

## SWOG

**Group Chair's Office**  
24 Frank Lloyd Wright Drive  
P.O. Box 483  
Ann Arbor, Michigan 48106

**Operations Office**  
4201 Medical Drive, Suite 250  
San Antonio, Texas 78229

**Policy Memorandum No. 33**  
**Subject:** Institutional Performance Review  
**Departments Affected:** All

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**Original Release Date:** April 1991  
**Revision Date:** October 2011

### INSTITUTIONAL PERFORMANCE REVIEW

The efficient conduct and the quality of clinical trials depend on accurate and timely submission of data. The Statistical Center monitors the submission of data collection forms by each Group institution. Reports on the timeliness of submission of initial forms, the percent of patients with overdue data submission while on protocol treatment, and the percentage of patients overdue for follow-up once off treatment are reviewed monthly. Each Principal Investigator is provided with data pertinent to his or her institution's performance, and to their affiliates, if applicable.

Monthly reports of institutional performance with respect to data submission are reviewed. An institution's registration privileges may be suspended when performance is inadequate for three consecutive months. Inadequacy includes:

1. 10% or more of the initial forms sets that are more than 30 days overdue for patients registered within the past 13 months to all studies requiring patient follow-up, , or if ANY initial forms are overdue on patients registered more than 13 months ago. The definition of an initial forms set is protocol specific and typically consists of the prestudy, relevant baseline tumor assessment forms, operative and pathology reports, and radiation materials or pathology (for verification of pathology eligibility) if applicable.
2. For patients still known to be alive and on protocol treatment: Greater than 15% of on-treatment forms are overdue for submission . Overdue applies to situations where the patient was not documented as having gone off protocol treatment and if there are missing cycle-specific adverse event or treatment forms, or if the most recent adverse event, treatment or follow-up tumor assessment form is more than 60 days overdue.
3. For patients still known to be alive and off protocol treatment: Greater than 20% of patients are overdue for follow-up, where overdue is defined if the patient's time since registration still requires follow-up (as defined in Section 7 of the study protocol) and the patient is off protocol treatment and the last known contact date is overdue for more than 2 months from the study specified follow-up timing (e.g. 8 months if the study requires follow-up every 6 months, and greater than 14 months for studies requiring annual follow-up).

A letter of warning will be sent after two consecutive months of inadequate performance. If performance is still inadequate at the third month, a letter of suspension will be automatic except under the following circumstance: if the amount of information across overdue categories is based on a small denominator then the Group Chair and Group Statistician may choose to waive the suspension at that time. When a suspension letter is sent, the institution is given until the following month's report before the suspension is activated, in order to give patients who are currently in the pre-registration evaluation process time to be registered. If the IPR statistics are found to be within compliance at this next report, the suspension will be waived.

To lift suspension, an institution must have all IPR categories fall within acceptable limits, regardless of which category caused the suspension.