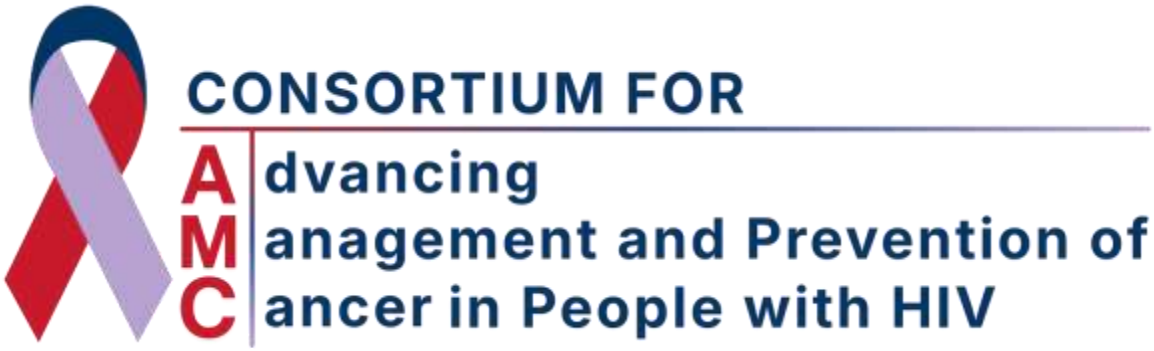



# Standard Operating Procedures for Disclosure and Management of Financial Conflicts of Interest

Version 5.0
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## 1.0 GENERAL PRINCIPLES

These guidelines are intended to identify researchers' financial interests in the Consortium for Advancing Management and Prevention of Cancer in People with HIV (AMC) clinical trials and activities, to manage financial conflicts of interest, or the appearance of such conflicts, in the activities of the AMC. AMC members play many professional roles in addition to AMC participation. Because AMC members have developed widely valued expertise and interests, it is anticipated that there will be relationships between some AMC members and companies that form a portion of their professional activities outside of the AMC. Such interactions should not be viewed as ones that necessarily engender conflicts of interest and/or influence the decisions of AMC members as they relate to AMC studies. This document outlines the AMC's approach to financial disclosure and management of any real or perceived conflicts of interest to avoid the potential for or appearance of bias in the AMC's research.

Title 42 CFR Part 50, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought," requires the AMC to establish and manage a system that ensures that the design, conduct, and reporting of research is not biased by any conflicting financial interest. Additionally, the AMC occasionally collaborates with pharmaceutical sponsors and conducts investigator-initiated studies that are subject to the requirement for an Investigational New Drug (IND) application, which necessitates investigator disclosure of financial interests for compliance with investigator reporting requirements at 21 CFR 312.64(d), as described in Title 21 CFR Part 54, "Financial Disclosure by Clinical Investigators." This guideline sets forth the procedures and forms to obtain investigator statements for both purposes.

Routine disclosure of significant financial interests (SFI) by AMC members (who are identified in the Definitions Section) will be reviewed by the AMC's designated institutional officials for FCOI identification, the AMC Executive Committee (EC). In cases where the designated institutional official and the Investigator cannot resolve a financial conflict of interest, the matter will be referred to the AMC Group Chair and/or OHAM representatives for resolution. The EC is ultimately responsible for reviewing and resolving any financial conflict of interest occurring in the AMC.

## 2.0 SCOPE

This policy applies to all PHS-funded research conducted by the AMC, including all clinical trials and laboratory studies from the time of EC or Steering Committee (SC) approval of the protocol concept thereafter, and other research activities sponsored by the AMC grant that are designed, conducted, and reported by AMC investigators, as the term "investigator" is defined herein.

## 3.0 GUIDING PRINCIPLES

Generally, AMC members who disclose SFIs that are identified as financial conflicts of interest consistent with this policy will be:

- Excluded from leadership on a protocol team for studies in which evaluating a product of that company is a major focus;
- Required to recuse himself or herself from voting on questions or matters involving products of that company; and/or,
- Required to limit accrual and/or abstain from participating in any AMC trials that are specifically related to the FCOI.

