Policy Memorandum No. 5
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AFFILIATE PROGRAM MEMBERSHIP

This policy serves to provide a basic understanding of the requirements of the Affiliate Program and procedures for participation. Further information can be provided by the SWOG Network Operations Center.

Recruitment Procedures

SWOG encourages each Member Institution to recruit potential Affiliate Program participants from competent oncologists of all disciplines in communities of geographic proximity to the Member. Former trainees in the Principal Investigator's institution are prime candidates for recruitment. It is strongly encouraged that the Affiliate Program investigators develop a close working relationship with the Principal Investigator at the Member Institution.

If an Affiliate institution ceases to be affiliated with the Group, it retains responsibility for the treatment and clinical management of all participants currently receiving treatment/intervention and active follow-up, and should provide necessary data forms and follow-up information. The Member institution may, in some cases, be willing to assume responsibility for clinical follow-up once the participant is being seen annually (or less frequently) for study purposes.

Criteria for Selection

Affiliate Program investigators are those with training in an oncological discipline (e.g., Medical Oncology, Surgical Oncology, Radiation Oncology, Pathology, Gynecological Oncology). They must have sufficient training to render them board eligible or certified (radiation oncologist must be board certified to become a Group member; however, they do not need to be board certified to treat study participants, as long as they are treating in an approved SWOG radiation therapy facility).

Potential Affiliate Program investigators are first considered for membership in the program when the Network Operations Center receives a letter of recommendation (sponsorship approval) from the Principal Investigator of the Member Institution with whom they will affiliate. Investigators who contact the Network Operations Center directly to become a member of SWOG are directed to a Member Institution who is geographically close to the location of the Affiliate Program participant. Upon receipt of a letter of recommendation, the Group Chair notifies the Affiliate Program investigator of the program and credentialing requirements.

All participating institutions are required to have a current assurance guaranteeing the protection of human research subjects on file in the Office for Human Research Protections (OHRP) at the National Institute of Health. Compliance with this assurance requires that initial and annual re-review of all Group protocols be performed by the designated institutional review board.

SWOG requires radiation therapy facility approval before institutions may register participants to Group trials containing radiation therapy as an aspect of treatment.

The Affiliate Program investigator is also required to complete an Application for New Investigator credentialing forms packet.

All registering sites are eligible for "per case" reimbursement to help offset data management costs. The execution of a Purchase Service Agreement (PSA) between the registering institution and/or investigator and SWOG prior to making payments will be required.

Following the receipt of all required institutional and investigator credentialing forms, the Affiliate Program participant is awarded preliminary approval and may begin registering participants to Group trials. Final membership approval is awarded by the Group Membership Committee, which meets twice yearly in conjunction with the semi-annual Group meetings and ratified by the Board of Governors.

Documentation of Institutional Review Board (IRB) Approval

According to federal regulations, SWOG must monitor the documentation of IRB approval of all protocols on which its members participate prior to each participant registration. Through the computerized SWOG IRB approval program, the Group is able to monitor timely board reviews and re-reviews, thereby eliminating the possibility of participant registration prior to full board review. Attempted registrations without current re-review dates or initial review are refused.

Clinical Research Associates Training Course

The Group offers an on-line Clinical Trials Training Course, which serves to familiarize participants with the policies and procedures of SWOG and the NCI. This includes a review of cooperative group research, protocol content, forms completion, flow of data, quality control, methods for long term follow-up, quality assurance audits, and reporting of adverse reactions.

One day prior to each Spring Group meeting, an on-site training course is offered. New members are encouraged to send clinical research associates to this course for an in-depth orientation to the Group. Notification of each training course will be posted to the Group website approximately nine weeks prior to the Spring Group meeting.

Criteria for Continued Participation

Affiliate Program institutions will be required to meet a minimal average accrual of five initial registrations based over a three year period.

