

SOUTHWEST ONCOLOGY GROUP

Group Chair's Office
24 Frank Lloyd Wright Drive
P.O. Box 483
Ann Arbor, Michigan 48106

Operations Office
4201 Medical Drive, Suite 250
San Antonio, Texas 78229

Policy Memorandum No. 40
Subject: International Participation/Membership
Departments Affected: All

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Original Release Date: April 2003
Revision Date: April 2009

MEMBERSHIP OF NON-UNITED STATES INSTITUTIONS

The Southwest Oncology Group has developed the following guidelines for institutions based outside the United States that have an interest in associating with the Southwest Oncology Group as a research base:

1. Non-United States-based institutions will be allowed to join the Group through one of the current membership programs (see Policies 3, 4 and 5 for descriptions) and would have all of the rights and responsibilities related to that membership program, though the specific details may require accommodation as listed below. Institutions 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.
2. 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 submit a Federalwide Assurance (FWA) to the Office for Human Research Protections (OHRP). Evidence of this must be submitted to the Operations Office to ensure that every protocol to be used by any physician affiliated with the institution will have prior approval by the appropriate hospital's IRB. IRB approvals of individual protocols will be submitted to the Coalition of National Cancer Cooperative Groups prior to initiation of patient registration. All patients must have given informed consent, in accordance with the National Cancer Institute and Southwest Oncology Group Guidelines, prior to registration and initiation of treatment. 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, the Southwest Oncology Group, and/or approved select drug monitors from the pharmaceutical industry involved in the protocol.
3. Every physician participating in Southwest Oncology Group protocol studies must have been approved for membership within the Group and must have a *curriculum vitae* on file in the Southwest Oncology Group Operations Office. An FDA 1572 (Statement of Investigator) and supporting documents must be submitted to the Pharmaceutical Management Branch (NCI) on an annual basis by all participating investigators. Other documentation is also required for submission from individual investigators as part of the membership application.
4. All communication regarding Group business will be done in English. Any necessary translation will be the responsibility of the non-U.S. institution for both costs and implementation.
5. Non-U.S. institutions will be audited according to the identical guidelines as U.S. institutions (from the NCI's Clinical Trials Monitoring Branch [CTMB]). Additional costs of travel for auditors, or alternate (contract) auditing will be arranged and funded by the non-U.S. institution (with agreement from the Group required).

6. If the non-U.S. institution wishes to participate in any studies involving radiation therapy or stereotactic radiosurgery, the institution and investigators must meet the criteria outlined in Group Policy #26, including approval by the Committee Chair, the ability to participate in rapid review of radiation planning by the Quality Assurance Review Center (QARC), and the ability to participate in equipment monitoring by the Radiologic Physics Center (RPC).
7. If the non-U.S. institution wishes to participate in any studies involving bone marrow or stem cell transplantation, the institution and investigators must meet the criteria outlined in Group Policy #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 #27.
8. Issues related to specific rules for regulatory documentation, IND requirements, contracts, drug shipment, shipment of patient materials (including specimens and images), customs regulations will be handled on a country-by-country, protocol-by-protocol, drug-by-drug basis. The non-U.S. institutions will be responsible for identifying issues related to their situation and informing the Operations Office of any potential obstacles to their participation. The Operations Office will work with the non-U.S. institution to resolve these issues and provide a complete and consistent response on the Group's behalf. It is possible that access to individual protocols would not be granted to non-U.S. institutions based on the degree to which obtaining access would require undue time and effort.
9. The non-U.S. institution 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.
10. Before any funds are paid on a trial involving a Federalwide Assurance (FWA) to a non-U.S. institution(s), the institution(s) requires clearance by the U.S. Department of State. This includes subcontracts, consortia and purchase service agreements (PSAs) supporting Southwest Oncology Group research and patient accrual.
11. Any budget requests, requests for funds, and 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.
12. The following information must be submitted to the Operations Office, who must in turn forward such to the State Department Clearance prior to their initiating any funding action:

Name of Principal Investigator of Subcontract

Institute Name

City, Country

OHRP Federalwide Assurance (FWA) #

Identify preferred auditing process (e.g., Group auditors or alternate contract auditor-provide alternate contractor information).

Identify any issues or potential obstacles related to regulatory documentation, IND requirements, contracts, drug shipment, shipment of patient materials (including specimens and images), etc.

Estimated annual Total Cost dollar award for the non-US component

Research Objectives at the site

If human subjects are involved include the following, as applicable:

- The demographics (age-range, gender, etc.)
- The number of subjects (and how they will be recruited, if known)
- What participation will entail (clinic visit, questionnaire, blood sample, treatment, etc.)
- How long subjects will participate (e.g., one clinic visit a month for a year)
- Statement on protection of welfare of humans subjects (describe informed consent and confidentiality procedures to be used or use general statement if suitable)
 - e.g. "Informed consent for participation will be obtained from all human subjects and confidentiality of subjects will be protected, in compliance with NIH and in-country guidelines under the assurance number provided."

If human subjects data or samples are pre-collected:

- State that data/samples were collected under another project.
- State that data/samples are anonymous or how confidentiality will be ensured if not anonymous.

If data/samples collected under another project *and* are anonymous: State that the study is not considered "human subjects research" because data/samples were previously collected and anonymous