Yes ☐No
- Record keeping and Retention ☐Yes ☐No
- Reporting Requirements ☐Yes ☐No
- Final Clinical Study Report ☐Yes ☐No
- Inventory Storage ☐Yes ☐No
- Drug/Device storage and management ☐Yes ☐No
- Facility is able to accommodate study requirements ☐Yes ☐No

Interviewer Comments/Observations:

Recommendation:

_____ Qualification site visit should be conducted.
_____ A qualification site visit has been conducted within the past year and I recommend this site for the current study without another Pre-study visit.
_____ I do not recommend this site.(See comments for rationale)
_____ The site is not suitable for this study but should be considered for others in the future.

_____ _____ _____

Name (please print) Signature Date