

**Table of Contents**

- Introduction
- Policy Statement
- Purpose
- Scope
- What is a Conflict of Interest?
- COG Member Responsibility
- Implementation Process
- De Minimis & Maximum Thresholds
- COG Role Identification Categories
- De Minimis Exception & Maximum Threshold Prohibition
- Definitions
- Managing Financial Interests Between De Minimis & Maximum Thresholds
- Mechanisms for Raising Concerns
- Accessibility of COI Information
- Other Related P&P
- References
- Who Should Be Knowledgeable About This Policy
- Policy Maintenance Responsibility
- Policy Authorization
- Version/Revision History

**Introduction**

As more and varied therapies are moved rapidly into clinical settings, it is imperative that the Children's Oncology Group (COG) addresses issues of conflicts of interest. The growing partnership between drug discovery and clinical practice is creating vastly expanded opportunities for patients to benefit from access to new therapies. These same processes are also creating new possibilities for investigators and institutions participating in these ventures to occupy positions where their interests may be conflicted. Public trust in the COG and the legitimacy of its role in society requires that the Group and its members be open to public scrutiny. The continued confidence of the public in the judgment of researchers and clinicians depends upon the integrity of this common endeavor.

**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, particularly financial, are identified and managed with respect to COG research.

The COG follows the Public Health Service (PHS) *Conflict of Interest Policy* (Title 42, Subpart F. Sec.50.603) regarding interests requiring disclosure as the De Minimis value. The COG follows the Food and Drug Administration's (FDA) *Conflict of Interest Policy* [21 CFR 54.2 (f)] regarding interests requiring disclosure as the maximum threshold above which an investigator cannot be involved in the development and management of a clinical trial.

## Conflict of Interest

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

---

**Scope** This policy applies to all COG Members who participate in the research, design, development, conduct, implementation, analysis, or reporting of any COG study, including any member of a study committee (e.g., pharmacists, CRAs and RNs).

**Note:** Potential for conflicts of interest between Group activities and either scientific integrity or subject protection varies with the role of investigators within the Group. Investigators will need to consider their personal investments/other business relationships and the roles they occupy within the Group structure. Refer also to [COG Role Identification Categories](#).

---

**What is a Conflict of Interest?**

Circumstances under which potential, perceived, or actual conflicts of interest may exist include but are not limited to:

- An investigator participates in clinical research on a product or technology owned by or contractually obligated to a business that the investigator or an immediate family member:
  - has a consulting relationship;
  - holds a stock or similar ownership interest; or
  - has any other financial interest that might benefit from the research results. This includes receiving a salary, royalty or other compensation following the commercial sale of the product or technology. Refer also to [De Minimis & Maximum Thresholds](#) for details.
- An investigator or immediate family member has played a substantial role in the development of a product or technology.
- An investigator who participates in a Speakers' Bureau (see [Definitions](#) and [COG Role Identification Categories II and III](#)).
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to these rights and interests.

*Continued on next page*

## Conflict of Interest

**What is a  
Conflict of  
Interest? (cont.)**

- An investigator or immediate family member has a substantial ongoing affiliation with an organization having a role in the development of sale of a product or technology, including organizations holding patents to or licenses for the development or sale of research products. This would include instances where the investigator or immediate family member serves as an officer, director, trustee, general partner, employee, or on a scientific advisory board, **regardless of whether the investigator is currently being compensated for that position**. An investigator who is negotiating for or considering potential future employment or compensation (including honoraria and consultative services) is in a position of conflict, even if current compensation is not received.
- An investigator has a significant financial interest in a business that could directly and significantly affect the design, conduct, development, analysis, or reporting of any COG study, whether therapeutic or non-therapeutic. A “significant financial interest” by the investigator or immediate family member is defined as anything of monetary value exceeding the [De Minimis Threshold](#).
- Reimbursed or sponsored travel related to COG responsibilities as defined in the [De Minimis Threshold](#).

