

SWOG
<http://swog.org>

Policy Memorandum No. 35
Subject: Conflict of Interest Policy
Departments Affected: All

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FINANCIAL CONFLICT OF INTEREST POLICY

I. BACKGROUND

The scientific credibility and the general acceptance of the results of a clinical investigation clearly depend on the integrity and objectivity of the investigators involved in SWOG trials. Even the perception that an investigator has a bias may cast doubt on the validity of the results. This policy was established to address such concerns.

The Public Health Service regulation entitled "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors" (42 CFR Part 50, 45 CFR 94, final rule published 8/25/2011) currently requires that grantee institutions, including cooperative groups, have written policy guidelines on financial conflict of interest. The intent of this regulation is to promote "objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator." Other funding or granting organizations have similar policies either published or under consideration. Therefore, most Group investigators will already be subject to conformance with the policy of their institution with respect to financial conflict of interest.

Additionally, the Hope Foundation Division of Continuing Medical Education (CME) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) as a provider of continuing medical education. The Hope Foundation requires that all presentations at CME activities be fair, balanced, free of commercial bias, and fully supported by scientific evidence. To promote bias-free educational presentations, the Hope Foundation solicits full disclosure of all financial interests from educational planning committee members, moderators and presenters of programs. A list of financial interests and/or potential conflicts relevant to CME activities will be published in the Group Meeting agenda.

This policy and the modified Declaration Form serves to collect data for both the purposes of promoting objectivity in research regarding the requirements of 42 CFR Part 50, 45 CFR 94 as well as to meet the requirements of ACCME.

The process of managing and minimizing the impact of potentially conflicting financial interests in Group research and education involves forthright internal disclosure with appropriate management and external disclosure when an individual investigator's interests rise above certain defined thresholds. In certain cases, the extent of an individual's interests may be such that he or she is precluded from some types of involvement in specific Group trials or educational activities. This policy will identify when internal disclosure is required, when a management plan will be implemented, and when an investigator may be precluded or otherwise limited from participation in Group activities, as determined by the Conflict of Interest (COI) Committee.

II. POLICY

Definitions

1. Financial conflict of Interest. A conflict of interest may exist whenever an Investigator or a member of his or her immediate family has a direct or indirect interest or relationship,

financial or otherwise, with a Third Party that may conflict, be perceived as conflicting, or be inconsistent with the Investigator's duties, responsibilities, or exercise of judgment in any Group Research. Federal regulations define financial conflict of interest as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

2. **Immediate Family Member.** Immediate Family Member includes a spouse and dependent child. There may be situations where other family members not defined as an "immediate family member" hold a financial or other interest in an Outside Entity such that a perceived conflict may exist. In such situations, disclosure is required (see Required Disclosure Level A.7. below).
3. **Investigator.** The term Investigator includes all scientists, clinicians, statisticians, nurses, Clinical Research Associates (CRAs) and patient advocates of SWOG whose participation in Group Research is not limited to registering patients. Participation includes having an active role in the development and conduct of the protocol, as well as the reporting of study results. This definition also includes those situations where there is more than one investigator, such as the potential with multidisciplinary or intergroup trials. In such cases, the Investigator who leads the research for the Group or is considered a co-Investigator will be required to comply with this policy.
4. **Outside Entity.** Any publicly-traded biotechnology, pharmaceutical, bioinformatics, or other similar company will be considered an outside entity for disclosure purposes.
5. **PHS Awarding Component.** The PHS Awarding Component shall mean the NCI's Cancer Treatment Evaluation Program, the Division of Cancer Prevention, or any other government component which provides funding for the Research of the Group.
6. **Research.** Research includes any Group protocol, investigation or analysis of a drug, technique, treatment or technology, and any correlative biologic investigations related to such protocols, investigations or analyses, and includes publication or other public disclosure of the results.
7. **Continuing Medical Education.** Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician or other health care provider uses to provide services for patients, the public, or the profession.
8. **Sponsor.** The sponsor is the entity providing funding, drug, materials, etc., in support of or for use during, the Research in which the Investigator is involved.
9. **Conflict of Interest Committee.** The Conflict of Interest Committee is composed of members of SWOG who represent the investigator membership of the Group, the executive leadership, the committee leadership and the statistical leadership. The Director of Operations and Protocols serves as a non-voting member for administrative support. The membership of the committee shall not be comprised of fewer than five persons. The Committee membership is appointed by the Group Chair and serves at the Chair's discretion.
10. **Conflict of Interest Committee Chair.** The Conflict of Interest Committee Chair is the institutional official who is responsible for ensuring implementation of SWOG's Financial Conflict of Interest policy and procedures and for reporting the Committee's decisions to the Group Chair and, via the grantee institution, to the appropriate PHS grantor. The Committee Chair is appointed by the Group Chair and serves at the Chair's discretion.

