Table of Contents

Introduction

The Children's Oncology Group's Institutional Performance Monitoring Program is established by the Executive Committee. The purpose of this Program is to institute a performance data monitoring mechanism that reviews COG Member Institutions for adherence to performance standards set forth by the COG.

Policy Statement

It is the policy of the Children's Oncology Group (COG) that all COG Member Institutions must comply with the standard performance requirements established by the Institutional Performance Monitoring Program.

Purpose

The purpose of this policy is to document the expected standards of performance of the Institutional Performance Monitoring Program and the consequences for failing to meet the established standards.

Scope

This policy applies to all COG Member Institutions' performance monitoring.

Institutional Performance Monitoring Committee

The Institutional Performance Monitoring Committee (IPMC) is a COG standing committee that is responsible for monitoring and reporting on COG Member Institutions' performance data. For more information about the committee, refer to the *Institutional Performance Monitoring Committee Charter*.

Monitoring Cycles

The IPMC reviews COG Member Institution's performance ***once a year***, though they can convene to review specific circumstances that may arise over the course of the year.

Performance Data

The IPMC and the IPMC Chair use the following reports/information to monitor an institution's performance:

- New Patient Registrations/Enrollments
- Therapeutic and non-therapeutic trial enrollment data
- Data currency information
- Eligibility information from study committees and audit reports
- Radiation therapy data submission and protocol compliance information
- Biopathology specimen submission reports
- Audit outcome reports
- Studies approved by the IRB
- Other information provided by the Statistics & Data Center as required

Annual Institutional Report Cards

The Statistics & Data Center provides Principal Investigators summaries of their institutional performance at annual intervals. These summaries are documented on an *Institutional Report Card* and include the current year assessments and in yearly composites for the past three years and a three-year rolling average where appropriate.

Deviation Letters to Principal Investigators

When an institution deviates from the standards of performance requirements, the IPMC Chair, after consultation with the Executive Committee, prepares a formal communication to the institution's Principal Investigator. This communication, in the form of a letter, includes the:

- deviation(s);
- institution's status change, if applicable; and
- expected corrective actions/improvements needed.

Performance Monitoring Requirements

The recommended minimal standards of performance are as follows:

- ***Data Currency*** – a score of ≥ 90% (case report forms based)

- ***IROC Rhode Island Submissions***

  - Radiation Therapy Data Submissions – a score of ≥ 90%
  - Radiation Therapy Protocol Therapy Compliance – a score of ≥ 90%
  - Diagnostic Imaging Submissions – a score of ≥ 90%

- ***New Patient Registrations/Enrollments –***

  - ***North American Institutions*** – Institutional investigators must enroll a minimum average of 12 new patients each year to the APEC14B1 (or ACCRN07 until it is phased out), based on a three year rolling average.
  - ***Non-North American Institutions*** – Institutional investigators must enroll a minimum average of 12 new patients each year to the APEC14B1 (or have 12 new patient registrations entered into the COG registry), based on a three year rolling average.

- ***Patient Eligibility –*** Patient eligibility ≥ 95% as determined by study committees and audit findings. Patients excluded on the basis of COG Pathology, Cytogenetic, or other laboratory review will not count against eligibility.

- ***Cases Available for QA Audit*** (Refer also to *Quality Assurance Audit Program*)

  - ***For Established COG Member Institutions*** – a minimum of 10 therapeutic cases to be audited for the three-year audit cycle.
  - ***For New COG Member Institutions*** – at least 5 therapeutic cases enrolled within 18 months of membership.

Note: Other performance monitoring criteria may be added as determined by the Executive Committee at the recommendation of the IPMC and the Statistics & Data Center.

Consequences for Failure to Meet Performance Monitoring Requirements

- ***Failing Data Currency or IROC Rhode Island Radiation Therapy or Diagnostic Imaging Data Submissions –*** If an institution fails to meet the (forms-based) data currency or IROC Rhode Island data submission requirement (see *Performance Monitoring Requirements*), the IPMC may make recommendations to suspend the institution until its delinquent data is received. Institutions with persistent or recurrent delinquent data deficiencies may be placed on probation with corrective actions/improvements required to remove the probation. This information will be communicated to the institution's Principal Investigator in a formal letter (see *Deviation Letters to Principal Investigator*).

- ***Failing IROC Rhode Island Protocol Compliance***–The consequences for failing to meet the RT protocol compliance performance requirement (see Performance Monitoring Requirements) is pre-review of radiation therapy treatment plans by IROC-Rhode Island for the next 10 patients or until radiation therapy compliance is 90% or greater (evaluated annually). If an institution fails to demonstrate timely improvement in RT Protocol Compliance, the institution may be placed on probation. This information will be communicated to the institution's Principal Investigator in a formal letter (see *Deviation Letters to Principal Investigator*).

- ***Failing New Patient Registrations/Enrollments or Patient Eligibility Requirement*** – If an institution fails to meet the new patient enrollment or patient eligibility requirement (see *Performance Monitoring Requirements*), the institution will be placed on probation with corrective actions/improvements required to remove the probation. This information will be communicated to the institution's Principal Investigator in a formal letter (see *Deviation Letters to Principal Investigator*).

  An institution that does not successfully meet the conditions of probation will be notified of impending termination. Refer to the *Member Institution Status Change Guidelines* for information about Probation, Suspension and Termination. Refer also to *Transition of Research Subjects for Terminated Member Institutions*.

- ***Failing QA Audit Case Requirement –*** If an institution fails to meet the required number of patient cases for a quality assurance audit: (See *Performance Monitoring Requirements*).

  - ***Established COG Member Institutions –*** The institution is referred to the IPMC Chair for consideration of probation or termination for cause. The IPMC Chair will determine if IPMC review is required or if the findings should be submitted directly to the Executive Committee for consideration.
  - ***New COG Member Institutions –*** The institution is referred to the IPMC Chair for consideration of continued provisional status or termination for cause. The IPMC Chair will determine if IPMC review is required or if the findings should be submitted directly to the Executive Committee for consideration.

Note: Certain U.S federal government facilities have been provided some flexibility regarding the therapeutic enrollment criteria.

Other Related P&P

- *Institutional Performance Monitoring Committee Charter*
- *Member Institution Status Change Guidelines*
- *Quality Assurance Audit Program*
- *Transition of Research Subjects for Terminated Member Institutions*
- *Conduct of Clinical Research for Member Institutions*
- *Radiation Oncology Participation Requirements*

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 – Institutional Performance Monitoring Committee
- Policy Contact – Committee Chair, Institutional Performance Monitoring Committee

Policy Authorization

Approval Indicator: Approved by the Executive Committee on 03/31/17
COG Executive Committee

Version/Revision History

Reassessment of this policy will occur 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.
06/2008 & 04/2010	V2.0	Re-assessment and revisions.
01/08/13	V3.0	Re-assessment and republication. Program information from Admin. Section 5.1.
04/12/13	V3.1	Note added to Consequences section.
09/19/14	V4.0	Re-assessment and republication.
03/11/16	V5.0	Re-assessment and republication.
03/31/17	V5.1	Update to IROC Rhode Island information.