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**Introduction**

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

**Policy**

It is the policy of COG that all COG 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 Main and Affiliate Member institutions.

**Scope**

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

**Conduct of Clinical Research Responsibilities**

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

- ***Record Keeping*** – Meeting the record keeping policies of COG, including the submission of all data and follow-up data in a timely fashion.

- ***Institutional Review Board*** – All U.S. institutions need to register with the National Cancer Institute (NCI) Pediatric Central Institutional Review Board (CIRB) before COG can activate the site. In addition, assurance is required that all ex-U.S. institutions for all protocols, and all U.S. institutions for non-National Clinical Trials Network (NCTN) and National Cancer Institute Community Oncology Research Program (NCORP) protocols, 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 Protections (OHRP), U.S. Department of Health and Human Services.

- ***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 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 COG, NCI, FDA, and applicable industry partners.

- ***NCI Registration*** – In accordance with NCI policy, all COG member institutions are required to register with NCI/Cancer Therapy Evaluation Program (CTEP)'s Enterprise Core Unit and have a 5 digit CTEP Institution Code to register with COG.

- ***NCI CTEP-Identity and Access Management (IAM) Account*** – In accordance with NCI policy, all COG individual members at COG member institutions are required to have an active CTEP IAM account. Refer to *NCI CTEP IAM User Access*.

- ***NCI Registration and Credential Repository (RCR) Registration*** – In accordance with NCI policy, all COG individual members at COG member institutions with the NCI registration types of Investigator, Non-Physician Investigator, and Associate Plus must register with NCI RCR. In addition, Investigators must file a signed FDA 1572 via NCI RCR 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.

**Other Related P&P**

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

**References**

- *OHRP – Database for Registered IORGs & IRBs, Approved FWAs, and Documents Received in Last 60 Days*
- *NCI Investigator's Handbook*
- *NCI CTEP IAM User Access*

**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.

**Policy Maintenance Responsibility**

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

**Policy Authorization**

Approval Indicator: _____Approved by the Executive Committee on 09/08/2023_____
COG Executive Committee

**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. (Admin. Section 3.1.3) |
| 12/07, 01/10 | V2.0 | Reassessments and revisions. |
| 04/12/13 | V3.0 | Reassessment and republication. |
| 10/09/15 | V4.0 | Reassessment and republication. |
| 03/11/16 | V4.1 | Added *CTEP Registrations for COG Members* to Other Related P&P section; approved by COG CAO. |
| 09/08/23 | V5.0 | Reassessment and republication. Updated applicability to COG Main and Affiliate Member institutions; clarified IRB and NCI RCR Registration requirements. |