**COG Member  
Responsibility**

- Recognizes situations that may be subject to potential conflicts of interest, considering personal investments/other business relationships and the roles they occupy within the COG structure.
- **As a new member** (including study committee member), completes the [Conflict of Interest \(COI\) Disclosure Form](#) as part of the new member application.
- **As an existing member**, completes the online [Conflict of Interest \(COI\) Disclosure Form](#) annually and, as applicable, completes and submits the *Conflict of Interest (COI) Disclosure Form* whenever an update is needed. **Note:** Failure to comply with the deadline for the annual COI Disclosures will result in loss of membership and all membership privileges, including access to the COG Members Web site and study committee appointments. Failure to comply by a Principal Investigator (PI) or Responsible Investigator (RI) could affect the PI's/RI's institutional membership status. Refer also to [Change in Member Institution Principal Investigator, Responsible Investigators, Individual Member Status Change Guidelines](#), and [Member Institution Status Change Guidelines](#).

For details, see [Implementation Process](#). Refer also to [COG Role Identification Categories](#).

**Conflict of Interest**

**Implementation Process**

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

**Note:** It is expected that material conflicts of interest will be resolved before an individual assumes a COG position that might compromise commitment to scientific goals or subject/patient safety as a clear, primary interest.

Step	Role	Responsibility
<b>Process for NEW Individual Members</b>		
1	New Individual Member	<p>Completes an initial <a href="#">Conflict of Interest (COI) Disclosure Form</a> as part of the new member application.</p> <p><b>Note:</b> New members will not be required to complete an annual COI Disclosure in the year they become a member.</p>
	New Committee Member	<ul style="list-style-type: none"> <li>• Completes an initial <a href="#">Conflict of Interest Disclosure Form</a> prior to appointment to any committee.</li> <li>• 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.</li> </ul>
<b>Process for EXISTING Individual Members</b>		
1	Existing Individual Member	<ul style="list-style-type: none"> <li>• By the specified deadline, completes an annual (online) <a href="#">Conflict of Interest Disclosure Form</a> and attests to the accuracy and completeness of the statement made therein. <b>Note:</b> An alert is generated upon sign-in to the COG Members Website.</li> <li>• If an update is needed to an already submitted COI Disclosure, completes the COG <a href="#">Conflict of Interest Disclosure Form</a> available on the COG Members Website, and e-mails it to <a href="mailto:MembershipInfo@childrensoncologygroup.org">MembershipInfo@childrensoncologygroup.org</a>.</li> </ul>
2	Executive Director of Administration (or designee)	<p>Prior to the deadline for <b>annual COI Disclosures</b> (for <b>existing individual members</b>), sends out at least two e-mail reminders to those who have not completed the Disclosure.</p>

Continued on next page

**Conflict of Interest**

**Implementation Process (cont.)**

Step	Role	Responsibility
<b>Process for EXISTING Individual Members (cont.)</b>		
3	Executive Director of Administration (or designee)	For those who <b>fail to complete</b> the annual <i>COI Disclosure</i> by the established deadline, sends an email extending the deadline for compliance by approximately two weeks, after which individual member suspensions will be processed. For details on Suspension and Termination Statuses, refer to <a href="#">Individual Member Status Change Guidelines</a> .
NOTE	The site PI and Lead Clinical Research Associate (CRA) are copied on at least one e-mail reminder to allow visibility as to who is delinquent at their site.	
<b>Approximately SIX MONTHS later, for any SUSPENDED member who still has NOT completed the annual COI Disclosure</b>		
4	Executive Director of Administration (or designee)	Approximately 30 days <b>prior to</b> termination, sends a termination notification email to the individual member.  <b>Note:</b> The site PI and Lead Clinical Research Associate (CRA) are copied on this e-mail notification to allow visibility as to who is being terminated at their site.
5	Executive Director of Administration (or designee)	Processes termination 30 days later and sends an e-mail notification of the termination to the terminated member.  <b>Note:</b> The site PI and Lead Clinical Research Associate (CRA) are copied on this e-mail notification to allow visibility as to who has been terminated at their site.
<b>Process for submitted COI Disclosures Forms that indicate a conflict of interest</b>		
1	Manager, Membership Department (or designee)	<ul style="list-style-type: none"> <li>• <b>For new member and new committee appointments</b> (initial) COI Disclosures Forms indicating a conflict of interest for <a href="#">Category II or Category III</a> investigators, e-mails the Form(s) to the Group Chair (or designee) for review.</li> <li>• <b>For annual</b> COI Disclosures Forms indicating a conflict of interest for <a href="#">Category II or Category III</a> investigators, forwards the Form(s) to the Executive Director of Administration (or designee) for review.</li> </ul>

