



Financial Conflict of Interest Policy for PHS-Funded Research of American Society of Clinical Oncology

(April 18, 2013)

I. Introduction

The American Society of Clinical Oncology (“ASCO”) is dedicated to conquering cancer through research, education, prevention and the delivery of high quality cancer care, and is a trusted source for cancer information world-wide. ASCO may from time apply for and receive grants for Research relevant to its mission.

The following Financial Conflict of Interest (“FCOI”) Policy for Public Health Service (“PHS”) Funded Research (“Policy”) describes ASCO’s approach to addressing financial relationships held by Investigators who are conducting or who are planning to conduct Research funded by the PHS under the auspices of ASCO. The purpose of this Policy is to establish standards for the management of FCOI to promote objectivity in the design, conduct, and reporting of research funded under PHS grants or cooperative agreements through ASCO.

This Policy applies to the PHS-Funded Research activities of ASCO and its affiliates, including the Conquer Cancer Foundation and the Institute for Quality LLC, if applicable.

II. DEFINITIONS

For purposes of this Policy, the following definitions shall apply:

“**Conflict Management Plan**” means the written plan instituted by ASCO for the management, reduction or elimination of a Financial Conflict of Interest.

“**Equity interest**” means any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.

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

“**Financial Interest**” means anything of monetary value, including but not limited to Compensation, Equity, Gifts, and Intellectual Property, of an Investigator or the Immediate Family Member of an Investigator, whether or not the value is readily ascertainable.

“**Immediate Family Member**” means a person's spouse and dependent children.

“**Institutional Official**” means one or more persons designated by ASCO as having responsibilities under this Policy to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

“Intellectual Property” means the rights comprising patents, copyrights and royalties from such rights.

“Investigator” Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

“PHS” means the Public Health Service of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health.

“PHS-Funded Investigator” means an Investigator applying for or participating in any PHS-Funded Research under the auspices of ASCO.

“PHS-Funded Research” means any Research funded through a PHS grant or cooperative agreement.

“Policy” means this Financial Conflict of Interest Policy.

“Reimbursed Travel” means travel activity for which the Travel Expenses are paid directly by the Investigator, who is then reimbursed by an Entity for such Travel Expenses.

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

“Senior/Key Personnel” means the Principal Investigator and any other person identified as senior or key personnel by ASCO in a PHS-Funded Research application, award, or contract or in any progress report, or any other report submitted to the PHS by ASCO under the regulation.

“SFI Disclosure” means a disclosure of a Significant Financial Interest as provided in this Policy.

“Significant Financial Interest” or **“SFI”** 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., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

1. Salary, royalties, or other remuneration from ASCO;
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. Income from service on advisory committees or review panels for public or nonprofit entities;
4. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable

measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

5. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

“Sponsored Travel” means travel activity, the Travel Expenses for which are paid on behalf of an Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available. Notwithstanding the foregoing, Sponsored Travel shall not include Travel Expenses that are paid by ASCO.

“Travel Disclosure” means a disclosure of Sponsored Travel or Reimbursed Travel as provided in this Policy.

“Travel Expenses” means expenses incurred for the purpose of engaging in travel activity, including but not limited to, costs for transportation, parking, food, drink, lodging, and related amenities.

III. PROCEDURES

A. Identification of Investigators

Investigators shall be responsible for ensuring that their SFI Disclosures and Travel Disclosures required to be disclosed under this Policy are submitted in a complete and timely manner to the Institutional Official and in accordance with procedures and guidelines established by ASCO. For all Research projects, the Principal Investigator shall be responsible for identifying all Senior / Key Personnel who are also Investigators as they become known and reporting their identity within ten (10) days thereafter.

B. Designation of Institutional Official

ASCO will appoint the Associate Counsel for Ethics or other appropriate person as the Institutional Official to administer and enforce this Policy. The Institutional Official will:

1. Obtain and review SFI Disclosures and Travel Disclosures under this Policy;
2. Develop and implement Conflict Management Plans;
3. Conduct any required late or retrospective FCOI reviews, including issuance of reports of findings and conclusions and development and implementation of conflict mitigation plans;
4. Communicate with federal and other sponsors on matters pertaining to this Policy;
5. Make recommendations to ASCO with respect to matters covered by this Policy; and
6. Develop and implement reasonable and appropriate summary procedures for the disposition of matters involving compliance with this Policy.

C. SFI Disclosures by Investigators to ASCO

ASCO Investigators conducting or included on an application to conduct PHS-Funded Research must disclose the information required herein in accordance with the process established by

ASCO. At a minimum and no later than the time of application for funding, Investigators planning to participate in PHS-funded Research are required to disclose all Interests as requested by ASCO namely,

1. Any SFIs belonging to the Investigator or the Investigator's Immediate Family, and
2. Any Reimbursed or Sponsored Travel. The following information must be provided in connection with any Travel Disclosure provided in the context of PHS-funded Research:
 - a) The purpose of the trip;
 - b) The identity of the sponsor/organizer of the trip;
 - c) The destination of the trip; and
 - d) The duration of the trip.

Investigators shall update their disclosures on an annual basis. In the updated disclosures, Investigators must: (i) include any SFI information that was not disclosed initially to ASCO; (ii) disclose any SFI that was transferred from another Institution; and (iii) include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

In addition to the requirement to update disclosures annually, Investigators shall disclose SFIs within thirty (30) days of discovering or acquiring a new SFI.

