Gynecologic Oncology Group  
Conflict of Interest Policy

I. PURPOSE

The Gynecologic Oncology Group (GOG) is committed to carrying out the design, conduct and reporting of clinical research with the highest standards of integrity and ethics and in compliance with applicable conflict of interest legal requirements. The scientific credibility and the general acceptance of the results of a clinical investigation clearly depend on the integrity and objectivity of the people conducting GOG studies. The purpose of this policy is to set forth the criteria for identifying conflicts of interest and the procedures for evaluating and addressing both potential and existing conflicts to assure that they do not improperly affect GOG research activities.

The U. S. Department of Health and Human Services requires that an institution receiving Public Health Service (PHS) research funds have a written financial conflict of interest (FCOI) policy. The intent of this requirement is to promote “objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.” 42 CFR Part 50 Subpart F.

This Policy describes types of conflicts of interest, identifies when disclosure should be provided, and explains GOG’s administration and enforcement procedures. The policy is applicable to Investigators, as defined below, who participate in GOG research. Participation includes having an active role in the development of protocols, the conduct of clinical trials, as well as the reporting of study results.

II. DEFINITIONS

“Conflict of Interest” means a situation in which an Investigator has a significant financial interest or other personal involvement that may compromise, or have the appearance of compromising, his or her professional judgment or integrity in designing, conducting, or reporting research.

“Financial Conflict of Interest” (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

“Immediate family member” means an Investigator’s spouse and dependent children.

“Institution” means the Gynecologic Oncology Group (GOG).
“Investigator” means the Principal Investigator, a study chair, any collaborating investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the Public Health Service (PHS), or proposed for such funding, and may include collaborators, consultants, and GOG employees.

“Research” means a systematic investigation, study, or examination designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development.

“Significant financial interest” (SFI) means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s GOG responsibilities:

a. With regard to a publicly or non-publicly traded entity, an SFI exists if the Investigator (or spouse or dependent children) received remuneration exceeding $5000 or had an equity interest exceeding $5000, in the aggregate, for the 12-month period preceding disclosure. Remuneration includes salary and other payment for services, and equity interests include, for example, stock or stock options;

b. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to these rights and interests.

The term “significant financial interest” does not include:

- remuneration, such as salary or consulting fees, from GOG;
- income from investment vehicles, such as mutual funds and retirement accounts, if the Investigator does not directly control their investment decisions;
- income from seminars, lectures, or teaching engagements sponsored by a government agency or an institution of higher education, an academic teaching hospital, a medical center, or a research institute;
- income from service on advisory committees or review panels for a government agency or an institution of higher education, an academic teaching hospital, a medical center, or a research institute.

III. GOG POLICY AND DISCLOSURE REQUIREMENTS

A. Policy

A conflict of interest related to GOG activities may occur when a GOG investigator or immediate family member has a significant financial or other personal interest that compromises, or appears to compromise, that individual’s independence and objectivity.
in the discharge of his/her GOG responsibilities in the design, conduct, or reporting of GOG research.

Investigators should avoid conflicts of interest and the potential for conflicts through financial arrangements with third parties that could have a special interest in a GOG protocol. Entities that could have such a special interest include all organizations that are involved in the development, production and/or distribution of products used in medical research protocols conducted by the GOG.

Following completion of a trial, Investigators providing leadership in the design or conduct of the study should refrain from activities primarily targeted at marketing of a product that was studied in that trial.

**B. Disclosure**

Every Investigator must file an annual GOG Conflict of Interest Disclosure Form with GOG disclosing known SFIs, as defined in this policy and in 42 CFR Part 50, and other personal interests that are potential conflicts of interest with GOG research activities. Examples of other such personal interests include, but are not limited to:

- participating in a research project expects to receive royalty payments for intellectual property derived from that study;
- having the authority to purchase goods and/or services on behalf of GOG from a business in which the Investigator and/or immediate family members have a significant financial interest.
- holding an official position in an entity or organization, other than GOG, involved in developing, producing, and/or distributing products that may be used in the course of conducting GOG research.

An Investigator must also disclose the occurrence of any reimbursed or sponsored travel related to the Investigator’s GOG 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 GOG, a government agency or institution of higher education, an academic teaching hospital, a medical center, or a research institute.

An Investigator must disclose to GOG any potential conflicts that develop during the design, conduct, or reporting of a clinical trial or during the dissemination of results. These must be disclosed to GOG within thirty (30) days of discovering or acquiring the conflict.

Disclosure is not necessary for individuals whose participation in GOG research is limited to registering patients.