## 4.0 DEFINITIONS

This SOP relies on the applicable regulatory definitions outlined at 42 CFR 50.603. Clarifications on the AMC's implementation of the regulatory definitions for this policy are provided where noted.

### 4.1 Investigator

Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of AMC research. For the AMC's purposes, investigators responsible for submitting financial disclosure forms include:

- Sites and sub-sites' principal investigators;
- All site sub-investigators, defined as qualified research personnel who directly perform clinical assessments to address research study endpoints (i.e., independently performs treatment response or adverse event evaluations reported in the source documents),
- Sub-investigators who serve as the local principal investigator on an AMC protocol;
- AMC statisticians;
- Anyone participating on a protocol team (excluding Federal Government employees, ACSR representatives, and industry representatives);
- AMC Working Group (WG) members;
- AMC Executive Committee members; and,
- The AMC Data Safety Monitoring Board (DSMB) members.

Each investigator must report his/her financial interests and those of his/her family members, defined as spouse/partner or dependent child.

### 4.2 Entity

Any domestic or foreign, public or private, commercial or nonprofit, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

### 4.3 Institution

Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding, such as the AMC.

### 4.4 Institutional Responsibilities

An Investigator's professional responsibilities on behalf of the AMC. For the AMC's purposes, this includes, but is not limited to, activities such as the performance, analysis, or reporting of clinical and laboratory research; protocol development, review, and consultation; WG membership; and service on the AMC Data and Safety Monitoring Board or other committees.

### 4.5 Financial Interest

Anything of monetary value received by the investigator (or his/her spouse or dependent children from a relevant entity. All payments made on behalf of a company, including its agent or contractor reimbursements, whether made directly or indirectly, or provided to the investigator or his/her spouse or dependent child, should be considered in determining the **aggregate** total of the monetary interest in an entity.

## 4.6 Significant Financial Interest

A financial interest of the investigator that reasonably appears to be related to the Investigator's responsibilities with the AMC (i.e., held in an entity whose products are or could reasonably become the subject of the AMC's research), consisting of one or more of the following interests:

### 4.6.1 Remuneration

Includes salary, direct salary support from research or service grants or contracts, membership on clinical or scientific advisory boards, and any payment for services not otherwise identified as salary, such as consulting fees (including lecturer fees), honoraria, gifts, or paid authorship received over the 12 months preceding the disclosure that, when aggregated for the investigator and family members, totals $5,000 or more.

### 4.6.2 Equity Interests

Any equity interest in an entity (e.g., stocks, stock options, or other ownership interests) that when aggregated for the investigator and family members totals $5,000 or more in value for publicly traded entities, or $0 for non-publicly traded entities, as determined through reference to public prices or by fair market value. In addition to the regulatory requirements, the AMC requires investigators to report any equity interest of more than a 5 percent ownership in any single entity.

### 4.6.3 Income from Intellectual Property Interests

Intellectual property rights with an entity (patents, copyrights, licensures, and royalties) that, when aggregated for the investigator and family members, totals $5,000 or more, upon receipt of income related to such rights and interests.

### 4.6.4 Sponsored or Reimbursed Travel

All travel that is either reimbursed or paid on behalf of an Investigator (and his/her family members) and not reimbursed to the Investigator (so that the exact monetary value may not be readily available), by an entity, that is related to his or her institutional responsibilities. Disclosure of sponsored or reimbursed travel will include the purpose of the trip, the identity of the sponsoring entity, the destination, and the duration of the trip. The approximate monetary value of the trip may be requested for review of any travel.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by a 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.

### 4.6.5 Exceptions

As per Title 42 CFR 50, the following do not constitute significant financial interests and do not require Investigator reporting:

- Salary, royalties or other remuneration provided by the Investigator's local institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- 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;

- Income from seminars, lectures, or teaching engagements sponsored by a 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
- Income from service on advisory committees or review panels for a 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.

### 4.7 Financial Conflicts of Interest

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.

