

Policy Memorandum No. 36
Subject: Affirmation of Integrity
Departments Affected: All

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AFFIRMATION OF INTEGRITY

I. BACKGROUND

The SWOG Affirmation of Integrity policy is designed to serve multiple purposes. One is to remind Group members of their ethical obligations for integrity in the conduct of clinical trials as determined by both the National Cancer Institute regulatory requirements and Group policies. Clinical research of the Network Groups is a publicly supported endeavor that is critically dependent upon the trust of the American people. Submission of falsified data is scientifically abhorrent and can destroy the public trust that is necessary for successful clinical research. Another purpose of the policy is to inform Group members of the consequences of failing to meet these standards. The penalty for submission of falsified data may include the inability of an investigator or the institution to participate in Cooperative Group activities, and repayment by the institution of National Cancer Institute funds that had been used in collecting and submitting the falsified data. A third purpose is to assure that Group members handling data are aware of and able to correctly utilize procedures to communicate concerns about research misconduct to the Group. A fourth purpose is to inform all personnel who are involved in conducting clinical trial research of required Form FDA 1572. To conduct studies in accordance with relevant regulatory requirements, and in order to qualify to participate in clinical investigations at the National Cancer Institute, no investigator may participate in an investigation until he/she provides a completed, signed Statement of Investigator, Form FDA 1572, with the Pharmaceutical Management Branch (PMB). PMB requires that investigators submit the required forms annually in order to maintain an active registration status.

II. POLICY

Applicability

This policy is applicable to all scientists, investigators, statisticians, clinical research associates, nurse oncologists, pathologists, surgeons, SWOG personnel, and others who participate in Group activities and come in contact in any way with study data.

Reporting

If submission of falsified data from an institution or other Group members is suspected, Group Policy #41 requires an immediate telephone call, which may be anonymous, to the Quality Assurance Department at the Operations Office, 24 hours a day: 210-614-8808 (leave a voice mail).

III. SANCTIONS

Failure to meet this obligation could result in the suspension of ability to register patients to Group trials and in the loss of privilege to participate in the activities of SWOG.