Multicenter Subject Serious Adverse Event Reporting

SCOPE

This policy applies to any multicenter research protocol for which MD Anderson Cancer Center (MDACC) is the lead institution and under the oversight of 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 procedures necessary to process Serious Adverse Event (SAE) Reports generated by subjects enrolled to protocols coordinated by the OPSM.

POLICY STATEMENT

The protocol will outline the methods to be used for SAE reporting. The OPSM will maintain documentation of all SAEs reported on the protocol. The OPSM shall promptly notify all concerned investigator(s)/institution(s) and regulatory authority(ies) of findings that could adversely affect the safety of subjects, impact the conduct of the trial, or alter the Institution Review Board (IRB/IEC’s approval/favorable opinion to continue the trial.

PROCEDURE

Participating Institutions

All subjects receiving treatment/interventions will be evaluated for safety. The participating institution’s IRB will be responsible for reviewing and approving the protocol, as well as monitoring the conduct of the study at their institution. Safety monitoring at the participating institution must be consistent with the data and safety monitoring guidelines delineated in the protocol. SAEs experienced by subjects treated at participating sites will be reported to the local IRB in accordance with the protocol defined procedures and the local IRB procedures. All SAEs must also be reported to the OPSM promptly, even if the local IRB does not require a prompt report. In these cases the local prompt/non-prompt reporting
policy must accompany the report that is submitted to the OPSM. SAEs reported to the OPSM must be accompanied by supporting source documentation.

**MD Anderson Subject SAEs**

The MD Anderson lead site will report any SAE experienced by MD Anderson subjects to the MD Anderson IRB according to the protocol defined procedure and MD Anderson policies for Prompt or Non-Prompt SAE reporting. If the lead Principal Investigator (PI) for the protocol is not an MD Anderson Physician, the Lead PI must review and acknowledge the SAE.

**OPSM SAE Processing**

It is the OPSM policy that all SAEs must be reported to the OPSM promptly, even if the local IRB does not require a prompt report. SAEs reported to the OPSM must be accompanied by supporting source documentation.

Upon receipt of an SAE report and its supporting source documents, the OPSM staff assigned to the protocol will review the report and source documents for completeness and accuracy and log the report into the OPSM’s electronic SAE tracking system. If there are any questions about the report or source documents, the OPSM staff will contact the site. Once all questions are resolved, the OPSM will forward the completed SAE report, with source documents, to the Lead PI for review and acknowledgement of the SAE.

Once the SAE has been signed and acknowledged by the Lead PI, the OPSM will report the SAE to the MD Anderson IRB in accordance with the MD Anderson policies for reporting Prompt and Non-Prompt SAEs. At the same time, the OPSM will report the SAE to the study sponsor, the FDA, and participating institutions, if directed by the protocol and if the SAE meets their reporting requirements.

Once the SAE has been reported to all required institutional and regulatory authorities the OPSM will file the reports in the subject’s electronic chart and the protocol master file. The OPSM staff will complete the processing in the OPSM electronic SAE tracking system.

**REFERENCES**

ICH GCP 5.16 Safety Information

ICH GCP 5.17 Adverse Drug Reaction Reporting

National Cancer Institute; Cancer Therapy Evaluation Program; Multicenter Guidelines: Responsibilities of the Coordinating Center

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

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