Continued on next page

**Conflict of Interest**

**Implementation Process (cont.)**

Step	Role	Responsibility
<b><i>Process for submitted COI Disclosures Forms that indicate a conflict of interest (cont.)</i></b>		
2	Group Chair/ Executive Director of Administration (or designee; see <i>Notes</i> )	<p>Reviews the disclosed potential conflicts along with the nature of the investigators' relationship to the Group.</p> <ul style="list-style-type: none"> <li>• If it is determined that the financial interests or relationships <b>DO NOT pose a conflict</b> to participation in Group studies, approves investigator's participation in the relevant activities.</li> <li>• If it is determined that the financial interests or relationships <b>DO pose a conflict but it is below the maximum threshold</b>, reviews the COI Management Plan for approval (see <a href="#">Managing Financial Interests Between De Minimis &amp; Maximum Thresholds</a> for details).</li> <li>• If it is determined that the financial interests or relationships <b>DO pose a conflict and it is above the maximum threshold</b>, prohibits investigator's participation in the relevant activities.</li> </ul>
<p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• A conflict of interest must be managed, reduced, or eliminated within sixty (60) days of its identification. Refer to <a href="#">Managing Financial Interests Between De Minimis and Maximum Thresholds</a>.</li> <li>• An <b>internal</b> Conflict of Interest Committee (a sub-committee of the Executive Committee) may serve as an advisory to the Group Chair for determination of the COI.</li> <li>• An <b>external</b> Conflict of Interest Committee may review COI Disclosures for key Group leaders, if the COG Conflict of Interest Committee deems it appropriate.</li> <li>• <i>If the conflict of interest involves the Group Chair, the Group Vice Chair or the Chief Operations Officer will assume the responsibilities of the Group Chair.</i></li> </ul>		

## Conflict of Interest

**De Minimis &  
Maximum  
Thresholds**

- ***De Minimis Threshold*** – Applies to payments to investigator, their spouse or their dependents (children or other dependents) must be disclosed as follows:
  - Salary, royalty, and other payments for services are greater than five thousand dollars (\$5,000) per year (not including salary or payments from public or nonprofit entities);
  - Equity interests are worth more than five thousand dollars (\$5,000) per year or more than five percent (5 %) ownership in a single entity;
  - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
  - An investigator must disclose the occurrence of any reimbursed or sponsored travel related to the investigator's COG responsibilities that is paid by a third party on behalf of the Investigator. However, this requirement does not apply to travel reimbursed or sponsored by the 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.
  
- ***Maximum Threshold*** – Applies to payments to investigator, their spouse or their dependents (children or other dependents) must be disclosed as follows and will prohibit participation in the development and management of a COG clinical trial:
  - Payments from sponsor in excess of \$25,000 per year during the research and for 1 year after, not including compensation for research costs;
  - Any financial arrangement where the value of compensation could be influenced by outcome of the study;
  - Equity interest in a publicly traded company sponsor exceeding \$50,000 a year during time of research and 1 year after; 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.

Refer also to [De Minimis Exception & Maximum Threshold Prohibition](#) for additional details.

---

COG Role  
Identification  
Categories**Category I – Investigators Involved Solely in the Conduct of Group Studies**

- **Definition** – Investigators whose major activity is enrollment and management of patients on studies, including nurses and clinical research associates, are unlikely to find themselves in a situation where their personal investments or other business relationships will create conflicts of interest that might impact study subjects.
- **Expected Compliance** – Disclosure of conflicts of interest as stated in this policy.

**Category II – Investigators Also Involved in the Design of Group Studies**

- **Definition** – Study and Strategy committee members. These investigators set priorities and design studies that include use of therapies and procedures whose applications have financial implications. Thus, these investigators are more likely to experience conflicts between their Group activities and their personal investments or other business relationships.
- **Expected Compliance** –
  - Disclosure of conflicts of interest as stated in this policy.
  - Does not serve on a Speakers' Bureau (see **Note** below).
  - Conformance to [De Minimis and Maximum Thresholds](#).

