**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](mailto: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