### 4.8 Manage

Manage means taking action to address a FCOI, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

### 4.9 Senior/Key Personnel

Senior/key personnel means the project director, principal investigator, and any other person identified as senior/key personnel by the AMC in the grant application, progress report, or any other report submitted to the PHS by the AMC. For the AMC's purposes, this will include all WG and other committee members, site principal investigators, protocol chairs, and co-chairs. FCOIs held by senior/key personnel are subject to public disclosure.

## 5.0 INVESTIGATOR RESPONSIBILITIES AND PROCEDURES

Each investigator should keep in mind the potential for FCOIs as he/she pursues AMC research. If an investigator has questions or concerns about undertaking an activity with which the investigator may have an FCOI, he/she shall bring such concerns to the attention of the responsible protocol team, WG, Group Chair, or EC.

### 5.1 Open Disclosure of Financial Interests during AMC Deliberations

As the AMC is continually involved in research protocol development with different entities' products, AMC investigators may have new conflicts of interest arise as new AMC studies are proposed. Open disclosure will facilitate preventing potential conflicts of interest. To encourage objectivity at all stages of research development, Investigators shall self-disclose significant financial interests or identified conflicts of interest with entities whose products the AMC is considering or employing for research during all AMC WG, SC, and EC deliberations, and any other committee or group meetings that concern AMC research, and abstain from voting on any such matters.

### 5.2 Agreement to Comply with the AMC FCOI Policy

Each AMC member site shall certify as part of its written sub-award agreement with EMMES and the Group Chair's institution that the AMC's financial conflicts of interest policy will apply to the sub-awardee institution for the purpose of AMC participation, for the duration of the member site's participation on the AMC grant. The principal investigator at each AMC member site will be

responsible for ensuring the compliance of all applicable AMC investigators at his/her site with this policy. Investigator disclosures of financial interests will be submitted using the AMC's Financial Interests Statement according to the time frames specified within this policy.

## 5.3 Financial Disclosure Form Submission

All AMC members are required to complete an annual AMC Financial Interests Statement (form provided at Appendix A) to disclose any SFIs **that appear to be reasonably related to the investigator's institutional responsibilities with the AMC**, or certify the absence of any SFIs. The Statement will be submitted to the AMC ODMC on September 1 of each year. Each completed statement should cover all SFIs received by the investigator during the prior 12 months, and include all previously reported SFIs still held by the investigator and any other updated information.

### 5.3.1 New AMC Investigators' Financial Disclosure Statements

Institutions applying for new AMC membership are required to submit the AMC Financial Interests Statement following acceptance of the AMC membership application. New AMC investigators at existing AMC member sites are required to submit a Statement within 30 days of joining the AMC. Subsequent Statements must be provided annually as required in section 5.3.

### 5.3.2 Required Updates to Financial Interests Statements

Investigators must provide a new AMC Financial Interests Statement within 30 days should he/she obtain any new SFIs that appear to be related to the Investigator's responsibilities with the AMC (e.g., through purchase, inheritance, or marriage), or immediately upon the AMC Leadership's discovery of noncompliance with this policy or other request for an updated Statement. Subsequent Statements must be provided annually as required in section 5.3.

The AMC EC will also request an updated Financial Interests Statement prior to the review of any new protocol concepts submitted. Alternatively, the investigator may indicate in writing there are no changes from the Financial Interest Statement currently on file with the AMC.

## 5.4 Investigator Training on Financial Disclosure

Federal regulation requires investigators to undergo quadrennial training on the regulatory requirements at 42 CFR 50, the AMC's FCOI policy, and the investigator's responsibilities to disclose financial conflicts of interest. For the AMC's purposes, initial training and retraining at four-year intervals will be accomplished by investigator review of the training materials provided on the AMC Operations web site and completion of the accompanying documentation. Retraining will occur by September 1 of every four year period, to coincide with submission of the AMC Financial Interests Statement. Questions regarding this policy, Investigator requirements, or Federal regulation may be sent to the Group Chair and AMC ODMC.

