General Administration
GA – 103.01

STANDARD OPERATING PROCEDURE FOR TRAINING AND EDUCATION

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President and CEO

(17 July 2014)
(Signature and Date)

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(22 July 2014)
(Signature and Date)

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I. INTRODUCTION AND PURPOSE

Research studies will be conducted according to FDA and HHS regulations to protect the safety and welfare of study subjects.

Georgia CORE staff and consultants who are overseeing research on humans will receive initial and ongoing training regarding the responsible conduct of research.

2. SCOPE

This standard operating procedure (SOP) describes the process and documentation required by Georgia CORE for the initial and ongoing education of the Georgia CORE staff and consultants in Good Clinical Practices (GCPs) and the ethical conduct of research.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General responsibilities of Investigators
45 CFR 46	46DHHS Part 46 Protection of Human Subjects
21 CFR 812	Subpart E Responsibilities of Investigators
May 1997	ICH Good Clinical Practice: Consolidated Guideline (E6 4.2.4)
December 8, 2008	FDA Internal Compliance Program Guidance Manual for Clinical Investigators: 7348.811
June 5, 2000	NIH Notice OD-00-029: Required Education in the Protection of Human Research Participants
September 12, 2000	Clarification on June 5, 2000 Notice (OD-00-39)

4. REFERENCES TO OTHER APPLICABLE SOPS

All SOPs are applicable to this SOP.

5. ATTACHMENTS

A. Educational Program Compliance Form

6. RESPONSBILITY

This SOP applies to Georgia CORE staff and consultants who participate in the selection, orientation, training of Investigator/Subinvestigator sites for studies and who monitor studies.

This includes the following:

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

7. DEFINITIONS

The following definitions from the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline apply to this SOP.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

8. EDUCATION AND DOCUMENTATION OF EDUCATION DESCRIPTION

• Contracts and Regulatory Administration	Georgia Core will direct all staff and consultants to the NCI website to complete web-based training in "Human Participant Protections Education for Research Teams," where a certificate of completion can be provided at the conclusion of the program. All Georgia CORE staff and consultants involved in research studies will be required to submit to Georgia CORE the NCI certificate of completion OR other such written evidence of training in the protection of human subjects. This evidence must be updated every three years. Upon approval of the President, Georgia CORE staff and consultants may attend courses and working group sessions. Additional courses may be found through the following sources: Society of Clinical Research Associates (SoCRA) Web site: http://www.socra.org/ Association of Clinical Research Professionals (ACRP) Web site: http://www.acrpnet.org Quintiles Web site: http://www.quintiles.com/locations/europe/netherlands/clinical-services/online-training-good-clinical-practices/ Georgia CORE staff and consultants will maintain a log of completed training. (Attachment A Education Program Compliance Form)

	Determine that each member of the Georgia CORE staff and consultants provides appropriate documentation that he/she has fulfilled the education and training requirement.
	Maintain a record of participants in all initial and ongoing educational activities and certifications that Georgia CORE provides and/or requires of all Georgia CORE staff and consultants.

10. History of Changes

Version Number	Section Number	Modification	Approval Date
103.00	All	Original Version	
103.01	3	Updated Reference	09 March 2012
103.01	8	Additional training website listed	09 March 2012
103.01	All	No changes necessary	01 July 2014

ATTACHMENT A

EDUCATIONAL PROGRAM COMPLIANCE FORM

Form for _____(Employee/Consultant Name)

Date	Education Program Title	Trainer's Initials	Date Reviewed	Staff Signature

Reviewed by: _____

Date: _____