

AAAP Conflict of Interest Policy

Revised May 2015

Preamble

The American Academy of Addiction Psychiatry (the Academy) promulgates this Conflict of Interest policy to assure its constituents of its continued commitment to the integrity of its staff and associates in the conduct of research and other activities.

Both the National Science Foundation (NSF) and the United States Public Health Service (PHS) require principal investigators and co-principal investigators "to certify that they have read and understood the institution's conflict of interest policy," that they have made all required financial disclosures, and that "they will comply with any conditions or restrictions imposed by the institution to manage, reduce, or eliminate actual or potential conflicts of interest." Moreover, the Academy's representative must certify that the Academy "has implemented and is enforcing a written policy on conflicts of interest," that all financial disclosures required by the conflict of interest policy were made, and that actual or potential conflicts of interests, if any, were, or prior to expenditure of funds under the award, will be satisfactorily managed, reduced or eliminated in accordance with the institution's conflict of interest policy, or disclosed to PHS or NSF.

In its Notice No. 117 dated June 30, 1994 and updated in its Notice No. 118 dated July 13, 1995 on the subject of Investigator Financial Disclosure Policy, the National Science Foundation requires that all grantee institutions employing more than fifty persons have in effect on October 1, 1995 a written and enforced conflict of interest policy. In addition, the Department of Health and Human Services published its final rule on "Objectivity in Research" on July 11, 1995 in the Federal Register (60 FR 35820) to coincide in effective date and requirements with NSF's Financial Disclosure Policy. As the NSF Notice states:

The National Science Foundation encourages the increased involvement of academic researchers and educators with industry and private entrepreneurial ventures. But NSF recognizes that such interactions carry with them an increased risk of conflict of interests.

The Public Health Service (PHS) wishes to assure the public that its support to researchers will follow standards and procedures:

to ensure that the design, conduct, or reporting of research funded under ...[its] grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research.

On August 25, 2011, the U.S. Department of Health and Human Services issued its final rule in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). An Institution applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e., August 24, 2012, and immediately upon making the Institution's Financial Conflict of Interest policy publicly accessible as described in 42 CFR part 50.604(a). Accordingly, a new Appendix E has been added to the AAAP Faculty Conflict of Interest Policy in order to implement the new regulation.

Policy Rationale

Funding sources and personal gain represent two aspects about which investigators must be ever mindful, because without clear guidelines there is a possibility for conflict of interest issues to arise. Donors, for example, providing grants to conduct research may sometimes possess a vested or proprietary interest in the research results. Investigators themselves may hold equity positions or policy making authority in an entity from which they would benefit personally by research or other activities sponsored by the entity, a government, or other private agency, and that is conducted using Academy facilities, equipment, or personnel.

In addition, there is a growing number of other types of funded and unfunded interactions between AAAP staff and government, industry and other non-Academy organizations through research, projects and consulting.

With the increased national emphasis on technology transfer and economic competitiveness, it is particularly timely for the American Academy of Addiction Psychiatry to articulate a conflict of interest policy to protect the integrity of the Academy, its staff, and the research process, to encourage the free flow of knowledge and ideas, and to ensure that public and institutional resources are used appropriately.

AAAP's conflict of interest policy now requires annual disclosure by all Investigators and other personnel associated with the Academy (listed in Appendix D).

Disclosure Process

How and to whom should the significant financial interest(s) of an investigator or other staff member be disclosed?

On or before August 31 annually or within sixty (60) days of appointment, each AAAP staff member and other individuals identified in Appendix D shall complete and submit a Conflict of Interest Disclosure Form to the Executive Director and/or current President. The Executive Director shall submit this form to the current President.

AAAP policy shall require Investigators to complete a Conflict of Interest Disclosure Form (see Appendix A) at the time the Principal Investigator submits a proposal to either PHS or NSF. This form includes check boxes in which the respondent shall indicate whether or not a conflict of interest exists or is likely to exist in connection with the proposal being submitted. Co-investigators and any other individuals who are expected to participate in the design, conduct, and/or reporting of the research also must complete a Conflict of Interest Disclosure Form (see Conflict of Interest Disclosure for NSF and PHS Submissions, Appendix B) concurrent with submission of the form by the Investigator.

Any Disclosure Statements, whether submitted in satisfaction of the NSF or PHS proposal submission requirement or in fulfillment of the AAAP annual disclosure requirement, must be updated when a new reportable Significant Financial Interest (SFI) or potential conflict of interest exists.

Annual Review Process

All staff identified in Appendix D must file the Annual Conflict of Interest Disclosure Statement contained in Appendix C with his/her Department Head annually by August 31 and as any significant changes occur. The individual shall, to the best of his/her knowledge, include in the Disclosure Statement the same information for his/her family, as defined by this Policy. The Executive Director and AAAP Board members shall file with the AAAP President.

