

Financial Conflicts of Interest (FCOI) Policy

Allander Biotechnologies, LLC

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Version 1

PURPOSE

The U.S. Department of Health and Human Services (HHS) has issued a 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). Allander Biotechnologies is an Institution subject to these regulations and must be in compliance.

Allander Biotechnologies will provide adequate guidelines consistent with the regulation to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI.

Therefore, Allander Biotechnologies has established standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest.

GLOSSARY OF TERMS

-*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.

-*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 Allander Biotechnologies.

-*Institutional responsibilities* means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

-*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. The term investigator includes the investigator's spouse and dependent children.

-*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.

-*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.

-*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:*

A. 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.

B. 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the 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.

C. 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.

POLICY

It is Allander Biotechnologies' highest priority to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI). It is also Allander Biotechnologies' responsibility to establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance.

DISCLOSURE AND REPORTING:

The following table illustrates when disclosures and reports must occur:

Table 1: When to disclose and report

Investigator Discloses known SFI(s) to Allander Biotechnologies	Allander Biotechnologies Reports identified FCOI(s) to NIH (Designated official(s) review the disclosures to make determinations of FCOIs and report any FCOIs to NIH)
At time of Application	Prior to the Expenditure of Funds
Within 30 days of acquiring or discovering SFI	Within 60 days of identification
Annually at the time period prescribed by the Institution during the award period	Annually: (For any Financial Conflict of Interest previously reported by the Institution) At the same time as when the grantee submits the annual progress report or the extension of project. Annual FCOI report is submitted through eRA Commons FCOI Module.

DISCLOSURE:

At time of Funding Application: In order to ascertain the existence of any FCOI, any investigator or sub recipient associated with the project will be required to fill out an FCOI Disclosure Statement and submit it to Human Resources. If an FCOI exists, Allander Biotechnologies will submit the FCOI report to NIH via the eRA Commons FCOI Module.

Post Award: An investigator or subrecipient must file an FCOI Disclosure statement within 30 days of acquiring or discovering that an FCOI exists for an ongoing project.

Annual Disclosure: All investigators and subrecipients working on NIH funded projects will be required to review Allander Biotechnologies' FCOI policy and fill out an annual FCOI Disclosure Statement.

REPORTING:

INITIAL REPORTS:

New Awards:

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

Ongoing Research Project:

Requirements for submission of Initial FCOI reports during an Ongoing NIH-funded Research Project:

A. The Institution must submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to Allander Biotechnologies during the period of award. Although the Institution has up to sixty days to report the identified FCOI to NIH, reports should be submitted during the ongoing project and not after the project period end date.

B. Whenever an Investigator does not disclose timely a previously existing Significant Financial Interest or Allander Biotechnologies fails to review a previously existing Significant Financial Interest during an ongoing NIH-funded project, the Allander Biotechnologies' designated official(s) shall, within sixty (60) days: review the Significant Financial Interest; determine whether it is related to the NIH-funded research; determine whether a Financial Conflict of Interest exists. If so, Allander Biotechnologies will implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such Financial Conflict of Interest going forward and submit an FCOI report to the NIH.

In addition to the FCOI report, Allander Biotechnologies will, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's research activities and the NIH-funded research project to determine whether any NIH- funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research.

Based on the results of the retrospective review, if appropriate, 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, NIH will promptly be notified and Allander Biotechnologies will submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and Allander's plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter Allander Biotechnologies will submit FCOI reports annually.

ANNUAL FCOI REPORT TO NIH:

For any Financial Conflict of Interest previously reported by Allander Biotechnologies to NIH, Allander Biotechnologies shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists.

These Annual FCOI Reports must be submitted to the NIH (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as Allander Biotechnologies is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable.)

In cases where Allander Biotechnologies identifies a FCOI and eliminates it prior to the expenditure of NIH-awarded funds, Allander Biotechnologies shall not submit an FCOI report to the NIH.

Annual FCOI reports are not required as part of the grant closeout requirements. The last submitted Annual Report will be required prior to the issuance of the last year noncompeting award within the project's competitive segment unless the grant is extended via the Commons or through the issuance of a revised Notice of Award.

Content of Reports:

Reports 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 the Allander Biotechnologies' management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- A. Project number;
- B. PD/PI or Contact PD/PI if a multiple PD/PI model is used;

- C. Name of the Investigator with the financial conflict of interest;
- D. Name of the entity with which the Investigator has a financial conflict of interest;
- E. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- F. 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 measures of fair market value;
- G. A description of how the financial interest relates to the PHS-funded research and the basis for Allander Biotechnologies' determination that the financial interest conflicts with such research; and
- H. A description of the key elements of Allander Biotechnologies' 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.

