SWOG http://swog.org

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

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Original Release Date: April 1995
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AFFIRMATION OF INTEGRITY

I. BACKGROUND

The SWOG Affirmation of Integrity policy and statement are 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. Another is to inform Group members of the consequences of failing to meet these standards. 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.

At the recommendation of the National Cancer Institute, any Group member who comes in contact in any way with Group data must sign an Affirmation of Integrity statement. The SWOG Operations Office has the responsibility of maintaining the signed statements on file.

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.

By signing the Affirmation of Integrity statement, each individual affirms awareness of and compliance with SWOG policy, specifically Policy #41, concerning integrity in the reporting of data.

III. SANCTIONS

Failure to sign an Affirmation of Integrity statement 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.

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SWOG

----- AFFIRMATION OF INTEGRITY IN THE SUBMISSION OF CLINICAL TRIAL RESEARCH DATA -----

In signing this document, I affirm my awareness of and compliance with the policies of SWOG relating to the submission of falsified data and other scientific misconduct.

- I recognize that the clinical research of the Cooperative 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.
- I recognize that the penalty for submission of falsified data by myself or by others from my institution may include: inability of myself or my institution to participate in Cooperative Group activities, and repayment by my institution of National Cancer Institute funds that had been used in collecting and submitting the falsified data.
- 3. If I suspect falsified data submission from my institution or other Group members, I understand that Group Policy #41 requires that I make an immediate telephone call, which may be anonymous, to the Quality Assurance Department at the Operations Office, 24 hours a day (leave a voice mail) at:

210-614-8808

(Signature) (Date) (Name – Please Print) (Institution)