

SOUTHWEST ONCOLOGY GROUP

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

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Departments Affected: All

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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 overdue for follow-up 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 for patients registered to all studies requiring patient follow-up are more than thirty days overdue. 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% are overdue for submission of follow-up information. Overdue is defined if the patient was not documented as having gone off protocol treatment, and the last contact date is >6 months.
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 >14 months.

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.