

Conflict of Interest in Cooperative Group Research: No Conflict, No Interest!



Spring Group Meeting
San Francisco, California
April 15, 2010



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SWOG COI Committee Why Do We Need a COI Committee?

- Managing real and perceived conflict of interest (COI) is vital to the success of SWOG



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THE SENATOR'S SLEUTH
Paul Thacker, a reporter turned Congressional investigator, has uncovered the careers of several top researchers with lucrative industry ties.
Nature 2009;461:330



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SWOG COI Policy Fundamental Principles

- SWOG's conflict of interest policies and procedures must conform to basic requirements of the FDA, the NCI Central IRB and CTEP
- Internal disclosure of financial interests is essential, does not automatically constitute conflict of interest
- External (public) disclosure and appropriate management by SWOG is necessary when financial interests rise above a certain threshold
- Where conflict of interests **may** jeopardize public trust in the outcome of the research, individuals may be precluded from participating in that research



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SWOG COI Policy Fundamental Principles (continued)

- Disclosure of financial interests must include the investigator, their spouse and dependent children and under certain circumstances other family members
- Relevant financial interests include study sponsors as well as other entities **directly** involved with or potentially **directly** influenced by the outcome of the study
- Conflicts of interest may exist at the onset of the study, or emerge during the course of the study and after completion of accrual, up to the final publication of study results
- SWOG's conflict of interest policies and procedures must conform to basic requirements of the FDA, the NCI Central IRB and CTEP



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SWOG Conflict of Interest Policy

DISCLOSURE
All SWOG members whose participation is not limited to registering participants will disclose, on an annual basis, the following information:

- Amount and source of payments \geq \$2000 per year including salary, honoraria and other payments for services rendered, excluding travel, from biotechnology, pharmaceutical, bioinformatics or other similar companies or any third party directly supported by them
- Funds received for research that total \geq \$30,000 from any biotechnology, pharmaceutical, bioinformatics or similar companies
- Number of shares and current value of stock held in any biotechnology, pharmaceutical, bioinformatics or other similar companies for which the current value is \geq \$2000



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SWOG Conflict of Interest Policy

DISCLOSURE (2)

All SWOG members whose participation is not limited to registering participants will report, on an annual basis, the following information:

4. Any ownership interests in biotechnology, pharmaceutical, bioinformatics or other similar companies
 - "Ownership" excludes stock equity totaling <5% of the estimated value of a publicly traded company
5. Nature and amount of any interest in a nonpublicly 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 SWOG research
7. Any additional interest, affiliation or relationship, financial or otherwise, 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 board member, director, officer, partner, trustee, etc



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SWOG COI Policy

"Ceiling" above which an individual cannot be involved in a SWOG study in any capacity other than patient accrual

- ☒ Any financial arrangement in which the value of compensation could be influenced by the outcome
- ☒ Payments >\$25,000 per year for services from sponsor, not including research compensation
- ☒ Equity interest >\$50,000 in companies directly involved in or potentially directly influenced by the outcome of the study
- ☒ Any significant interest [determined on a case-by-case basis] in a nonpublicly traded company directly involved in or potentially influenced by the outcome of the study whose value cannot be readily determined by referencing public prices



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SWOG COI Policy

"Floor" above which COI management plan is required

- Payments >\$10,000 per year (honoraria, royalty, other payments) for services from sponsor during the course of the study, not including research compensation
- Equity interests >\$10,000 in companies directly involved in or potentially directly influenced by the outcome of the study during the course of the study
- Any ownership interest in any entity directly involved in or potentially directly influenced by the outcome of the study



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SWOG COI Policy

Other situations in which participation may be restricted or precluded

The Conflict of Interest Subcommittee also has the authority to institute a management plan or to preclude a Group member from involvement in Group Research in any capacity other than patient accrual in the event it finds any other interest, affiliation or relationship, financial or otherwise, by the Investigator, an Immediate Family Member or other family member with any Outside Entity may create or be perceived as a Conflict of Interest of sufficient magnitude to justify taking such action.



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SWOG COI Policy

- COI Management Plan for SWOG investigators whose interest disclosures fall in between the "floor" and the "ceiling"
 - Independent review of study by SWOG COI Committee
 - Independent review of study by NCI
 - No role in statistical management of data
 - Independent review of study by SWOG Data Safety Monitoring Board (if phase III trial)
 - Managed role in assessment of objective response to therapy and gradation and attribution of toxicities
 - Consideration for appointment of co-study coordinator without COI
 - Additional terms as determined by COI Subcommittee



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Conflict of Interest

Are we worried about the right things?



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"There now. We get our wish of continuing our work unimpeded, and they get their wish of being in a position of direct oversight at all times."

