

## FINANCIAL CONFLICT OF INTEREST POLICY (FCOI)

### 1. Introduction

Adamas Nanotechnologies, Inc. is committed to objective research where Adamas employees are able to conduct research and development in a productive and unbiased environment. This policy is intended to ensure the research is free from bias due to financial conflicts of interest, and that potential financial conflicts of interests are identified, managed, reduced, or eliminated. This policy provides a framework to comply with requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research" for which PHS Funding is Sought" (FCOI Regulation), of the Federal Register pertaining to PHS-funded research.

Conflict of interest, which arises when a secondary objective could affect the performance of a person's primary mission, is a normal part of human existence. The potential for financial gain is one of many potential incentives that can lead to bias in a subjective activity, often subtle and unrecognized by the affected individual. Adamas is committed to advancing knowledge, including accelerating the translation of novel research ideas into practice. The application of knowledge, its dissemination and utilization, involves engagement with outside institutions and persons. Thus, Adamas must have policies that both encourage interaction with outside institutions and persons, and at the same time define ground rules so individuals have clear boundaries within which to operate. There should be a balance between engagement with outside entities that may have economic incentives, and the professional expectations staff at Adamas, so that research is performed in a manner that maintains the utmost in integrity and objectivity.

A financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

This policy is intended to be consistent with federal and state law. Where there is a discrepancy, the applicable federal or state law or rule of the funding agency will take precedence, unless the law or rule is less restrictive than Adamas's more stringent standard.

### 2. Definitions

**Equity Interest:** Any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

**Institution:** Any domestic or foreign, public or private, entity or organization (excluding a federal agency), including Biotechnology and Pharmaceutical companies, that submits a proposal, or that receives, PHS research funding. Adamas is considered an "Institution" for the purposes of this policy.

**Investigator:** Someone who is defined as the PI/PD and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed such funding. This may include collaborators, consultants, subaward recipients, contractors, and consortium participants. For any investigator, the policy includes a financial interest of any immediate family member (spouse or spousal equivalent, and dependent children) as if any financial interest of that family member were one of the investigators.

PHS: 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).

Remuneration: Salary and any payment for services, including consulting fees, honoraria, and paid authorship.

Research: A systematic investigation, study, or examination designed to develop or contribute to generalizable knowledge relating broadly to public health including behavioral and social sciences research or basic and applied research (e.g., a published article, book or book chapter) and product development. The term includes any such activity for which research funding is available from PHS but excludes applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

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.

Significant Financial Interest: A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that that reasonably appears to be related to the individual's duties and responsibilities, including, but not limited to:

With regards to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) 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.

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 (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;

Reimbursed or sponsored travel (i.e., travel 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 at Adamas; 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 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Adamas's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the destination, and the duration. Adamas's Designated Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

The term significant financial interest does not include the following types of financial interests:

Salary, royalties, or other remuneration paid by the Adamas to the Investigator if the Investigator is currently employed or otherwise appointed by the Adamas, including intellectual property rights assigned to Adamas and agreements to share in royalties related to such rights;

Any ownership interest in Adamas held by the Investigator;

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;

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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.

3. • Policy

A financial conflict of interest related to Adamas's activities may occur when an investigator employed or appointed by Adamas has a significant financial interest that compromises, or appears to compromise, that investigator's independence and objectivity in the discharge of his/her Adamas responsibilities in the design, conduct, or reporting of Adamas's research. Adamas will review each Investigator's SFI disclosure to determine if a SFI is related to the NIH-supported research (i.e., could be affected by the research or is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the NIH-funded research. Investigators should avoid conflicts and the potential for conflicts resulting from financial arrangements with third parties that could have a special interest in a Adamas's research or product development.

Disclosure

Investigators are required to disclose SFIs (and those of the investigators immediate family) to Adamas. This disclosure will be made prior to placement of a PHS funded award and at least annually during the award period and within 30 days of discovering or acquiring a new SFI (such as through purchase, marriage or inheritance).

Adamas will name a Designated Official(s) to manage the FCOI policy. The designated official(s) will take 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.

If a determination is made that a FCOI exists Adamas's Designated Official(s) will recommend a suitable action plan or management plan to eliminate or manage the FCOI consistent with the objectives of this policy.

The action plan shall provide for its periodic review and updating at least annually. In the event that there is no reasonable way to manage a FCOI then the investigator may be prohibited from participating in the related Research until such a time as the FCOI is eliminated.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts; and
- Adamas shall review the proposed action plan or management plan and can approve, modify and approve additional work. Final review and determination must be completed prior to the expenditure of any PHS funds for the applicable Research.

A conflict should be managed, reduced, or eliminated within sixty (60) days of its identification by designated official(s). Adamas's Designated Official(s) shall be responsible for monitoring and enforcing any management plan.

This shall also apply when, in the course of an ongoing PHS-funded research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new significant financial interest to Adamas.

#### Enforcement

If an investigator fails to comply with Adamas's FCOI policy, within 120 days of discovery by Adamas, Adamas shall complete a retrospective review of the investigator's activities to determine potential bias.

If a bias is found, Adamas shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias.

Adamas will work with the investigator to set up an FCOI management plan to mitigate the situation.

Companywide, Adamas is required to mandate that investigators disclose the FCOI in each public presentation with research results if it was not reported up front. In extreme cases of bias, the investigator may lose the right to work on the project.

#### Training, Reporting and Records

All persons subject to the Adamas Financial Conflict of Interest Policy will be required to train on the policy by reading and affirming their understanding of, and intent to comply with the FCOI policy and every four (4) years thereafter. Immediate training will be required if Adamas revises this policy in a manner that affects the investigator, when an investigator is new to Adamas, or as a result of a finding of noncompliance with this policy or a management plan, or other related misconduct.

Unless otherwise covered by a third-party FCOI Policy as agreed with QBI, each investigator/senior/key personnel is required to complete training on QBI's FCOI Policy by reading and affirming the policy or demonstrate training on the NIH web based training on the following occasions:

- Prior to engaging in research related to any PHS-funded grant,
- At least every 4 years, and
- Immediately if:
  1. Adamas revises the FCOI Policy in a manner that affects requirements of investigator/senior/key personnel,
  2. Investigator/senior/key personnel is new to Adamas, or
  3. An investigator is not in compliance with the FCOI Policy or management plan.

As required by 42 CFR Part 50, Subpart F, Adamas shall file a report with the NIH providing information on every identified FCOI and the manner in which the FCOI is being or has been managed, reduced, or eliminated. Reports shall include the elements required by these regulations. Adamas will notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research, and file a Mitigation Report in accordance with federal regulations.

The records of all financial disclosures and all actions taken by Adamas will be maintained for at least three years from the date of submission of the final expenditures report.

#### Other

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When carrying out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), Adamas must incorporate by written agreement (e.g., subaward) that the investigator(s) of the subrecipient institution is required to either:

Comply with the Adamas's FCOI Policy, or

Comply with the FCOI Policy of the subrecipient institution and have said institution certify that its policy complies with 42 CFR Part 50 Subpart F. The written agreement, under either policy, must specify the time period for the subrecipient to provide investigator disclosure and report of any FCOI to Adamas.

Adamas's Financial Conflict of Interest Policy shall be posted on the public portion of the Adamas website. In addition, upon receipt of a written request for information concerning identified FCOI's held by investigators (as defined by regulation), Adamas will make that information available within five (5) business days of the request. The information shall include all elements required by 42 CFR Part 50, updated through the date of the response.