Upon receipt of each annual or updated Disclosure Statement, the Executive Director and/or AAAP President will make a review for adequacy, requesting additional information from the

individual who completed the form, as necessary. If the answers to the four questions on Part I of the Disclosure Statement are “no,” then no further review is required. The Disclosure Statement should be maintained in the AAAP general file, the central repository for all Disclosure Statements. No additional action will be required of the submitting individual unless a significant change occurs prior to the next annual due date. If the answer to any of the four questions on Part I of the Annual Conflict of Interest Disclosure Form is “yes, the Executive Director and/or AAAP President will determine if any identified real or apparent conflict appears to be significant. If so, the Executive Director and/or President will forward the disclosure to the Full Board to gather further information and supporting documentation from the individual. The Disclosure Statement will then be brought to the attention of the Committee on Professional Development and Continuing Medical Education (CPD/CME) for resolution. All such documentation and subsequent discussions will be confidential. The individual will have an opportunity to meet with the CPD/CME Committee to explain the financial documentation and to discuss options for management of the conflict. Should the findings indicate significant potential conflict of interest, the CPD/CME Committee will consult with the submitting individual to devise a plan to effectively eliminate, reduce, or otherwise manage the conflict. If the Committee cannot come to an agreement with the individual and concludes that a significant conflict of interest to AAAP’s interests appears to remain, the Committee will refer the matter to the AAAP President to inform the individual.

Review Process for NSF and PHS Proposals

Should a disclosure associated with any NSF or PHS submission indicate a potential or actual conflict of interest, the Executive Director will advise the AAAP President, who will gather further information and supporting documentation from the investigator and take the matter to the CPD/CME Committee for resolution. All such documentation and subsequent discussions will be confidential. The investigator will have an opportunity to meet with the CPD/CME Committee to explain the financial documentation and to discuss possible conditions or restrictions. Should the findings indicate significant financial interest, the CPD/CME Committee will impose conditions or restrictions to effectively manage, reduce, or eliminate the conflicts. The CPD/CME Committee will use as guidelines this policy statement and, as appropriate, Appendix E for PHS submissions, including the definitions of significant financial interest and conditions or restrictions found in the section of **Definitions**.

If the CPD/CME Committee determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology

transfer, or the public health and welfare, then the CPD/CME Committee may recommend to the AAAP President that the research be permitted to go forward without imposing such conditions or restrictions. In such cases, the conflict of interest of the investigator(s) will be disclosed to the government agency as required.

Appeal Process for NSF and PHS Proposals

Should the disclosing individual (as defined in Appendix D) not agree with the CPD/CME Committee's conditions or restrictions, he/she can appeal in writing to the AAAP President within ten (10) days after receipt of notification from the Executive Director, outlining specific issues and why such conditions and restrictions are inappropriate. The AAAP President will then consult with the CPD/CME Committee; it is possible that a modification of the conditions and restrictions will be agreeable to all parties. However, the decision of the AAAP President is final.

Definitions (Note that several different and/or additional definitions are contained in Appendix E to this policy relating to the PHS regulations)

Conflict of Interest

A *conflict of interest* may take various forms but arises when an individual is or may be in a position to influence Academy business, research, or other decisions in ways that could lead to any form of personal gain for the individual or his/her family, or give improper advantage to others. A real or perceived conflict of interest may also arise when someone engages in an action or decision that compromises the integrity of teaching, research, advising, or scholarship.

Family

The *family* of a disclosing individual means spouse, minor children, parents, grandparents, and other persons who may be financially dependent upon the disclosing individual.

Investigator

The term *Investigator* means the principal investigator, co-principal investigators, and any other person at the Academy who is responsible for the design, conduct, or reporting of research or educational activities.

Relationships which can give rise to conflicts of interest

Relationships as used in this policy include relationships with others which can give rise to real or perceived conflicts of interest. These include, among others, personal relationships created by kinship, friendship, or professional contacts, and financial relationships created by contracts, shared property rights, or state or Federal law. Though a domestic partnership may create a real or perceived conflict of interest, this policy is not meant to force disclosure of one's sexual orientation. By policy, AAAP does not discriminate on the basis of sexual orientation.

Significant Financial Interest

The term *significant financial interest (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) when related to the subject matter of the individual's research and/or scholarly activities, including teaching and advising. The term does not include:

- salary, royalties or other remuneration from the Academy;

- income from service on advisory committees or review panels for public or nonprofit entities;

- financial interests in business enterprises or entities if the value of such interests does not exceed \$5,000 or does not represent more than a 5% ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's family;

- royalties or other payments that, when aggregated for the investigator, and the investigator's family, are not expected to exceed \$5,000 during the twelve-month period preceding or following submission; or

- income from self-authored textbooks, software, etc. that are used for teaching purposes.

A significant financial interest becomes a conflict of interest if it could result in personal gain, advantage to others to the detriment of AAAP, or influence the outcomes of research and/or other activities.

