

Gynecologic Oncology Group *Conflict of Interest Policy*

I. PURPOSE

The Gynecologic Oncology Group (GOG), and its employees and investigators are 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 federal and state laws related to conflict of interest. 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 Gynecologic Oncology Group trials. Even the suggestion that an investigator has a bias may cast doubt on the validity of study results. The purpose of this policy is to set forth the principles for identifying the potential for conflicts and the procedures for evaluating and addressing both potential and existing conflicts to assure that they do not improperly affect GOG research or other activities.

The Public Health Service, in 42 CFR Part 50, Subpart F, requires that grantee institutions have written conflict of interest policies. The intent of this regulatory requirement 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.” In addition, the Food and Drug Administration (FDA) requires clinical investigators participating in studies submitted with FDA marketing applications to file disclosures of significant financial interests. 21 CFR Part 54.

This Policy describes types of conflicts of interest, identifies when disclosure should be provided, and explains the mechanism for administration and enforcement. **This policy is applicable to all employees and investigators, as defined below, whose participation in GOG research is not limited to registering patients.** 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 employee or investigator has 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.

“Employee” means any member of the GOG Board of Directors or a GOG committee, any individual holding a full-time or part-time position within GOG, and any consultant

or subcontractor who provides services to GOG related to the design, conduct or reporting of GOG research.

“FDA” means the Food and Drug Administration of the U.S. Department of Health and Human Services.

“Immediate family member” includes an employee’s or investigator’s spouse and dependent children.

“Investigator” means the Principal Investigator, a study chair, any collaborating investigator, and any other person who is responsible for the design, conduct, or reporting of research funded by the Public Health Service, or proposed for such funding.

“PHS” means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS.

“PHS Awarding Component” means the organizational unit of the PHS that funds the research undertaken by GOG.

“Research” means a systematic investigation 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” means anything of monetary value including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stock, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

The term does not include:

- remuneration, such as salary or consulting fees, from GOG;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- income from service on advisory committees or review panels for public or non profit entities;
- equity interest in business enterprises or entities where the value of such interests, when aggregated for the investigator or employee and immediate family members meets both of the following tests: does not exceed \$10,000 in value as determined on the basis of public prices or other reasonable measures of fair market value, and does not represent more than a five percent (5) ownership interest in any single entity; or
- salary, royalties or other payments that when aggregated for the employee or investigator and immediate family members over the next twelve months, are not expected to exceed \$10,000.

III. CONFLICT OF INTEREST

A. Policy

A conflict of interest is considered to occur whenever a GOG employee, investigator, or an immediate family member has an existing or potential significant financial interest that impairs, or appears to impair, that individual's independence and objectivity in the discharge of his/her responsibilities. A conflict of interest also exists when, in the reasonable determination of the Group Chair, a significant financial interest could directly and significantly affect the design, conduct, or reporting of GOG research.

Employees and investigators should avoid conflicts of interest and/or the potential for conflicts through financial arrangements with third parties that could have a special interest in a protocol or its findings. 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.

Conflict of interest could include:

- Compensation that could increase with favorable trial results. Such compensation could be equity in the company or companies sponsoring such protocols. Compensation also could include royalties from sales.
- Payments to the investigator(s) conducting the sponsored protocol. These payments could be in the form of grants, equipment, and retainers for consultation or honoraria.
- Proprietary interests in the product under investigation in the sponsored protocol. Such interests include patents, copyrights, trademarks or license agreements.
- Any ownership interest, stocks or stock options whose value cannot be determined readily by reference to public prices.
- Equity in a publicly traded corporation.

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

B. Disclosure

All employees and investigators, as defined above, must file annual statements with GOG identifying potential conflicts of interest and disclosing their known significant financial interests and those of their spouses and dependent children. They must also disclose any official positions in an organization, other than GOG, involved in developing, producing, and/or distributing products that may be used in the course of conducting research protocols performed by the GOG. This is done by submitting a GOG Conflict of Interest Disclosure Form to the GOG Administrative Office each year. **Disclosure is not necessary for individuals whose participation in research is limited to registering patients.**

Conflicts that develop subsequently during the design or conduct of a clinical trial or during the dissemination of results must also be disclosed in the same manner.

