

Financial Conflict of Interest

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Policy Statement

It is the policy of the Children’s Oncology Group (COG) to conduct its affairs with the highest standards of integrity and to ensure that all potential, perceived, and actual conflicts of interest (COI), particularly financial, are identified and managed with respect to COG research.

COG follows [42 C.F.R. § 50.604](#) and [21 C.F.R. § 54.2](#) as it pertains to guidance regarding financial COI.

Purpose

The purpose of this policy is to identify the standards and responsibilities related to potential, perceived, and actual financial conflicts of interest, and to provide guidance for select COG members as they balance their roles as staff, clinicians, clinical investigators, scientific leaders, and translational researchers.

Scope

This policy applies to all COG members who hold a Qualifying Role (see [Definitions](#)) These COG members will herein be referred to as select COG members. The policy also applies to all COG staff.

Note: Potential for financial COI between COG activities and either scientific integrity or participants protection varies with the role of member within COG. Members will need to

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consider their personal investments/other business relationships and the roles they occupy within COG structure. Refer also to [Definitions](#).

Definitions

- **Financial Conflict of Interest (FCOI)** – A significant financial interest that could directly and significantly affect the design, conduct, or reporting of COG activities/funded research.
- **Immediate Family Member** – Spouse, life partner, dependent child, or other dependent of the COG member.
- **Maximum Threshold** – The following disclosures will prohibit participation on a COG study committee for the duration of the time disclosures are required for that study committee or may prohibit participation in other COG roles requiring disclosure:
 - payments from sponsor in excess of \$25,000 per year, not including compensation for research costs;
 - any financial arrangement where the value of compensation could influence the outcome of the study;
 - equity interest in a publicly traded company sponsor exceeding \$50,000 a year; or
 - any ownership interest, stock options, or other financial interest in non-publicly traded company whose value cannot be readily determined through reference to public prices.
- **Qualifying Role** – A role where a select COG Member serves on a disease or domain committee, the Executive Committee, Scientific Council, Data & Safety Monitoring Committees, Patient Advocacy Committee, and/or a study committee. Select COG members are required to complete a FCOI form at the time of assignment to the role and annually thereafter.

Note: To be included, a study committee must have one of the following committee statuses – **Proposed**, **Open**, **Closed**, or **Completed** (primary manuscript is not published) and not be a committee related to an industry fully-funded study.
- **Significant Financial Interest (SFI)** - A financial interest consisting of one or more of the following interests of a select COG member, COG staff, and immediate family members that reasonably appears to be related to COG activities:
 - With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid

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authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the COG member (or the immediate family member) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Any reimbursed or sponsored travel, that may be related to COG activities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by COG, a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- The term SFI **does not** include the following types of financial interests:
 - ❖ salary, royalties, or other remuneration paid by COG to the COG member if the member is currently employed or otherwise appointed by COG, including intellectual property rights assigned to COG and agreements to share in royalties related to such rights;
 - ❖ income from investment vehicles, such as mutual funds and retirement accounts, as long as the COG member does not directly control the investment decisions made in these vehicles;
 - ❖ income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
 - ❖ income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- **Speakers Bureau** – A Speakers Bureau has one (or more) of the following characteristics:
 - The company has the contractual right to dictate or control the content of the presentation or talk.
 - The company creates the slides or presentation material and has final approval of the content and edits.

- The Member is expected to act as a company’s agent or spokesperson for the purpose of disseminating company or product information.

SFI Disclosure Requirements

Select COG Members and COG staff should complete the [Conflict of Interest Disclosure Form](#) to the best of their ability. Failure to comply with the deadline to complete the [Conflict of Interest Disclosure Form](#) will result in loss of membership and all membership privileges, including access to the COG Member Website and committee appointments. Failure to comply by a Principal Investigator (PI) or Responsible Investigator (RI) (when the PI or RI holds a qualifying role) could affect the PI’s/RI’s institutional membership status. Refer also to [Change of Main Member Institution Principal Investigator/Affiliate Member Institution Lead Investigator, Responsible Investigators](#), and [Individual Member Status Change Guidelines](#).

It is the expectation of COG that select COG members will disclose anything that could potentially be considered an SFI as identified above (see [Definitions](#)). SFIs above the maximum threshold will result in termination from service on a study committee and may require termination of other COG roles requiring disclosure OR recusal from certain activities of the COG role that are related to those SFIs. Participation in a Speakers Bureau negates the select COG member’s ability to participate in any COG activities which prompted the request for the member to complete a *Conflict of Interest Disclosure Form*.

