

Advanced Materials Applications, LLC

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FINANCIAL CONFLICT OF INTEREST IN RESEARCH POLICY

Policy Number: RCO1

Version Number: 1.0

Classification: Research Compliance

Effective Date: March 1, 2013

Responsible Party: Owner of Advanced Materials Applications, LLC

I. Introduction

An important part of the mission of Advanced Materials Applications, LLC (hereinafter “AMA”) is to seek excellence in the fulfillment of research. In support of this goal, AMA encourages and supports research in all fields, including engineering and science fields.

Corporate organizations play an important role in research and research at AMA can benefit from corporate involvement in many ways; however, financial incentives accompanying this involvement have the potential to lead to conflicts of interest. Financial conflicts of interest have the potential to bias research endeavors, which may compromise or appear to compromise research integrity. Such conflicts of interest may affect or appear to affect research-related administrative duties, including the selection of equipment and supplies on sponsored research projects. Such conflicts of interest may have the negative consequence of reducing public trust in the integrity of AMA's research.

To protect against the potential risks involved with financial conflicts of interest in research and to comply with federal regulations, AMA has developed this Financial Conflict of Interest in Research Policy. AMA believes that establishing clear guidelines and principles for disclosing and managing

potential, actual, and apparent conflicts of interest will assist in ensuring that the highest level of integrity is maintained in AMA's research endeavors. The existence of a financial conflict of interest does not indicate wrongdoing on the part of the investigator. However, if a conflict exists, it must be reduced, managed, or eliminated.

II. Purpose

This policy is intended to assist investigators, as that term is defined in this Policy, in structuring their relationships with industry and other Outside entities in ways that will not compromise their regular-AMA duties or research obligations. This policy is also intended to maintain public trust in AMA's research and to support institutional compliance with the Public Health Service (PHS) regulations contained in "Responsibility of Applicants for Promoting objectivity in Research for Which PHS Funding is Sought," 42 CFR part 50, subpart F, as revised by NOT-OD-1 I-109, "Issuance of the Final Rule - Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors"; and the National Science Foundation (NSF) requirements for conflict of interest policies; NSF Proposal and Award Policies and Procedures Guide at IV.A.; and other relevant government regulations.

III. Applicability

This policy applies to all AMA employees involved in the design, conduct, and reporting of research and research-related educational activities. Questions about the applicability of the Policy or the requirements imposed by this Policy should be referred to the Dr. Kathleen Morse, owner of AMA, at 408-960-1474.

IV. Government Rules and Regulations

The Public Health Service (PHS), which includes the National Institutes of Health (NIH), requires institutions seeking PHS funding for research to maintain a written, enforced policy on conflicts of interest that complies with applicable PHS regulations. The purpose of the PHS conflict of interest regulations is to "promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest." The National Science Foundation (NSF) also requires that each grantee institution employing over fifty persons maintain an appropriate written and enforced policy to ensure that research is not biased by an investigators' financial interests. Furthermore, other federal agencies also maintain similar guidelines regarding conflicts of interest.

V. Definitions

The following definitions apply to this Policy:

V.1 Awarding Component means the organizational unit of the federal agency that awarded the funds contributing to the subject research or educational activity.

V.II **Business** means any corporation, partnership, firm, or other legal entity, whether for-profit or non-profit, whether publicly or privately held, but excluding AMA.

V.III **Financial Conflict of Interest** (FCOI) means a financial interest of an investigator that could directly and significantly affect the design, conduct, or reporting of the investigator's research or research-related activities.

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

V.IV **Significant Financial Interest** (SFI) means a financial interest consisting of one or more of the following interests that reasonably appears to be related to the Investigator's responsibilities within AMA and/or sponsored activities:

V.IV.I With regard to any publicly traded entity, an SFI 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 to the Investigator, including the investigator's spouse and dependent children. 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;

V.IV.II With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure when aggregated, exceeds \$5,000, or when the investigator (or the Investigator's spouse and dependent children) holds any equity interest (i.e., stock, stock option, or other ownership interest) regardless of the value; or

V.IV.III Intellectual Property rights and interests of the Investigator, including the Investigator's spouse and dependent children (e.g., patents, copyrights), upon receipt of income related to such rights and interest.

V.IV.IV Investigators, including the investigator's spouse and dependent children, also must disclose 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 AMA 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.

V.IV.V Significant Financial Interest does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by AMA to the Investigator if the Investigator is currently employed or otherwise appointed by AMA, including property rights assigned to AMA and agreements to share in royalties related to such rights;
- Any ownership interest in AMA held by the Investigator

- 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.