### 5.4.1 New Investigators' Financial Disclosure Training

New investigators at new AMC sites and new investigators at existing AMC sites will be required to complete training and submit required documentation within 30 days of initiating AMC membership and before participation in any AMC trials or discussion of any AMC concept, LOI, or trial.

#### 5.4.2 Investigator Retraining

All investigators must complete re-training on the AMC's financial disclosure policy by September 1 every four years, upon a revision of this policy that affects the nature of investigator reporting of SFIs, or immediately upon the AMC Leadership's discovery of noncompliance with this policy. Training completion documentation must be provided for each instance of re-training as required in section 5.4.

### 5.5 Management Plans

The EC or its designee may request that investigators who report SFIs that are related to AMC studies and appear to be FCOIs to provide a description of how the SFI relates to the AMC's research and a suggested management plan for reducing or eliminating an FCOI. The final decision on an appropriate management plan will be made by the EC or its designee, and will require the Investigator's agreement to comply with the management plan and the conditions for monitoring the management plan, if necessary.

### 5.6 Penalties for Noncompliance

Investigator noncompliance with this policy will be strictly enforced in accordance with Federal requirements. The AMC is required to report to NIH any investigator who fails to disclose any SFIs that constitute FCOIs, fails to comply with the conditions of a management plan, or otherwise fails to comply with the Institution's policy. Noncompliance with this policy will require the AMC to conduct a retrospective review and report the noncompliance to NIH, and to develop a mitigation plan if bias is found.

An Investigator's participation in all AMC studies will be temporarily suspended upon discovery of the following instances of noncompliance with this policy, until further notice from the EC or its designee:

- Failure to supply an AMC Financial Interests Statement by required SOP deadlines;
- Failure to complete initial or repeat training on financial disclosure as outlined in Section 5.4;
- Failure to comply with follow-up requests for information or supply the investigator's proposed management plan within requested timelines by the EC or AMC ODMC;
- Participation in prohibited activities as indicated in the EC approved conflict of interest management plan; or,
- Other noncompliance with the required timelines or stipulations of this SOP.

Suspension of the investigator's participation in all AMC studies will continue until the Investigator submits any delinquent Statements, training certification, management plans, or required information and compliance with this policy and/or the absence of any FCOIs is confirmed by the EC or its designee. Further sanctions against the offending individual(s) or specific remedies for serious cases of noncompliance (e.g., failure to comply with the conditions of a management plan) will be determined by the Group Chair in consultation with the EC, up to and including suspension or termination from further AMC participation.

## 6.0 AMC INSTITUTIONAL RESPONSIBILITIES AND PROCEDURES

The responsibility for reviewing Investigator's AMC Financial Interests Statements for FCOI identification, coordinating development and monitoring of appropriate management plans, securing investigator agreements, reporting to NIH, and enforcing compliance with this policy and Federal Regulation will be shared by the EC, AMC WG Chairs, and the AMC ODMC, as those roles and procedures are defined below.

## 6.1 Role of AMC ODMC

The AMC ODMC will assign a Financial Disclosure Coordinator (FDC), who will serve as a designated institutional official for the AMC for the purpose of soliciting information required by this policy. The AMC ODMC will generally be responsible for soliciting Statements, facilitating communications between investigators, WGs, and the EC for review of Statements, assisting in the development of training materials, maintaining records of disclosed SFIs and providing reports as required for review, monitoring reporting timelines and Investigator compliance with this policy, providing guidance on compliance with Federal regulation, and compiling information and reports for the Group Chair's institution to perform all reporting requirements via eRA Commons.

## 6.2 Role of AMC Working Group (WG) Chairs

The AMC WG Chairs, led by the Group Chair, will hold the primary responsibility for identifying significant financial interests held by AMC Investigators that constitute FCOIs during early development of new protocol concepts. As supplied by the AMC ODMC, the appropriate AMC WG Chair(s) will review reported SFIs at the time of the review of new protocol concept review. The WG chairs, with assistance from the Group Chair as needed, will be responsible for determining whether a new protocol team has a FCOI for a proposed research study prior to submitting new protocol concepts to the SC for approval.

