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RE: Revised NCI Guidelines for Expedited Reporting of Adverse Events

MEMORANDUM

On March 28, 2011, NCI/CTEP issued revised guidelines for expedited reporting of adverse events, in compliance with the Food and Drug Administration's (FDA) 'Final Rule' that also became effective Mar 28, 2011.

The FDA 'Final Rule' was issued with goals of improving the overall quality of safety reporting, strengthening the agency's ability to review critical safety information and to harmonize safety reporting internationally. By clarifying definitions and revising the process for safety reporting for investigational new drug (IND) applications found in 21 CFR part 312, the FDA hopes to ensure that the information it receives is relevant and useful, and ultimately improves the safety of patients in clinical trials.

All new protocols approved by NCI after March 28, 2011 will contain the new reporting instructions found in *NCI's Guidelines for Investigators: Adverse Event Reporting Requirements,* issued March 28, 2011. However, current ongoing, actively accruing trials will retain their existing expedited reporting instructions for adverse events, and sites should continue to follow these guidelines as specified in Section 16 of each protocol.

NCI's revised guidelines can be found on the Serious Adverse Events page of the SWOG website (https://swog.org/Members/AdverseEvents/Index.asp) or on the CTEP page of the NCI Website (http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines3-29-11.pdf).

The new reporting guidelines will be reviewed during the Clinical Trials Training Course (CTTC) at the SWOG Group Meeting, April 13-16. For any questions regarding the FDA's 'Final Rule' or NCI's new reporting guidelines, please contact the SAE Coordinator at the SWOG Operations Office at (210) 614-8808.