Conditions or Restrictions

Examples of *conditions or restrictions* that might be imposed to manage, reduce or eliminate actual or potential conflicts of interest include:

public disclosure of significant financial interests;

monitoring of funded research by independent reviewers;

modification of the funded research plan;

disqualification from participation in the portion of the NSF- or PHS-funded research that would be affected by the significant financial interests;

divestiture of significant financial interests; or

severance of relationships that create actual or potential conflicts.

Committee on Professional Development and Continuing Medical Education (CPD/CME)

membership shall consist of two members of the AAAP Board, AAAP Executive Director and/or the AAAP President, as well as the Director of the CPD/CME Committee. In the event that more than one alternate should be needed, the AAAP President shall appoint additional alternates as necessary. Recusal shall be required when it appears that a member of the CPD/CME Committee will be unable to fairly judge a potential conflict raised by a disclosure statement. All such potential conflicts of interest of committee members must be disclosed to the committee in advance of the proceedings, and the committee will vote to determine whether recusal is required.

Instructions

To comply with this policy regarding the submission of an annual Disclosure Statement, each AAAP staff member must complete the Conflict of Interest Disclosure Form and any updates on or before August 31 of each year and forward it to the AAAP Executive Director and/or AAAP President.

In addition, to comply with this policy regarding authorization for the submission of a proposal for funded research to the NSF and/or PHS, an Investigator will

1. in accordance with the Explanation and Instructions, complete and sign the Conflict of Interest Disclosure Form and require any co-investigators and/or other key personnel to complete and submit a Conflict of Interest Disclosure Form for funded research, Appendix B.

2. submit a request to the AAAP Executive Director and/or AAAP President to review the Conflict of Interest Disclosure Form and any accompanying Conflict of Interest Disclosure Forms and sign them.
3. submit the Conflict of Interest Disclosure Form(s) together with the NSF or PHS proposal to AAAP's Director, Grants Administration and Compliance, when requesting submission authorization.

(Revised July 16, 2012)

(Revised September 12,

2012)

September 8th, 2014

CONFIDENTIAL

Appendix A
**The American Academy of Addiction Psychiatry
Conflict of Interest Disclosure for PHS Submissions**

Name _____ Title _____

Department _____ Sponsor _____

Proposal Title _____

PI Name (if not same as above) _____ Expected Submission Date _____

Part I Conflict of Interest Screening Questions (For yes answers, please list and explain in an attached statement)

1. Do you have a consulting or other financial relationship with a sponsor of your research? ____yes ____no
2. Do you have a managerial role or a significant¹ financial relationship with a company in a field of your research or with a company that does business with the Academy? ____yes ____no
3. Do you have non-Academy professional or income-producing activities involving AAAP staff? ____yes ____no
4. To your knowledge, do you or any member of your immediate family have any other relationships, commitments, or activities that might represent or appear to present a conflict of interest with your AAAP appointment? Such relationships may include financial or fiduciary interests or uncompensated activities. ____yes ____no

Part II Listing of Significant Financial Interests

Please list non-Academy income-producing activities including, but not limited to, salary or other payments for services, equity interests in excess of \$5,000, and intellectual property rights (see Explanation and Instructions for detailed requirements and exclusions). Please report only the activities. The AAAP Executive Director and/or AAAP President will seek additional information, as necessary.

Activity/Interest

For Whom

Part III Affirmation

I affirm that I have read the *Conflict of Interest Policy*² and that the above information is true to the best of my knowledge.

Staff Member's Signature _____ Date _____

(Please submit to the AAAP Executive Director or AAAP President, as appropriate)

Administrative Review and Approval

If No Activity is Reported:

____ No activity is reported and, to the best of my knowledge, no conflict of interest or commitment exists.

(Sign form and File in AAAP PHS Proposal File)

If Any Activity is Reported: (Please complete the Conflict of Interest/Commitment Review and sign below)

Conflict of Interest/Commitment Review

Based on the activity reported and, to the best of my knowledge and in my judgment:

- a) ____ No conflict of interest or commitment exists.
- b) ____ A conflict of interest or commitment may exist, but does not appear to be significant.
(If so, please attach an explanation and forward to the AAAP President)

c) ____ A conflict of interest or commitment that warrants further review may exist.

Please complete if question 3 on this form is answered in the affirmative:

As described by the staff member, the involvement of AAAP staff in his/her non-Academy activities does not appear to be detrimental to those individuals.

- a) ____ Agree
- b) ____ Disagree ***(If so, please attach an explanation and forward to the AAAP President)***

Authorized Signature _____ Date _____¹ The PHS considers an ownership interest of more than 5% by you or members of your immediate family to be a significant conflict in purchasing decisions; this may differ in other situations.

²Copies of the *Conflict of Interest Policy* may be obtained from the AAAP Executive Director and/or AAAP President.