D. Management of Financial Conflict of Interests

1. Prior to expenditure of any funds under a PHS-Sponsored Research award, the Institutional Official must reasonably determine whether any disclosed SFI by any Investigator is related to the PHS-Sponsored Research; if so, whether it constitutes an FCOI; and if an FCOI is determined to exist, how the FCOI will be managed. The determinations of the Institutional Official will be informed by the ASCO Vice President and General Counsel or ASCO CEO, as determined by ASCO.
2. ASCO reserves the right to impose any requirements it deems necessary on any disclosed interest, even if they are not determined to constitute an FCOI under this Policy and/or applicable regulations.
3. Conflict Management Plans shall be implemented to appropriately manage an identified FCOI. Conflict Management Plans shall be consistent with all legal and regulatory requirements, the requirements of this Policy, and may include one or more of the following
 - a) Public disclosure of significant financial interests;
 - b) Monitoring of research by independent reviewers;
 - c) Modification of the research plan;
 - d) Disqualification from participation in all or a portion of the research funded by the PHS
 - e) Divestiture of significant financial interests; or
 - f) Severance of relationships that create actual or potential conflicts.

4. Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement a management plan acceptable to ASCO. Investigators have an ongoing obligation to comply with Conflict Management Plans and ASCO will continue to monitor, as necessary, the Investigator's compliance with the Conflict Management Plans.

E. Access to SFI Disclosures and Travel Disclosures

1. ASCO shall permit access to Investigators' disclosures as it deems appropriate for the purpose of implementing this Policy.

2. For PHS-Funded Research, ASCO will ensure public accessibility of information concerning the FCOIs currently held by Senior/Key Personnel subject to this Policy. Unless and until ASCO establishes a mechanism of making such information available through a publicly accessible website, ASCO will, upon receipt of a complete written request for information, provide a written response within five (5) business days regarding any SFI disclosed and still held by the Senior/Key Personnel that has been determined to relate to the PHS-Funded research and constitute an FCOI pursuant to this Policy. The response will include: (i) the Investigator's name; (ii) the Investigator's title and role on the research project; (iii) the name of the entity in which the SFI is held; (iv) the nature of the SFI; (v) the approximate value. The FCOI information of each Senior/Key Personnel shall remain available for at least three (3) years from the date the information was most recently updated.

F. Reporting

1. ASCO is responsible for reporting matters involving FCOI disclosures in accordance with applicable federal requirements. Reports will be made:

- a) Prior to the expenditure of any funds under a PHS-Funded Research project;
- b) Within 60 days of identification for an Investigator who is newly participating in the project;
- c) Within 60 days of new, or newly identified FCOIs for existing investigators;
- d) At least annually, at the same time as ASCO is required to submit applicable progress reports; and
- e) Following retrospective review to update a previously submitted report, as appropriate.

2. All FCOI reports to PHS awarding components shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of ASCO's Conflict Management Plan.

G. Retrospective Reviews of PHS-Funded Research; Mitigation Plans

1. Retrospective Review: For PHS-Funded Research, in the event of failure to meet PHS regulations, including failure by the Investigator to disclose timely an SFI that is determined to constitute an FCOI; ASCO's failure to review or manage such an FCOI; or Investigator failure to comply with an FCOI management plan, ASCO will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-Funded Research project to determine any bias in the design, conduct or reporting of Research

during the time period of the noncompliance. ASCO will document the retrospective review in accordance with its policies and procedures and applicable PHS regulations.

2. Mitigation. If bias is found during the retrospective review of PHS-Funded Research, ASCO will notify the PHS awarding agency promptly, and if applicable, develop and implement a mitigation plan, and submit the PHS required mitigation report, which will include at least the elements documented in the retrospective review and a description of the impact of the bias on the Research project and the steps taken to eliminate or mitigate the effect of the bias. Any FCOI report submitted to the PHS awarding agency with respect to such Research will be updated as necessary in light of the results of the retrospective review.

H. Training for Investigators Participating in PHS Funded Research

For PHS-Funded Research, Investigators must complete all required conflicts of interest training prior to engaging in Research at or under the auspices of ASCO, and at least every four years following the initial training. Additionally, Investigators will be required to receive training immediately in any of the following circumstances:

- a) ASCO revises its Policy or procedures governing FCOI in PHS-funded Research in any manner that affects the requirements applicable to Investigators;
- b) An Investigator is new to ASCO;
- c) ASCO finds that an Investigator is not in compliance with this Policy or an imposed management plan.

I. Sanctions and Remedies for Violation of Policy

Whenever the Institutional Official determines that an Investigator has violated this Policy, including any failure to make a required SFI Disclosure or Travel Disclosure or comply with a requirement of a Conflict Management Plan, the Institutional Official shall recommend appropriate sanctions, including but not limited to termination of the employment, or other relationship, consistent with ASCO policies.

J. Record Retention

Unless some other applicable record retention law, requirement, or policy requires a longer period of retention, records created and maintained under this Policy, including SFI Disclosures, Travel Disclosures and Conflict Management Plans, shall be retained by ASCO for a period of no less than three (3) years after the termination or completion of the Research to which they relate.

K. Subrecipient Compliance

When proposed PHS-Funded Research is to be funded through ASCO and carried out through a subrecipient, ASCO will either (i) apply this Policy; (ii) establish, as part of a written agreement with the subrecipient, minimum FCOI terms that mirror this Policy and meet the requirements of 42 CFR part 50; or (iii) ensure that the subrecipient's FCOI policy meets the minimum criteria

established in the regulation in order to ensure that ASCO is able to meet its reporting obligations to the PHS awarding agency.

L. Auditing and Oversight Monitoring

The Institutional Official shall take such actions that it deems reasonable to audit and/or monitor compliance with Conflict Management Plans.

Application:

Applies to ASCO and its affiliates

History:

Approved by the ASCO Executive Committee on April 18, 2013.