**Category III – Investigators Involved in Setting Scientific Priorities of the Group Studies**

- **Definition** – Investigators who occupy scientific leadership positions within COG, including the Group Chair, Chairs of Strategy Groups and Discipline Committees, and other key leadership positions. These investigators set the research agenda, determine scientific priorities, and determine which innovative therapies will be advanced or not pursued. To ensure that the research agenda of the Group is perceived as unencumbered, potential conflicts of interest will be more rigorously limited for these Group leaders.
- **Expected Compliance** –
  - Disclosure of conflicts of interest as stated in this policy.
  - Does not serve on a Speakers' Bureau (see **Note** below).
  - Conformance to [De Minimis and Maximum Thresholds](#).

**Note:** Refer to *Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice*; Lo B, Field MJ, editors. Conflict of Interest in Medical Research, Education, and Practice. Washington (DC): National Academies Press (US); 2009. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK22942/>.

---



## Conflict of Interest

**De Minimis Exception & Maximum Threshold Prohibition**

- **De Minimis Exception** – Category II and Category III Investigators may continue to hold stock or similar ownership interest in a business if **all** the following conditions are met:
  - The stock or similar ownership interest is in a publicly held, widely traded business;
  - The current value of the stock, similar ownership interest, or other compensation does not exceed the [De Minimis Threshold](#); and
  - There is no relationship between acquisition of the stock or similar ownership interest and the research to be conducted (complete independence between a purchase decision and the research).
- **Maximum Threshold Prohibition** – Any Category II or Category III investigator who meets or exceeds the [Maximum Threshold](#) shall **not** be permitted to be involved in the development and management of a COG study.
- **Financial Interests Between De Minimis Exception and Maximum Threshold Prohibition** – These financial interests of Category II or Category III investigators need to be disclosed to COG as indicated in this Policy and included in any application to the NCI Pediatric Central IRB (PedCIRB) or Central IRB (CIRB). The financial interests must be managed as stated in [Managing Financial Interests Between De Minimis & Maximum Thresholds](#).

**Definitions**

- **Immediate Family Member** – Spouse, dependent child or other dependent of the investigator.
- **Research Product** – A drug, technique, or technology that is the subject of the conduct of research. Use of proven, commercially available pharmacological agents or technologies that may be included in therapies but are not the subject of a research study, are not considered research products for the purpose of identifying conflict of interest. However, investigators involved in designing studies or determining the Group research agenda must appreciate that their decisions to include a specific therapy in a protocol could be, or give the appearance of being, affected by their financial interests.
- **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 your presentation or talk, and/or
  - the company creates the slides or presentation material and has final approval of the content and edits, and/or
  - you are expected to act as a company's agent or spokesperson for the purpose of disseminating company or product information.

## Conflict of Interest

**Managing  
Financial  
Interests  
Between De  
Minimis &  
Maximum  
Thresholds**

Financial interests **between** De Minimis Exception and Maximum Thresholds as indicated [above](#), shall be managed as follows.

- If an Institutional Conflict of Interest Management Plan **exists**, the Group Chair reviews the Plan for approval.
- In the event that an Institutional Conflict of Interest Management Plan **does not** exist or is not acceptable, **the following process will be implemented:**

If the Group Chair/committee delegated responsibility for reviewing potential conflict-of-interest determines that such conflict does not disqualify investigator from a leadership position in the study (involvement in development and analysis of COG clinical trials), then **one of the Research Teams' Senior Directors/designee must submit a Conflict of Interest Management Plan** accompanying the Pediatric Central Institutional Review Board (PedCIRB) Application.

The **Conflict of Interest Management Plan** will discuss the general elements that pertain to assuring unbiased data collection and review in Group trials that include the following:

- Independent review of study by Cooperative Group beyond Disease Committee;
- Independent review by NCI/DCTD;
- Independent review by a Data and Safety Monitoring Board;
- Statistical management of data independent of study chair; and
- Any additional measures proposed by the Group.

