**POLICY**

The NCI OPEN registration system captures most NCI registrations but does not currently capture all NCI NCORP registrations. This policy is to provide a consistent method of tracking registrations completed by each of the Upstate Carolina NCORP (UC-NCORP) sites and to help assure eligibility.

**RESPONSIBILITY**

Affiliate Research Staff

**PROCEDURES**

1. The following procedures will be followed for patient registration:

**Eligibility Review**

* + Eligibility Review prior to NCI patient registration
	+ Verify eligibility timeframes are within window per protocol (i.e. imaging studies)
	+ Verify that adequate source documentation is in place

**Informed Consent Form Review**

* + Informed Consent Form, verification current version is used
	+ Quality check will be completed of the informed consent form assuring:
		- Signatures and dates are accurate
		- All fields are completed
		- Any corrections made are indicated with single horizontal strike through and errors are initialed and dated

**Patient Forms**

* + Review all patient completed forms or other protocol specific items, assuring they were completed after the consent date

**Registration**

* + Registration of the participant is to be performed according to the protocol requirements within the system indicated

**Event Form**

* + An Event Form is used for registration and grant payment event notification
		- Patient Registration
		- Correlative Studies
		- Bio-Specimens
		- Procedures
		- Assessments
		- CCDR
	+ Multiple events can be completed on one Event Form if they occur on the same day
	+ Each registration is to have a completed UC-NCORP Event form sent to the UC-NCORP office
		- Email Event Form to: UpstateNCORPEventForm@srhs.com (preferable)
		- Event Form may be faxed to 864-560-1055
	+ The Event Form should be submitted within 24hrs of registration
	+ Subsequent registrations or events will require a separate UC-NCORP Event Form (i.e. Step 2 re-registrations) within 5 business days
		- Minimum required identifiers for subsequent event form:
			* Protocol Number
			* Patient Study ID
			* Date of Birth
	+ Sites may have modified event forms to meet certain needs

**Registration - Event Verification**

* + Monthly Registration-Event Report will be provided by UC-NCORP QA Coordinator to each affiliate site for review and verification of credit/registration and/or study events
		- Affiliate site will review monthly Registration-Event Report for accuracy and submit within 1 week of receipt any corrections needed to the UC-NCORP QA Coordinator

**ASSOCIATED FORMS:**

Event Form #5005F

***COMMITTEE APPROVAL:***

UC Policy and Procedure Committee