

<i>Policy</i>	3.1.3	<i>Section</i>	3	Membership	<i>Completion Date</i>	1/20/01 Rev12/07 Rev1/20/10
<i>Subject</i>	Institutional Membership: Definitions, Personnel, Responsibilities, Performance, Participation				<i>Pages</i>	3
					<i>Approved by</i>	EC 5/02

INSTITUTIONAL MEMBERSHIP

Definitions

Member Institutions are defined as those that meet the minimum requirements as defined in Section 3.1.1 of the Administrative Manual.

The Uniformed Services Oncology Consortium is a special member with a single Principal Investigator comprising the institutions of the Army, Navy and Air Force. The member institutions must meet the requirement for treatment of twelve new patients annually, but have been provided some flexibility regarding the enrollment criteria because of the high transfer rate.

Personnel

Principal Investigator (PI). The member institution designates a principal investigator who must be a full individual member of COG. The principal investigator is responsible for all COG activities in his/her member institution. New PIs must be approved by a majority of the Executive Committee.

The PI is the contact person at the member institution for all communication with the COG Chair, Operations Center, and Research Data Center and has the responsibility for:

- The performance of COG members in his/her member institution
- The accuracy of records
- The prompt processing and dispersal of diagnostic materials, required data, research materials and pathological specimens
- Recommendation of qualified individuals in the institution for individual membership in COG and for assuring the cooperation and participation of such persons in COG activities
- Circulation or distribution of information on all pertinent matters from COG sources to appropriate members in the member institution
- The Principal Investigator will represent his/her institution in all votes (no proxy voting)

In the event of a vacancy in the position of PI, the member institution must immediately designate a temporary successor for up to 6 months until a replacement PI is recommended and approved by the Executive Committee at the next COG meeting.

The institution will be suspended immediately in the event of a PI vacancy. If a replacement PI is not named within one month the institution will be terminated.

Provisional PI

Individuals not yet board certified in their subspecialty, but requested by their institution to assume the position of PI will be granted Provisional PI status. The Provisional PI is expected to attain board certification within two years of appointment.

Responsible Investigator (RI). In each member institution the PI will designate an RI for each of the required major disciplines (Surgery, Pathology, Radiation Oncology, and Hem/Onc if the Principal Investigator is not an Oncologist). The RI has the delegated responsibility for the performance of that discipline.

Responsibilities

Conduct of Clinical Research -all member institutions agree to adhere to the procedures of the Children's Oncology Group for the conduct of clinical research. At a minimum, this would involve:

Record Keeping: Meeting the record keeping policies of the Children's Oncology Group, including the submission of all data and follow-up data in a timely fashion.

Institutional Review Board Assurance: that each protocol will have approval by an Institutional Review Board (IRB). The IRB should have an assurance document which has been approved by the Office for Human Research Protection, NIH. (FWA)

Informed Consent: Assurance that each patient will sign a copy of the IRB approved consent form prior to enrollment and the start of protocol therapy.

Investigational Drugs : Compliance with the policies and regulations of the NCI and FDA concerning the use of investigational drugs including the use of NCI Investigational Drug Accountability logs.

Audit: Agreement that primary medical records of patients may be audited in accordance with policies of the Children's Oncology Group, the NCI and the FDA.

Registration: In accordance with NCI policy, all member institutions are registered with the Children's Oncology Group Operations Center. Members will file a signed FDA 1572 with the NCI prior to participating in any research protocol utilizing any investigational drugs. Investigational drugs will not be provided to unlisted investigators, and will not be used to treat patients who have not been entered on an NCI-approved Children's Oncology Group protocol.

IAM Accounts (Identity and Access Management Accounts) for CTSU (Clinical Trial Support Unit): All COG members at COG institutions are required to have an active IAM account.

Performance

Institutions are expected to enter all eligible patients with cancer into the CCRN (ACCRN07) if the patient/family consents to participation, irrespective of their eligibility or participation in COG trials. Additionally, institutions are encouraged to enroll all patients eligible for COG therapeutic and non-therapeutic protocols if the patient/family consents to participation.

Institutional contributions are defined in terms of patient enrollment onto the CCRN for patients in North American institutions and/or minimal audit requirements and the submission of data as determined by study coordinators, the discipline committees, the Statistical Office and the Institutional Performance Review Committee. All institutions will be evaluated in terms of:

- Patient eligibility
- CCRN enrollments (North America)
- Patient evaluability
- Protocol compliance
- Timeliness of data submissions
- Completeness of data submissions
- Legibility of data submissions
- Pathology submissions and compliance (as appropriate)
- Radiotherapy data submissions and compliance (as appropriate)
- Surgery data submissions (as appropriate)
- Periodic institutional audits

Group Administrator:

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