V.V Investigator means the principal investigator, co-investigator, and/or any other person(s) regardless of title or position, who have the potential to influence the design, conduct, or reporting of research or educational activities funded by a federal government agency or other external sponsor, or research that is proposed for such funding.

V.VI Senior/Key Personnel means the principal investigator, co-investigator(s), program director or any other persons who contribute to the scientific development or execution of a project in a substantive, measurable way.

V.VII Research means a systematic investigation, study or experiment designed and conducted to develop or contribute to the body of knowledge. Research includes basic and applied research as well as product development. This includes but is not limited to research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program project, or research resources awards.

V.VIII Disclosure means a formal written statement of relevant information about financial interests related to the investigator's sponsored research or educational activities. Saint Louis University requires that disclosures are made on-line using the University's eRS (Electronic Research Services) system. Annual disclosures are required, as well as ad hoc disclosures when changes to annual disclosures occur. Investigators who have not submitted an annual disclosure must do so prior to submitting a proposal for submission to an external funder.

V.XI Public Health Service (PHS) means the operating division of the U.S. Department of Health and Human Services and any components of the PHS to which authority may be delegated.

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

V.IX National Science Foundation (NSF) refers to the independent agency of the federal government responsible for the promotion of progress in science and engineering by supporting programs in research and education.

V.IIX Sponsor means an entity providing financial support for research, educational activities, or travel, which includes all federal and private agencies.

V.XIII ***Sponsored Travel*** means reimbursed or compensated travel which is paid to the Investigator (including the investigator's spouse and dependent children), to AMA, or paid on behalf of the investigator, even in cases where the exact monetary value may not be readily available.

- ***Institutional Responsibility*** means all professional activities an Investigator provides to AMA within his or her appointment including research and administration.

VI. Policy

VI.I Guiding Principles

Although AMA expects its employees to conduct themselves with the utmost integrity and honor in the engagement of all activities, there are certain activities that require particular sensitivity and attention. The following activities fall within this category:

- **Research.** Decisions concerning the nature and direction of research at AMA should be governed by judgments of scholarly merit and intellectual importance. An employee's involvement with, or interest in, outside commercial or professional applications of research should not bias judgment concerning the employee's own scholarly research or that of other employees.
- **Publication.** Free and open communication of the results of research is an important to AMA. Involvement in outside professional or commercial activities should not unnecessarily delay or inhibit the publication of research or the sharing of information derived from such research. Short-term delays in publication for consideration of proprietary information or related to patent applications are sometimes necessary. Investigators are expected to disclose relevant outside consulting arrangements or affiliations in their published scholarly works.
- **Intellectual Property.** Any research involving patents, materials, devices, or procedures invented or discovered by employees (Whether such development took place at AMA or elsewhere) with the intention of commercial development requires careful scrutiny.

VI.II Recognizing Conflict of Interest

A conflict of interest exists under this Policy when the owner of AMA, Dr. Kathleen Morse, reasonably determines that a significant financial interest of an investigator could directly and significantly affect the design, conduct, or reporting of sponsored research or educational activities. If a conflict of interest is identified, it must be reduced, managed, or eliminated within 60 days of its discovery.

A critical step in handling potential conflicts is full disclosure of significant financial interests and, if a conflict of interest is identified, development and implementation of an appropriate management plan. The owner of AMA is committed to advancing research and fostering an entrepreneurial spirit at AMA maintaining objectivity and integrity in research. If a conflicting situation arises that will require management, the owner of AMA will work in cooperation with the individual to develop and implement an appropriate management plan.

VI.II Termination of a Conflict

A conflict affecting a particular study or project continues to exist until the conflicted Investigator from AMA has completed the project and their portion of any subsequent publications or presentations, understanding that research data may take several years before publication takes place.

VII. Responsibilities

VII.I AMA Responsibilities

AMA has the following responsibilities under this Policy, in order to fully comply with the requirements of federal regulations:

- i. Maintaining on a publicly accessible web site, a written, enforced policy on financial conflicts of interest that complies with federal regulations.
- ii. Informing each investigator and other covered persons of this Policy and reporting obligations under this policy, including relevant time frames;
- iii. Requiring each investigator to submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring a new significant financial interest.
- iv. Requiring each investigator to complete training regarding this policy prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following occur:
 - a. AMA revises this policy or procedures in ways that affect the requirements of the investigators
 - b. An Investigator is new to an Institution; or
 - c. AMA finds that an investigator is not in compliance with AMA's financial conflict of interest policy or management plan.
- v. Identifying and approving the Manager of Responsible Conduct of Research, who is responsible for soliciting and reviewing Conflict of Interest Disclosure Forms as specified in Section VIII of this Policy, and providing guidelines consistent with federal regulations to determine whether an investigator represents a financial conflict
- vi. Ensuring that all sub-grantees, subcontractors, and collaborators of federally funded research activities comply with federal requirements regarding Financial Conflict of Interest by either requiring investigators working for those entities to comply with this Policy or by requiring the entity to provide an assurance to AMA that will enable AMA to comply with federal regulations.
- vii. Providing initial and on-going FCOI reports to awarding agencies. Reporting the existence of any FCOI by AMA investigators or subrecipients to the appropriate sponsoring entity and assuring that they have been managed, reduced, or eliminated. For PHS-funded research, prior to expending any sponsored funds, the institution must report an FCOI to the PHS-awarding

component and must report any interest identified as conflicting subsequent to the initial report within 60 days of that identification. For PHS funded research, this is accomplished through the eCommons website.

Information to be reported initially includes the following:

- Grant/ Contract Number;
- Project Director/Principal Investigator or Contact PD/PI;
- Name of Investigator with Financial Conflict of Interest;
- Whether FCOI was managed, reduced, or eliminated;
- Name of the entity with which the Investigator has a FCOI;
- Nature of FCOI, (e.g.: equity, consulting fees, travel reimbursement, honoraria);
- Value of the financial interest (0-4,999; \$5K - 9,999; \$10K - 19,999; amounts between \$20K and \$100 K by increments of \$20K; amounts above \$100K(by increments of \$50K or statement that a cannot be readily determined;
- A description of how the financial interest relates to PHS-funded research and the basis for the AMA's determination that the financial interest conflicts with such research; and
- Key elements of the AMA's management plan.

In addition, an Annual Report will be filed noting the status of the FCOL and any changes to the management plan.

viii. Promptly notifying federal sponsors and, where required by the funding agreement, private sponsors, if the failure of any investigator to comply with this Policy has, in the opinion of the owner of AMA, biased the design, conduct, or reporting of the sponsored research activity.

ix. Maintaining records of all financial disclosures and all actions taken by AMA with respect to each conflicting interest in accordance with Section XII of this Policy.

x. Overseeing the establishment of adequate enforcement mechanisms to promote conformance with this Policy and sanctions, as appropriate, against investigators who fail to comply with this Policy.

xi. Making information available, upon request, to federal sponsors, regarding all disclosures of financial interests and AMA's review of, and response to, such disclosures, whether or not AMA determined that it resulted in a financial conflict of interest.

xii. Making information available, upon request, to federal sponsors, regarding all conflicting interests identified by AMA in research or educational activities sponsored by the entity in which the conflict exists and how those interests have been managed, reduced, or eliminated to protect the objectivity of the research activity.

xiii. Certifying in each application for funding sought from the PHS that AMA has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research project for which funding is sought or received from the PHS.

VII.II Investigator Responsibilities

The effectiveness of this Financial Conflict of Interest in Research Policy relies upon the accurate and timely reporting of the investigators. Investigators have the following responsibilities under this Policy:

- i. Completing and submitting an annual Conflict of Interest in Research Disclosure Form, as specified in Section VIII.I of this Policy, to AMA within thirty days of receiving the Form. The Investigator is also responsible for updating the Disclosure Form to account for changes in his/her financial interests that render the annual disclosure inaccurate or incomplete, also within thirty days of identifying the change.
- ii. Cooperating with the owner of AMA in the development and verification of a management plan in those instances where the owner of AMA has determined that a conflict of interest exists that must be managed, reduced, or eliminated.
- iii. Complying with the terms and conditions of management plans, including providing required reports in a timely manner and updating information as needed.
- iv. Informing co-investigators, and other individuals involved in the design, conduct, or reporting of the investigators externally sponsored research projects of their obligation to comply with this Policy, in accordance with any management plans.
- v. Participating in required financial conflict of interest training within 30 days of the issuance of this and at least once every four years thereafter.
- vi. The Investigator is responsible for the accuracy of Conflict of Interest references in all grant-related documents submitted both within the Institution and outside the Institution.

VIII. Procedures for Disclosure and Review

VIII.I Annual Disclosure

Each investigator engaged in or applying for externally sponsored research is required to complete an annual Conflict of Interest in Research Disclosure form. The disclosure form requires the investigator to list: (1) current and proposed sponsored research activities; (2) all significant financial interests, as well as those of investigator's spouse and dependent children and, (3) an explanation of the connection, if any, between the sponsored activities and the significant financial interest.

Annual Disclosure Forms shall be emailed to the owner of AMA.

