

SWOG
<http://swog.org>

Policy Memorandum No. 29

Subject: Roster of Institutions, Investigators and Associates
Maintenance Policies and Procedures

Departments Affected: All

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**ROSTER OF INSTITUTIONS, INVESTIGATORS AND ASSOCIATES
MAINTENANCE POLICIES AND PROCEDURES**

INTRODUCTION

There are five types of membership programs within SWOG: Lead Academic Participating Sites (LAPS)/Main Members, Affiliate Program, NCI Community Oncology Research Program (NCORP), Special Membership, and International Members. Each Affiliate Program member must have a designated Data Management institution which is a LAPS or Main Member.

The Roster of SWOG Institutions, Investigators and Associates is a computerized list of performance sites, physicians and staff members approved by the Group 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 institution's name, address, CTEP code and OHRP Federalwide Assurance (FWA) number and expiration date; and each individual's name, address, phone number, fax number, e-mail address, institution(s) of affiliation, type of membership and registration status. Institutions and individuals are 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 institution, investigator, and associate/staff member, are assigned a unique and everlasting identification number. These assignments are based on documented approval for participation in SWOG.

INSTITUTIONS AND INVESTIGATORS

For purposes of registering patients on Group protocols, an investigator must have an affiliation with at least one institution or private office clinic, or be designated by the Group Chair 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 and associates 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An institution's or investigator's privilege to register patients may be temporarily or permanently withdrawn by the Group or NCI or by individual decision.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.

If an institution is withdrawn from active Group participation, the institution and individual participants remain responsible for the follow-up (see Policy 30) of all patients registered by the institution and/or individual at the institution for as long as the patient remains alive (or for a protocol specified length of time). Individuals at the institution will be granted continued access to the Members side of the SWOG website to continue any patient follow-up activities. Once all follow up activities conclude, the institution's affiliation with SWOG will permanently end.

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PATIENT REGISTRATION

In order for a patient to be registered, the individual registering the patient 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 individual registering the patient must also identify themselves by their assigned roster identification number.

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 or by submission through the DCP NCI Community Oncology Research Program Roster Maintenance System (NCORPSYS) or CTSU Roster Update Management System (RUMS). 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 communication, names and addresses of other SWOG participants may be stored in the Roster. Group meeting attendees, pharmaceutical company representatives, laboratory personnel, report recipients and other selected personnel may also have identification numbers and institutional affiliations assigned.

USE OF ROSTER

Personnel at the Group Chair's Office, Operations Office and 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.