**POLICY**

It is the policy of Upstate Carolina NCORP (UC-NCORP) to establish, maintain, and assure the compliance by member communities with the required Federalwide Assurance (FWA) for the Protection of Human Subjects.

**RESPONSIBILITY:** Affiliate sites, Regulatory Manager

**DEFINITIONS:**

**CTSU**: Cancer Trials Support Unit is a service of the NCI designed to facilitate access to NCI-funded clinical trials for qualified clinical sites and to support the management and conduct of theses clinical trials.

**FWA**: Federalwide Assurance is an assurance of compliance with the United States Federal Regulations for the Protection of Human Subjects in research.

**NCORP-SYS**: National Cancer Institute Community Oncology Research Program System is a private system that performs a variety of functions to support the NCI Community Oncology Research Program (NCORP).

**OHRP**: Office of Human Research Protections is an organization that provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the United States Department of Health and Human Services.

**GUIDELINES**

* UC-NCORP requires each community to maintain a current and active FWA.
* OHRP requires institutions/communities to renew or update FWAs every five years. A notice is sent by OHRP to the institution when the FWA is expiring soon.

**PROCEDURES**

* OHRP requires institutions to renew or update the FWA online (<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/index.html>).
* UC-NCORP uses the CTSU and NCORP-SYS to monitor the status of community FWAs.
* If an institution/community lacks the ability to submit its FWA update or renewal electronically, the institution/community must consult with OHRP and submit the FWA update or renewal application to OHRP in writing.
* The UC-NCORP Regulatory maintains a current listing of FWAs associated with community site codes.

**REFERENCE:**

U.S. FDA regulations at 45 **CFR** part 46 (“Common Rule”) and 21 CFR parts 50 and 56

**ASSOCIATED FORMS:** N/A

**COMMITTEE APPROVAL:**

UC Policy and Procedure Committee