

SOUTHWEST ONCOLOGY GROUP

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Policy Memorandum No. 29
Subject: Roster of Investigators
Maintenance Policies and Procedures
Departments Affected: All

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ROSTER OF INVESTIGATORS MAINTENANCE POLICIES AND PROCEDURES

INTRODUCTION

The Roster of Southwest Oncology Group Investigators is a computerized list of physicians approved by the Group Board of Governors as currently and previously eligible to register patients on Group protocols. It is maintained by the Operations Office Membership Program in San Antonio. The Roster contains each physician's name, address, phone number, fax number, e-mail address, institution(s) of affiliation, type of membership and registration status. An investigator is never removed from the Roster, as research on patient data is on-going. Keeping this information up-to-date is of paramount importance.

IDENTIFICATION NUMBERS

Each investigator, Clinical Research Associate (CRA), Nurse Oncologist, and each institution is assigned a unique and everlasting identification number. These assignments are based on documented approval for participation in the Southwest Oncology Group.

INSTITUTIONS AND INVESTIGATORS

For purposes of registering patients on Group protocols, an investigator must have an affiliation with at least one institution, or be designated by the Group Chairman and Board of Governors as a "Special Member." When an institution becomes disqualified to register patients, the "registration status" for that institution as well as its affiliated investigators are changed to "no" or "suspended."

An institution's or investigator's privilege to register patients may be temporarily or permanently withdrawn by the Group or NCI or by individual decision. When an investigator's privilege to register patients at a designated institution is terminated or suspended, his or her "registration status" is changed from "yes" to "no" or "suspended." Reinstatements require printed documentation from the Group.

There are five types of membership programs: Members, Affiliate Programs (AFFIL), Community Clinical Oncology Programs (CCOPs), Urologic Cancer Outreach Programs (UCOPs), and Special (SPEC) Membership. Each AFFIL must have a designated Data Management institution which is a Member.

PATIENT REGISTRATION

In order for a patient to be registered, the caller must identify an investigator and an institution which are both currently approved for patient registration. These two items are recorded on the patient's record in the database. The caller must also identify themselves by their assigned roster identification number.

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Occasionally, there may be disagreement as to an investigator's or institution's ability to register patients. If a "no" or "suspended" registration status" is encountered when a registration is attempted, the situation will be referred to the Operations Office Membership Program for resolution.

The Statistical Center Data Operations Section will monitor the "Priority List of Studies" for allowing investigators to register patients on designated protocols.

DOCUMENTATION REQUIRED

The Operations Office Membership Program will enter or change information in the Roster ONLY as received in printed form sent to the Group Operations Office. Entries and changes to the Roster will be made within two working days of receipt. Written confirmation must follow any oral communication within one working day.

NEW INVESTIGATORS

A "new" investigator is added to the Roster only as notification is received by the Operations Office Membership Program and all credentialing paperwork have been computed and the appropriate approvals have been received. At that time, a unique "investigator number" will be assigned. The Group Chair may decide that for a stated period of time, an investigator may register patients while his or her approval to do so is "pending".

"OTHERS" IN ROSTER

For purposes of mailings, names and addresses of other Southwest Oncology Group participants may be stored in the Roster. Group meeting attendees, pharmaceutical company representatives, report recipients and other selected personnel may also have identification numbers and institutional affiliations assigned.

USE OF ROSTER

Personnel at both the Operations Office and the Statistical Center may view information in the Roster and print reports, e.g., lists of investigators by institution. The Roster is also available for viewing by Group members through the Members side of the Group website. Lists will be sent to participating institutions upon written request, stating intended purpose of report.