The American Academy of Addiction Psychiatry Conflict of Interest Disclosure for NSF Submissions

Name _____ Title _____

Department _____ Sponsor _____

Proposal Title _____

PI Name (if not same as above) _____ Expected Submission Date _____

Part I Conflict of Interest Screening Questions (For yes answers, please list and explain in an attached statement)

3. Do you have a consulting or other financial relationship with a sponsor of your research? ____yes ____no
4. Do you have a managerial role or a significant¹ financial relationship with a company in a field of your research or with a company that does business with the Academy? ____yes ____no
3. Do you have non-Academy professional or income-producing activities involving either AAAP staff? ____yes ____no
4. To your knowledge, do you or any member of your immediate family have any other relationships, commitments, or activities that might represent or appear to present a conflict of interest with your AAAP appointment? Such relationships may include financial or fiduciary interests or uncompensated activities. ____yes ____no

Part II Listing of Significant Financial Interests

Please list non-Academy income-producing activities including, but not limited to, salary or other payments for services, equity interests in excess of \$10,000 or 5% ownership, and intellectual property rights (see Explanation and Instructions for detailed requirements and exclusions). Please report only the activities. The AAAP Executive Director and/or AAAP President will seek additional information, as necessary.

Activity/InterestFor Whom**Part III Affirmation**

I affirm that I have read the *Conflict of Interest Policy*² and that the above information is true to the best of my knowledge.

Staff Member's Signature _____ Date _____

(Please submit to the AAAP Executive Director or AAAP President, as appropriate)

Administrative Review and Approval**If No Activity is Reported:**

____ No activity is reported and, to the best of my knowledge, no conflict of interest or commitment exists.

(Sign form and file in AAAP NSF Proposal File)

If Any Activity is Reported: (Please complete the Conflict of Interest/Commitment Review and sign below)**Conflict of Interest/Commitment Review**

Based on the activity reported and, to the best of my knowledge and in my judgment:

- a) ____ No conflict of interest or commitment exists.
- b) ____ A conflict of interest or commitment may exist, but does not appear to be significant.
(If so, please attach an explanation and forward to the AAAP President)
- c) ____ A conflict of interest or commitment that warrants further review may exist.

Please complete if question 3 on this form is answered in the affirmative:

As described by the staff member, the involvement of AAAP staff in his/her non-Academy activities does not appear to be detrimental to those individuals.

- a) ____ Agree
- b) ____ Disagree (If so, please attach an explanation and forward to the AAAP President)

Authorized Signature _____ Date _____

¹The NSF considers an ownership interest of more than 5% by you or members of your immediate family to be a significant conflict in

purchasing decisions; this may differ in other situations.

²Copies of the *Conflict of Interest Policy* may be obtained from the AAAP Executive Director and/or AAAP President.

APPENDIX C

The American Academy of Addiction Psychiatry Annual Conflict of Interest Disclosure

Name _____ Title _____

Part I Conflict of Interest Screening Questions (For yes answers, please list and explain in an attached statement)

1. Do you have a consulting or other financial or managerial relationship with a sponsor of your research? ____yes ____no
2. Do you have a managerial, fiduciary, or advisory role, a *significant*¹ financial interest² or relationship with a company or organization in a field of your research and/or scholarly activities, including teaching and advising, or with a company or organization that does business with the Academy? ____yes ____no
3. Do you have non-Academy professional or income-producing activities involving AAAP staff? ____yes ____no
4. To your knowledge, do you or any member of your immediate family have any other relationships, commitments or activities that might represent or appear to present a conflict of interest with your AAAP appointment? Such relationships may include financial or fiduciary interests or uncompensated activities. ____yes ____no

Part II Affirmation

I affirm that I have read the Conflict of Interest Policy³ and that the above information is true to the best of my knowledge.

Staff Member's Signature _____ Date _____
(Please submit to the AAAP Executive Director or AAAP President, as appropriate)

Administrative Review and Approval

If No Activity is Reported:

____No activity is reported and, to the best of my knowledge, no conflict of interest exists.
(Sign form and file in the AAAP General File)

If Any Activity is Reported: (Complete the Conflict of Interest Review and forward to the AAAP President)

Conflict of Interest Review

Based on the activity reported and, to the best of my knowledge and in my judgment:

- a) ____No conflict of interest exists.
- b) ____A conflict of interest may exist, but does not appear to be significant.
(If so, attach an explanation)
- c) ____A conflict of interest that warrants further review may exist.

Please complete if question 3 on this form is answered in the affirmative:

As described by the staff member, the involvement of AAAP staff in his/her non-Academy activities does not appear to be detrimental to those individuals.

- a) ____ Agree
- b) ____Disagree (If so, attach an explanation)

Authorized Signature _____ Date _____

¹AAAP considers an ownership interest of more than 5% by you or members of your immediate family to be a significant conflict in

purchasing decisions.

²Here *significant financial interest* is used as defined in the AAAP Conflict of Interest Policy.

³Copies of the *Conflict of Interest Policy* may be obtained from the AAAP Executive Director and/or AAAP President.