Required Disclosures and Implications

A. Required Disclosure Level

All Investigators on active protocols and for one year following the publication of the results for which they participated, will report on an annual basis or more frequently as the need arises as addressed herein, the following information:

1. Amount and source of payments which total \$2,000 or greater per year including salary, honoraria, royalties and other payments for services rendered, excluding travel (see A.9 below), from any Outside Entity;
2. Number of shares and current value of stock held in any Outside Entity for which the current value is \$2,000 or greater;
3. If, during any twelve month period that falls between annual reporting periods, the investigator's amount of payment or stock value in either of the above two categories (including amounts previously disclosed) exceeds \$5,000 from any single Outside Entity, specific disclosure to SWOG is required within 30 days of exceeding this threshold.
4. Any ownership interest in an Outside Entity, excluding stock equity totaling less than 5% of the estimated value of a publicly traded company;
5. Amount and nature of interest in a non-publicly traded company whose value cannot be readily determined by referencing public prices;
6. Funds received for research which total \$30,000 or greater from any individual Outside Entity for the most recent three-year period;
7. Any financial arrangement in which the value of compensation could be influenced by the outcome of any Group Research or presentation of educational material;
8. Any additional interest, affiliation or relationship, financial or otherwise, by the Investigator, an Immediate Family Member or other family member (as discussed in Section II.2. above) with an Outside Entity which may create or be perceived as a Conflict of Interest, such as intellectual property rights, the receipt of trips, gifts, or incentives, or a position as a director, board member, officer, partner, trustee, etc.
9. Any reimbursed or sponsored travel that is associated with any of the above disclosures and is related to the Investigator's SWOG responsibilities must be disclosed according to federal standards. Upon written request from SWOG, the monetary amount of any travel reimbursement and any further information required by SWOG to determine whether this travel might constitute a financial conflict of interest must be disclosed within 30 days.

B. Floor for Management Plan

In the following situations, a Management Plan, as further discussed herein, must be in place to ensure objectivity and minimize the potential for public mistrust of the Research and medical education.

1. Payments totaling greater than \$5,000 in a twelve month period for salary, honoraria, royalties, or other similar purposes, but excluding research compensation, from the Research Sponsor;
2. Equity interests totaling greater than \$5,000 in an Outside Entity, including the Sponsor, directly involved in or potentially directly influenced by the outcome of the Research during the course of the Research;
3. Any ownership interest in any Outside Entity, including the Sponsor, directly involved in or potentially directly influenced by the outcome of the Research;
4. Any interest in a non-publicly traded company whose value cannot be readily determined by referencing public prices;

C. Ceiling Affecting Participation

The following is the ceiling levels that, if one or more exist, preclude a Group member from involvement in Group Research or as a CME presenter in any capacity other than patient accrual during the course of the Research;

1. Any financial arrangement with the Sponsor or Outside Entity in which the value of compensation could be influenced by the outcome of the Research or educational program;
2. Payments totaling greater than \$25,000 per year for salary, honoraria, royalties, or other similar purposes, but excluding research compensation, from the Research Sponsor;
3. Equity interest totaling greater than \$50,000 in an Outside Entity, including the Sponsor, directly involved in or potentially influenced by the outcome of the Research or educational program;
4. Any significant interest, as determined by the COI Committee, in a non-publicly traded company directly involved in or potentially influenced by the outcome of the Research or educational program whose value cannot be readily determined by referencing public prices.

