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Introduction The Children’s Oncology Group (COG) Institutional Performance Monitoring Program is established by the [COG Constitution & Bylaws](#). 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 COG.

Policy Statement It is the policy of COG that all COG member institutions are expected to comply with performance requirements established in the Institutional Performance Monitoring Program.

Purpose The purpose of this policy is to document the expected standards for Main Member and Affiliate Member institution performance and the consequences for failing to meet the established standards.

Scope This policy applies to all COG Main Member and Affiliate Member institutions’ performance monitoring.

**Institutional
Performance
Monitoring
Committee**

The Institutional Performance Monitoring Committee (IPMC) is a COG administrative 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**

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

For example, IPMC can be called upon throughout the year to review sites referred to them by COG Quality Assurance (QA) & Audit or the Statistics & Data Center (SDC). If the investigation yields potential Executive Committee action, IPMC will discuss at their next meeting.

**Performance
Data**

IPMC and the IPMC Chair use various reports/information to monitor an institution's performance including but not limited to:

- APEC14B1 enrollments for North American institutions and new patient registrations for Non-North American institutions*
- therapeutic and non-therapeutic trial enrollment data*
- data currency information *
- radiation therapy data submission and protocol compliance information*
- diagnostic imaging data submissions*
- biopathology specimen submissions*
- audit information*
- studies approved by the Institutional Review Board (IRB)*
- audit outcome reports
- other information provided by QA & Regulatory Affairs and SDC

*Information included in the [annual Institutional Report Cards \(IRC\)](#).

**Annual
Institutional
Report Cards**

SDC posts institutional performance summaries at annual intervals to the COG Member Website. These summaries are documented on an IRC and include the current year assessments based on the yearly composites provided for the past three years as well as a three-year rolling average where appropriate.

**Performance
Data Review
Process**

IPMC reviews the IRC for member institutions that are not in compliance with the [performance monitoring requirements](#). IPMC may contact member institutions to provide the opportunity to discuss site specific issues that may help explain compliance issues. In addition, sites currently on probation or suspension may be contacted to discuss their progress.

IPMC uses this information to create recommendations to present to the Executive Committee. IPMC meets before and at the time of the Spring Group Meeting to discuss the information. IPMC meets at the Fall Group Meeting to evaluate ongoing issues. Committee recommendations are presented to the Executive Committee for review and guidance.

IPMC notifies the sites of the Executive Committee's decisions which may result in a warning, probation, suspension, or site termination. See [Deviation Notification to PIs/LIs](#).

**Performance
Monitoring
Requirements**

COG member institutions are expected to meet the following minimum standards in order to remain in good standing. These requirements apply equally to both Main Member and Affiliate Member institutions unless otherwise identified.

- **Data Currency** – a score of $\geq 90\%$ (case report forms based)
- **Imaging and Radiation Oncology Core (IROC) Rhode Island Submissions**
 - **Radiation Therapy Data Submissions** – a score of $\geq 90\%$.
 - **Radiation Therapy Protocol Therapy Compliance** – a score of $\geq 90\%$ (sites are only considered out of compliance if score is due to more than one non-compliant case).
 - **Diagnostic Imaging Submissions** – a score of $\geq 90\%$.
- **New Patient Registrations/Enrollments** –
 - **North American Institutions** – Main Member institutions must enroll a minimum of 12 and Affiliate Member institutions a minimum of 6 new patients each year on APEC14B1 based on a three-year rolling average.
 - **Non-North American Institutions** – Main Member institutions must register a minimum of 12 and Affiliate Member institutions a minimum of 6 new patients each year based on a three-year rolling average.
- **Cases Available for QA Audit** (refer also to [Quality Assurance Audit Program](#))
 - **For Established Main Member Institutions** – a minimum of 10 therapeutic cases to be audited for the three-year audit cycle.
 - **For Established Affiliate Member Institution** – a minimum of 5 therapeutic cases to be audited for the three-year audit cycle.
 - **For Provisional Main Member Institutions** – at least 5 therapeutic cases enrolled within 18 months of membership.

Notes:

- Other performance monitoring criteria may be added as determined by the Executive Committee at the recommendation of IPMC and SDC.
- The Executive Committee may temporarily modify the performance monitoring requirements due to unique circumstances. Sites will be notified of the change in requirements and the information will be posted to the COG Member Website. During this time, the temporary audit case number requirements approved by the motion will take precedent over the requirements noted above.

