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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 The purpose of this policy is to provide the personnel and service requirements for a Comprehensive Pediatric Hematology/Oncology Program.

Note: This policy does not imply the need for all personnel and services to necessarily be on-site. 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 much of the care as close to the patient's home as is possible while maintaining state-of-the-art medical care.

Scope This policy applies to all COG Member Institutions. *Note:* Certain U.S. federal government facilities have been provided some flexibility regarding personnel/service requirements.

Personnel & Service Requirements for
Member Institutions**Single Member Institution**

Member institutions are independently administered hospitals, medical centers or research institutes with which one or more qualified individual members are affiliated. Each member institution is identified by its Cancer Therapy Evaluation Program (CTEP) Identification Code (see **Note** below). National Cancer Institute (NCI) Community Oncology Research Program (NCORP) institutions may have more than one IRB per the National Cancer Institute (NCI) guidelines but must identify one local administrative contact for the 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: The definition of an institution, as defined in 45 CFR 46.102 (b) is "any public or private entity or agency (including federal, state or other agencies)". Additionally, it must also be a distinct physical location where research is conducted under Health and Human Services 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:

- Board certified/eligible or equivalent pediatric hematologist/oncologist
- Board certified pathologist(s) committed to handling specimens according to COG protocols
- Nurses with additional training in the management of children and adolescents with cancer and blood disorders, and documented in-house training in chemotherapy administration
- Clinical research associates trained in data management support of cooperative research
- Respiratory therapists with expertise in pediatrics
- Anesthesiologist
- Radiologist
- Pharmacist with expertise in chemotherapy
- Social worker with additional training in the management of children and adolescents with cancer and blood disorders

**Personnel & Service Requirements for
Member Institutions****On-site Services** The following services are required to be on-site at the facility:

- 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
 - Computed axial tomography
 - Ultrasonography
 - Pharmacy with capability of storage, accurate preparation, dispensing, and accounting for investigational drugs, and other antineoplastics
 - 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
 - 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 and coagulation assays on small samples
 - Availability of therapeutic apheresis
 - Immediate interpretation of organism stains
 - Capabilities to provide appropriate isolation for patients with severe immunosuppression
 - Expertise available to determine the need to deliver and monitor total parenteral nutrition for critically and chronically ill children and adolescents
 - Pain management and sedation guidelines
 - Long term follow-up services for survivors of pediatric cancer
 - Internet connectivity and readily accessible workstations
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**Personnel -
Readily
Accessible**

The facility must be able to document that they have the following, readily available and accessible personnel *with expertise in the management of children and adolescents with cancer and blood disorders*:

- Board certified/eligible or equivalent surgeon with expertise in the general surgical management of children and adolescents with cancer and blood disorders
 - Radiation oncologists qualified treatment of children and adolescents with cancer and blood disorders
 - Orthopedic surgeons
 - Urologic surgeons
 - Neurosurgeons
 - Ophthalmologist
 - Otolaryngologist
 - Plastic surgeon
 - Nuclear medicine physician
 - 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 expertise in the dietary requirements of children and adolescents
 - Physical therapist(s)
 - Pediatric psychologist(s)
 - Occupational therapist(s)
 - Child Life specialist
 - Nephrology
 - Pulmonology
 - Cardiology
 - Dentistry
 - Gastroenterology
 - Neurology
 - Infectious disease
 - Endocrinology
 - Psychiatry
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**Services -
Readily
Accessible**

The facility must be able to document that they have the following services available and readily accessible:

- Diagnostic imaging and radiation oncology equipment and services, including:
 - Magnetic resonance imaging
 - PET Scan
 - Nuclear medicine
 - Angiography
 - Interventional radiology
 - Rotational linear accelerator
 - Conventional or CT simulator for radiation therapy planning
 - Treatment planning system capable of doing multiple point calculations on irregular fields
 - Adequate physics support for calibration, dosimetry, and regular quality assurance
 - Anesthesia resources to meet the sedation/anesthesia needs of pediatric patients
 - Agree to be surveyed by the Imaging and Radiation Oncology Course (IROC) Houston and to submit data including benchmarks to IROC Rhode Island
- CLIA approved (or equivalent) Clinical laboratories with expertise in the assessment and diagnosis of pediatric hematologic/oncologic disorders offering:
 - Cell marker studies
 - Bone marrow aspirate and biopsy analysis
 - Histopathology
 - Cytogenetic analysis
 - Immunohistochemistry for tumor diagnosis
 - Comprehensive microbiology and virology
 - Clinical chemistry expertise in monitoring antibiotic and methotrexate levels
 - **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
 - ❖ Therapeutic apheresis
 - ❖ Transfusion program for the efficient and safe administration of blood products to ambulatory patients
- Services for dialysis of children and adolescents
- Rehabilitation

Personnel & Service Requirements for
Member Institutions**Travel Costs for
Site Visits**

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

**When an
Institution's
Personnel/
Services
Change**

COG member institutions' Principal Investigators must notify the chair of the Membership Committee 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 Principal Investigator – refer to [Vacancy of Member Institution Principal 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 Committee Chair 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. The outpatient clinic should ensure the long-term follow-up of successfully treated patients and those with lifelong chronic disorders.
 - 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 JCAHO or equivalent.
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**Other Related
P&P**

- [COG's Constitution and Bylaws](#)
 - [Conduct of Clinical Research for Member Institutions](#)
 - [Member Institution Status Change Guidelines](#)
 - [Vacancy of Member Institution Principal Investigator](#)
 - [Responsible Investigator](#)
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References

- [CTEP Site Code Policy](#)
- [DHHS Unified Site Coding Procedure](#)

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), 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.

Policy Maintenance Responsibility

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

Policy Authorization

Approval Indicator: Approved by the Executive Committee on 09/19/14
COG Executive Committee

Version/Revision History

Reassessment of this policy will occur once every 24 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	Re-assessments/revisions to Admin Sections 3.1.1 and 3.1.2.
12/11/12	V3.0	Re-assessment 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	Re-assessment and republication.