



Acenxion Biosystems

Financial Conflict of Interest Policy (FCOI)

Effective Date: 12.01.2020

Policy Summary

By law, all Investigators applying for and working on Public Health Services (PHS), National Institutes of Health (NIH), or National Science Foundation (NSF) funded research must disclose significant financial interests (SFIs) that are related to the Investigator's institutional (whereas "institution" includes Acenxion Biosystems, a Delaware corporation) responsibilities. Investigators are ALL persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by the PHS, NIH, or NSF, including collaborators or consultants. This policy provides the framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

Definitions/Glossary

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

Financial conflict of interest (FCOI) – a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report – an Institution's report of a financial conflict of interest to a PHS Awarding Component.

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

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

Investigator – 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.

Manage – 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.

PD/PI – a project director or principal Investigator of a PHS-funded research project.

PHS – 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).

Research – 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 policy, 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.

Senior/key personnel – the PD/PI and any other person identified as senior/key personnel by Acenxion Biosystems in the grant application, progress report, or any other report submitted to the PHS by the institution.

Significant financial interest –

(1) 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 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 spouse or dependent children) 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 (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. Investigator recipients of sponsored travel are required, at minimum, to disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The CEO or appropriate executive within Acenxion Biosystems 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) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by Acenxion Biosystems to the Investigator if the Investigator is currently employed or contracted by the institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

This Policy Applies to: ALL persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by the PHS/NIH/NSF, including collaborators or consultants.

Reason(s) for the Policy

Acenxion Biosystems is required, by federal law (C.F.R. Part 50 Subpart F), to comply with regulations pertaining to Financial Conflicts of Interest in government-funded research. As an institution that regularly competes for and receives federal funding for research, Acenxion Biosystems is required to have a written and enforced policy on conflict of interest.

The policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS), National Institute of Health (NIH), National Science Foundation (NSF) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. The policy further provides a mechanism for all conflicts of interest for each award to be managed, reduced or eliminated prior to the expenditure of the award funds.

Policy. 42 CFR 50.604(b)

The CEO will inform each Investigator of Acenxion Biosystem's policy on financial conflicts of interest, the Investigator's responsibilities regarding timely disclosure of significant financial interests, and federal regulations governing federally funded research prior to submitting an application to a federal funding agency.

Investigator Responsibilities. 42 CFR 50.603 & 42 CFR 50.604(e)(1)-(3) & 42 CFR 50.604(b)



Each Investigator who is planning to participate in the PHS/NIH/NSF-funded research must disclose to the CEO the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS/NIH/NSF-funded research.

Investigators must complete the appropriate Financial Disclosure Form found in the appendix of this policy (either the PHS/NIH or NSF specific form). Any Investigator who is participating in any PHS/NIH/NSF-funded research must submit an updated disclosure of significant financial interest at least annually during the period of the award.

In the event a financial conflict of interest arises during the period of the award, the Investigator is required to notify the CEO within thirty days of discovering or acquiring a new significant financial interest.

Investigators are required to complete training, 42 CFR 50.604(b), prior to engaging in research related to any PHS/NIH-funded grant and at least every four years thereafter. Training is also required in cases where an Investigator is new to Acenxion Biosystems and continues to serve as an Investigator in a funded project transferred from another institution to Acenxion Biosystems. Refresher training is required in the event an Investigator is not in compliance with Acenxion Biosystems financial conflict of interest policy or management plan. At this time, Financial conflict of interest training is administered and available through the CEO.

Investigators Engaged in Subrecipient Research or Engaging Others as Subrecipients. 42 CFR 50.604(c) (also see NIH Grants Policy Statement 15.2.1) & 42 CFR 50.604(c)(1)(i)-(iii)

Acenxion Biosystems personnel engaged in funded research as a subrecipient may be required by the awardee institution to comply with the awardee institution's own financial conflict of interest policy. Likewise, in cases where Acenxion Biosystems serves as the awardee institution in PHS/NIH/NSF-funded research projects, Acenxion Biosystems may require subrecipients to comply with its financial conflicts of interest policy. In these cases, the awardee institution or subrecipient and Acenxion Biosystems must incorporate, in a written agreement, whether the financial conflicts of interest policy of the awardee institution or that of the subrecipient will apply to the subrecipient's Investigators.

If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with applicable law. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by law. Alternatively, if the subrecipient's

Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee institution. Such time period(s) shall be sufficient to enable the awardee institution to comply timely with its review, management, and reporting obligations under the law.

Significant Financial Interests Identified

The CEO is designated as Acenxion Biosystems' institutional official to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS/NIH/NSF-funded research as detailed above. In the event the Investigator discloses a significant financial interest, the CEO will notify the company Treasurer to form an ad hoc Financial Conflict of Interest Committee, hereafter, the Committee. The Committee is tasked with determining if an Investigator's significant financial interest is related to a PHS/NIH/NSF-funded research project and, if so related, whether the significant financial interest is a financial conflict of interest. The committee will solicit written statements from all concerned parties, evaluate all available evidence, and issue a report to the Board of Directors or relevant committee for risk management. After consideration of the committee's report, the Board of Directors will make the final decision.

