

**General Administration
GA – 103.02**

**STANDARD OPERATING PROCEDURE FOR
Training and Education**

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President and CEO

04 Feb 2021

(Signature and Date)

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04 Feb 2021

(Signature and Date)

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1. 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 to Good Clinical Practice (GCP) and the ethical conduct of research.

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

All SOPs are applicable to this SOP.

5. ATTACHMENTS

A. Training and Education Documentation Form

6. RESPONSIBILITY

This SOP applies to Georgia CORE staff and consultants who participate in the selection, orientation, training, and monitoring of Research Network site Investigators/ Subinvestigators. Included are the following:

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

7. DEFINITIONS (See GA Appendix A Glossary of Terms)

Good Clinical Practice (GCP)

8. PROCESS OVERVIEW

- A. Training and Education
B. Documentation of Training and Education

9. PROCEDURES

A. Training and Education

Georgia CORE President
and CEO

Ensure that all Georgia CORE staff and consultants involved in research studies complete a program on human subjects research (HSR) where a certificate of completion can be provided at the conclusion of the program.

Chief Medical Officer
Georgia CORE staff and
consultants

Complete a program on human subjects research (HSR) every two 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:

CITI Program Training on Human Subjects Research

<https://about.citiprogram.org/en/series/human-subjects-research-hsr/>

Society of Clinical Research Associates (SoCRA)

Web site: <http://www.socra.org/>

Association of Clinical Research Professionals (ACRP) Web site: <http://www.acrpnet.org>

Office for Human Research Protection (OHRP) Webinars

https://www.youtube.com/watch?v=_8Ku4b1fW18&feature=youtu.be

Additional educational resources on human research protection can be found at:

<https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html>.

Georgia CORE staff and consultants will maintain a log of completed training. (Attachment A Education Program Compliance Form)

B. Documentation of Training and Education

Georgia CORE President and CEO or designee

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.

C. HISTORY OF CHANGES

Version Number	Section Number	Modifications	Approval Date
103.00	All	Original Version	
103.01	3	Updated reference	09 March 2012
103.01	8	Additional training websites listed	09 March 2012
103.01	All	No changes necessary	01 July 2014
103.01	3	Updated reference	12 December 2017
103.02	All	Edits for clarity, revision of form, updated links for all educational training	30 June 2020

Georgia CORE Staff/Consultant _____

[illegible]

***If provided, attach Certificate of Completion to the Training and Education Documentation Form**