

**GUIDELINES FOR FULL GROUP INSTITUTIONAL MEMBERSHIP
IN SWOG**

SWOG has developed the following guidelines for institutions applying for Membership in SWOG. Two broad categories of Members are described: Accruing Members, and Non-accruing Members. Additional criteria are required for Accruing Member institutions to be eligible for election as a Governing Member of the SWOG Board of Governors.

A. Accruing Members:

1. Definition

Accruing members include those institutions that enter participants on SWOG trials, and include the categories of LAPS members, NCORP members, Clinical Members, and Sponsored Affiliates. Non-Accruing Members are described separately.

2. Full Members

a. LAPS Member Institutions:

These are SWOG Member Institutions/Networks with active Lead Academic Participating Site (LAPS) U10 agreements with the National Cancer Institute that are funded for their accrual through these grants.

b. NCORP Member Institutions:

These are SWOG Member Institutions/Networks with active NCI Community Oncology Research Program (NCORP) UG1 agreements with the National Cancer Institute that are funded for their accrual through these grants.

c. Clinical Member Institutions:

These are clinical institutions without U10 or UG1 Cooperative Agreements that receive limited support through the SWOG Network Operations Center grant. They are reimbursed on a per case basis for their accrual.

3. Affiliate Members

These are institutions that are unable to independently meet the requirements for Full Clinical Member Institutions and are therefore sponsored and mentored by a LAPS or Clinical Member. Sponsored Affiliates receive limited support through the SWOG Network Operations Center grant. They are directly reimbursed on a per case" basis for their accrual. Sponsored Affiliate Members are strongly encouraged to become Full Clinical Member Institutions whenever feasible. The process for becoming an Affiliate Member may be prompted by contacting the SWOG Membership Department and, at minimum, will require a letter of support from the Principal Investigator of a LAPS or Clinical Member agreeing to sponsor the Affiliate.

4. Member Components

Any of the above Accruing Member categories (LAPS, NCORP, Clinical, and Affiliates) may include institutions that are considered part of a network of institutions. Member components may require institutional roster designations for pharmacy and other requirements, but for the purposes of membership requirements and privileges they are not considered separately from the principal category. They do not receive per case reimbursement from SWOG; reimbursement goes to the principal institution.

5. Criteria for Membership Status

a. Administrative Organization/Support:

At least one participant in the institution should have a compelling interest in SWOG programs and be willing to organize and supervise the institutional SWOG 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 credit their accrual to SWOG on NCTN studies or who serve as Study Chairs must be members of SWOG.

b. Participant Accrual:

Accruing Full Member institutions should have the capability of entering a minimal annual average accrual of ten initial SWOG-credited registrations over a three-year period 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 participant accrual by disease and stage should be listed. Affiliate Members should have the capability of entering a minimal average accrual of five initial SWOG-credited registrations based over a three-year period.

SWOG 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.

6. Probationary Period

Institution applications will undergo a review by an established Professional Review Committee with a formal recommendation presented to the SWOG Board of Governors for ratification. All Accruing Member institutions nominated and approved by the Board of Governors for Group membership are initially activated as Probationary Institutions for a period of six to eighteen months. To obtain full Accruing Member status, the following criteria must be met:

- a. Projected minimal annual SWOG-credited accrual of at least ten evaluable participant registrations based on the probationary period for Full Members, and five evaluable participant registrations for Affiliate Members.
- b. An acceptable Quality Assurance Audit within 6-18 months
- c. Acceptable timeliness of data submission and quality of data
- d. Full Member applicants must send representation to one or more semi-annual group meetings annually during the probationary period.

If non-U.S. Accruing Member institutions have not reached full Accruing Member status within a period of six to eighteen months, they may be granted an additional three-year provisional probationary period if one or more other criteria have been met.

Failure to achieve Full or Affiliate membership status after the probationary period may result in revocation of SWOG membership.

