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Policy Memorandum No. 20 **Page 1 of 1 page**
Subject: New Agent Studies and Safety Monitoring **Original Release Date:** July 1985
Departments Affected: All **Revision Date:** May 2015

NEW AGENT STUDIES AND SAFETY MONITORING

There is an agreement between the NCI and the FDA regarding protocol monitoring for human safety. The Group statistical report for each Group meeting is a critical element in safety monitoring (Description of Procedures Regulating Clinical Trials Within the Cooperative Groups, Page 12):

> "The Statistical Center prepares for each group meeting current reports on each protocol for review by the investigators. Data reviewed includes numbers of patients on study, toxicity and unusual reactions. Based on the data, decisions are made to discontinue the study if the protocol objectives have been achieved or to modify the protocol based on information obtained in the current trial or from other studies where significant changes in risk-benefit ratio have occurred."

Thus, it is essential that statistical reports of new agent studies be based on the rapid flow of current data in order to be relevant to safety monitoring. In order to meet the needs of the National Cancer Institute and the FDA, a quick response system for new drug monitoring has been implemented. This system requires that each Study Chair involved in Phase II studies make a commitment to review toxicities experienced during the accrual period of the study under his/her supervision. Whenever a CTEP-AERS report is filed for a patient on a new agent study, an automatic email is sent to the Study Chair and Study Statistician for the trial. This automatic email is also sent to the SWOG Physician reviewer and SAE Coordinator to allow the information to be incorporated into the SAE review process. In addition, a monthly adverse event report is sent to the Study Chair and Statistician. The Study Chair is provided with online access to the adverse event and evaluation forms by the Statistical Center and he/she should annotate response and toxicity data. These data will then immediately be entered into the Statistical Center database for prompt update as appropriate.

This system allows for early recognition of adverse toxicity, early identification of responses, and careful monitoring of the total case accrual on all Phase II new agent studies. The Statistical Center has built early stopping criteria into all Phase II new agent studies to limit case accrual to studies of ineffective agents.