At the beginning of any presentation of the results of a Gynecologic Oncology Group clinical trial, through either oral presentation or publication, an investigator should disclose, if applicable, private sources of funding provided specifically for the study.

Examples of interests that must be disclosed include, but are not limited to:

- An employee or investigator participating in a research project expects to receive royalty payments for intellectual property derived from that study.
- An employee or investigator has the authority to assign other professionals to complete tasks and activities in connection with a research project in which he or she and/or immediate family members have a significant financial interest, as that term is defined in this policy.
- An employee or investigator receives sponsored research support or contributions (whether in cash or in kind) from a business in which he or she and/or immediate family members have a significant financial interest.
- An employee or investigator takes administrative action on behalf of GOG that benefits a business in which he or she and/or immediate family members have a significant financial interest.
- An employee or investigator who has influence over procurement decisions purchases goods and/or services on behalf of GOG from a business in which he or she and/or immediate family members have a significant financial interest.

IV. INSTITUTIONAL RESPONSIBILITIES

A. Enforcement; Sanctions

The Group Chair shall review the annual submissions of the Conflict of Interest Disclosure Forms no later than 30 days from the deadline for their submission. He shall review all other submitted Disclosure Forms within 30 days of their submission. For those situations which he believes may constitute a conflict of interest, the Group Chair shall convene an ad hoc committee of no less than 3 members to review the matter and recommend ways in which the conflict may be managed, reduced, or eliminated. 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.

The conflict should be managed, reduced, or eliminated, at least on an interim basis, within 60 days of its identification.

The Group Chair shall make the final decision about the action to be taken, with the advice of the ad hoc committee. The Secretary of GOG shall review the annual submission of the Group Chair. If the Secretary believes that there may be a conflict of interest involving the Group Chair, the Secretary 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.

If it is determined that an employee or investigator has a conflict of interest, that individual may not serve as study chair, study statistician, or Data Monitoring Committee member for any protocol involving the research product for which there is a conflict.

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

B. Reporting; Record Keeping

Prior to expending grant funds, GOG shall report to the PHS Awarding Component the existence of a conflicting interest and assure that the interest has been managed, reduced or eliminated. GOG will also report any subsequently identified conflict and manage, reduce, or eliminate that conflict within 60 days of identification. GOG will make conflict information available to the Department of Health and Human Services (HHS) upon request.

GOG shall maintain records of all financial disclosures and all actions taken with respect to each conflict of interest for at least three (3) years from the date of submission of the final expenditures report.

C. Additional Procedures for Certain Disclosed Interests in Phase 3 Trials

If the GOG believes that a disclosed interest does not disqualify an employee or 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 the 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

The CIRB will be asked to comment on this Conflict of Interest Policy for GOG Phase 3 clinical trials and it will add three questions to the CIRB Application as follows: 1) Does the Study Chair or any principle involved in the development or coordination of this study have any significant financial conflicts of interest as defined in the Conflict of Interest Policy? 2) If so, does the Cooperative Group have a management plan in place to address the conflicts disclosed in question #1? 3) If so, a copy of the Management Plan should be attached.

D. Disqualification from Leadership Role in Clinical Trials

If an employee or investigator discloses a significant financial interest 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 1 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 1 year after; and any significant interest in nonpublicly traded company whose value cannot be readily determined referencing public prices.

V. NONCOMPLIANCE

GOG shall notify the PHS Awarding Component if the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the PHS-funded research.

In any case in which HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with a conflicting interest that was not disclosed or managed as required by this policy, GOG will require that investigator to disclose the conflicting interest in each public presentation of the results of the research.

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