An Investigator's significant financial interest is related to PHS/NIH/NSF-funded research when Acenxion Biosystems, through its designated officials, reasonably determines that the significant financial interest: could be affected by the PHS/NIH/NSF-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when Acenxion Biosystems, through its designated officials, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS/NIH/NSF-funded research.

Financial Conflict of Interest Identified

In cases where the Financial Conflict of Interest Committee identifies a financial conflict of interest, the Committee is tasked with taking such actions as necessary to manage the financial conflict of interest. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to §50.605(a). Additionally, the Committee must comply with, and provide, initial and ongoing FCOI reports to the PHS as required pursuant to §50.605(b).

The Committee must maintain records relating to all Investigator disclosures of financial interests and Acenxion Biosystems' review of, and response to, such disclosures (whether or not a disclosure resulted in the institution's determination of a financial conflict of interest) and all actions under the institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

Management of Financial Conflicts of Interest

The Financial Conflict of Interest Committee is required to develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage financial conflicts of interest when they arise. The following examples are conditions or restrictions that may be imposed by the Committee to manage a financial conflict of interest, but they are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) 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;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

Penalties and Enforcement - 42 CFR 50.604(j)

Federal regulations require Acenxion Biosystems to impose sanctions or take other administrative actions where appropriate. Acenxion Biosystems maintains the right to impose sanctions on Investigators for failure to disclose significant financial interests and for failure to abide by this policy. Sanctions may include restrictions on future submission of research proposals and other disciplinary actions up to and including dismissal in accordance with the personnel policies of Acenxion Biosystems.

Confidentiality

Except to the extent required by law and federal regulations, the information disclosed throughout these processes will be kept confidential. Acenxion Biosystems, however, is required to report the existence of real or potential conflicts of interest to certain federal agencies.

Reporting of Financial Conflicts of Interest

Prior to Acenxion Biosystem's expenditure of any funds under a PHS-funded research project, the institution shall, consistent with §50.604(f): review all Investigator disclosures of significant financial interest; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a



management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

Whenever, 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 Acenxion Biosystems, the Committee shall, within sixty days: review all Investigator disclosures of significant financial interest; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by Acenxion Biosystems to constitute a financial conflict of interest; failure by Acenxion Biosystems to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the institution shall, within 120 days of the institution's determination of noncompliance, 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 noncompliance, was biased in the design, conduct, or reporting of such research.

Acenxion Biosystems is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the FCOI; (5) Name of the entity with which the Investigator has a financial conflict of interest; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, Acenxion Biosystems shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, Acenxion Biosystems is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and Acenxion Biosystem's plan of action or actions taken 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). Thereafter, Acenxion Biosystems will submit FCOI reports annually, as specified elsewhere in the policy. Depending on the nature of the financial conflict of interest, Acenxion Biosystems may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded



research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Acenxion Biosystem's retrospective review.

Whenever Acenxion Biosystems implements a management plan pursuant to this policy, Acenxion Biosystems shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Prior to Acenxion Biosystem's expenditure of any funds under a PHS-funded research project, it 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 disclosed to it that meets the following three criteria: (A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart; (B) Acenxion Biosystems determines that the significant financial interest is related to the PHS-funded research; and (C) Acenxion Biosystems determines that the significant financial interest is a financial conflict of interest.

The information that Acenxion Biosystems makes available via a written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity 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 (the following dollar ranges will be used: \$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 measures of fair market value.

The written response will contain a note that "the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor."

Additional Reporting Requirements

Prior to Acenxion Biosystem's expenditure of any funds under a PHS-funded research project, it shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by Acenxion Biosystems to be conflicting and ensure that it has implemented a management plan in accordance with this subpart. In cases in which the institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, Acenxion Biosystems shall not submit an FCOI report to the PHS Awarding Component.

For any significant financial interest that Acenxion Biosystems identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Acenxion Biosystems shall provide



to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart. Where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), Acenxion Biosystems also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, Acenxion Biosystems is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Any FCOI report required under this policy shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Acenxion Biosystem's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following: (i) Project number; (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used; (iii) Name of the Investigator with the financial conflict of interest; (iv) Name of the entity with which the Investigator has a financial conflict of interest; (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); (vi) Value of the financial interest (dollar ranges will be used: \$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 measures of fair market value; (vii) 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 (viii) A description of the key elements of the Institution's management plan, including: (A) Role and principal duties of the conflicted Investigator in the research project; (B) Conditions of the management plan; (C) How the management plan is designed to safeguard objectivity in the research project; (D) Confirmation of the Investigator's agreement to the management plan; (E) How the management plan will be monitored to ensure Investigator compliance; and (F) Other information as needed.

For any financial conflict of interest previously reported by Acenxion Biosystems with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. Acenxion Biosystems shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.



Exclusions and Special Situations

Not applicable

Policy Contact(s)

Responsible Office: Chief Executive Officer

Dr. Roy R. Swiger

roy@acxbio.com

Appendix

- I. NSF Financial Conflict of Interest (FCOI) Disclosure Form – Used for all National Science Foundation (NSF) funded projects
- II. PHS/NIH Financial Conflict of Interest (FCOI) Disclosure Form – Used for all Public Health Services (PHS) and National Institutes of Health (NIH) funded projects