
MEMBER INSTITUTION

Personnel & Service Requirements for Main and Affiliate Member Institutions



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Introduction

The proven effectiveness of Comprehensive Pediatric Hematology/Oncology Programs has demonstrated the need for a multidisciplinary team approach. The Children's Oncology Group (COG) has implemented this policy because of the unique nature of the disorders as well as the special medical and psychosocial requirements of children, adolescents, and young adults with cancer.

Policy Statement

A COG member institution must meet the general criteria and guidelines for pediatric cancer centers established and published by the Section on Hematology-Oncology of the American Academy of Pediatrics and the American Society of Pediatric Hematology/Oncology.

Purpose

Comprehensive Pediatric Hematology/Oncology Program in an approved COG Main or Affiliate Member institution.

Note: The requirements as outlined in this policy are meant to describe the personnel and services needed for COG institutional membership. They are not meant to imply the location for all COG activities as in many situations, although initial diagnosis and treatment planning may

be done by a Comprehensive Pediatric Hematology/Oncology Program, it will be desirable to develop outreach services to bring some aspects of care as close to the patient's home as possible while meeting or exceeding appropriate standards of medical care for pediatric cancer patients.

Scope

This policy applies to all COG Main and Affiliate Member Institutions.

Note: Certain U.S. federal government facilities have been provided some flexibility regarding personnel/service requirements.

Single Member Institutions

Member institutions are defined in Health and Human Services (HHS) regulation [45 CFR 46.102 \(f\)](#) as “any public or private entity or agency (including federal, state or other agencies).” Each member institution is identified by its Cancer Therapy Evaluation Program (CTEP) Identification Code. National Cancer Institute (NCI) Community Oncology Research Program (NCORP) institutions may have more than one Institutional Review Board (IRB) or Independent Ethics Committee (IEC) per NCI guidelines but must identify one local administrative contact for COG.

Separate entities must be able to stand alone as hematology/oncology centers, as defined in this policy; though it is recognized that not all COG member institutions have all care and support facilities in one location, but certain minimum requirements are expected (as described in this policy).

Note: An institution must be a distinct physical location where research is conducted under HHS regulations by an investigator responsible for the oversight of patients/research participants.

On-Site Personnel

The following personnel are required to be on-site at the facility for both COG Main and Affiliate Member institutions:

- board certified/eligible or equivalent pediatric hematologist/oncologist
 - nurses with additional training in the management of children and adolescents with cancer and blood disorders, and documented in-house training in chemotherapy administration through a course recognized by a professional nursing organization (e.g., Association of Pediatric Hematology/Oncology Nurses (APHON), Oncology Nursing Society (ONS))
 - respiratory therapists with expertise in pediatrics
 - anesthesiologist with expertise in the management of children
 - pharmacist with expertise in chemotherapy and expertise with investigational drugs (only required for Affiliate Member institutions who will be administering investigational drugs)
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- social worker with expertise/experience in the management of children and adolescents with cancer and blood disorders

The following personnel are required to be on-site at the facility for ONLY COG Main Member institutions:

- board certified pathologist(s) committed to handling specimens according to COG protocol guidelines and methodologies
 - clinical research associates trained in data management, specimen collection, and regulatory support of cooperative research
 - radiologist with expertise in the management of children
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On-Site Services

The following services are required to be on-site at the facility for both COG Main and Affiliate Member institutions:

- pediatric unit (i.e., personnel trained in taking care of children even if beds are in an adult unit)
- intensive care unit with the ability to treat critically ill children
- outpatient clinic for the acute and chronic care and treatment of children and adolescents with cancer and serious blood disorders
- computed tomography (CT)
- ultrasonography
- pharmacy with capability of storage, accurate preparation, dispensing, and accounting for general antineoplastic agents
- pharmacy with capability of storage, accurate preparation, dispensing, and accounting for investigational drugs (only required for Affiliate Member institutions who will be administering investigational drugs)
 - anatomic pathology services necessary for the immediate handling of specimens:
 - ability to perform and interpret rapid frozen sections
 - ability to rapidly freeze specimens for storage
 - frozen storage (at least -70°C) available
- laboratory services necessary for the care of critically ill children that must be available 24-hours a day:
 - ability to perform routine blood gas, clinical chemistry, hematology, microbiology, and coagulation, and coagulation factor assays on pediatric samples
 - timely interpretation of organism and other special stains
- capabilities to provide appropriate isolation for transplant patients
- expertise available to deliver and monitor total parenteral nutrition for critically and chronically ill children and adolescents
- pain management and sedation expertise

The following services are required to be on-site at the facility for ONLY COG Main Member institutions:

- long term follow-up services for survivors of pediatric cancer

Personnel- Readily Accessible

The facility must be able to document that they have, either on-site or readily available and accessible, the following personnel for both COG Main and Affiliate Member Institutions. For Affiliate Member institutions, it needs to be noted if an Affiliate will be using Main Member resources:

- board certified/eligible or equivalent surgeon with surgical expertise in the management of children with cancer and adolescents and blood disorders
- radiation oncologist with pediatric expertise in the treatment of children and adolescents with cancer and blood disorders
- orthopedic surgeon with pediatric expertise
- urologic surgeon with pediatric expertise
- neurosurgeon with pediatric expertise
- ophthalmologist with pediatric expertise
- otolaryngologist with pediatric expertise
- nuclear medicine physician with pediatric experience
- board certified pathologist with special training and/or certification in pediatric pathology
- board certified pathologist with special training and/or certification in hematopathology
- board certified pathologist with special training and/or certification in neuropathology
- nutritionist(s) with pediatric expertise
- physical therapist(s) with pediatric expertise
- pediatric psychologist(s)/ neuropsychologist(s) with experience in the management and neuropsychology testing of children and adolescents with cancer and blood disorders
- occupational therapist(s) with pediatric expertise
- child life specialist(s)
- pediatric subspecialties in:
 - nephrology
 - pulmonology
 - cardiology
 - gastroenterology
 - neurology
 - infectious disease
 - endocrinology
 - psychiatry

The facility must be able to document that they have, either on-site or readily available and accessible, the following personnel for ONLY COG Affiliate Member institutions

- board certified pathologist(s) committed to handling specimens according to COG protocol guidelines and methodologies
- clinical research associates trained in data management, specimen collection, and regulatory support of cooperative research

Note: If not on-site, CRA must be readily available to come on-site to handle time sensitive study-required activities such as specimen collections or site must have onsite personnel available to cover this activity. Under certain circumstances, due to geographic distance or different electronic medical records (EMRs) systems, COG may require a CRA on-site.

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- radiologist with expertise in the management of children
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Remote Work

COG acknowledges that some personnel, although described here as being on-site or readily available, have transitioned to performing work functions in a remote setting. It is at the discretion of the member institution and/or subspecialty to determine if a role can be performed remotely. At a minimum, COG needs confirmation that any on-site role, if performed remotely, requires that individual to be readily available and have direct access to the site's EMRs.

Services- Readily Accessible

The facility must be able to document that they have, either on-site or readily available and accessible, the following services for both COG Main and Affiliate Member institutions (for Affiliate Member institutions, it needs to be noted if an Affiliate will be using Main Member resources):

- radiation therapy equipment designed for state-of-the-art treatment of children, including:
 - rotational linear accelerator(s)
 - dedicated radiation simulator(s) or CT simulator(s)
 - treatment planning system capable of doing multiple point calculations on irregular fields
 - facility must agree to be surveyed by the Radiologic Physics Center (RPC) and to submit data including benchmarks to Imaging and Radiation Oncology Core (IROC)
- diagnostic imaging equipment and services, including:
 - magnetic resonance imaging
 - positron emission tomography (PET) scan
 - nuclear medicine
 - angiography
 - interventional radiology
 - anesthesia resources to meet the sedation/anesthesia needs of pediatric patients requiring sedated imaging
- Clinical Laboratory Improvements Amendments (CLIA) approved (or equivalent) clinical laboratories with expertise in the assessment and diagnosis of pediatric hematologic/oncologic disorders offering:
 - flow cytometry
 - bone marrow aspirate and biopsy analysis
 - histopathology
 - cytogenetic analysis
 - molecular genetic analysis
 - immunohistochemistry for tumor diagnosis
 - cytopathology
 - comprehensive microbiology and virology testing
 - clinical chemistry expertise in drug level monitoring, including but not limited to methotrexate (MTX) levels
 - Note: Facility will need to provide the range (hours) in turn-around time of results after blood draw if MTX levels are off-site.