Proper Procedure

The proper procedure for disclosure of potential conflict of interests, as discussed above, on the part of an Investigator as required is as follows:

1. Prior to developing a protocol or serving in a leadership role in Research or educational program, Investigators must complete the enclosed Financial and Affiliation Declaration Form and forward to the COI Committee for review.
2. If the COI Committee receives a Form marked with no actual or potential financial conflict of interest declaration, the Form will be held on file at the Operations Office and be available for any future review as may be required.
3. If the COI Committee receives a Form disclosing an actual or potential financial conflict of interest declaration, the noted conflict(s) will be forwarded to the Conflict of Interest Committee for review to determine whether a Management Plan or any other action is necessary.

4. Actual or potential financial conflicts which develop during the conduct of the Research or up to the final publication of the results must also be disclosed as set forth in section A.3 above. While COI declaration information will be required and collected annually, it is incumbent upon each Investigator to notify and disclose to the COI Committee any relevant changes to their annual COI declaration information. Upon receipt of updated information, the COI Committee will further review and consider any management action necessary.
5. The COI Committee reserves the right to review public domain resource information to supplement or confirm any information disclosed by a SWOG Investigator.

Management Plan

For all Investigators whose interest disclosures fall between the floor and ceiling levels, the COI Committee shall create a Management Plan applicable to the Investigator and the conduct of the Research or educational program. The Management Plan will be presented to the Investigator for discussion and modification if deemed appropriate by the COI Committee. The Management Plan may include some or all of the following:

- Independent review of the Research or presentation by the COI Committee
- Independent review of the Research by the National Cancer Institute
- Independent review of the Research by the Group's Data Safety Monitoring Board
- Preclusion of Investigator from any role in the statistical management of the Research data
- Managed/reviewed role of the Investigator in the assessment of objective response to therapy and gradation and attribution of toxicities
- Appointment of Co-Investigator who has no conflict of interest with the Research
- Public disclosure of the existence of a potential conflict
- Disclosure of the existence of a potential conflict in the informed consent document
- Modification of the Research or presentation to eliminate or reduce the conflict
- Divestiture or minimization of the Investigator's conflicting interest
- Monitoring of the Investigator or Research by impartial observers
- Other actions deemed appropriate by the COI Committee

All executed management plans will be forwarded to the grantee Institution appropriate Sponsored Programs Office and, via the grantee institution, to the appropriate PHS grantor (generally, either the Director of the Cancer Therapy Evaluation Program and/or the Director of the Division of Cancer Prevention of the National Cancer Institute) within 60 days. In addition, the Group Chair, the Executive Officer and the Disease and Research Committee Chair will also be informed.

For Phase III studies, the Management Plan will also be submitted to the NCI's Central Institutional Review Board (CIRB) with the accompanying Research Application, with the appropriate responses to the two conflict of interest questions contained in the Application.

All Management Plans will be reviewed every six months by the COI Committee at their bi-annual meeting.

Acknowledgement of a conflict of interest management plan does not automatically preclude an individual from having a role in the authorship of manuscripts relating to this or other Group studies, subject to the requirements of institutional and journal disclosure policies. The Conflict of Interest Sub Committee will work with the appropriate Disease and Research Committee Chairs and the Group Chairs Office when publications arise from studies involving individuals with conflict of interest management plans in place.