Electronic Research Administration (eRA) Commons FCOI Module: Reporting tool for submitting FCOI reports for grants and cooperative agreements, more information on the FCOI Module can be found at http://era.nih.gov/services_for_applicants/other/fcoi.cfm

Table 2: Required Reports to be Provided to NIH Through eRA Commons FCOI Module

Report	Content	When
Initial FCOI Report	Grant Number, PI, Name of Entity with FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan	1) Prior to expenditure of funds 2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI and Changes to Management Plan	For any Financial Conflict of Interest previously reported by the Institution - Due at same time as when submitting annual progress report or at time of extension
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward	After completion of retrospective review, if needed
Mitigation Report	Project Number, Project Title, Contract PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion	When bias is found as a result of a retrospective review

RETROSPECTIVE REVIEWS:

In the case when identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Allander Biotechnologies during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a sub recipient), the designated official(s) shall, within 120 days: review the significant financial interest; determine whether it is related to PHS-funded research;

determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

In addition, 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 Allander Biotechnologies to constitute a financial conflict of interest; failure by Allander Biotechnologies 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, Allander Biotechnologies shall, within 120 days of Allander Biotechnologies' 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.

Allander Biotechnologies will document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- i. Project number;
- ii. Project title;
- iii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- iv. Name of the Investigator with the FCOI;
- v. Name of the entity with which the Investigator has a financial conflict of interest;
- vi. Reason(s) for the retrospective review;
- vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- viii. Findings of the review; and
- ix. Conclusions of the review.

Revised FCOI: Based on the results of the retrospective review, if appropriate, Allander Biotechnologies shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. When bias is not found following the completion of a Retrospective Review, the Institution should not submit a "Revised" FCOI report.

NEW REPORTS:

The Institution must submit a new FCOI report if any of the following elements of a previously submitted FCOI report changes:

- Project Number
- Name of Investigator with the FCOI
- Name of the entity
- Nature of the Significant Financial Interest

If the value of a reported SFI changes during the year, the Investigator should disclose the change to the Institution in his/her annual disclosure. Changes in the value of an SFI do not constitute a "new" FCOI report. The annual FCOI report will provide the status of the existing FCOI and any changes to the management plan that may result due to the increase in value.

NEGATIVE REPORTS:

There is no requirement for the Institution to submit negative FCOI reports to NIH.

MITIGATION REPORT:

If bias is found, Allander Biotechnologies will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will 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 Allander's 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).

DESIGNATED OFFICIAL RESPONSIBILITIES:

Allander Biotechnologies has designated the President as the 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-funded research. It is the official's responsibility to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

Upon receipt of any FCOI Disclosure Statement, Allander's official, shall:

- A. Review all Investigator disclosures of significant financial interests;
- B. Determine whether any significant financial interests relate to PHS-funded research as defined in the glossary of terms above
- C. 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.

These requirements shall be conducted:

- A. When required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI; or
- B. Within sixty days whenever Allander Biotechnologies identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by Allander

An Investigator's significant financial interest is related to PHS-funded research when Allander's official(s), reasonably determines that the significant financial interest could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research.

A financial conflict of interest exists when Allander's official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Allander Biotechnologies may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. Allander's official(s) shall have the authority to establish adequate enforcement mechanisms and provide for sanctions where appropriate.

The Allander Biotechnologies official(s) must inform each Investigator of the:

- A. PHS Regulation;
- B. Allander's policy on FCOI; and
- C. Investigator's responsibilities regarding disclosure of SFIs

MANAGEMENT:

Allander Biotechnologies shall certify in each application for funding to which FCOI regulations apply, that Allander Biotechnologies:

- A. 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 projects for which funding is sought or received from the PHS;

- B. Shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of significant financial interests;
- C. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart; and
- D. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and Allander's review of, and response to, such disclosure, whether or not the disclosure resulted in a determination of a financial conflict of interest.

Allander Biotechnologies may use the following examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

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

MANAGEMENT PLAN:

FCOI Management Plans shall be monitored with their associated projects and include the following items:

- A. The 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.

Allander's management plans may include reduction or elimination of the SFI.

INVESTIGATORS:

The Allander Biotechnologies official(s) shall require that by the time an application is submitted to PHS, each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/ her spouse and dependent children):

- A. That would reasonably appear to be affected by the research for which PHS funding is sought; and
- B. In entities whose financial interests would reasonably appear to be affected by the research.

