

**AMERICAN CANCER SOCIETY, INC.
FINANCIAL CONFLICT OF INTEREST POLICY
FOR PROMOTING OBJECTIVITY IN RESEARCH**

Introduction

The American Cancer Society, Inc. (“ACS”) seeks excellence in the discovery and dissemination

This Policy should be read in conjunction with ACS's Code of Ethics and Conflict of Interest Policy (the "Code of Ethics") which provides general instruction on preventing, recognizing, and mitigating conflicts of interest. The requirements of this Policy are intended to supplement, not replace, the disclosure obligations and processes set forth the Code of Ethics. To access the Code of Ethics, please visit www.cancer.org.

I. DEFINITIONS

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Research.

Financial Conflict of Interest Committee (FCOI Committee) means a committee appointed to review and provide recommendations for the management of Significant Financial Interests in accordance with this Policy. The FCOI Committee will be comprised of one representative from the Office of the Chief Financial Officer, the Office of the Chief Medical Officer and the Office of Corporation Counsel.

Financial Conflict of Interest Management Plan (FCOI Management Plan) means a plan developed in accordance with this Policy for the management, reduction, or elimination of an identified Significant Financial Interest.

Financial Conflict of Interest Report (FCOI Report) means ACS's report of a Financial Conflict of Interest to the awarding agency of PHS.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities means an Investigator's professional activities on behalf of ACS (e.g., teaching, administration, research, clinical care, or service on IRB panels, editorial boards or peer review panels).

Investigator means any principal investigator, project manager, research analyst, or member of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report; and/or other individuals that the principal investigator/project manager identifies as responsible for or having substantial independent decision making with respect to the

Significant Financial Interest (SFI) means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (aggregated together with those of the Investigator's spouse, same-sex domestic partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities:

- (i) With regard to any **publicly traded entity**, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- (ii) With regard to any **non-publicly traded entity**, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse, same-sex domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
- (iii) **intellectual property rights and interests** (e.g., patents, copyrights), a *significant financial interest* exists upon receipt of income of related to such rights and interests; or
- (iv) **any third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse, same-sex domestic partner and dependent children) that is related to the Investigator's Institutional Responsibilities. This disclosure requirement excludes travel paid for by ACS or travel that is reimbursed or sponsored by an U.S. Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- (v) holding any **position of influence** (e.g., director, officer, trustee, dean, or faculty) in a non-ACS entity.

(2) The term *significant financial interest* does not include the following:

- (i) Salary, royalties, or other remuneration paid by ACS to the Investigator if the

- (ii) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by an U.S. Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- (iv) Income from service on advisory committees or review panels for an U.S. federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

II. OVERVIEW

All Investigators covered by this Policy are required to disclose Financial Interests that could affect or be affected by Research on which they are working or proposing to work for or on behalf of ACS. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this Policy and must undergo regular training as described herein. Any Investigator with

III. DISCLOSURE PROCEDURES

A. Annual Disclosure Requirements

regarding appropriate procedures to afford the maximum confidentiality and privilege protection for the investigation.

The Institutional Official will forward all SFI Disclosure Forms revealing a Significant Financial

justification will be reviewed by the FCOI Committee. If the FCOI Committee determines that compelling circumstances justify a waiver of this Policy, the FCOI Committee Research with support from the Institutional Official will develop a FCOI Management Plan with stringent management measures to ensure the safety of the human participants and the integrity of the Research.

For all Research involving human subjects, the outcome of FCOI Committee reviews and any recommended FCOI Management Plans will be communicated to the appropriate Institutional Review Board (IRB) for review and approval. The IRB may require additional measures to protect the safety and welfare of Research subjects under their purview.

