

SOUTHWEST ONCOLOGY GROUP

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Departments Affected: All

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GUIDELINES FOR FULL GROUP INSTITUTIONAL MEMBERSHIP IN THE SOUTHWEST ONCOLOGY GROUP

The Southwest Oncology Group has developed the following guidelines for institutions applying for Full Group Membership in the Southwest Oncology Group:

1. Scientific Contributions

The institution should have members capable of offering and investigating unique and new ideas, programs or techniques for use in evaluating and treating cancer patients. The application should propose the potential scientific contribution of the various individuals in each discipline at the institution (medical and surgical oncology, radiation therapy, pathology, etc.). Specific services provided by the institution, such as serum or tissue banks, which contribute to the aims of the Group also strengthen the affiliation.

2. Administrative Organization/Support

a) At least one participant should have a compelling interest in Southwest Oncology Group programs and be willing to organize and supervise the institutional Southwest Oncology Group activities (Principal Investigator). Copies of curricula vitae and other required documentation from investigators who will be involved in the institutional program are to be submitted for review. All investigators who will accrue to Group studies must be members of the Southwest Oncology Group.

The Southwest Oncology Group will request information related to an institution's past performance from the current parent institution or other cooperative group, as applicable, to complete an evaluation of the institution's potential for success as a Member institution.

b) Active cooperative group and/or committee leadership, protocol development and coordination, and significant publications by participating investigators.

c) Required representation of the institution at a minimum of one semi-annual Group meeting every two years.

3. Patient Accrual

In order to remain funded the institution should have the capability of entering a minimal average accrual of 50 initial registrations based over a three year period on Southwest Oncology Group and Group endorsed treatment studies, with acceptable quality control, record-keeping, and excellent protocol compliance. Evidence of prior accrual to clinical trials (intra-institutional and/or through cooperative group membership, tumor registry data, or summary of clinical data) by disease and stage must be included. Further data on potential patient accrual by disease and stage should be listed.

4. Probationary Period and Criteria for Full Member Status

Institution applications will undergo a review by an established Professional Review Committee with a formal recommendation presented to the Southwest Oncology Group Board of Governors for ratification. All Member institutions nominated and approved by a majority of the Board of Governors for Group membership are initially activated as Probationary Institutions for a period of six to eighteen months.

In order to obtain full Member status, the following criteria must be met:

- a. Projected minimal accrual of at least 20 evaluable patient registrations based over a three year period
- b. An acceptable Quality Assurance Audit within 6-18 months
- c. Acceptable timeliness of data submission and quality of data

5. Compliance with Federal Regulations

Each Member must comply with all applicable federal regulations governing the conduct and monitoring of clinical trials, to include ensuring compliance with the Code of Federal Regulations (45 CFR 46, 21 CFR 50, and 21 CFR 56) in the protection of human subject research and Institutional Review Board review and approval of research studies and consent forms, conducting research in compliance with the ethical principles embodied in The Belmont Report (respect for persons, beneficence and justice), and ensuring the confidentiality of patient data (e.g., the Health Insurance Portability and Accountability Act – HIPAA). Non-compliance with federal regulations may result in investigation or censure.

6. Criteria for Continuing Participation and Support

Each Member Institution will abide by the rules and performance criteria governing all Southwest Oncology Group members in regards to patient eligibility and evaluability, timeliness of data submission, acceptable quality assurance audits, and scientific contributions to the Group.

All Member Institutions in good standing and meeting the below listed Funded U10 Member criteria will be eligible to request Group Chair permission to compete for U10 funding during each Group grant renewal cycle.

There are two categories for Member Institutions: funded U10 Member Institutions and unfunded Member Institutions.

Funded U10 Member Institutions:

SWOG Member institutions with active U10 Cooperative Agreements with the National Cancer Institute are funded for their accrual, scientific contributions, and travel expenses through these grants. In addition, these institutions are paid on a “per case basis” for accrual over and above their individual accrual baseline. These institutions must maintain a three year average annual accrual of 50 initial registrations to SWOG endorsed treatment studies, plus management of their follow up responsibilities. These institutions have membership and voting privileges on the Group's Board of Governors. U10 funded institutions submit non-competing continuation applications annually during a grant cycle.

Unfunded Member Institutions:

SWOG unfunded Member institutions, those without U10 Cooperative Agreements, receive limited support through the Group Chair's Office. They are reimbursed on a "per case" basis for their accrual. They also receive limited travel support to attend Group Meetings. These institutions also have voting privileges with the Group's Board of Governors.

The Unfunded Member Institution, apart from its affiliates, must maintain a minimal accrual contribution of 20 initial registrations to Group and Group endorsed treatment studies. The accrual will be measured as an average annual accrual of the previous three (3) years. The accrual is reviewed annually.

Failure to meet the minimum accrual standard listed above will result in the site being put into a probationary period of one year and will lose the privileges associated with being a member-in-good standing.

SWOG unfunded Member institutions in on probation or in good-standing may be eligible for travel funding for participation in the bi-annual SWOG Group meetings, subject to the availability of funding.

#Accruals*	# funded trips at the Group rate
≥ 32	6 for the year
20-31	4 for the year
10-19	2 for the year
1-9	At the discretion of the Chair

*Initial registration to SWOG/SWOG endorsed studies in the proceeding calendar year.