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- Note: Laboratory services necessary for the care of critically ill children that must be available 24 hours a day:
 - transfusion service that can supply leukocyte reduced, irradiated cellular products appropriate for immunocompromised patients
 - transfusion program for the efficient and safe administration of blood products to ambulatory patients
 - therapeutic apheresis
 - services for dialysis of children and adolescents
 - physical medicine and rehabilitation

For COG Affiliate Member institutions, the facility must be able to document that they have, either on-site or readily available and accessible, the following service (it needs to be noted if it will be using Main Member resources):

- long term follow-up services for survivors of pediatric cancer

The following personnel and services available on-site or off-site for both COG Main and Affiliate Member institutions should be noted but are not required for membership:

- education specialist (to teach patients and liaise with schools and others on educational issues on behalf of patients)

Site Visits

The travel costs for in-person site visits, which are a part of the application process, are charged to all sites (U.S. or non-U.S.) applying as a COG Main Member institution.

The in-person site visit requirement for all sites (U.S. or non-U.S.) applying as a COG Affiliate Member institution is the responsibility of the Main Member Principal Investigator (PI). The PI should perform the Affiliate Member institution site visit as soon as feasible after preliminary membership approval; the PI is required to submit the Site Visit Checklist to COG for review before final Affiliative membership approval.

When an Institution's Personnel/Services Change

COG member institution PIs and Lead Investigators (LIs) must notify the Membership Committee Chair when there is a change in their personnel and/or services that will affect their ability to meet the requirements listed in this policy. Such changes include, but are not limited to:

- vacancy of the PI or LI (refer to [Change of Member Institution Principal Investigator/Affiliate Member Institution Lead Investigator](#))
- vacancy of a Responsible Investigator (refer to [Responsible Investigators](#))
- changes in required on-site personnel or services
- changes in required readily accessible personnel or services

The notification to the Membership Department should include an outline of the changes and the effective dates for the changes. Note: If the changes have not yet been finalized, it is recommended that a notification of pending changes be sent to the Membership Committee Chair

in the interim.

Other Requirements

Comprehensive Pediatric Hematology/Oncology Programs should have regularly scheduled multidisciplinary tumor boards as well as case conferences designed to discuss children and adolescents with serious hematologic problems.

Comprehensive Pediatric Hematology/Oncology Programs must be affiliated with or part of a hospital and laboratory approved for the care of children and adolescents by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or equivalent.

Other Related P&P

- [COG Constitution & Bylaws](#)
 - [MI-002 \(Conduct of Clinical Research for Main and Affiliate Member Institutions\)](#)
 - [MI-003 \(Responsible Investigator\)](#)
 - [MI-005 \(Member Institution Status Change Guidelines\)](#)
 - [MI-006 \(Change of Main Member Institution Principal Investigator/Affiliate Member Institution Lead Investigator\)](#)
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References Or Linked Forms

- [CTEP Institution Site Codes](#)
 - [DHHS Unified Site Coding Procedure](#)
 - [45 CFR 46.102 \(f\)](#)
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Who Should Be Knowledgeable About This Policy

Those who are responsible for following the guidelines/performing the procedures that implement this policy (including all COG members, and applicable operations/administrative personnel involved in the Scope of this policy), those who have the oversight and/or supervisory responsibility for these guidelines/procedures, and those who have the responsibility to authorize this policy and its related guidelines/procedures should be knowledgeable about this policy.

SOP Maintenance Responsibility

- SOP Owner – COG Membership Department
- SOP Contact – Manager, COG Membership Department

SOP Authorization

Approval Indicator: Approved by the Executive Committee on 11/21/2023

Version/Revision History

Per COG Policy & Procedure (P&P) Documentation, reassessment of this policy will occur at least once every 36 months; interim revisions will be incorporated as needed. The table below documents the version/revision history for this policy. A cumulative history for this document is maintained for ten years.

| Approval Date | Version | Version/Revision Summary |
|-------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 05/2002 | V1.0 | Initial documentation/publication of Admin Sections 3.1.1 and 3.1.2. |
| 06/2008 & 12/2007 | V2.0 | Reassessments/revisions to Admin Sections 3.1.1 and 3.1.2. |
| 12/11/12 | V3.0 | Reassessment and republication. Top portion of Admin Section 3.1.1 and all of Admin Section 3.1.2. |
| 10/11/13 | V3.1 | Updated Single Member Institution and to include communications for changes in personnel/services, travel costs for site visits, and a note for U.S. federal government facilities. |
| 09/19/14 | V4.0 | Reassessment and republication. |
| 11/21/23 | V5.0 | Reassessment and republication. Added language addressing Main and Affiliate Member institution requirements. Updated the types of on-site and readily accessible personnel and services necessary for member institutions. Added Remote Work section and clarified CRA requirements. |
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