Group Leadership Disclosures

In addition to disclosures by Investigators, the Group Chair, Group Chair Elect, Deputy Chair, Associate Chair for Cancer Control and Prevention, the Executive Officers, Statisticians, Committee Chairs, Co-chairs, and Vice-chairs and Subcommittee Chairs, primary, and secondary Study Chairs as listed on the title page of the protocol, members of the COI Committee, members of the Scientific Advisory Board, members of the Board of Governors, members of Data and Safety Monitoring Committee, the Chief of Administration for SWOG, the Director of Operations and Protocols and the Director of The Hope Foundation are required to comply with this policy, and complete the Financial and Affiliation Declaration Form annually.

Such Group leadership disclosures will be reviewed by the COI Committee to determine if any action is required to ensure the existence and public perception of objectivity in research. COI Committee members whose own disclosure is being reviewed shall be recused from the review and action decision, if any. Disclosure is not necessary for Group members who are not in a leadership role or whose participation is limited to registering patients.

III. NOTIFICATION OF GOVERNMENT

The Group shall make all conflict information and related documentation available to the Department of Health and Human Services (HHS). The Group is obligated to report any interest identified as conflicting to the Public Health Service (PHS) awarding component and identify what steps have been taken to manage, reduce or eliminate the conflict. Further, the Group will promptly notify the PHS awarding component of the corrective action taken or to be taken if it is determined that an Investigator has biased the Group's research. All executed management plans will be forwarded to the grantee institution appropriate Sponsored Programs Office and, via the grantee institution, to the appropriate PHS grantor (generally, either the Director of the Cancer Therapy Evaluation Program and/or the Director of the Division of Cancer Prevention of the National Cancer Institute) within 60 days. If HHS determines that a PHS-funded project of clinical research, whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed, the Group must require the Investigator to disclose the conflicting interest in any public presentation of the results of the applicable research.

a. NOTIFICATION OF PUBLIC

The current SWOG Conflict of Interest Policy will be made available to the public via the publicly accessible portion of SWOG's website. The current policy document is available publicly at http://swog.org/Visitors/Download/Policies/Policy_35.pdf.

Management plans will be made available within 5 business days upon written request to info@swog.org. Questions about this policy may be sent to the same email address.

V. SANCTIONS

Failure to disclose a potential or existing conflict of interest as required or otherwise comply with the provisions of this policy may subject an Investigator to disciplinary action, including, but not limited to, prohibition from participating on Group trials or acting as a Study Chair, restrictions on

authorship rights fro Group trials, or probation or termination from Group membership. Investigators who fail to or erroneously make the required disclosures in the requisite Financial and Affiliation Declaration Form, or who later obtain an interest that may be perceived as a conflict after the publication of the Research results, may be required to disclose his/her interest in any public presentation of the applicable study.

VI. APPEALS

Any Investigator who disagrees with the findings of the COI Committee may request an independent review by the Group Chair or his/her designee. The decision of the Group Chair or designee shall be final.

VII. RECORD RETENTION

Records of all financial disclosures and any actions taken concerning such disclosures will be maintained for at least three (3) years from the date of the final publication of the applicable study results.

VIII. TRAINING

It is recognized that individual SWOG members may receive financial conflict of interest training from other sources. However, SWOG will provide financial conflict of interest training to Investigators subject to the requirements of this policy in the form of annual distribution of this policy and its associated disclosure form. Regardless of whether or not they have significant financial interests to disclose, SWOG Investigators will be asked to sign and return the form indicating that they have read and understood the information provided. SWOG reserves the right to require additional training prior to engaging in Group Research and/or on a periodic basis thereafter.

