Study Management
SM – 301.00

STANDARD OPERATING PROCEDURE FOR
Communication

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24 May 2017
(Signature and Date)

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30 May 2017
(Signature and Date)

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I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the various ways of communicating with the research sites as all regulatory, medical and ethical requirements are fulfilled, including telephone and written interactions.

2. SCOPE

This SOP applies to communications between Georgia CORE and the sites with regard to any 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

17 March 2017	Federal Code of Regulations
21 CFR 312.32	IND safety reports
21 CFR 312.33	Annual reports
21 CFR 312.44	Termination
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
FDA Information Sheets, October 1998	Sponsor-Investigator-IRB Interrelationship
October 2009	Guidance for Industry Investigator Responsibilities--- Protecting the Rights, Safety, and Welfare of Study Subjects
May 1997	International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline

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 leadership, staff members and consultants involved in trials. This includes the following:

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

7. DEFINITIONS AND GLOSSARY

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.

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.

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. General Communications
B. Communication Records

9. PROCEDURES

A. General Communications

• Research Staff/Consultant	Ensure the Investigator and Subinvestigators have complied with Georgia CORE's confidentiality agreement requirements (e.g. master clinical research agreement, specific study confidentiality agreement) before distributing the protocol, Investigator Brochure or other confidential documents to them or their staff. Review the required communications and the documentation of those communications with the participating 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, the Investigator, Subinvestigators, appropriate site staff, the central IRB, and appropriate government 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. 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. Request that the Subinvestigators and their staff send Georgia CORE a copy of all study related documents received directly at the site; then forward relevant documents to all of the study sites. Inform sites about the study's progress through written updates, teleconferences, or by other selected means. Provide copies of relevant communications to other Georgia CORE staff members, as appropriate.

B. Communication Records

• Research Staff/Consultant	Document pertinent verbal communications with the Investigator, Subinvestigators, site study 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. This record will be kept to follow and document the content and frequency of verbal communications, as well as assess the effectiveness of those communications. Each communication should be signed and dated by the party documenting the

	communication. Maintain originals or photocopies of all relevant 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 Documentation and Records Retention. Confirm, through monitoring, that sites are maintaining appropriate documentation in their study files. Follow-up with 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

Attachment A

TELEPHONE CONTACT LOG

Date/Time: _____ Conversation between:_____and _____

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Summary of discussion:

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Date: _____

Conversation between:_____and _____

Summary of discussion:

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Date/Time: _____

Conversation between:_____and _____

Summary of discussion:

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