**Consequences
for Failure to
Meet
Performance
Monitoring
Requirements**

Consequences for failure to meet performance requirements apply equally to both Main Member and Affiliate Member institutions unless otherwise noted.

- ***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](#)), 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/Lead Investigator (PI/LI) in a formal notification (see [Deviation Notification Letters to PI/LI](#)). If the failure results in a status change of an institution in an Affiliate/Main Member relationship, the PI/LI(s) will all be notified as the status change will apply to all (see **Notes** below).
- ***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 5 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 PI/LI in a formal notification (see [Deviation Notification Letters to PI/LI](#)). If the failure results in a status change of an institution in an Affiliate/Main Member relationship, the PI/LI(s) will all be notified as the status change will apply to all (see **Notes** below).
- ***Failing New Patient Registrations/Enrollments***– If an institution fails to meet the new patient enrollment (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 PI/LI in a formal notification (see [Deviation Letters Notification to PI/LI](#)). If the failure results in a status change of an institution in an Affiliate/Main Member relationship, the PI/LI(s) will all be notified as the status change will apply to all (see **Notes** below).

**Consequences
for Failure to
Meet
Performance
Monitoring
Requirements
(cont.)**

- **Failing QA Audit Case Requirement** – if an institution fails to meet the required number of patient cases for a QA audit (see [Performance Monitoring Requirements](#)).
 - **Established Member Institutions** – The institution is referred to the IPMC Chair for consideration of probation or termination for cause. The IPMC Chair will determine if a full committee review is needed and then if the findings should be submitted to the Executive Committee for consideration.
 - **Provisional Main 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 a full committee review is needed and then if the findings should be submitted to the Executive Committee for consideration.

An institution that does not successfully meet the conditions of probation will be notified of impending termination. Refer to [Member Institution Status Change Guidelines & Process](#) for information about probation, suspension, and termination. Refer also to [Transition of Research Subjects for Terminated Member Institutions](#).

Notes:

- In all cases of a Main Member/Affiliate Member relationship, all member institutions involved will maintain the same institutional status. An institutional status change for one member institution in the relationship, including a change for failing to meet performance monitoring requirements, will apply to all institutions in the relationship per the [COG Constitution & Bylaws](#). For example, if the Executive Committee approves an IPMC recommendation to place an Affiliate Member institution on probation for failing the new patient registrations/enrollments requirement, the status of the Main Member institution will also be changed to probation. For example, if the Executive Committee approves an IPMC recommendation to place a Main Member institution on probation for failing the QA audit case requirement, the status of any associated Affiliate Member institution(s) will also be changed to probation. Refer to [Member Institution Status Change Guidelines & Process](#).
 - Certain U.S. federal government facilities have been provided some flexibility regarding the therapeutic enrollment criteria.
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**Deviation
Notifications to
PIs/LIs**

When an institution deviates from the [standards of performance requirements](#), the IPMC Chair, after consultation with the Executive Committee, prepares a formal notification to the institution's PI/LI. This notification includes the:

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

**Other Related
P&P**

- [COG Constitution & Bylaws](#)
- [Institutional Performance Monitoring Committee Charter](#)
- [Member Institution Status Change Guidelines & Process](#)
- [Quality Assurance Audit Program](#)
- [Transition of Research Subjects for Terminated Member Institutions](#)
- [Conduct of Clinical Research for Member Institutions](#)
- [Radiation Oncology Participation Requirements](#)
- [Affiliate Member Institution Guidelines](#)

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

**Policy
Authorization**

Approval Indicator: Approved by the Executive Committee on 12/14/2023
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.
06/2008 & 04/2010	V2.0	Reassessment and revisions.
01/08/13	V3.0	Reassessment and republication. Program information from Admin. Section 5.1.
04/12/13	V3.1	Note added to Consequences section.
09/19/14	V4.0	Reassessment and republication.
03/11/16	V5.0	Reassessment and republication.
03/31/17	V5.1	Update to IROC Rhode Island information.
12/14/23	V6.0	Reassessment and revisions. Added requirements for Affiliate Member institutions, updated performance data information, added <i>Performance Data Review Process</i> , and added Lead Investigators throughout.