SWOG/The Hope Foundation

Operations Office
Email: COI@swog.org
Fax: 210-614-0006
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Financial and Affiliation Declaration Form

Investigator: _____
(Please Print or Type)

Affiliated Academic/Research Institution: _____

Investigator, please provide a description of any proprietary or financial interest related to an Outside Entity for you or any member of your immediate family. The term Investigator includes all scientists, clinicians and statisticians of SWOG whose participation in Group Research is not limited to registering patients. Participation includes having an active role in the development and conduct of the protocol, as well as the reporting of study results. An outside entity is any publicly-traded biotechnology, pharmaceutical, bioinformatics, or other similar company. Immediate Family Member includes a spouse and dependent child. There may be situations where other family members not defined as an "immediate family member" hold a financial or other interest in an Outside Entity such that a perceived conflict may exist. In such situations, disclosure is required (see number 7 below). Use a separate sheet of paper if necessary. If you have no financial interests and/or affiliation to declare, indicate by checking the applicable box at the end of this form. If any disclosed financial relationship included travel, the SWOG Conflict of Interest Committee reserves the right to contact you for more information.

1. Amount and source of payments which total \$2,000 or greater per year including salary, honoraria, royalties and other payments for services rendered, excluding travel support or reimbursement, from any Outside Entity (list each source separately)

None

Source	Purpose for payment	Amount
		\$
		\$
		\$
		\$
		\$

Did this support include travel? Yes No

Was the travel specifically related to your SWOG responsibilities? Yes No

2. Funds received for research which total \$30,000 or greater from any individual Outside Entity for the most recent three-year period

None

Source	Nature of research	Amount
		\$
		\$
		\$
		\$
		\$

Did this support include travel? Yes No

Was the travel specifically related to your SWOG responsibilities? Yes No

3. Number of shares and current value of stock held in any Outside Entity for which the current value is \$2,000 or greater

None

Stock name	No. shares	Current value
		\$
		\$
		\$
		\$
		\$

4. Any ownership interest in an Outside Entity, excluding stock equity totaling less than 5% of the estimated value of a publicly traded company;

None

Entity name	Ownership type	Current value
		\$
		\$
		\$
		\$
		\$

5. Amount and nature of interest in a non-publicly traded company whose value cannot be readily determined by referencing public prices;

None

Company name	Nature of interest	Estimated Current value
		\$
		\$
		\$
		\$
		\$

6. Any financial arrangement in which the value of compensation could be influenced by the outcome of any Group Research;

None

Source of compensation	Nature of arrangement	Estimated Current value
		\$
		\$
		\$
		\$
		\$

Did this arrangement include travel? Yes No

Was the travel specifically related to your SWOG responsibilities? Yes No

7. Any additional interest, affiliation or relationship, financial or otherwise, by the Investigator, an Immediate Family Member or other family member (as discussed in Section II.2. of policy 35) with an Outside Entity which may create or be perceived as a Conflict of Interest, such as intellectual property rights, the receipt of trips, gifts, or incentives, or a position as a director, board member, officer, partner, trustee, etc.

None

Source of compensation	Nature of arrangement	Estimated Current value
		\$
		\$
		\$
		\$
		\$

Did this interest include travel? Yes No

Was the travel specifically related to your SWOG responsibilities? Yes No

Further description, if necessary, can be provided on a separate page.

I have read SWOG's Financial Conflict of Interest Policy. I understand that by reading this policy and signing below, I have received training regarding my disclosure and other responsibilities regarding financial conflict of interest as outlined in this policy. I am making the above declaration(s) concerning any possible conflict of interest that I or my family members may have with respect to Group research activities.

I represent and warrant that to the best of my knowledge I am, and will continue to be, in compliance with the conflicts of interest and disclosure policies of the institution with which I am affiliated, and there is not now, nor do I know that there will be in the future, any material discrepancy between information disclosed pursuant to those policies and the information disclosed herein. I agree to supplement this document, or provide separate documentation, as required by this policy and as reasonably required by the Group to comply with rules and regulations of governmental agencies to which applications for grants or other funding are made by or on behalf of the Group.

Signature

Date

Complete the form online, print, sign and either scan to confidentially email to COI@swog.org or fax to Operations at (210) 614-0006