At the beginning of any presentation of the results of a GOG clinical trial, through either oral presentation or publication, an Investigator should disclose, if applicable, private sources of funding provided specifically for the study.
IV. MANAGEMENT, ENFORCEMENT AND REPORTING TO NIH

A. Management

The Group Chair will review the annual Conflict of Interest Disclosure Forms no later than thirty (30) days from the deadline for their submission. The Group Chair will review all other submitted Disclosure Forms within thirty (30) days of their submission. For any disclosed interests that the Group Chair believes relate to GOG’s PHS-funded research and that may constitute a conflict of interest, the Group Chair shall convene an ad hoc committee of no less than three members to review the matter and advise the Group Chair, who will make a final determination whether a conflict exists and how the conflict should be managed. These may include:

- Public disclosure of the conflict of interest
- Monitoring of research by independent reviewers
- Modification of the research plan
- Disqualification from participation in all or a portion of the research
- Divestiture of significant financial interests
- Severance of relationships that create actual or potential conflicts.

A conflict should be managed, reduced, or eliminated within sixty (60) days of its identification by the Group Chair. The ad hoc committee shall be responsible for monitoring and enforcing any management plan.

The Group Chair shall make the final decision about the action to be taken, with the advice of the ad hoc committee. The Vice Chair of GOG shall review the annual Disclosure Statement of the Group Chair. If the Vice Chair believes that there may a conflict of interest involving the Group Chair, the Vice Chair shall serve in the place of the Group Chair in reviewing the possible conflict and making the final decision about any action to be taken.

GOG shall require other institutions that are sub-recipients of GOG PHS funding to comply with the GOG Conflict of Interest Policy.

B. Enforcement

If GOG determines that an Investigator has not complied with the disclosure requirements for SFIs or that an FCOI was not identified and managed in a timely manner, GOG shall complete a retrospective review within 120 days and document the review as required by federal regulation.

If it is determined that an Investigator has an FCOI or other conflict of interest, that individual may not serve as study chair, study statistician, or Data Safety and Monitoring
Board member for any protocol involving the research product for which there is a conflict.

If an Investigator discloses a SFI that is above one of the following maximum thresholds, then he or she cannot be involved in the development and management of a GOG clinical trial: payments from Sponsor in excess of $25,000 per year during the research period and for one year after, not including research compensation; any financial arrangement in which 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 one year after; and any significant interest in nonpublicly traded company.

Failure to disclose a conflict of interest as required by this policy or participation in GOG activities after such participation has been prohibited may result in the loss of privileges to participate in any GOG research activities.

If the Department of Health and Human Services determines that a PHS-funded clinical research project whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by GOG as required, GOG shall require the Investigator to disclose the FCOI in each public presentation of the research and request an addendum to previously published presentations.

C. Training; Reporting; Record Keeping

GOG shall inform its Investigators annually about the GOG Conflict of Interest Policy and disclosure requirements, and the Federal FCOI regulations. In addition, GOG shall require Investigators to complete conflict of interest training prior to engaging in research related to a PHS-funded grant, and at least every four (4) years thereafter, and more frequently, if required by Federal regulations.

GOG shall file a reports with the NIH providing information on every identified FCOI and the manner in which the FCOI is being or has been managed, reduced, or eliminated, as required by 42 CFR Part 50, Subpart F. All reports shall include all the elements required by these regulations.

GOG will notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research, and file a Mitigation Report in accordance with federal regulations. GOG will similarly notify NIH if an Investigator fails to comply with GOG’s FCOI policy or a FCOI management plan.

GOG shall maintain all FCOI-related records for at least three (3) years from the date the final expenditures report is submitted to the PHS.
D. Public Accessibility

The GOG Conflict of Interest Policy shall be posted on the public portion of the GOG Website. In addition, upon receipt of a written request for information concerning identified FCOI’s held by senior/key personnel (as defined by regulation) GOG will make that information available within five (5) business days of the request. The information shall include all elements required by 42 CFR Part 50, updated through the date of the response.

V. ADDITIONAL PROCEDURES FOR CERTAIN DISCLOSED INTERESTS IN PHASE 3 TRIALS

If the GOG believes that a disclosed interest does not disqualify an Investigator from a leadership position in a GOG Phase 3 clinical trial, AND if the disclosed interest is less than $25,000 per year during the research period and for one year thereafter in the case of payment from an entity, or is less than $50,000 a year during the research period and one year thereafter in the case of equity interest in a publicly traded company, then GOG shall follow these additional procedures:

GOG will submit a Conflict of Interest Management Plan to the Central Institutional Review Board (CIRB) of the National Cancer Institute (NCI) with the CIRB Application that GOG files. The management plan will discuss the general elements that pertain to assuring unbiased data collection and review in GOG trials, including the following:

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

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