Multicenter Protocol Deviations, Violations and Unanticipated Problems Reporting

SCOPE

This policy applies to any multicenter research protocol for which MD Anderson Cancer Center (MD Anderson) 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

To protect human subjects by ensuring that all multicenter protocol deviations, violations and unanticipated problems are reported to MD Anderson Institutional Review Board (IRB) and/or protocol sponsor in a manner according to institutional policies and protocol specific guidelines.

POLICY STATEMENT

It is the policy of the OPSM to comply with the regulations governing human subjects’ safety as mandated by MD Anderson IRB.

PROCEDURE

Participating Institutions

All participating institutions will be evaluated for protocol compliance and safety. Although the participating institution’s IRB is responsible for reviewing and approving the protocols, as well as, monitoring the conduct of the study at their institution, all protocol deviations, violations and unanticipated problems occurred at the participating site must be reported to both the local IRB and MD Anderson IRB for review and approval. In the event that a deviation, violation or unanticipated Multicenter Protocol Deviations, Violations and Unanticipated Problems Reporting
problem is considered non-reportable per the local IRB, it still is required to be reported to MD Anderson IRB in accordance with the reporting guidelines delineated in the protocol.

**MD Anderson Participating Department**

The MD Anderson participating department must adhere to MD Anderson policies on reporting protocol deviations, violations and unanticipated problems, and protocol specific procedures.

**OPSM Deviation Processing**

Upon receipt of a protocol deviation report and/or its supporting source document(s), the assigned OPSM project staff will review all documents for completeness and accuracy and log the event to the Protocol Deviation Log and the Patient Safety Incident Log in SharePoint. The Protocol Deviation Log is required to be submitted to MD Anderson IRB on an annual basis with the Protocol Continuing Review submission.

**OPSM Violation Processing**

Upon receipt of a protocol violation report and/or its supporting source document(s) the assigned OPSM project staff will review all documents for completeness and accuracy and log the event to the Protocol Violation Report and the Patient Safety Incident Log in SharePoint. The complete report will be forwarded to the lead Principal Investigator for review and approval before it gets submitted to MD Anderson IRB in accordance to the institutional policies.

**OPSM Unanticipated Problem Processing**

Upon receipt of an unanticipated problem report and/or its supporting source document(s) the assigned OPSM project staff will review all documents for completeness and accuracy and log the event to the Unanticipated Problems Tracking Log in SharePoint. The complete report will be forwarded to the lead Principal Investigator for review and approval before it gets submitted to MD Anderson IRB in accordance to the institutional policies.

**Record Keeping**

All reports and associated source documents will be filed in the subject’s electronic chart and Protocol Regulatory Document file in the Electronic Data Management System (EDMS).

**REFERENCES**

ICH GCP 4.5 Compliance with Protocol

ICH GCP 5.1 Quality Assurance and Quality Control

21 CRF 312.50 (b): General responsibilities of sponsors
## DOCUMENT HISTORY

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