VIII.II Travel Disclosures

Investigators, including the investigator's spouse or dependent children, also must disclose the

occurrence of any reimbursed or Sponsored Travel. However, this disclosure requirement does not apply to travel that is reimbursed or sponsored by the federal, state, or local government agency.

Such disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

IX. Management of Conflict of Interest

If it is determined that an actual or apparent conflict of interest exists, the owner of AMA, in collaboration with the conflicted individual, will prepare a management plan to ensure the reduction, management, or elimination of the conflict. The input from the affected individual will help in devising an appropriate management plan.

Examples of conditions or restrictions that might be imposed include:

- public disclosure of relevant significant financial interests
- modification of research plan
- severance of relationship that created actual or potential conflict of interest

X. Sanctions for Non Compliance

Violation of full and prompt disclosure may result in the loss of grant funding and sanctions regarding future funding from federal agencies.

XI. Notice to External Sponsors

Prior to the expenditure of any funding under the PHS award, AMA will report to the PHS Awarding Component within 60 days of its discovery the existence of any conflicting interest related to the specific PHS award that was identified by AMA under the procedures set for in this Policy. AMA will report on that information regarding the conflict as required by agency guidelines. This notification will include the assurance that the conflict of interest has been managed, reduced or eliminated.

In addition, if a financial conflict of interest is identified subsequent to AMA's report to PHS as specified above, AMA will notify the PHS Awarding Component of the existence of the conflicting interest and implement a management plan to manage, reduce, or eliminate the interest within 60 days of its identification.

If an investigator fails to comply with this Policy and has a financial conflict of interest in research funded by PHS that was not identified or managed in a timely manner due to noncompliance, AMA will conduct 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 noncompliance, was biased in the design, conduct or reporting of such research. AMA will notify the PHS awarding agency within 120 days of the corrective action taken or to be taken by AMA.

A copy of all notifications to PHS under this section will be kept in the office of the owner of AMA and in the grant files to which the notifications pertain.

XI.I Notification to NSF

In the event that AMA is unable to satisfactorily manage, reduce, or eliminate a conflict of interest related to an NSF award, AMA will notify NSF of the situation using the NSF FastLane System.

XI.II Notification to Other External Sponsors

For external sponsors other than PHS and NSF, AMA will notify the sponsor of identified conflicting interests when specifically required to do so by the sponsoring agency or in the funding agreement.

XII. Record of Retention

XII.I PHS-Funded Research

AMA will maintain records of all financial disclosures and all actions it takes with respect to each conflicting interest in connection with PHS-funded research for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. §74.53(b) for different situations.

XII.II NSF-Funded Research

AMA will maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest related to NSF-funded research activities for at least three years beyond the termination or completion of the activity to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

XII.III Other Externally Sponsored Research Activities

For all other externally sponsored research activities, AMA will maintain records of all financial disclosures and all actions it takes with respect to each conflicting interest for at least three years from the completion of the research activities to which they relate.

XIII. Access to Records

AMA will make information available, upon request, to PHS, NSF, and any other federal sponsors regarding all conflicting interests identified by AMA that relate to research funded by the federal sponsor and how those interests have been managed, reduced, or eliminated

to protect the sponsored research from bias.

Prior to expenditure of any funds under a PHS-funded research project, AMA shall ensure public accessibility, via a written response to any requestor within five business days of a request, of information concerning any significant financial interest of senior/key personnel disclosed to AMA that meets the following three criteria:

- i. The significant financial interest was disclosed and is still held by the senior/key personnel;
- ii. The Institution determines that the significant financial interest is related to the PHS-funded research; and
- iii. The Institution determines that the significant financial interest is a financial conflict of interest.

This information will include the Investigator's name, title, and role with respect to the research project; the name of the sponsor in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest or a statement that the value of the interest cannot be readily determined.

XVI. References

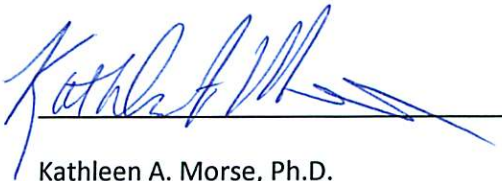
Public Health Service Regulations, 42 CFR Part 50, subpart F and 45 CFR Part 94

NOT-OD-II-109, " Issuance of the Final Rule - Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is South and Responsible Prospective Contactors, " issued August 22, 2011

National Science Foundation Policies, NSF Proposal and Award Policies and Procedures Guide at IV.A

XV. Approval Signatures

This policy has been approved by:



Kathleen A. Morse, Ph.D.

Date 03/01/13

Owner of Advanced Materials Applications, LLC