

Study Management SS - 202.01

STANDARD OPERATING PROCEDURE FOR Investigator Selection

Approval: Lynn M. Durham, Ed.D.
President and CEO

04 Feb 2021

(Signature and Date)

Approval: Frederick M. Schnell, MD, FACP
Chief Medical Officer

04 Feb 2021

(Signature and Date)

Issue Date: 01 June 2017
Effective Date: 01 September 2020
Expiration Date: 01 September 2022
Document Review Date: 30 June 2020
Reviewer: Jane Clark, PhD, RN, AOCN, OCN (2020)
Previous Reviewers: Joni Shortt, BSN, RN, CCRC (2017)
Alice Kerber, MN, APRN (2014)
Primary Author: Anita Clavier, BSN, MPH (2013)

1. INTRODUCTION AND PURPOSE

Georgia CORE is responsible for ensuring that potential Research Network site Investigators for studies subject to investigational new drug (IND) regulations for drugs and biologics and those which are IND exempt during all investigational phases of development are identified and qualified to conduct the study. The purpose of this SOP is to describe the process by which Research Network site Investigators are identified and qualified for participation in studies.

2. SCOPE

This SOP applies to the steps involved in identification and selection for all Investigators and Subinvestigators participating in 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.

This SOP described the steps followed by Georgia CORE staff and consultants from the time a list of potential Investigators is created to the completion of a list of Investigators qualifying for a Pre-study Site Visit (PSV) to be in the study. A Research Network site Investigator also may be identified and qualified if he/she has participated on a study with Georgia CORE within the last 12 months and no major changes have occurred at the site as assessed by telephone communication.

3. APPLICABLE REGULATIONS AND GUIDELINES

The Code of Federal Regulations and the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline and selected program and guidance documents apply to this SOP (Appendix A).

4. REFERENCES TO OTHER APPLICABLE SOPS

SM - 201 Assessing Protocol Feasibility
SS - 203 Pre-study Site Visit (PSV)
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 Program Exclusions
- B. Georgia CORE Site Solicitation Feedback Form
- C. Potential Investigator Assessment Form

6. RESPONSIBILITY

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

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

7. DEFINITIONS

The following definitions apply to this SOP (Appendix B):

Clinical trial/study

Investigator

Investigator's Brochure

NCORP Lead Investigator

Protocol

Sponsor

Subinvestigator

8. PROCESS OVERVIEW

- A. Identifying potential investigators
- B. Screen potential investigators
- C. Create a list of investigators for PSVs
- D. Create a list of approved investigators

9. PROCEDURES

A. Identifying Potential Investigators

President and CEO
Chief Medical Officer
Georgia CORE Staff
and consultants

Identify potential Investigators to participate in the study under consideration. Potential Investigators will:

- meet the experience and eligibility requirements to conduct the study,
- have sufficient time to complete the study in the required timeframe
- meet study population requirements and subject accrual,
- have adequate support personnel with necessary training by experience or education and credentials,
- have facilities and equipment that are required suitable to conduct the study.

The following sources may be used to identify potential Investigators:

- Georgia CORE Research Network on www.Georgiacancerinfo.org
- Investigators associated with the American College of Surgeons Commission on Cancer Approved Cancer Programs (Accessed 01.31.20 from <https://www.facs.org>) (<https://www.facs.org/search/cancer-programs?state=GA>),
- Referrals from other qualified and approved Investigators.

Prior to contacting a potential Investigator, ascertain whether the potential Investigator:

- has been debarred or otherwise disqualified from participating in FDA-regulated activities,
- has received any FDA Warning Letters,
- has been excluded from any federal health care program, including Medicare and Medicaid (Resources listed in Attachment A).

To assess general interest and qualifications, the initial contact with a potential Investigator ~~site~~ may be made by telephone or e-mail.

