

**SWOG**  
<http://swog.org>

**Policy Memorandum No. 40**

**Subject:** International Participation/Membership

**Departments Affected:** All

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**MEMBERSHIP OF EX-UNITED STATES INSTITUTIONS**

SWOG (hereinafter known as "the Group") membership for institutions outside of the United States (ex-US) may be granted if the Group and the institution agree there is mutual scientific benefit to collaboration. SWOG will consider full membership primarily for institutions with prior experience in clinical trials and demonstrated ability to recruit to multiple disciplines and tumor types.

SWOG has developed the following guidelines for ex-US institutions that have an interest in associating with SWOG as a research base:

1. Ex-US institutions who join SWOG through one of the current membership programs (see SWOG Policy No. 3 for description of memberships) have all of the rights and responsibilities related to that membership program. This includes ensuring compliance with US federal policies and regulations [U.S. Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), National Cancer Institute (NCI) grant policy, U.S. federal government, U.S. Department of State].
2. Ex-US institutions are expected to meet SWOG's membership requirements to maintain their member status, including aiming to credit an average of 10 patients to SWOG over three years.
3. All communication regarding Group business will be done in English. Any necessary translation will be the responsibility of the ex-US institution for both costs and implementation.
4. Ex-US institutions must have internet access and all software necessary to obtain Group materials through the Group website and to register patients and report Serious Adverse Events through the internet. All Group data must be submitted on the standard protocol-specific data collection forms, using the laboratory units outlined in the form.
5. Each institution that is engaged in U.S. Department of Health and Human Services (DHHS) supported or conducted human subject research must register their Institutional Review Board (IRB) or Independent Ethics Committee (IEC) and file a Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP). This ensures that the corresponding IRB/IEC will provide prior approval for every protocol used by any physician affiliated with the institution.
6. Each institution must have obtained a Cancer Therapy Evaluation Program (CTEP) site code. Components (Affiliates or Sub-Affiliates) of Main Member institutions must have a separate CTEP site code.
7. Before protocol participation will be authorized, ex-US institutions must have received U.S. Department of State clearance by submitting a clearance request form to the SWOG Operations Office who will in turn notify the institution once this clearance is obtained.
8. A formal application must be submitted to the Operations Office identifying and describing the lead institution, all participating clinical research facilities, clinical trial management and quality assurance processes, patient resources for accrual, the Principal Investigator, participating investigators and support staff, and regulatory oversight.

9. Before any funds are paid on a trial involving a Federalwide Assurance to an ex-US institution(s), the institution must have begun patient accrual, have received U.S. Department of State clearance, executed subawards, consortia and purchase service agreements (PSAs) supporting SWOG research. The SWOG Group Chairs' Office may require SWOG Member institutions to fulfill additional requirements before executing subawards.
10. Budget requests, requests for funds, or financial reports must be stated in U.S. dollars (USD). If an award is made, the Group will not compensate for currency fluctuations through the issuance of the award.
11. All investigators and staff participating in SWOG protocols must have obtained Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) credentials and obtained user authorization with ID.me (see SWOG Policy No. 7 for details). Investigators and staff who are significant contributors to research must also register in the Registration and Credential Repository (RCR) system. Registration must be renewed annually.
12. Institutions must have a Principal Investigator and Head Clinical Research Associate (HCRA) always assigned to respond to administrative or study-related inquiries. Principal Investigator responsibilities are outlined in SWOG Policy No. 46; HCRA responsibilities will be available in a policy soon.
13. Institutions must keep their institution's membership roster updated of all investigators and staff through the use of the Clinical Trials Supporting Unit (CTSU) Roster Update and Management System (RUMS).
14. Before joining SWOG, ex-US institutions should be aware that not all SWOG or other collaborative group protocols can be open to ex-US member institutions. Ex-US Member institutions will submit a request to participate in protocols of interest and will only be approved to participate in previously vetted protocols. Participation in each protocol may be authorized on a case-by-case, site-by-site basis (see paragraphs #22-24 below). Common protocol participation limitations for ex-US Member institutions are listed in #24.
15. All institutions will abide by the rules and performance criteria governing all SWOG members in regard to patient eligibility and evaluability, timeliness of data submission, acceptable Quality Assurance Audits, and scientific contributions to the Group.
16. IRB/EC approvals of individual protocols will be submitted to the Coalition of National Cancer Cooperative Groups prior to initiation of patient registration. At the time of writing this policy, this submission occurs through the Regulatory Portal on the CTSU website.
17. All informed consents will give permission for the patient's original hospital record to be reviewed for quality assurance by representatives of the National Cancer Institute, SWOG, and/or approved select drug monitors from the pharmaceutical industry involved in the protocol. Any institution not using the Central Institutional Review Board (CIRB) of the National Cancer Institute in the United States is required to notify and request SWOG's approval for any significant informed consent changes. Any informed consent changes must be compliant with U.S. Federal Regulations.
18. All patients must have given informed consent, in accordance with the National Cancer Institute and SWOG Guidelines, prior to registration and initiation of treatment.
19. Ex-US institutions will be audited according to the identical guidelines as US institutions (from the NCI's Clinical Trials Monitoring Branch [CTMB]).

20. If the ex-US institution wishes to participate in any studies involving radiation therapy, the institution and investigators must meet the criteria outlined in SWOG Policy No. 26, including the ability to fulfill quality assurance and other requirements defined by the Imaging and Radiation Oncology Core (IROC), and the ability to participate in equipment monitoring by the Radiologic Physics Center (RPC).
21. If the ex-US institution wishes to participate in any studies involving bone marrow or stem cell transplantation, the institution and investigators must meet the criteria outlined in SWOG Policy No. 27, including accredited by the Foundation for the Accreditation of Cellular Therapy (FACT). Information about guidelines and procedures for accreditation may be obtained via the internet from the FACT website or from FACT directly as outlined in Policy No. 27.
22. When expressing interest in individual protocols or study proposals, ex-US institutions will be responsible for identifying country and institution specific issues and informing the Operations Office of any potential obstacles to participation. The Operations Office will work with the ex-US institution to resolve these issues and provide a complete and consistent response on the Group's behalf. Access to individual protocols may not be granted to ex-US institutions when including ex-US institutions would require undue time and effort. Protocol participation can be limited by many factors in collaborative groups or at the local site. Common considerations include:
  - a. National regulations not compatible with US regulations
  - b. IND requirements
  - c. Contracts
  - d. Study drug shipment authorizations
  - e. Differences in standard of care between countries
  - f. Standard of care not covered in collaborative group protocols
  - g. Shipment or shipment calendar for patient materials (including specimens and images)
  - h. Availability/cost of study materials on-site (e.g., protocol-specific reagents, Streck tubes)
  - i. US-specific or time sensitive endpoints
  - j. Funding
23. Customs regulations will be handled on a country-by-country, protocol-by-protocol, drug-by-drug basis.