7. Compliance with Federal Regulations

Each Accruing Member Institution 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 participant data (e.g., the Health Insurance Portability and Accountability Act – HIPAA). Non-compliance with federal regulations may result in investigation or censure.

8. Criteria for Continuing Membership in Good Standing

Each Accruing Member Institution will abide by the rules and performance criteria governing all SWOG members regarding participant eligibility and evaluability, timeliness of data submission, acceptable quality assurance audits, and scientific contributions to the Group.

All accruing Full Member Institutions must maintain a minimal average annual accrual of ten SWOG-credited registrations over a three-year period. Affiliate Members must maintain a minimal average annual accrual of five SWOG-credited registrations over a three-year period. In addition, all Full Member Institutions are required to send representation from the institution/network at a minimum of one semi-annual Group meeting every year.

Failure to meet these minimum standards will result in the institution being put into a probationary period of one year.

B. Non-Accruing Member

1. Definition:

A Non-accruing member is an academic institution with members capable of offering and investigating unique and new ideas, programs or techniques for use in evaluating and treating study participants, that does not intend to accrue participants on SWOG clinical trials.

2. Administrative Organization/Support

- a. At least one individual member has a compelling interest in SWOG programs and is willing to organize and supervise the institutional SWOG activities (Principal Investigator).
- b. Institutions that apply to join SWOG as Non-Accruing Members will be required to outline their proposed scientific contributions to SWOG in terms of planned numbers and types of formal proposals for retrospective use of specimens, plans for creating working relationships with research committees to explore prospective research collaborations, specific areas of applicable expertise of proposed individual member investigators, as well as the investigators' record of publication and an outline for plans for publication of SWOG collaborations.

3. Criteria for Membership in Good Standing

For Non-Accruing Members, projected minimal participation in five SWOG translational medicine research projects based over a three-year period. Non-Accruing members undergo a review by an established Professional Review Committee with a formal recommendation presented to the SWOG Board of Governors for ratification. Required representation of the institution at a minimum of one semi-annual Group meeting every year.

C. Governing Member Institution

1. Guidelines for Governing Institutional Membership

- a. A Governing Member of SWOG is a Full Accruing Member Institution in good standing that has been elected to hold a seat on the SWOG Board of Governors (BOG).
- b. New institutions will become eligible for Governing status following three years of membership (inclusive of the probationary period).
- c. Participant Accrual: A governing institution should have the capability of maintaining a minimal average annual accrual of 25 SWOG-credited registrations based over a three-year period.
- d. Scientific Contribution: In addition to a higher accrual requirement, governing institutions should have members capable of offering and investigating unique and new ideas, programs or techniques for use in evaluating and treating study participants.
- e. Participation: Governing Institutions should have one or more individuals attend each semi-annual SWOG meeting. Participation in SWOG activities including protocol proposal and development, and/or SWOG committee participation is expected.

2. Election of Governing Member Institutions

- a. Nominations for new Governing Membership will occur every six months based on a review of 3three-year accrual, followed by an evaluation by an established Professional Review Committee.
- b. The Professional Review Committee will present nominations for Governing Status to the SWOG BOG at each semiannual Group Meeting.
- c. Institutions nominated for Governing Status must be approved by a majority of the standing BOG.
- d. Once elected, Governing Membership is maintained by the institution for two years at which point the institution must be re-reviewed by the Professional Review Committee and then re-elected by the BOG.
- e. Governing Member Institutions placed on probation prior to the two-year review will have Governing Membership revoked until the probation is resolved.
- f. All Governing institutions nominated and approved by a majority of the BOG become voting members of the Board effective at the conclusion of that Board meeting.
- g. Governing institutions appoint the SWOG member from the institution who will serve as the representative to the SWOG BOG. It is not required that the Institutional Principal Investigator serve in this role.
- h. If an Accruing Member Institution is NOT nominated for governing status, it may be re-reviewed every six months for eligibility to be a Governing Member.