APPENDIX D

CONFLICT OF INTEREST POLICY

Individuals Who Must Sign Disclosure

Anyone in a position to affect research, teaching, advising, scholarship, or an AAAP-sponsored CME activity that could affect the Academy adversely including:

1. AAAP President
2. AAAP Executive Committee Members
3. AAAP Executive Director
4. AAAP Staff
5. Any other individuals who might affect research or research results
 - Visiting Scientists
 - Visiting Scholars
 - Anyone submitting a research proposal

Appendix E

AAAP Conflict of Interest Policy (Draft 07/16/12)

Implementation of the Final Rule on Conflicts of Interest in Public Health Service Funded Research

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors

The following policy sets forth the American Academy of Addiction Psychiatry's (AAAP) implementation of the above referenced Final Rule and is applicable to each AAAP Investigator, as defined by the regulation that is planning to participate in or is participating in Public Health Service (PHS) funded research. Relevant sections of the AAAP Conflict of Interest Policy to which this Appendix relates will remain in effect unless superseded by the requirements, as stated in this Appendix.

The policy, which is primarily intended to cover financial assistance awards (grants and cooperative agreements), also shall be used in cases in which the Academy submits a proposal to or receives Public Health Service (PHS) funding by means of a contracting action. Regulatory citations incorporating appropriate parts of 45 CFR Part 94 relating to contracting actions are provided throughout the policy, as needed.

Sections:

- 1. Definitions**
- 2. Disclosure, Review, and Monitoring**
- 3. Reporting to NIH**
- 4. Enforcement Mechanisms**
- 5. Public Accessibility**
- 6. Subrecipient Requirements**
- 7. Training Requirements**
- 8. Records Maintenance**

1. Definitions

Academy means The American Academy of Addiction Psychiatry (AAAP).

Contractor means an entity that provides property or services under contract for the direct benefit or use of the federal government.

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

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.

FCOI report means an institution's report of a financial conflict of interest to a PHS Awarding Component that provides sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict and to assess the appropriateness of the Organization's management plan. Elements of FCOI reports include, but are not limited to, the following information:

- Project number,
- PI/PD or Contact PI/PD if a multiple PI/PD model is used,
- Name of the Investigator or Key Person with the financial conflict of interest,
- Name of the entity with which the Investigator has a financial conflict of interest,
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium),

- Value of the financial interest (dollar ranges are permissible: \$0 - \$4,999, \$5,000 - \$9,999, \$10,000 - \$19,999, amounts between \$20,000 - \$100,000 by increments of \$20,000, amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value,
- A description of how the financial interest relates to the PHS-funded research and the basis for the institution's determination that the financial interest conflicts with such research, and
- A description of the key elements of the institution's management plan, including
 - o Role and principal duties of the conflicted Investigator in the research project,
 - o Conditions of the management plan,
 - o How the management plan is designed to safeguard objectivity in the research project,
 - o Confirmation of the Investigator's agreement to the management plan,
 - o How the management plan will be monitored to ensure Investigator compliance, and
 - o Other information, as needed.

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

HHS means the United States Department of Health and Human Services and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a federal agency) that submits a proposal for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, which includes the following:

- Promoting high quality evidence-based screening, assessment and treatment for substance use and co-occurring mental disorders.

Translating and disseminating evidence-based research to clinical practice and public policy.

Strengthening Addiction Psychiatry specialty training and foster careers in Addiction Psychiatry.

Providing evidence-based addiction education to health care trainees and health professionals to enhance patient care and promote recovery.

Educating the public and influence public policy for the safe and humane treatment of those with substance use disorders.

Promoting prevention and enhance addiction treatment and recovery across the life span.

Promoting research on the etiology, prevention, identification and treatment of substance use and related disorders.

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 PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Key personnel includes the Project Director/Principal Investigator and any other personnel considered to be essential to work performance in accordance with the Health and Human Services Acquisition Regulation (HHSAR) subpart 352.242-70 and identified as key personnel in the contract proposal and contract.

Manage means taking action to address a financial conflict of interest, 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.

Mitigation report means a report submitted to the PHS Awarding Component on a research project as a result of having discovered bias while conducting a retrospective review. Each mitigation report must include, at a minimum, the key elements documented in the retrospective review (see definition of retrospective review) as well

as a description of the impact of the bias on the research project and the institution's plan for taking action(s) to eliminate or mitigate the effect of the bias (e.g., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm, analysis of whether the research project is salvageable).

PD/PI means a Project Director or Principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or *PHS Act* means the statute codified at 42 U.S.C. 201 *et seq.*

Research means a systematic investigation, study or experiment 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 (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Retrospective review means a review that is undertaken after learning that a significant financial interest was not disclosed on a timely basis by an Investigator or was not reviewed by the institution during an ongoing PHS-funded research project. The minimum required information that must be included in a retrospective review includes:

- award number,
- project title,
- Project Director/Principal Investigator (PD/PI) or contact PD/PI for multiple PI models,
- name of the Investigator/Key Person with the financial conflict of interest,
- name of the entity with which the Investigator has a financial conflict of interest,
- reason(s) for the retrospective review,
- detailed methodology used for the retrospective review (e.g., review process, composition of the review panel, documents reviewed),
- findings of the review, and
- conclusions of the review.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant financial interest means:

- (1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's family) that reasonably appears 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. For purposes of this definition, 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 family) holds any equity interest (e.g., stock, stock option, or other ownership interest); or (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel. Please see section 2.A.2) of this policy for a complete discussion of instances requiring Investigator disclosure of travel and exceptions under which such disclosure is not required.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for profit organization; 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.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

2. Disclosure, Review, and Monitoring

A. Disclosure

- 1) Significant financial interests (SFI) that are subject to disclosure by an Investigator to the Academy are those that reasonably appear to be related to the Investigator's "Institutional Responsibilities," as defined by AAAP and in Section 1 of this Appendix. Such disclosure shall take place, a) concurrent with and no later than the submission of an application for a PHS-funded research activity, b) in the absence of an application for a PHS-funded research activity, at least annually during the period of any current PHS-funded award, and/or c) within 30 days of discovering or acquiring a new SFI.

In the case of a) above, disclosure of an SFI shall be made to the AAAP Executive Director or AAAP President, as appropriate, via the completion of a AAAP Conflict of Interest Disclosure Form, which must be provided no later than the day on which an application for a PHS-funded research is to be submitted.

For b) above, on or before August 31 annually or within sixty (60) days of appointment, each individual individual(s) identified in Appendix D shall complete and submit a disclosure of SFI to the AAAP Executive Director or AAAP President, as appropriate.

And in the instance when c) above applies, a new disclosure must be completed and submitted within 30 days of discovering or acquiring a new SFI during the period of any current PHS-funded award. It should be noted as well that any previously submitted disclosures must be updated when a new reportable Significant Financial Interest or potential financial conflict of interest exists.

- 2) In addition to the disclosure of significant financial interests as specified above, investigators must disclose within thirty (30) days from completion of a trip the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that 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. Please note that no *de minimus* has been prescribed under the PHS Final Rule; thus, all qualifying reimbursed or sponsored travel must be disclosed.

Each Investigator travel disclosure must include, at a minimum, the following key elements:

- a) an explanation of the purpose of the trip,
- b) the identity of the sponsor/organizer paying for the trip,
- c) the destination(s), and
- d) the dates/duration.

Upon receipt of each travel disclosure, the AAAP institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

3) Guidelines for institutional official

The Academy is developing guidelines for use by the designated institutional official in determining whether an Investigator's significant financial interest is related to PHS-funded research and, if so, whether the significant financial interest represents a financial conflict of interest.

B. Review

All qualifying individuals participating in the submission of a PHS application shall be required to disclose whether or not such participation is affected by a significant financial interest (SFI). Each disclosure of a SFI by an AAAP staff member or officer participating as a Principal Investigator or Key Person on a PHS application shall be reviewed by the Director, Grants Administration and Compliance, AAAP's designated institutional official.

1) Initial Review

The review will focus primarily on the nature of the disclosure(s) to determine a) whether the SFI constitutes a financial conflict of interest of the Investigator or other Key Person, as well as the Investigator/Key Person's family, and b) whether the SFI could be affected by the PHS-funded research or is in an entity external to AAAP whose financial interest may be affected by the research.

In the event a determination reveals that a SFI is, in fact, a financial conflict of interest, AAAP's Director, Grants Administration and Compliance will inform AAAP Executive Director or AAAP President, who, with the Director, Grants Administration and Compliance, shall review the documentation leading to such determination and take action to develop a management plan specifying any actions that have been, or will be, taken in order to appropriately oversee the financial conflict of interest. The management plan will be reviewed and approved by the CPD/CME Committee prior to implementation.

2) Mid-Project Review

In the event that an Investigator who is new to an ongoing PHS-funded project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest, the Director, Grant Administration and Compliance shall, within sixty (60) days of such disclosure, review the disclosure of SFI, determine whether it is related to the PHS-funded research and determine whether a financial conflict of interest exists. If so, the Director, Grants Administration and Compliance shall inform the Executive Director or AAAP President, as appropriate, who together with the Director, Grants Administration and Compliance, shall develop, at least on an interim basis, a management plan specifying the actions that have been, and will be, taken to manage the financial conflict of interest. The management plan will be reviewed and approved by the CPD/CME Committee prior to implementation.

If warranted by virtue of the results obtained in the Mid-Project Review, the CPD/CME Committee will consider additional interim measures that may be taken regarding the Investigator's participation in the PHS-funded research between the date of disclosure and completion of the Academy's review.

3) Retrospective Review

In the event the Academy identifies a significant financial interest that was not disclosed on a timely basis by an Investigator or Key Person or was not previously reviewed by AAAP during the timeframe of an ongoing PHS-funded project, the Director, Grants Administration and Compliance shall, within sixty (60) days of learning of the SFI, review the SFI, determine whether the SFI is related to the PHS-funded research project, and determine whether a financial conflict of interest exists. If such determination is positive, the Director of Sponsored Programs shall inform the AAAP Executive Director or AAAP President, as appropriate, who together with the Director, Grants Administration and Compliance, shall develop, at least on an interim basis, a management plan specifying the actions that have been, and will be, taken to manage the financial conflict of interest. The management plan will be reviewed and approved by the CPD/CME Committee prior to implementation.