Affiliate Program investigators are also strongly encouraged to attend at least one semi-annual Group meeting every two years. Regular attendance at SWOG meetings ensures a high level of involvement in Group activities and continued education of current and future Group initiatives.

Mailing Policy

SWOG disseminates information to Group members electronically. Following preliminary membership approval, Affiliate Program participants will be issued a roster identification number and password to access the Group website. Affiliate Program participants will be required to download all bi-monthly protocol information (activations, closures, amendments, etc.) on the 1st and 15th of each month (members section only).

All SWOG protocols, policies and manuals, and newsletters are available for viewing or downloading on the Group website.

Protocol Availability

Affiliate Program participants have access to a multitude of Phase II, III, limited institution/pilot studies, and intergroup trials. Automatic Affiliate Program participation is provided for most Phase III and intergroup trials. Some Phase II Group-wide trials are available to Affiliate Program participants, including studies containing investigational new agents. In addition, Affiliates may be selected, on an individual basis, for assignment to a large number of pilot or limited institution trials.

Additionally, trials containing laboratory studies are available for Affiliate Program participation. These could include trials containing flow cytometry, surface marker analysis, cytogenetics, and proto-oncogene expression analysis and cancer control research aspects.

Trials in which the majority of Affiliate Program participants are excluded include studies of bone marrow transplantation and Phase I investigations. Finally, the NCI has reserved the authority to limit participants based upon the complexity of treatment or availability of drugs.

Performance Evaluations

Each Affiliate Program participant is continuously monitored for quality and quantity of contributions and performance. This entails the review of accrual contributions, eligibility and evaluability percentages, successful completion of Quality Assurance Audits (see Group Policy #19), and scientific contributions to the Group (study coordination, publication authorship, committee membership and meeting attendance). Administrative and scientific contributions are assigned point values, tallied and quartiled to allow comparison between all Affiliate Program institutions. All Affiliate Program contributions and their associated quartile figures are annually reported to the NCI.

Committee Participation

Affiliate Program investigators are eligible to participate in Group Disease and Research Committees and Administrative Committee activities. Participation as a Group Committee member requires attendance at semi-annual Committee meetings, participation in protocol review and manuscript review when applicable. Refer to Group Policy #2 for a list of current committees within SWOG.

A letter of recommendation must be provided by the Member Institution's Principal Investigator nominating the Affiliate Program investigator to Group Committee(s). This letter of recommendation is submitted to the Committee Chair and the Network Operations Center for consideration and approval. Following approval, the Affiliate Program investigator is informed, and is then added to the appropriate Committee membership roster for future mailings.

Monitoring Accrual Contributions

All Affiliate Program registrations count toward justifying the grant funding request. These contributions are tallied and provided annually with the Group Continuation Application. Monthly reports are provided by the Statistical Center which tabulates Affiliate Program accrual by Member Institution and eligibility of the participants entered and evaluability of the cases. These reports are provided to the Group Chair. Previously high accruing Affiliate Program members who suddenly experience a decrease in registrations are contacted in the hopes of identifying solvable problems. In addition, a decrease in the eligibility/evaluability rates would warrant communication with the parent Member Institution to appraise the Principal Investigator of the deficiency and request immediate attention to reverse a possible trend. This process of rapid review and detection of participant contribution variations will serve to correct deficiencies in a timely fashion before further decreases in performance occur.

Participant Reimbursement/Payment

SWOG provides financial reimbursement on a quarterly basis for each accrued eligible participant. Approximately 60 days following each three-month report period, the Statistical Center provides a listing of participant contributions to the Network Operations Center, individually tabulated for each Affiliate Program member. Cases are identified by phase (II versus III). Along with accrual and eligibility data, general demographic information for mailing purposes and tax identification numbers are provided for rapid dispersal of funds. The Affiliate's Member institution is also nominally financially rewarded for Affiliate Program registrations for their data management support.

Compliance with Federal Regulations

Each Affiliate 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 – HIPPA). Non-compliance with federal regulations may result in investigation or censure.