## 6.3 Role of AMC Executive Committee

The EC, led by the Group Chair as the AMC grant holder, will develop, maintain, and oversee this Financial Disclosure Policy. The EC will educate AMC members about the requirements and ensure their compliance with the Guidelines. The EC will serve as the designated institutional officials for providing guidelines for FCOI identification, rendering final determinations on identified FCOIs, approving management and mitigation plans, providing conclusions for retrospective reviews, and issuing and monitoring enforcement mechanisms and remedies to address noncompliance with this policy.

Not less than annually, the EC will review reports provided by the FDC regarding the compliance and management of the program, including conflicts of interest for EC members. The EC will also address conflict of interest issues pertaining to AMC members if the Group Chair or WG chair are conflicted as per this SOP. If the EC determines a conflict exists for an EC member in the course of the EC's deliberations, it will request that the EC member submit in writing a proposed conflict management plan for the conflicting interest and at a minimum, abstain from voting on the related AMC research.

## 6.4 Review of SFIs and Identification of FCOIs

### 6.4.1 Review Process and Timelines

The FDC will solicit and collect Statements from investigators on an annual basis and as new Statements are required from new AMC sites, new investigators, or updated forms are needed from existing AMC members. Within 3 business days of the September 1 submission deadline, the receipt of any new or updated Statements, or notification that a new AMC protocol concept has been approved by the WG for development, the FDC will perform a review of the applicable Statements for completion and forward information on reported SFIs, if any, to the AMC EC (or WG for protocol concepts) for review.. The FDC will report AMC members who are delinquent in providing annual Statements and/or

training certification to the AMC Group Chair and will provide a summary list of disclosed SFIs and related information to the EC for review.

Within 3 weeks of receipt of a list of any new SFIs, the EC will review those reported SFIs to determine whether those SFIs are related to the AMC's research, and if related, whether the SFI constitutes an FCOI. The EC's determination for each investigator's reported SFIs will be documented. The EC may also recommend a management plan at the time of this review. If a WG chair identifies a potential FCOI with a proposed AMC protocol concept, the WG chair will request a written management plan and require that the investigator eliminate any identified FCOIs with the proposed research or alter the investigation and/or protocol team prior to submitting the protocol concept for SC review.

Once the FDC is informed of the FCOI review outcome, the FDC will notify the Investigator within 3 business days of the FCOI determination and request that the investigator provide a management plan or address a suggested management plan. At a minimum, an interim management plan for any identified FCOIs must be negotiated and approved by the EC or Group Chair within 8 of the weeks of the Investigator's submission of the Statement (September 1 annual Statement, new investigator Statement, or updated Statement). All identified FCOIs, including all required reporting elements will be reported to NIH within 60 days of receipt or at the time of progress report submission, in compliance with Federal regulation.

#### 6.4.2 FCOI Criteria

A FCOI exists when the institutional officials (the AMC EC) reasonably determine that the SFI is: 1) related to the PHS-funded research, and 2) could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. An Investigator's SFI is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. Generally, a SFI could affect the design, conduct, or reporting of research if the SFI could compromise the investigator's actual or perceived objectivity. If the EC is unable to determine whether an FCOI exists, the final determination will be made by the Group Chair. The EC will review any SFIs reported by the Group Chair.

## 6.5 Management of Identified FCOIs

If the EC, WG chair, or other designee, determines a FCOI exists, the AMC ODMC will request that the AMC member submit in writing a proposed conflict management plan to ensure that the design, conduct, and reporting of research will be free from bias. At a minimum, the management plan will:

- Identify role and principal duties of the investigator
- Detail the conditions of the management plan, and
- Describe how the plan will safeguard the objectivity of the affected research.