E. FCOI Reporting to Public Health Service

Federal regulations require that ACS report to the funding agency Financial Conflicts of Interest related to PHS-sponsored Research. No expenditure of funding shall occur with respect to any PHS-supported Research project for which the FCOI Committee has determined that a FCOI Management Plan is required unless and until ACS has provided the funding agency with a FCOI Report containing the following information:

- i. Project Number
- ii. PD/PI or Contact PD/PI if multiple PD/PI model is used;
- iii. Name of the Investigator with the Financial Conflict of Interest;
- iv. Name of the entity with which the Investigator has a Financial Conflict of Interest;
- v. Nature of the Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium)
- vi. Value of the Financial Interest, or a statement that the interest is one whose valued cannot be readily determined through reference to public prices or other reasonable measure of fair market value;
- vii. A description of how the Financial Interest relates to the PHS-funded Research and the basis for ACS' determination that the Financial Interest conflicts with such Research; and
- viii. A description of key elements of the Institution's FCOI Management Plan including:
 - a. Role and principal duties of the conflicted Investigator in the Research project;
 - b. Conditions of the FCOI Management Plan;
 - c. How the FCOI Management Plan is designed to safeguard objectivity in the Research project;
 - d. Confirmation of the Investigator's agreement to the FCOI Management Plan;
 - e. How the FCOI Management Plan will be monitored to ensure Investigator compliance; and
 - f. Other information as needed or requested by the funding agency.

For any Significant Financial Interest that is identified after the funding for the Research is awarded, including Significant Financial Interests identified by Investigators new to the project,

ACS will determine whether a Financial Conflict of Interest exists and whether a FCOI Management Plan is required. For PHS-sponsored Research, ACS shall provide a FCOI Report with the information above to the PHS funding agency within sixty (60) days of identification of the Significant Financial Interest.

Additionally, each award year ACS must provide the PHS-funding agency an annual FCOI Report that addresses the status of the Financial Conflict of Interest and any changes to the FCOI Management Plan for the duration of the project period (including extensions with or without funding). The annual FCOI Report shall specify whether the Financial Conflict of Interest is still

For Research covered by this Policy that involves subcontractors, sub-grantees or sub-awardees at other institutions (collectively “Sub-recipients”), ACS must take reasonable steps to ensure that any Sub-recipient Investigator complies with Federal regulations by:

(1) Requiring a written agreement from Sub-recipients that establishes whether ACS’s policy or the Sub-recipient’s policy shall apply to the Sub-recipient’s Investigators

a. If the Sub-recipient’s policy is used, the Sub-recipient must certify that its financial conflict of interest policy is compliant with 42 CFR Part 50 and 45 CFR Part 94 and will be responsible for ensuring that the Sub-recipient institution and its Investigators comply with the Federal regulations. Sub-recipients must report to ACS as the awardee institution, any identified Financial Conflict of Interest no later than 45 days after identification of the Financial Conflict of Interest by the Sub-recipient. The details of the Financial Conflict of Interest will be reported to the funding agency as required under applicable regulations or policies.

b. If ACS’s policy is used, the Sub-recipient must ensure that its Investigators subm8(p)-0.956417-0

VII. COMPLIANCE

A. Oversight

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the date that the Financial Conflict of Interest or the Investigator's noncompliance is determined and the completion of ACS's retrospective review.

7. In any case that a clinical Research project, 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 reported or managed as required by this Policy or the applicable regulations, then ACS shall, at minimum, require the Investigator involved to disclose the conflicting interest in each public presentation of the results of the Research and to request an addendum to previously published presentations. An Investigator who has failed to report a Significant Financial Interest related to clinical Research will also be subject to sanctions under this Policy.

VIII. GENERAL PRINCIPLES

A. Confidentiality

To the extent permitted by law, all SFI Disclosure Forms, FCOI Management Plans, and related information will be treated as privileged and confidential. However, ACS may be required to make such information available to PHS and/or HHS, to a requestor of information concerning Financial Conflict of Interests related to PHS funding or to the primary entity who made the funding available to ACS, if requested or required. If ACS is requested to provide SFI Disclosure Forms, FCOI Management Plans, and related information to a78(i)-.671(i)-2.53585(n)-0.9f6(n)-0.956417()-100.671(t)

