**POLICY**

Quality Assurance is a critical process that assists in ensuring clinical trials are conducted according to the protocol. Verification of study data, that could affect the interpretation of primary study endpoints, is a primary goal of this routine monitoring process. It assures that the research subjects received treatment, interventions, assessments and/or testing according to the protocol and trial instructions. Monitoring also assures the data is collected and reported accurately in a timely manner. This policy outlines the elements of the monitoring process performed by the Quality Assurance Program.

**RESPONSIBILITY**

Principal Investigators, QA Coordinator and site Coordinators

**GUIDELINES**

Each site’s Principal Investigator is responsible for ensuring that program requirements are followed and that there is a process in place to help assure research protocol requirements are followed. The consortium PI’s have established a QA program to assist each site in identifying adherence items that may require additional training and/or new processes.

* QA monitoring visits will be performed quarterly or more frequently depending on registrations and other QA needs that arise.
* Sites will be contacted by the QA Coordinator to set up a monitoring visit. Notification of Patient/Subject charts to be monitored will be provided.
* Selection of charts will be according to registrations, focusing on those that may be difficult, have large numbers of registrations or have other factors that lead to errors.
* A minimum of 10% of all patient accruals will be monitored.
* A full data review will occur on at least one patient chart during each monitoring visit
* Periodic focused monitoring visits may also occur. The following situations may result in a scheduled internal QA monitor visit:

1. A staff team member who has less than 6 months experience in the department
2. Newly activated trial
3. Registration of ineligible case
4. Repetitive queries received from a research base
5. Request from site

* The Protocol specific checklists and calendars will be used to verify eligibility and protocol compliance. The use of the NCI audit forms may also be utilized, see links below.

**PROCEDURES**

* The QA Coordinator will contact the site to be monitored to arrange a mutually agreed upon date with a minimum 14 day notice. A written notice will follow confirming the date and time and provide a list of the research participant records that will be monitored.
* The site is to ensure charts are complete and properly tagged identifying required key items.
* An appropriate location with ample space for review of charts will be arranged by the site being monitored
* The QA coordinator will arrive at the designated time and proceed with the chart reviews. The Quality review check lists will be utilized for focus, target and routine QA audits of source documents and research base data. Any combination or all of the following items may be the focus of a monitoring visit:
  + Informed consent
    - Eligibility/Evaluability
    - Stratification or randomization
    - Trial Management or Treatment (correct dose/schedule/therapy)
    - Site pharmacy inspection and Drug Accountability
    - Scheduled assessments such as lab work, diagnostic tests, specimen submissions
    - Completion and submission of required patient questionnaires
    - Toxicities/adverse events
    - Response determination when appropriate
    - Study/ Treatment withdrawal criteria or safety assessments as written
    - Off study evaluation
    - Source Data verification
    - Regulatory Documentation

A review of findings will be discussed with the study PI and site research staff at end of visit or the next day depending on timing. This will be an educational format with discussion of options or strategies that may be implemented at the site to ensure compliance.

**REFERENCE:**

* [NCI Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program Including NCI Community Oncology Research Program (NCORP) and NCORP Research Bases [Sept 2017]](https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/ctmb_audit_guidelines.pdf)

[***https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring\_coop\_ccop\_ctsu.htm***](https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm)

* *NCI Patient Case Review Worksheet* [*https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Appendix\_3.pdf*](https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Appendix_3.pdf)
* SWOG QA Guidelines ***-*** [***https://www.swog.org/sites/default/files/docs/2017-10/QAGuidelines.pdf***](https://www.swog.org/sites/default/files/docs/2017-10/QAGuidelines.pdf)

**ASSOCIATED FORMS:**

[**https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Appendix\_1.pdf**](https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Appendix_1.pdf)

[*https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Appendix\_2.pdf*](https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Appendix_2.pdf)

[*https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm*](https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm)

**COMMITTEE APPROVAL:**

UC Policy and Procedure Committee