

1. Objective

As a professional research corporation, Atila Biosystems is committed to protecting the integrity and objectivity of its research activities.

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children).

This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought

2. Scope

This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by Public Health Service (PHS) or National Institute of Health (NIH).

If a research project involves subcontractors, sub grantees, or sub awardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Institute of Health (NIH) funds be subcontracted by Atila Biosystems to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

3. Responsibilities

a. Designated Official

- Inform Atila Biosystems Investigators of their obligations under this policy and any related regulations
- Review disclosures of significant financial interest to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest
- Screen and manage potential financial conflicts of interest
- Maintain all records relating to disclosures of financial interests, Atila Biosystems review of and response to such disclosures, and any related actions under this policy
- Ensure inclusion of any required certifications in applications for funding or contract proposals; and
- Report and disclosure as required under this policy and applicable regulations.

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b. Investigator

- Disclose all significant financial interests
- Provide updates to disclosed information as needed
- If acting as the PI/PD, providing a list of individuals who meet the definition of “investigator” within the required disclosure timeline
- Complete all required training and education
- Complete the annual disclosure form even if they have no financial interests to report.
- Ensuring that an updated FCOI in Research Disclosure is on file at the time of Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) approval for any new research proposals.

4. Terms and Definitions

- a) Designated Official - is the individual designated by Atila Biosystems to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests.
- b) Investigator - means the project director/principal investigator and any other person who is responsible for the design, conduct, or reporting of the research or proposed research.
- c) Equity interest - includes any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.
- d) PHS - means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.
- e) Remuneration - includes, for example, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
- f) 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). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.
- g) Financial Interest - means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether or not the value is readily ascertainable.

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- h) Financial Conflict of Interest - means a Significant Financial Interest (see below) related to a research program or project that could directly and significantly affect the design, conduct, or reporting of research.
- i) Significant Financial Interest (SFI) means:
 - 1. A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities
 - 2. 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 the disclosure, when aggregated, exceeds \$5000. For purpose of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship). Equity interests includes any stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - 3. Regarding 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 (and/or the Investigator's spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
 - 4. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - 5. For PHS-funded investigators, any reimbursed or sponsored travel related to an Investigator's institutional responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.
 - 6. The term significant financial interest does not include the following types of financial interests:
 - a) Salary or consulting fees paid by Atila Biosystems to the Investigator if the Investigator is currently employed or otherwise appointed by Atila Biosystems.
 - b) Income from seminars, lectures, or teaching engagements sponsored by U.S. federal, state or local agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with U.S. institutions of higher education.
 - c) Income from service on advisory committees or review panels for U.S. federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with U.S. institutions of higher education.

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- d) Travel by a PHS-funded Investigator that is reimbursed or sponsored by U.S. federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with U.S. institution of higher education.

5. Policy

a. Internal Reporting Requirements

For PHS-funded research in particular, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form and submit the SFID Form to the Designated Official. This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research. The Designated Official will review SFID submissions. The information reported on the SFID Form includes a listing of the Investigator's known significant financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.

Atila Biosystem's Investigators in non-PHS-funded research who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete the SFID Form and submit it to the Designated Official.

Investigators are expected to submit an updated SFID Form during the period of the award as necessary (at least annually for PHS-funded research). The annual update will typically be done in conjunction with completion of the annual training. Such disclosures shall include any information that was not previously disclosed; any change in information regarding any previously disclosed significant financial interest; or, within 30 days of discovery or acquisition, any new significant financial interest (e.g., an interest acquired through purchase, marriage, or inheritance).

b. Determination and Management of Financial Conflict of Interest

Upon receipt of a completed SFID Form, the Designated Official shall determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If Atila Biosystems determines that a financial conflict of interest exists, a financial conflicts of interest management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;

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- Modification of the research plan;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, Atila Biosystems may require the management of conflicting financial interests in other ways as it deems appropriate.

c. External Reporting Requirements

Atila Biosystems will disclose financial conflicts of interest as required by applicable laws or regulations. Before expending any funds under a PHS award, Atila Biosystems will ensure public accessibility by posting financial conflicts of interest information on a publicly available web site or by responding in a timely manner to written requests as required under the regulations. The Designated Official will also report to the PHS Awarding Component, as detailed in the regulations, the existence of any financial conflict of interest that has not been eliminated and will ensure that Atila Biosystems has implemented a plan to manage the conflict.

If a financial conflict of interest is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, Atila Biosystems will provide the PHS Awarding Component with an update within 60 days and ensure that it has implemented a plan to manage the conflict. If the financial conflicts of interest report involves a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Atila Biosystems (e.g., not reviewed or reported by a subrecipient in a timely manner), Atila Biosystems will undertake a retrospective review. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. If bias is found, Atila Biosystems will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, Atila Biosystems will provide HHS with information relating to any Investigator disclosure of significant financial interests; Atila Biosystem's review of, and response to, such disclosure; and whether the disclosure resulted in Atila Biosystem's determination of a financial conflict of interest.

d. Confidentiality

Atila Biosystems will, to the extent possible, protect the confidentiality of disclosures. In every instance, Atila Biosystems will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to Atila Biosystems staff only on a need-to-know basis and will not be disclosed outside of Atila Biosystems unless necessary to comply with contractual, legal, or regulatory requirements.

e. Investigator Noncompliance

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), Atila Biosystems may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations shall result in the following:

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- If the Investigator's failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, Atila Biosystems shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
- Atila Biosystems will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts;
- If HHS determines that a clinical PHS-funded research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was neither disclosed nor managed, Atila Biosystems shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

f. Training and Education

Investigators receive training to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations. The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH website.

Atila Biosystems requires Investigators to complete such training annually, and when any of the following occurs:

- Atila Biosystems revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's obligations;
- An Investigator is new to Atila Biosystems
- Atila Biosystems finds that an Investigator is not in compliance with this policy or a financial conflicts of interest management plan.

g. Retention of Records

Atila Biosystems shall maintain all records related to the implementation of this policy for at least three years after:

- the date of creation
- the date of termination or completion of a research award or contract
- the submission of the final expenditures report
- the date of final resolution of any investigation, audit, or similar action involving the records.

6. References

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought