**POLICY**

It is the policy of Upstate Carolina NCORP that all staff actively involved in human subject research must complete continuing education training every 3 years in order to understand their obligations to protect the rights and welfare of subjects in research.

**RESPONSIBILITY**

All staff

**DEFINITION**

**Good Clinical Practice (GCP)** is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials. It also serves to protect the rights, integrity and confidentiality of trial subjects.

**GUIDELINES**

* Continuing education training is accomplished via CITI Training at ([https://www.citiprogram.org/)](https://www.citiprogram.org/%29).
* Employees must take the Good Clinical Practice (GCP) course and exam.
* A copy of the GCP training certificate must be given to the Regulatory Office upon completion.
* The course is to be taken every 3 years.
* Employees will be notified by CITI when the course is due.

**PROCEDURES**

Affiliate Site Responsibility:

1. Staff will take GCP course every 3 years
2. Staff will send completion certificates to the consortium regulatory office
3. If CITI training expires, investigators or staff will not be allowed to perform study procedures including, but not limited to: consenting and enrolling of subjects, data entry, performing study procedures.

Consortium Staff:

1. Quarterly reports of individuals whose CITI training is expiring within 30 days will be generated and sent to site administrators
2. Quarterly reports of individuals whose CITI training has expired will be issued to the Consortium Leadership Council

**REFERENCE:** ICH-GCP Guidelines

[A Vijayananthan](https://www.ncbi.nlm.nih.gov/pubmed/?term=Vijayananthan%20A%5BAuthor%5D&cauthor=true&cauthor_uid=21614316) and [O Nawawi](https://www.ncbi.nlm.nih.gov/pubmed/?term=Nawawi%20O%5BAuthor%5D&cauthor=true&cauthor_uid=21614316). The importance of Good Clinical Practice guidelines and its role in clinical trials. [Biomed Imaging Interv J](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3097692/). 2008 Jan-Mar; 4(1): e5.

**ASSOCIATED FORMS:** N/A

**COMMITTEE APPROVAL:**

UC Policy and Procedure Committee