Before disclosing the study details, the potential Investigator must:

- sign the Confidentiality Agreement for the clinical study or,
- be covered by the Georgia CORE Research Network Master Clinical Research Agreement which incorporates the confidentiality agreement,
- Review the contractual confidentiality provision of the Master Clinical Research Agreement and concur with the provisions.

Once the appropriate confidentiality agreement has been executed, 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).

B. Screening Potential Investigators

Georgia CORE staff and consultants	Complete the Potential Investigator Qualification Form (Attachment C) by telephone communication.
------------------------------------	---

C. Create a List of Potential Investigators for Pre-study Visits (PSV)

Georgia CORE staff and consultants	Create a list of potential investigators best qualified to conduct the study with supporting documents.
------------------------------------	---

Review potential investigator screening procedure and when questions exist, review findings with the Chief Medical Officer or Sponsor representative to determine which Investigators/sites qualify for a Pre-study Visit or qualify for the study and are exempt from the Pre-study Visit.

D. Create a List of Approved Investigators

Georgia CORE staff and consultants	Create a list of approved Investigators for the study after completion of the Pre-study Visit, review or PSV findings and approval by Georgia CORE administration.
------------------------------------	--

Notify appropriate regulatory authorities, IRB, and Sponsors of the approved study Investigators and sites.

10. History of Changes

Version Number	Section Number	Modification	Approval Date
202.00	All	Original Version	
202.00	All	No change necessary	09 March 2012
202.00	All	No change necessary	01 July 2014
202.00	All	No change necessary	10 March 2017
202.01	All	Edited for clarity and logical consistency, updated links on Attachment A, added Section 9D	30 June 2020

ATTACHMENT A:

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

Task to Perform	Website	Date of Update
Check to confirm that an investigator has not been disbarred	https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications	12/20/2019 Frequency of Updates Not Listed
Check to confirm that investigator or site has not been disqualified or restricted	https://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true	12/20/2019 Frequency of Updates Not Listed
Check to confirm if an investigator or organization has not received a FDA Warning Letter (Form 483)	https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters	12/20/2019 Frequency of Updates Not Listed
Check to confirm that an investigator has been inspected within the past	https://www.accessdata.fda.gov/scripts/cder/cliil/dsp_Search.cfm	12/02/2019 Updated Quarterly
Check to confirm that an investigator, practice staff, or organization has not been excluded from Medicare and Medicare	https://exclusions.oig.hhs.gov/	Frequency of Updates Not Listed

Source: Food and Drug Administration <https://www.fda.gov> (Accessed 30 June 2020)

Source: Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOS) Letters (As of 1/16/2009) (Accessed 30 June 2020)
<https://www.fda.gov/regulatory-information/electronic-reading-room/cder-notice-initiation-disqualification-proceedings-and-opportunity-explain-nidpoe-letters-date>

ATTACHMENT B:
Georgia CORE Site Solicitation Feedback Form

Date

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)

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 _____ 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	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Approx. number of clinical research studies	_____
• Experience in which phases (check all that apply)	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV
• Have you ever held an IND or IDE	____IND ____IDE ____Other
Investigational Product	
• Prior Experience with this Investigational drug/device?	<input type="checkbox"/> Yes <input type="checkbox"/> No
• If No, Prior Experience with similar drugs/devices?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Human Subject Protection	
• Have the Investigator ever been audited by the FDA?	<input type="checkbox"/> Yes <input type="checkbox"/> No
○ If yes, were there any 483s issued?	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Has the Investigator ever been audited by a Sponsor?	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Has the Investigator ever been sanctioned by a Regulatory Agency?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Study Team	
• How many potential Sub-investigators?	_____
• Does he/she have experience in this or other clinical studies?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Does the Investigator's patient population meet the study subject requirements?	<input type="checkbox"/> Yes <input type="checkbox"/> No
• The protocol requires a certain number and type of monitoring visits (describe). Will the Investigator and study team be available for them?	<input type="checkbox"/> Yes <input type="checkbox"/> 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