Multicenter Protocol Compliance Assessment

SCOPE

This policy applies to any multicenter research protocol for which MD Anderson Cancer Center is the lead institution and under the oversight of the Office of Protocol Support & Management (OPSM). It is the policy of the OPSM to ensure that participating sites conduct the trial in compliance with the currently approved protocol/amendment(s), Good Clinical Practice (GCP) Guidelines, Standard Operating Procedures (SOPs) and Federal and State Regulations.

PURPOSE

Define the process necessary to assess compliance to protocol guidelines for multicenter trials.

POLICY STATEMENT

The quality assurance process for multicenter clinical research studies that are under the oversight of the OPSM, requires the monitoring of the participating institutions’ compliance to protocol guidelines. Monitoring begins at the time of subject registration and continues during protocol performance and completion. The assessment will include the data submission timeliness, completeness and accuracy, and adherence to protocol requirements.

PROCEDURE

All multicenter participating institutions are required to conduct a clinical research project according to the guidelines outlined in the protocol and/or the protocol data management plan. Protocol compliance is determined by evaluating affiliate performance with the assessment in the following categories. Performance metrics may be established on a project by project basis.

- **Study Participant Eligibility**
  The eligibility verification will be performed on all enrolled study participants.

- **Evaluability Rate**
  Participants enrolled in clinical trials are evaluated at specific intervals as outlined in the protocol for toxicity and/or response. The evaluability rate applies to protocols that have response as an endpoint.
• **Study Compliance**
  Study treatment compliance assessment is based on protocol interventions that are administered/performed according to the plan outlined in the protocol.

  For example, dosages, including attenuation and escalations, and the timing of administration, are assessed in the following three categories:

  ▪ **Schedule per Protocol**
    Study treatment doses must be given according to the schedule specified in a protocol. Schedule per Protocol is assessed for each dose given or missed within a course/cycle/regimen defined by the protocol.

  ▪ **Dose per Protocol**
    Study treatment doses delivered must be within the total accumulated dose for each course/cycle/regimen defined by the protocol. Dose per Protocol is assessed for each dose given or missed within a course/cycle/regimen defined by the protocol.

  ▪ **Follow-up Tests/Procedures per Protocol**
    Test/Procedures for the evaluation of study must be performed according to the guidelines specified in the protocol.

• **Data Quality**
  Protocol data are checked for timeliness of submission as per the Data Quality Management Plan (DQMP). The completeness and accuracy of the data are also taken into consideration in the overall compliance performance for each participating institution.

• **Serious Adverse Events (SAEs), Deviations, Violations and Unanticipated Problems Reporting**
  SAEs, Deviations, Violations and Unanticipated Problems must be reported within the timeline specified by the protocol and/or the protocol DQMP.

**REFERENCES**

ICH GCP 4.5 Compliance with Protocol

ICH GCP 5.1 Quality Assurance and Quality Control
## DOCUMENT HISTORY

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