The investigator must agree to the management plan, monitoring of the plan, and any other requirements as needed. A template management plan that outlines all required elements is provided in Appendix B. Management plans should include one or more actions to manage, reduce, or eliminate such conflicts of interest, including but not limited to the following options:

- Public disclosure of significant financial interests in the informed consent form for participants, study publications, or reporting to grant staff and/or IRBs;

- Monitoring of research by independent reviewers, such as the AMC DSMB, NIH, or other third party;
- Modification of the research plan;
- Change of personnel or responsibilities, or disqualification from participation in all or a portion of the study;
- Limiting enrollment by that investigator's institution in the particular protocol(s) associated with the FCOI to no more than 10% of the total sample size;
- Limiting the investigator's role in subject selection, consent, participant evaluations, or data analysis;
- Disallow an investigator to serve as protocol chair;
- Peer review of investigator's research records;
- Reduction or divestiture of significant financial interests;
- Severance of relationships that create conflicts;
- Requiring prior notification to AMC leadership before divesting financial interests;
- Redirecting royalties to a nonprofit organization; and/or,
- Limiting compensation for conflicting activity.

The management plan may be modified by the EC, who will render the final approval of the management plan. Monitoring of any management plans for the duration of the conflicting research activity/ies may be delegated to the AMC ODMC and/or WG Chairs, as appropriate.

### 6.6 Retrospective Reviews

Regulation requires that the AMC conduct a retrospective review of an Investigator's activities in AMC research in the event a FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a SFI that is determined to constitute a FCOI, the AMC fails to review or manage a FCOI, or an Investigator fails to comply with a management plan for an FCOI. This retrospective review will occur within 120 days of the AMC's discovery of noncompliance. The Group Chair and/or assigned review team members, which may include WG chairs, protocol chairs, EC members, and/or AMC statisticians, will perform an assessment of the Investigator's involvement in the conflicting research activity/ies to determine whether any portion of the research conducted during the period of noncompliance was biased in the design, conduct, or reporting. The FDC will assist the review team in scheduling the review, compiling any required materials, documenting the retrospective review for the AMC's files, and reporting the FCOI and the retrospective review to NIH. A template is provided at Appendix C for certifying completion of retrospective reviews to meet regulatory reporting requirements.

### 6.7 Mitigation Plans for Instances of Bias

In the event that bias is found during a retrospective review or any other aspect of the AMC's research, NIH will be notified within 5 business days. This notification will be followed by the findings from the retrospective review, to also include an assessment of the effect of the bias on the affected protocol(s) and the AMC's actions to eliminate or mitigate the effect of the bias. The Group Chair, with input from the review team, the EC, and OHAM and/or CTEP representatives as necessary, will determine the necessary measures to address any bias.

### 6.8 Annual Reporting to NIH

As the grant awardee, the Group Chair, with his/her office, will report annually to the National Cancer Institute a summary of the AMC Disclosure Policy and any modifications of the policy via the eRA Commons FCOI module, beginning with an initial report by August 24, 2012 to comply

with the enactment date for the revised reporting requirements. This report will be made in accordance with regulatory requirements for content, to include a copy of the AMC's current policy, and: the project number, PI/PD name, name of each Investigator with a FCOI, entity with the FCOI, the nature of SFI, the SFI amount in dollar ranges, a description of how the SFI relates to the research, the WG or Group Chair's basis that the SFI constitutes an FCOI, and key elements of management plan. Subsequent reports will be made annually on July 1, to include any changes to the AMC's policy, any new or ongoing FCOIs, and associated management plans. The Group Chair's office, with assistance from the AMC ODMC, will perform all other reporting to NCI as described by this policy within the timelines required by regulation.

### 6.9 Public Disclosure

The AMC ODMC will maintain a copy of the AMC's Financial Conflicts of Interest Policy on the AMC's publicly-accessible website, located at www.amcoperations.com. Any updates to the AMC's policy will be posted to the website within 30 days of the EC's approval of that revision.

The AMC ODMC will provide a web e-mail link on the AMC's publicly-accessible website for interested members of the public to submit a written request to the AMC ODMC for information concerning identified FCOIs held by senior/key personnel. This report will consist only of identified FCOIs that have not been eliminated by the senior/key personnel. The content of the report to interested parties will be limited to the investigator's name, his/her role in the AMC, the entity in which he/she holds the SFI, the amount of the SFI in dollar ranges, and nature of the SFI (stock, royalty, etc.). The AMC ODMC will provide this information to any interested party via e-mail within 5 days of receipt of the request.