COG staff with an SFI related to their employment that is above the maximum threshold or who participate on a Speakers Bureau will be further reviewed by COG leadership on a case-by-case basis.

FCOI Disclosure Process

The table below describes the processes (roles and responsibilities) for the completion of a new, annual, or updated [Conflict of Interest Disclosure Form](#).

Note: It is expected that FCOIs will be reviewed by the appropriate party before an individual assumes a COG position that might compromise commitment to scientific goals or participant safety.

Step	Role	Responsibility
<i>Process for NEW COG Staff</i>		
1	New COG Staff	Completes an initial Conflict of Interest Disclosure Form as part of starting employment with COG.

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		<p>Note: New staff members will not be required to complete an annual Conflict of Interest Disclosure Form in the year they become a member.</p>
Process for NEW Appointment to Qualifying Role		
1	Select COG Member Appointed to New Qualifying Role	<ul style="list-style-type: none"> • Completes a new Conflict of Interest Disclosure Form prior to appointment to any qualifying role. • When participating in committee activities (meetings, conferences, and discussions), openly discloses any potential conflicts so that participants in these activities are aware of this information during discussions. <p>Note: Members in a new qualifying role will not be required to complete an annual Conflict of Interest Disclosure Form in the year they assume their role.</p>
Process for EXISTING Individual Members in Qualifying Role and COG Staff		
1	Existing Select COG Member in Qualifying Role or COG Staff	<ul style="list-style-type: none"> • By the specified deadline, completes an annual Conflict of Interest Disclosure Form Note: An alert is featured across the top upon sign-in to the COG Member Website. • If an update is needed to an already submitted Conflict of Interest Disclosure Form (due to a significant change in disclosures), completes a new form within 30 days, and e-mails it to: MembershipInfo@childrensoncologygroup.org
2	COG Communications	Prior to the deadline for completing the annual Conflict of Interest Disclosure Form , sends out at least four e-mail reminders to those who have not completed the Form.
3	COG Membership Department	<p>For those who fail to complete the annual Conflict of Interest Disclosure Form by the established deadline, oversees the system auto-generated e-mail extending the deadline for compliance by approximately two weeks (14 days), after which individual member suspensions will be processed in the system. For details on Suspension and Termination Statuses, refer to Individual Member Status Change Guidelines.</p> <p>Note: The site PI and Lead Clinical Research Associate (CRA)/Site LI and Affiliate Lead CRA are copied on the auto-generated e-mail notifications to allow visibility as to who is</p>

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		delinquent at their site. Throughout the agreement request period, the site PI and Lead CRA/site LI and Affiliate Lead CRA can view the Institutional COI Delinquency Report for a list of delinquent members at their site.
Approximately SIX MONTHS later, for any SUSPENDED member who still has NOT completed the annual COI Disclosure		
4	COG Membership Department	Approximately 30 days prior to termination, oversees the system auto-generated termination notification email with the termination date to the individual member.
5	COG Membership Department	<ul style="list-style-type: none"> On day of the termination date, oversees the system auto-generated termination notification e-mail sent to the individual member. Processes the termination in the system.
Note: The site PI and Lead CRA/site LI and Affiliate Lead CRA are copied on the auto-generated e-mail notification to allow visibility as to who has been terminated at their site.		

Process for Reviewing FCOIs

The table below describes the processes (roles and responsibilities) for the identification and management of potential FCOIs at COG.

Step	Role	Responsibility
1	COG Membership Department	For select COG member appointments to a new qualifying role or a new COG staff member, initial Conflict of Interest Disclosure Form indicating a disclosure, and e-mails the form(s) to the Group Chair (or designee) for review.
2	Senior Director of Group Administration (or designee)	For annual Conflict of Interest Disclosure Form indicating a disclosure for a select COG member in a qualifying role or a COG staff member, e-mails the form(s) to the Group Chair (or designee) for review.
3	Group Chair (or designee)	Reviews the disclosed potential FCOI(s) along with the nature the select COG member's/COG staff member's activities at COG. <ul style="list-style-type: none"> If it is determined that the FCOI(s) DO NOT pose a conflict, approves the select COG member's participation in the relevant activities.

