

SOUTHWEST ONCOLOGY GROUP

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

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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 Southwest Oncology Group (Group) 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" (42 CFR Part 50, Subpart F) currently requires that grantee institutions, including cooperative groups, have written policy guidelines on 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 conflict of interest. In the event a funding or granting organization also has conflict of interest policies, those policies will also apply.

The process of managing and minimizing the impact of potentially conflicting financial interests in Group research involves forthright internal disclosure with appropriate management and external disclosure only 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. 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 Subcommittee of the Scientific Advisory Board.

II. POLICY

Definitions

1. **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.
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 and statisticians of the Southwest Oncology Group 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. 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.

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, from any Outside Entity;
2. Funds received for research which total \$30,000 or greater from any individual Outside Entity for the most recent three-year period;
3. Number of shares and current value of stock held in any Outside Entity for which the current value is \$2,000 or greater;
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. Any financial arrangement in which the value of compensation could be influenced by the outcome of any Group Research;
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. 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.

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.

1. Payments totaling greater than \$10,000 per year for salary, honoraria, royalties, or other similar purposes, but excluding research compensation, from the Research Sponsor;
2. Equity interests totaling greater than \$10,000 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 in any capacity other than patient accrual or authorship (as described in the Management Plan section below) 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;
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;
4. Any significant interest, as determined by the Conflict of Interest Subcommittee, in a non-publicly traded company directly involved in or potentially influenced by the outcome of the Research 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, an Investigator must complete the Financial and Affiliation Declaration Form (pages 7-9 of this Policy) and send it to the Group Chair via the Operations Office.
2. When the Group Chair via the Operations Office receives a Form marked with no conflict or potential conflict of interest, the Form will be held on file at the Operations Office and be available for review by the Conflict of Interest Subcommittee.

3. When the Group Chair via the Operations Office receives a Form disclosing an actual or potential conflict of interest, the noted conflict(s) will be typed onto a preformatted disclosure confirmation form and returned to the Investigator for a second signature, allowing the confirmation of disclosure(s). When the second disclosure/signature is received by the Group Chair via the Operations Office it will be forwarded to the Conflict of Interest Subcommittee for review and determination whether a Management Plan or other action is necessary.
4. Conflicts or potential conflicts which develop during the conduct of the Research or up to the final publication of the results must also be disclosed in a timely manner as set forth in #1 above. Upon receipt of the new Form, the Operations Office shall forward to the Conflicts of Interest Subcommittee for further review and consideration concerning whether a Management Plan or other action is necessary.

Management Plan

For all Investigators whose interest disclosures fall between the floor and ceiling levels, the Conflict of Interest Subcommittee shall create a Management Plan applicable to the Investigator and the conduct of the Research. The Management Plan will be presented to the Investigator for discussion and modification, if deemed appropriate by the Conflict of Interest Subcommittee. The Management Plan may include, but need not be limited to the following:

- Independent review of the Research by the Conflict of Interest Subcommittee
- 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 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 Conflict of Interest Subcommittee

Once the final Management Plan is completed, it will be provided to the appropriate Group Protocol Coordinator. For Phase III studies, the Management Plan will be submitted to the NCI's Central Institutional Review Board (CIRB) with the accompanying Research Application, with the appropriate responses to the three conflict of interest questions contained in the Application. Following approval of the Research Application by the CIRB and the requisite applicable approvals for Phase I and II studies, the Management Plan will be forwarded to all Group members or advisory personnel who have a role in the implementation and continued review of the Management Plan. 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 Discipline Committee Chairs and the Group Chairs Office when publications arise from studies involving individuals with conflict of interest management plans in place.

All executed management plans must be forwarded to the Sponsored Programs Office of the grantee institution, the Director, Cancer Therapy Evaluation Program (a program under the Division of Cancer Treatment and Diagnosis) and the Director of the Division of Cancer Prevention of the National Cancer Institute.

Group Leadership Disclosures

In addition to disclosures by Investigators, the Group Chair (GC), Group Chair Elect (CCE), Deputy Chair (DC), Executive Officers (EO), Statisticians (STAT), Disease and Discipline Committee Chairs (DDC), primary (SC-1) and secondary (SC-2) Study Coordinators, members of the Conflict of Interest Subcommittee (COI), members of the Scientific Advisory Board (SAB), members of the Board of Governors (BOG) and members of Data and Safety Monitoring Committees (DSMC) are required to comply with this policy, and complete the Financial and Affiliation Declaration Form annually and return it to the Group Chair via the Operations Office. Such Group leadership disclosures will be reviewed by the Conflict of Interest Subcommittee to determine if any action is required to ensure the existence and public perception of objectivity in research such as, removal from the review, triage or results analysis of a study where a conflict exists. Conflict of Interest Subcommittee 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 not in any of these roles 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. 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.

IV. 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 Coordinator, restrictions on authorship rights from 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.

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V. APPEALS

Any Investigator who disagrees with the findings of the Conflict of Interest Subcommittee may request a formal hearing at a convened meeting of the COI Committee. If the disagreement cannot be resolved at that level, the investigator may then request an independent review by the Group Chair or his/her designee. The decision of the Group Chair or designee shall be final.

VI. 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.

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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 the Southwest Oncology Group 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.

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, from any Outside Entity (list each source separately)

None.

Source	Amount	Purpose for payment

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	Amount	Nature of research

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	Number of 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

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. 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.

None.

Source of compensation	Nature of arrangement	Estimated current value

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

I have read the Conflict of Interest Policy of the Southwest Oncology Group, and 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 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