### 6.10 Recordkeeping

The FDC at the AMC ODMC will maintain files of all Statements of Significant Financial Interests submitted to the Operations Office and any associated documentation regarding SFI review and FCOI management. The FDC will maintain database records of AMC members disclosing significant interests by relevant entity and supply those records to assist the Group Chair, EC, and WG Chairs as required. The FDC will also maintain documentation for all management plans, all retrospective reviews, any relevant documentation for mitigation plans, and relevant communications associated with these records. The AMC ODMC will maintain records of all actions taken by the AMC with respect to each conflict of interest for at least three years from the date of the final expenditure report of the grant and make information available to NIH as necessary regarding all conflicts of interests identified by the AMC and how those conflicts of interest have been managed, reduced, or eliminated.

The AMC ODMC will update the report of senior/key personnel's FCOIs for public disclosure within 60 days of any newly identified FCOI. Copies of the report and each update will be maintained for three years after each update. The AMC ODMC will also maintain a log of the name, e-mail address, and affiliation of any parties who request information on AMC investigators' FCOIs.

### 6.11 Group-level Conflict of Interest

At the time of protocol submission to CTEP for review, the AMC will indicate the extent of any non-government funding for the given study. Should subsequent non-government support for the study be forthcoming that was not known at the time of original protocol submission, notice will be provided to CTEP and OHAM if the support constitutes a financial conflict of interest.

## 7.0 ROLE OF THE NATIONAL CANCER INSTITUTE

As the PHS Awarding Component, when NCI staff have concerns that a conflict or perceived conflict of interest may exist, this information will be forwarded to the EC for determination and appropriate action. The NCI will consult with the EC about any general issue or specific problem that may arise during the course of any NCI-sponsored trial, and the NCI may provide instructions or further guidance on managing any issues, ensuring objectivity in research, or addressing specific instances of Investigator noncompliance with this policy.

The Director of OHAM or his/her designee may review these guidelines, make appropriate recommendations, and provide final approval for this SOP.

An audit of the Financial Disclosure and Conflict of Interest Program of the AMC (including guidelines, education, and implementation) may be undertaken by NCI as part of the performance evaluation of the group.

Should the NCI or any other reviewing party at the NIH determine that an AMC research study that was conducted to evaluate the safety or effectiveness of a drug, medical device, or other treatment was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by regulation, the AMC will ensure that the Investigator discloses the FCOI in each public presentation of the results of that research and amend any previously published presentations or publications to disclose the FCOI.

## APPENDIX A: AMC FINANCIAL INTERESTS STATEMENT

Name of AMC Member (Please Print): _____ Date of Statement: _____

Primary Institution: _____

Position I hold within the AMC that requires submission of this form: _____

**I have significant financial interests to disclose (initial one).** Yes _____ No _____

| Entity Name | SFI Type | Value Range | Investigator Comments* |
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* Provide any comment and/or describe how the SFI is reasonably related to your institutional responsibilities. If the SFI is sponsored or reimbursed travel, the investigator is required to report the duration, destination, and purpose of the travel.

**Investigator Statement**

The financial interests I have disclosed above, or absence thereof, are true, complete, and correct. I give my permission to disclose this information to the AMC and the NIH, and for the AMC to publicly disclose identified financial conflicts of interest with AMC research upon written request, in compliance with Federal regulation.

