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Introduction

Member institutions are defined as those that meet the four criteria for institutional membership as defined in the COG's *Constitution and Bylaws*, and the minimum requirements for personnel and services as defined in the COG's *Personnel & Service Requirements for Member Institutions*.

Policy

It is the policy of the Children's Oncology Group (COG) that all member institutions are expected to adhere to COG's conduct of clinical research responsibilities and performance requirements as described in this policy and in other COG policies and procedures.

Purpose

The purpose of this policy is to describe the responsibilities for the conduct of clinical research for COG Member Institutions.

Scope

This policy applies to all COG Member Institutions.

Conduct of Clinical Research Responsibilities

All member institutions agree to adhere to the policies and procedures of the COG for the conduct of clinical research. At minimum, this includes:

- ***Record Keeping*** – Meeting the record keeping policies of the COG, 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 must have an active Federal Wide Assurance (FWA) that has been approved by the Office for Human Research Protection, National Institute of Health.

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Conduct of Clinical Research Responsibilities (cont.)

- ***Informed Consent*** – Assurance that each subject or legal guardian will sign a copy of the IRB-approved consent form prior to enrollment and the start of protocol therapy and that assent will be obtained according to institutional guidelines.
- ***Investigational Drugs*** – Compliance with the policies and regulations of the National Cancer Institute (NCI) and Food and Drug Administration (FDA) concerning the use of investigational drugs including the use of NCI Investigational Drug Accountability logs.
- ***Audit*** – Agreement that primary medical records of subjects may be audited in accordance with policies of the COG, the NCI, the FDA, and applicable industry partners.
- ***Registration*** – In accordance with NCI policy, all member institutions are registered with the COG 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 subjects who have not been entered on an NCI-approved COG protocol.
- ***Identity and Access Management (IAM) Accounts*** – All COG members at COG institutions are required to have an active Cancer Therapy Evaluation Program (CTEP) IAM account. Refer to *CTEP Identity and Access Management (IAM)*.

Other Related P&P

- *COG Constitution & Bylaws*
- *Personnel & Service Requirements for Member Institutions*
- *Institutional Performance Monitoring Program*
- *CTEP Registrations for COG Members*

References

- *OHRP – Database for Registered IORGs & IRB, Approved FWAs*
- *NCI Investigator's Handbook*
- *CTEP Identity and Access Management (IAM)*

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), 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 – Children's Oncology Group
- Policy Contact – Chief Administrative Officer, Children's Oncology Group

Policy Authorization

Approval Indicator: Approved by the Executive Committee on 10/09/15
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. (Admin. Section 3.1.3)
12/07, 01/10	V2.0	Reassessments and revisions.
04/12/13	V3.0	Re-assessment and republication.
10/09/15	V4.0	Re-assessment and republication.
03/11/16	V4.1	Added *CTEP Registrations for COG Members* to Other Related P&P section; approved by COG CAO.