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		<ul style="list-style-type: none"> • If it is determined that the FCOI(s) DO pose a conflict but it is below the maximum threshold, confirms there is an institutional COI Management Plan and validates the document; OR works with the select COG member to create a COI Management Plan. • If it is determined that the FCOI(s) DO pose a conflict and it is above the maximum threshold, prohibits the select COG member's participation on a study committee. For other COG roles requiring disclosure, may prohibit service or may require recusal from relevant activities of the role related to the FCOI(s). <p>If it is determined that the FCOI(s) involve serving on a Speakers Bureau, prohibits the select COG member's participation in the relevant activities unless they resign from the Speakers Bureau.</p>
<p>Note:</p> <ul style="list-style-type: none"> • An internal COI Committee (a sub-committee of the Executive Committee) may serve as an advisory to the Group Chair for determination of the COI. • An external COI Committee may review COI disclosures for key COG leaders if the COI Committee deems it appropriate. • If the FCOI involves the Group Chair, the Group Vice Chair will assume the responsibilities of the Group Chair. 		

Mechanism for Raising Concerns

A COG member who is aware of a situation or observes behavior that they believe constitutes a FCOI that would adversely impact COG research should report the findings to the Group Chair. Calls from COG members will be handled with the strictest confidentiality, and the privacy of those who in good faith report apparent conflicts of interest will be protected to the maximum extent possible.

Note: Persons outside COG may also contact the Group Chair and set the process below in motion, but anonymity may not be provided.

The table below describes the processes (roles and responsibilities) for when the Group Chair is contacted about a potential FCOI.

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Step	Role	Responsibility
1	Group Chair (or designee)	Contacts the select COG member to inform them that questions have been raised and request they: <ul style="list-style-type: none"> • review the Financial Conflict of Interest policy, and • complete a new Conflict of Interest Disclosure Form, using the policy as guidance.
2	Select COG Member	Completes the Group Chair guidance as outlined in step 1, and forwards the Conflict of Interest Disclosure Form to the Group Chair.
3	Group Chair (or designee)	Reviews the disclosed potential FCOI(s) along with the nature the select COG member’s activities at COG and follows the actions outlined in Procedures for Reviewing FCOIs , step 2. Note: Further course of action may involve consultation with an internal Conflict of Interest Committee (a sub-committee of the Executive Committee) to serve as an advisory for determination of a FCOI.
4	Group Chair (or designee)	Informs the select COG member who initially raised the issue that either no FCOI was identified, or that a conflict was identified and is being addressed by COG Executive Leadership.
Note: If the FCOI involves the Group Chair, the Group Vice Chair will assume the responsibility of the Group Chair.		

Accessibility of FCOI Information

Requests for FCOI Information

Information about compliance with the FCOI process will be available to COG members on the COG Member Website.

Persons outside COG who request FCOI information about an identified COG member must request such information in writing from COG Group Administration. Upon the written request and after conferring with the Group Chair, COG Group Administration may provide confirmation that a COG member has not filed a disclosure, has disclosed no conflicts, or has disclosed conflicts that meet acceptable COG guidelines. Such requests for disclosures to outside persons will be communicated to the identified COG member.

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COG reserves the right to deny a request for FCOI information if it is determined by COG that the information requested is being used for unrelated activities. It is at the Group Chair's discretion to release FCOI information.

Record Retention

COG will maintain all FCOI-related records for ten calendar years.

Other Related P&P

- [COG Financial Conflict of Interest Disclosure Form](#)
 - [Change in Member Institution Principal Investigator/Affiliate Member Institution Lead Investigator](#)
 - [Responsible Investigators](#)
 - [Individual Member Status Change Guidelines](#)
 - [Member Institution Status Change Guidelines & Process](#)
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References

- [42 C.F.R. § 50.604, Promoting Objectivity in Research, Responsibilities of Institutions regarding Investigator financial conflicts of interest](#)
 - [21 C.F.R. § 54.2, Financial Disclosure by Clinical Investigators, Definitions](#)
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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
 - Policy Contact – Senior Director of Group Administration, COG
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Policy Authorization

Approval Indicator: Approved by the Executive Committee on 05/31/2024
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
01/20/01	V1.0	Initial documentation/publication. Admin Sections 5.2.4a and 5.2.4b.
05/2006	V2.0	Reassessment/revisions.
12/11/12	V3.0	Reassessment and republication.
04/04/14	V4.0	Reassessment and republication.
01/23/18	V5.0	Reassessment and republication.
09/08/23	V6.0	Reassessment and republication. Updated the definition of FCOIs/SFIs; redefined member categories/responsibilities; eliminated unused terms; updated FCOI review process.
05/31/24	V7.0	Reassessment and republication. Revised who must complete an FCOI by removing the category types. Added the definition for Qualifying Role and revised the definition for Maximum Threshold. Updated the <i>FCOI Requirements</i> to <i>SFI Disclosure Requirements</i> . Changed the record retention from three to ten years.