Signature: _____ Date: _____

## GUIDELINES FOR COMPLETING STATEMENT OF FINANCIAL, EQUITY, AND INTELLECTUAL PROPERTY INTERESTS

On the attached *AMC Financial Interests Statement*, please refer to the following instructions for each form field for reporting Significant Financial Interests. A reportable significant financial interest meets all three of the following criteria:

1. **The financial interest reasonably appears to be related to your responsibilities as an AMC member (i.e., the financial interest could be reasonably related to AMC studies).**

   AND

2. **The financial interest was received in the prior 365 days.**

   AND

3. **When aggregated for the investigator and his/her family members for each entity:**
   a. The total value of the SFI **exceeds $5,000** (SFI types listed below); *OR*,
   b. The SFI is an equity interest (stock, stock option, or other ownership interest) **in a non-publicly traded company that exceeds $0**; *OR*,
   c. The SFI is **reimbursed or sponsored travel that exceeded $0** (non-government, academic, or medical center).

If the investigator does not have any significant financial interests to disclose, initial "No," sign the form, and submit the form to the AMC ODMC. If the investigator does have significant financial interests to disclose, initial "Yes" and complete the subsequent table fields for each reportable SFI, by entity.

**Entity**: List the designated business name of the entity in which the investigator holds an SFI.

**SFI Type:** List one or more of the following SFI types to identify the nature of the SFI.

1. Salary/salary support (paid directly to you by a non-government, academic, or medical center entity)
2. Consultant fee (paid directly to you or resulting in direct salary support if paid to the institution)
3. Lecture fee (paid directly to you or resulting in direct salary support if paid to the institution)
4. Equipment
5. Gift
6. Honorarium
7. Research grant (paid directly to you by a non-government, academic, or medical center entity)
8. Research contract (paid directly to you by a non-government, academic, or medical center entity)
9. Service grant (paid directly to you by a non-government, academic, or medical center entity)
10. Service contract (paid directly to you by a non-government, academic, or medical center entity)
11. Membership on a scientific or clinical advisory board membership
12. Stock (owned by you or a family member)
13. Stock option (owned by you or a family member)
14. Patent (held by you, or you and others)
15. Pending patent (held by you, or you and others)
16. Patent (held by third party)
17. Copyright
18. Trademark
19. Licensing agreement
20. Royalty (assigned to the investigator)
21. Travel that is reimbursed to you or sponsored (non-government, academic, or medical center)

**Value Range:** The value of any reported SFIs may be reported in the following ranges: amounts between $0 - $29,999 by increments of $5,000 (e.g., $0 - $4,999, $5,000 - $9,999, $10,000 - $14,999), amounts between $30,000 - $100,000 by increments of $10,000, amounts above $100,000 by increments of $50,000, or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value (list "indeterminate").

**Comment on Relationship to AMC Research**: Provide any comments regarding the interest and a brief description of how the SFI appears to be reasonably related to your institutional responsibilities (i.e., entity's products are the subject of current or planned research). If the financial interest is reimbursed or sponsored travel, investigators must also report the duration (in days), destination(s), and the purpose of the sponsored travel.

If additional rows are required to disclose SFIs, attach additional pages as necessary.

## APPENDIX B: MANAGEMENT PLAN FOR FINANCIAL CONFLICTS OF INTEREST WITH AMC RESEARCH STUDIES

| |
|---|
| **Investigator name:** |
| **AMC role and principal duties:** |
| **Identified FCOI(s) to be managed by this plan:** |
| **Conditions of the management plan:** |
| **Description of how the management plan is designed to safeguard objectivity:** |
| **Procedures for monitoring:** |
| **Milestones or timeframe for monitoring:** |
| **Comments or additional considerations:** |

**Certification of Approval and Compliance**

I approve the management plan describe above for the Investigator's reported financial conflicts of interest and agree to comply with its stated conditions. I understand that any noncompliance will be reported to NIH and will lead to disciplinary action, up to and including termination from the AMC.

Investigator Signature:_____ Date: _____

Group Chair Signature:_____ Date: _____

## APPENDIX C: FCOI RETROSPECTIVE REVIEW CERTIFICATION

| |
|---|
| **Investigator with FCOI:** |
| **Entity with FCOI:** |
| **Reason for Retrospective Review:** |
| **Review Team Members:** |
| **Documents Reviewed:** |
| **Methodology for Review:** |
| **Findings:** |
| **Conclusions:** |

Group Chair Approval: _____ Date: _____