In addition, whenever a financial conflict of interest is not identified or managed in a timely manner, including a) failure by the Investigator to disclose a significant financial interest that is determined by AAAP to be a financial conflict of interest, b) failure by AAAP to review or manage such a financial conflict of interest, or c) failure by the Investigator to comply with a financial conflict of interest management plan developed by the Academy, AAAP shall complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct, or reporting of such research. The Academy shall complete the retrospective review within 120 days of the Academy's determination of non-compliance.

Based on the results of the retrospective review, if appropriate, the Academy, through its CPD/CME Committee, will update the previously submitted financial conflict of interest report by specifying the actions that will be taken to manage the financial conflict of interest. If, as a result of the retrospective review, bias is found, AAAP will notify the PHS Awarding Component promptly and submit a mitigation report (see definition for mitigation report and what it must include) to the PHS Awarding Component.

Following submission of a mitigation report, AAAP is required to submit financial conflict of interest reports annually (see section 3). It should be noted that, depending on the nature of the financial conflict of interest, AAAP, through its CPD/CME Committee, may determine that additional interim measures are warranted with regard to the Investigator's participation in the PHS-funded research project between the mitigation report submission date and the expiration of the PHS-funded research project.

C. Monitoring

In all instances in which the disclosure of a financial conflict of interest has necessitated the development and implementation of a management plan, the Academy shall monitor compliance with the plan by the affected Investigator on a continuing basis throughout the life of the PHS-funded research project. Actual monitoring activities shall be determined on a case by case basis by the CPD/CME Committee as part of the management plan review process, prior to implementation.

3. Reporting to NIH

Whenever a significant financial interest (SFI) has been identified and found to be conflicting, the Academy shall, prior to the expenditure of any funds under a PHS-funded research project, submit to the PHS Awarding Component a financial conflict of interest (FCOI) report and provide assurance that a management plan has been developed, approved by the CPD/CME Committee, and implemented. Conversely, if a financial conflict of interest is identified, but eliminated prior to the expenditure of PHS funds, a report is not required.

After an initial FCOI report is submitted during an ongoing PHS-funded research project, if the Academy identifies a conflicting significant financial interest (e.g., upon the participation of an Investigator or other Key Person who is new to a PHS-funded research project), it will, within sixty (60) days of such discovery, submit a second FCOI report regarding the financial conflict of interest and provide assurance that the Academy, through its CPD/CME Committee, has implemented a management plan.

Another instance in which AAAP is required to submit a FCOI report is when a significant financial interest is discovered that was not disclosed on a timely basis by an Investigator or other Key Person or, for whatever reason,

was not previously reviewed or managed by the Academy (e.g., was not timely reviewed or reported by a subrecipient). In such cases, the Academy will undertake a retrospective review, as specified in section 2.B.3) of this policy, to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of the research. If bias is discovered, the Academy, through its CPD/CME Committee, will notify the PHS Awarding Component promptly by submission of a mitigation report (see definition of mitigation report in section 1 for required contents).

For instances when a financial conflict of interest was previously reported by the Academy on an ongoing PHS-funded research project, AAAP will provide to the PHS Awarding Component an annual FCOI report, as approved by the CPD/CME Committee, that addresses the status of the FCOI and any changes to the management plan. Such reporting shall continue for the duration of the PHS-funded research project, including any extension periods, in the time and manner specified by the PHS Awarding Component. As part of the annual FCOI reporting process, the Academy will specify whether the financial conflict is still being managed or explain why the FCOI no longer exists.

4. Enforcement Mechanisms

AAAP Committee on CPD/CME Committee shall determine an appropriate enforcement mechanism and, if necessary, sanctions in the event of non-compliance by an Investigator or Key Person with either the Academy's financial conflict of interest policy or financial conflict of interest management plan in cases in which the non-compliant activities appear to have biased the design, conduct, or reporting of the results of PHS-funded research. In addition, the Academy, through its CPD/CME Committee, shall promptly report to the PHS Awarding Component each instance of such non-compliance, provide notification of the corrective action that was or is to be taken, and forward upon request (or permit HHS on site review of) all records developed during and relating to the Academy's review, monitoring, and enforcement activities.

In the event that HHS reviews FCOI-related materials provided by the Academy and makes a determination of additional corrective actions that should be taken, the Academy, through its CPD/CME Committee, will enforce such corrective actions, which may include imposition of special award conditions or suspension of funding. Should HHS determine that a PHS-funded project involving 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 financial conflict of interest that was not managed or reported by the Academy, AAAP shall require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

5. Public Accessibility

The Academy shall maintain and update, prior to the expenditure of funds under a PHS-funded research project and at least annually thereafter, a publicly accessible website on which is posted this policy and related forms and procedures. In addition, AAAP will respond within five (5) business days to requests for information concerning any significant financial interest disclosed to the Academy that meets the criteria specified in the PHS final rule.

6. Subrecipient Requirements

The Academy is responsible for taking reasonable steps to ensure that any subrecipients (i.e., subcontractors or consortium members) performing work under a PHS-funded research project comply with the PHS Financial Conflict of Interest regulations, as revised, and shall do so, as follows:

A. Pre-Award

In connection with any proposal to be submitted for PHS funding that includes research to be conducted by a subrecipient organization (e.g., subcontractor, subawardee, consortium member), the Academy will require an advance understanding of which institution's conflict of interest policy will apply to each subrecipient's Investigator(s) in the event of an award.

B. Post-Award

Upon receipt and acceptance of a PHS-funded research award, the Academy shall draft a subrecipient agreement based upon the advance understanding(s) in A. above, for each collaborating organization. The

subrecipient agreement shall specify which institution's financial conflict of interest policy applies, as follows:

- 1) If the subrecipient's Investigator(s) must comply with the subrecipient's financial conflict of interest policy, the subrecipient shall certify as part of the subrecipient agreement that its policy complies with the PHS regulation. In the event the subrecipient is unable to provide this certification, the subrecipient agreement shall state that subrecipient Investigators are subject to this AAAP Conflict of Interest Policy for disclosing significant financial interests that are directly related to the subrecipient's work for the Academy.
- 2) If the Subrecipient's Investigator(s) must comply with the subrecipient's financial conflict of interest policy, the subrecipient agreement shall specify time periods for the subrecipient to report all identified financial conflicts of interest to the Academy. The specified time period shall be sufficient to enable AAAP to provide timely FCOI reports, as necessary and required by the PHS regulation and the AAAP Conflict of Interest Policy.
- 3) If the subrecipient's Investigator(s) are required to comply with the AAAP Conflict of Interest Policy, the subrecipient agreement shall specify time periods for the subrecipient to submit all Investigator disclosures of significant financial interests to the Academy, which time periods shall be sufficient to enable AAAP to comply with its timely review, management, and reporting obligations under the PHS regulation.

Further, the subrecipient agreement shall require any subrecipient organization(s) receiving funding under a prime PHS-funded research award to the Academy to provide financial conflict of interest reports to the PHS Awarding Component (with a copy to the Director, Grants Administration and Compliance) regarding financial conflicts of interest of all subrecipient Investigators prior to the expenditure of funds and within sixty (60) days of any subsequently identified financial conflict of interest.

7. Training Requirements

Training in the requirements of the PHS regulation and the AAAP Conflict of Interest Policy is required of each Investigator prior to engaging in research relating to any PHS-funded project. Such training is to be repeated every four (4) years. Training also is required immediately whenever any of the following circumstances are known to occur:

- A. The Academy revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- B. An Investigator who is to be engaged in PHS-funded research is new to the Academy; or
- C. The Academy discovers that an Investigator is not in compliance with either this policy or any specifically developed and implemented management plan.

AAAP will provide an on-line training program, e.g., the Collaborative Institutional Training Initiative (CITI) online Financial Conflict of Interest (FCOI) module, which will be supplemented by case studies and/or other instructional materials through the Director, Grants Administration and Compliance, as appropriate.

The Director, Grants Administration and Compliance, as designated institutional official, shall be responsible for maintaining and updating the Academy's registry of qualifying AAAP and subrecipient Investigators and for scheduling and conducting training, as required above.

8. Records Maintenance

The Academy shall maintain all records of Investigator disclosures of financial interests and its subsequent review of, and/or response to, such disclosures (whether or not a disclosure resulted in the Academy's determination of a financial conflict of interest), and all actions taken under the Agency's policy or retrospective review for a period of at least three (3) years from the date of submission of the final expenditure report or, where applicable, from other

dates specified in 45 CFR 74.53(b) and 45 CFR 92.42(b) for differing situations. Such records shall be maintained for each competitive segment of an award for PHS-funded research, as follows:

45 CFR 74.53(b) - Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report. The only exceptions are the following: (1) If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken. (2) Records for real property and equipment acquired with federal funds shall be retained for 3 years after final disposition. (3) When records are transferred to or maintained by the HHS awarding agency, the 3-year retention requirement is not applicable to the recipient.

45 CFR 92.42(b) - *Length of retention period.* (1) Except as otherwise provided, records must be retained for three years from the starting date of any PHS funded award. (2) If any litigation, claim, negotiation, audit or other action involving the records has been started before the expiration of the 3-year period, the records must be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular 3-year period, whichever is later. (3) To avoid duplicate recordkeeping, awarding agencies may make special arrangements with grantees and subrecipients to retain any records which are continuously needed for joint use. The awarding agency will request transfer of records to its custody when it determines that the records possess long-term retention value. When the records are transferred to or maintained by the federal agency, the 3-year retention requirement is not applicable to the grantee or subrecipient.