The PedCIRB will be asked to comment on this "Conflict of Interest Policy for NCI/DCTD-supported Cooperative Group or Network Group Randomized Phase 2 and Phase 3 Clinical Trials" and add three questions to the CIRB Application as follows:

- 1) Does the Study Chair or any principal involved in the development or coordination of this study have any significant financial conflicts of interest as defined in the "Conflict of Interest Policy for NCI/DCTD-supported Cooperative Group or Network Group Randomized Phase 2 and Phase 3 Clinical Trials"?
- 2) If so, does the Cooperative Group or Network Group have a management plan in place to address the conflicts disclosed in question #1?
- 3) If so, a copy of the Conflict of Interest Management Plan must be attached.

**Note:** The information above is from National Cancer Institute (NCI)/Division of Cancer Treatment and Diagnosis (DCTD) Conflict of Interest Policy, dated August 2012.

---

## Conflict of Interest

**Mechanisms for  
Raising  
Concerns**

A Group member who is aware of a situation or observes behavior that he/she believes constitutes conflicts of interest that would adversely impact COG research should report the findings to the Group Chair. Calls from Group 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 the Group may also contact the Group Chair and set the process below in motion, but anonymity may not be provided.

When the Group Chair is contacted about a potential conflict of interest, the following applies:

- The Group Chair or designee will contact the investigator to inform him/her that questions have been raised and to request that he/she
  - review the Conflict of Interest Policy;
  - complete a new *Conflict of Interest Disclosure* form, using the Policy as guidance; and
  - forward the Disclosure form to the Group Chair.
- When the Disclosure form is received, the Group Chair will decide the further course of action, which 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 the COI.
  - If it is determined that the financial interests or relationships **DO NOT pose a conflict** to participation in Group studies, the Group Chair approves investigator's participation in the relevant activities.
  - If it is determined that the financial interests or relationships **DO pose a conflict but it is below the maximum threshold**, the Group Chair reviews the COI Management Plan for approval (see [Managing Financial Interests Between De Minimis & Maximum Thresholds](#) for details).
  - If it is determined that the financial interests or relationships **DO pose a conflict and it is above the maximum threshold**, the Group Chair prohibits investigator's participation in the relevant activities.
- The Group member who initially raised the issue will be informed either that no conflict of interest was identified, or that a conflict was identified and is being addressed by the Group Leadership.

**Note:** If the conflict of interest involves the Group Chair, the Group Vice Chair or the Chief Operations Officer will assume the responsibilities of the Group Chair.

---

## Conflict of Interest

**Accessibility of COI Information** Information about compliance with the COG conflicts of interest process will be available to Group members through a secure electronic site.

Persons outside the Group who request conflict of interest information about an identified investigator must request such information in writing from the Operations Center. Upon the written request, the Operations Center will provide confirmation that an investigator has not filed a disclosure, has disclosed no conflicts, or has disclosed conflicts that meet acceptable Group guidelines (usually falling into the category of De Minimis). Such disclosures to outside persons will be communicated to the identified investigator. **Note:** When unresolved conflicts are felt to exist, no information will be provided without consultation with the Group Chair or designee, and the investigator will be informed of the request and discussion.

---

**Other Related P&P**

- [COG Conflict of Interest Disclosure Form](#)
  - [Change in Member Institution Principal Investigator](#)
  - [Responsible Investigators](#)
  - [Individual Member Status Change Guidelines](#)
  - [Member Institution Status Change Guidelines](#)
- 

**References**

- [FDA Conflict of Interest Policy](#)
  - [PHS Conflict of Interest Policy](#)
  - [NCI/DCTD/CTEP's Conflict of Interest Policy for NCTN Phase 3 Clinical Trials](#)
  - [DHSS Regulatory Requirements for Conflict of Interest](#) (outlined by NIH Grants Policy)
  - [NCTN Program 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. Refer also to [Implementation Process](#).

---

**Conflict of Interest****Policy  
Maintenance  
Responsibility**

- Policy Owner – Children’s Oncology Group
  - Policy Contact – Executive Director of Administration, Children’s Oncology Group
- 

**Policy  
Authorization**

Approval Indicator: Approved by the Executive Committee on 01/23/18  
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
01/20/01	V1.0	Initial documentation/publication. Admin Sections 5.2.4a and 5.2.4b.
05/2006	V2.0	Re-assessment/revisions.
12/11/12	V3.0	Re-assessment and republication.
04/04/14	V4.0	Re-assessment and republication.
01/23/18	V4.0	Re-assessment and republication.