Study Management
SM – 301.01

STANDARD OPERATING PROCEDURE FOR Communication

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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

Clear, frequent, and documented communications among multiple parties and agencies is essential to ensure the scientific, clinical, regulatory, and ethical requirements of conducting clinical trials are being fulfilled.

The purpose of this SOP is to describe the various ways that Georgia CORE communicates with the Georgia CORE Research Network sites through oral, written, and electronic methods.

2. SCOPE

This SOP applies to communications between Georgia CORE, the Georgia CORE Chief Scientific Officer and the Georgia CORE Research Network site Investigators and staff with

regard to any aspects of a clinical study subject to investigational new drug (IND) regulations for drugs and biologics and those that are IND exempt during all phases of development. These communications serve to protect the safety and well-being of subjects by keeping Georgia CORE and the sites fully apprised of study activities and to ensure that the studies are carried out appropriately.

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

GA-102	Sponsor Responsibility and Delegation of Responsibility
SS -201	Assessing Protocol Feasibility
SS -203	Pre-study Site Visit
SS -204	Site Initiation Visit
SM-302	Interactions with the Institutional Review Board
SM-303	Documentation and Records Retention
SM-304	Routine Monitoring Visits
SM-305	Closeout Visits
SM-306	Adverse Event Reporting

5. ATTACHMENTS

A. Telephone Contact Log

6. RESPONSIBILITY

This SOP applies to Georgia CORE administration and staff and consultants involved in communicating the Georgia CORE Research Network site personnel, regulatory agencies, Sponsors, and the IRB, including the following:

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

7. DEFINITIONS

The following definitions apply to this SOP (Appendix B).
Clinical trial/study
Investigator
Sponsor
Subinvestigator

8. PROCESS OVERVIEW

A. General Communications
B. Communication Records

9. PROCEDURES

A. General Communications

Georgia CORE staff and consultants	Ensure the Research Network site Investigator and Subinvestigators have complied with the Georgia CORE confidentiality agreement requirements (e.g. master clinical research agreement, specific study confidentiality agreement) before distributing the protocol, Investigator Brochure or other confidential documents to the Research Network site. Review the required communications and the documentation of those communications with the participating Research Network Investigator, Subinvestigators and key study personnel at Georgia CORE and the sites at the initiation of the study. Communicate regularly and appropriately with Georgia CORE staff, Research Network site Investigator, Subinvestigators, and staff, the central IRB, and appropriate state and federal regulatory agencies about study-related issues. The frequency of communications depends on the subject matter and context, but should be regular enough that parties are thoroughly apprised of current study status. **NOTE:** For Investigator-initiated studies, request that the Investigator send Georgia CORE a copy of all new and revised study documents in a timely manner for distribution to the Subinvestigators, their staff, and to the IRB, as appropriate. Inform Research Network sites about the progress of the study through written updates, teleconferences, electronic or by other communication means. Provide copies of relevant communications to other Georgia CORE staff members, as appropriate.

B. Communications Records

Georgia CORE staff and consultants	Document pertinent verbal communications with the Research Network site Investigator, Subinvestigators, and site staff, the IRB and any other applicable parties. Documentation will be on a Telephone Contact Log (Attachment A) or by other appropriate memorandum to the file.

Each communication should be signed and dated by the party documenting the communication.

This record will be kept as documentation of the content and frequency of verbal communications.

Maintain originals or photocopies of all relevant communication documentation, including the Telephone Contact log, facsimile confirmations, printed e-mails newsletters and other pertinent communications and meeting notes, on file as required by SOP SM-303.02 Documentation and Records Retention.

Confirm, through monitoring, that Georgia CORE and Research Network sites are maintaining appropriate documentation in their study files. Follow-up with Georgia CORE staff and consultants and Research Network site staff as required.

10. HISTORY OF CHANGES

Version Number	Section Number	Modification	Approval Date
301.00	All	Original Version	
301.00	All	No change was necessary	09 March 2012
301.00	All	No change was necessary	01 July 2014
301.00	3	Updated date of Code of Federal Regulations	17 March 2017
301.01	All	Edits for clarification, update of forms, addendum of Georgia CORE Job Description: Chief Medical Officer	30 June 2020

ATTACHMENT A:
Telephone Contact Log

Date/Time:_____

Conversation between:_____ and _____

Summary of discussion:

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Date/Time:_____

Conversation between:_____ and _____

Summary of discussion:

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Date/Time:_____

Conversation between:_____ and _____

Summary of discussion:

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