All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

Whenever Allander Biotechnologies implements a management plan, Allander Biotechnologies shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS- funded research project.

Allander Biotechnologies shall inform each Investigator of its policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of the regulations. Due to the serious nature of intentional FCOI violations, our enforcement mechanisms and employee sanctions to ensure Investigator compliance are also serious.

Allander may have grounds to terminate any Investigator who willfully avoids, misreports or falsifies information related to FCOI and SFIs.

Allander will require that each Investigator who is planning to participate in the PHS-funded research disclose to Allander's official(s) 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-funded research.

Allander Biotechnologies will require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed during the period of the award. Such disclosure shall include any information that was not disclosed initially to Allander, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS- funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Allander Biotechnologies will require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

In any case which the Department of Health and Human Services determines that a PHS-funded research project of 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 an FCOI that was not managed or reported by Allander Biotechnologies as required by regulation, Allander Biotechnologies shall require the Investigator involved to: 1) Disclose the FOCI in each public presentation of the results of research, and 2) Request an addendum to previously published presentations.

SUBRECIPIENTS:

Allander Biotechnologies is responsible for ensuring any subrecipient's compliance with the regulation required by 42 CFR Part 50 Subpart F and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH.

Allander Biotechnologies shall incorporate, as part of a written agreement with subrecipient terms, which establish whether the Financial Conflict of Interest policy of Allander Biotechnologies or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements.

If using the subrecipient's FCOI policy, the official(s) shall obtain a certification in the form of a formal letter from the subrecipient stating that its FCOI policy complies with the regulation.

The written subrecipient agreement shall either a) require the subrecipient to report identified FCOIs for its Investigators in a time frame that allows Allander Biotechnologies to report identified FCOIs to the NIH or b) require Allander Biotechnologies to solicit and review subrecipient Investigator disclosures that enable Allander Biotechnologies to identify, manage and report identified FOCIs to the NIH. The method chosen to be incorporated into the subrecipient agreement shall be determined by official(s) based upon the subrecipient's sophistication and needs.

Allander's official is responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.

TRAINING:

Each Investigator, including sub recipient Investigator(s), must complete training prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

- A. Allander Biotechnologies's Financial Conflict of Interest policies change in a manner that affects Investigator requirements
- B. An Investigator is new Allander Biotechnologies
- C. Allander Biotechnologies finds that an Investigator is not in compliance with this policy or management plan.

Allander Biotechnologies will utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at <http://grants.nih.gov/grants/policy/coi/> to satisfy some of the training requirements. This tutorial is related to the Financial Conflict of Interest (FCOI) regulation provided at 42 CFR Part 50 Subpart F on Promoting Objectivity in Research. The tutorial is also available in PDF format (PDF - 2.5 MB). The August 2, 2012 posting provides the capability to easily save and print the FCOI Certificate. <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. However, Allander Biotechnologies will also provide additional training regarding Investigator's responsibilities for disclosure of Significant Financial Interests and of Allander's specific policy on financial conflicts of interests.

REMEDIES:

If the failure of an Investigator to comply with Allander Biotechnologies' financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Allander shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

PUBLIC INFORMATION:

Prior to Allander Biotechnologies' expenditure of any funds under a PHS-funded research project, Allander shall ensure public accessibility, via a publicly accessible web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to Allander 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. Allander Biotechnologies determines that the significant financial interest is related to the PHS-funded research; and
- C. Allander Biotechnologies determines that the significant financial interest is a financial conflict of interest.

The information that Allander Biotechnologies makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following:

- a) the Investigator's name;
- b) the Investigator's title and role with respect to the research project;
- c) the name of the entity in which the significant financial interest is held;
- d) the nature of the significant financial interest; and
- e) the approximate dollar value of the significant 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 measures of fair market value.

The information that Allander Biotechnologies posts shall be updated at least annually on Allander Biotechnologies' publicly accessible web site. In addition, Allander shall update the Web site within sixty days of Allander's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS- funded research project, if

Allander determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest.

The web site shall note that information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of Allander's identification of a new financial conflict of interest. If Allander responds to written requests for the purposes of this subsection, Allander will note in its written response 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 Allander's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the significant financial interests of an individual subject to this section shall remain available, for responses to written requests or for posting via Allander's publicly accessible web site for at least three years from the date that the information was most recently updated.

RECORDS:

Allander Biotechnologies shall maintain records of all financial disclosures and all actions taken by Allander Biotechnologies with respect to each conflicting interest for three years from the date the final expenditures report is submitted to the PHS (NIH) or, where applicable, for the other time periods specified in 48 CFR parts 4, subpart 4.7.