

Study Management SS - 202.01

STANDARD OPERATING PROCEDURE FOR Investigator Selection

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04 Feb 2021

(Signature and Date)

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04 Feb 2021

(Signature and Date)

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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	Section Number	Modification	Approval Date
Number			
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 interestedHave competing protocols for this patient population
LukewarmNo interest
Would serve as investigator and enter patients on the trial. Our practice sees# of patients per month who would qualify for the study trialwould 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)

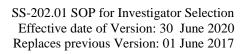
ATTACHMENT C:



Potential Investigator Qualification Form

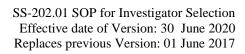
The purpose of this form is to:

	tors and their facilities as a clinical site and igators 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 th sponsored by (Name of Sponsored	re potential Investigator selected to conduct a clinical study or)?YesNo			
If Yes, did the investigator me _YesNo	et the requirements of the previous study(s)?			
If Not selected previously, wh	y not?			
Names/Titles of site personnel	involved in that study:N/A			
Name:	Title:			
Name:	Title:			
Name:	Title:			
If the potential Investigator is him/her at another time to com	unable to answer any of these questions, arrange to contact applete the form.			
Is the Investigator covered by Agreement?	an executed site Master Clinical Research Yes No			
Has the Investigator signed/ret Confidentiality Agreement?	turned the study specific Yes No NA			
If Yes, has the Investigator rec	ceived and reviewed the protocol? YesNo			
If Yes, has the Investigator con Solicitation Feedback Form?	mpleted the Georgia CORE Site YesNo			





Investiga	tor'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 Other	IDI	∃
Investiga	tional Product			
•	Prior Experience with this Investigational drug/device?	Yes	☐ No	
•	If No, Prior Experience with similar drugs/devices?	Yes	☐ No	
Human S	ubject Protection			
•	Have the Investigator ever been audited by the FDA?		Yes	☐ No
	o 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 Tea	am			
•	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 proje sample size and timeline for each site). Will the Investigator be ab 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 visi (describe). Will the Investigator and study team be available for the] 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 Yes	□ No
Record keeping and Retention	Yes	☐ No
Reporting Requirements	Yes 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