

INTRALYTIX, INC.
FINANCIAL CONFLICT OF INTEREST POLICY

I. INTRODUCTION.

The biotechnology industry is highly competitive, and Intralytix, Inc. (the “Company” or the “Institution”) and the people associated with it must balance the urge to share new data, suppositions, and discoveries with the public against the need to protect the Company’s business interests and intellectual property and discoveries. In addition, people associated with the Company may advise or own interests in companies engaged in similar businesses or in companies with which the Company desires to do business. The relationships that the individuals associated with the Company have with other these companies may create real or apparent conflicts of interest between the Company and the individual. This Financial Conflict of Interest Policy is designed to identify and address potential, actual and apparent conflicts of interest between the Company and those individuals associated with it. The procedures established by this Financial Conflict of Interest Policy are intended to protect the Company’s business and to assure the integrity of its decision making. This Policy is intended to supplement any applicable laws governing conflicts of interest applicable to the Company.

II. GENERAL PRINCIPLES.

The purpose of this Conflict of Interest policy is to

- Define the circumstances giving rise to a “conflict of interest” between the Company and any individual who is associated with the Company;
- Establish a policy pursuant to which individuals associated with the Company disclose such conflicts to the Company, and
- Establish procedures for the Company’s Board of Directors (the “Board”) and management to: (1) assess when an actual, threatened, or apparent financial conflict of interest could or does (a) compromise or appear to compromise an affiliated person’s ability to act on the Company’s behalf in a fair and unbiased manner or to otherwise discharge his or her duties or responsibilities to the Company, or (b) provide an incentive for the affiliated person to act other than in a fair and unbiased manner in the Company’s best interest; and (2) determine the action to be taken to eliminate a threatened, actual, or apparent financial conflict.
- To inform each Investigator of the Company’s FCOI policies, their disclosure responsibilities, and their requirements to meet the regulations related to the 2011 Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F).

III. *DEFINITIONS.*

- A. Designated official means institutional official(s) designated to solicit and review disclosures of significant financial interest from each investigator who is planning to participate in, or is participating in the PHS-funded research
- B. Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.
- C. 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.
- D. FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- E. Financial interest means anything of monetary value, whether or not the value is readily ascertainable.
- F. 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.
- G. Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding. Also referred to in this document as the "Company"
- H. Institution of Higher Education (as defined at 20 U.S.C. 1001(a)) means an educational Institution that:
 - 1. Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the requirements of 20 U.S. Code section 1091(d);
 - 2. Is legally authorized within such State to provide a program of education beyond secondary education;
 - 3. Provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary;
 - 4. Is a public or other nonprofit institution; and
 - 5. Is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted preaccreditation status by such an agency or association that has been recognized by the Secretary for the granting of preaccreditation status, and the Secretary has determined that there is satisfactory

assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

- I. 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.
- J. Interested Person means a person who either discloses the existence of a Financial Conflict of Interest with the Company or who the institution determines has, could have, or appears to have, either directly or by virtue of his or her relationship with a Related Person, a Financial Conflict of Interest with the Company.
- K. 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.
- L. 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.
- M. 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.
- N. 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).
- O. PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this policy.
- P. Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.
- Q. Related Person means a spouse, domestic partner, grandparent, parent, brother, sister, brother-in-law, sister-in-law, aunt, uncle, or child of an Interested Person.
- R. Relevant Entity means (1) any Person with which the Company has an agreement, a contract, or a business relationship or with whom the Company proposes to enter into an agreement, a contract, or a business relationship and (2) any Person in substantially the same business as the Company.
- S. 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.

T. 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 policy.

U. Significant Financial Interest (SFI) -

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. 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. Reimbursed or sponsored travel must be disclosed if the value of that travel exceeds, when aggregated, \$5,000.

3. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Company 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.
- V. Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

IV. TRAINING REQUIREMENTS

- A. Each PHS-supported Investigator must complete FCOI training (1) prior to engaging in research related to any PHS-funded grant (2) at least every 4 years or (3) immediately if (i) the company revises its FCOI policy that affects requirements of the Investigators (ii) an Investigator is new to the Company (iii) An Investigator is not in compliance with the policy or management plan.
- B. Each Interested Person will be required to review this policy annually and acknowledge in writing that he or she has done so.

V. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS (SFIS)

- A. Each Interested Person who is planning to participate in PHS-funded research must submit to the Designated Official a listing of his or her known Significant Financial Interests (and those of his/her spouse and dependent children). An Interested Person's significant financial interest is related to PHS-funded research when the Institution, through its designated 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. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. Each Interested Person must disclose SFIs no later than at the time of application for PHS-funded research and review and update, as necessary, all financial disclosures during the period of the award, either on an annual basis or within 30 days as new reportable Significant Financial Interests are obtained.
- B. Within 30 days following the end of each calendar year, each Interested Person will complete and deliver to the Designated Official a Conflict of Interest questionnaire in the form provided by the Company.
- C. Within 30 days of any Interested Person becoming aware that, with respect to any matter, arrangement, or proposed arrangement between the Company and a Relevant Entity, he or she or a Related Person (1) is an Affiliate of the Relevant Entity, (2) has an Ownership Interest, a Business Interest or a Significant Financial Interest in the Relevant Entity, or (3) has any other external economic or other private interest in the arrangement or in the Relevant Entity that could give rise to a Conflict of Interest with respect to the, matter, the arrangement, or the proposed arrangement, the Interested Person will notify the Designated Official in writing of the existence and nature of the Ownership Interest, the Business Interest, or a Significant Financial Interest or other interest.
- D. Within 30 days of an Interested Person becoming aware that such person or a Related Person's relationship to a Relevant Entity has changed so as to make a prior Conflict of Interest disclosure incorrect in any respect, the Interested Person will notify the Conflict Committee in writing of such change.
- E. Each Interested Person must disclose all financial interests received from a foreign Institution of Higher Education or the government of another country.
- F. The Institution shall designate an officer or director of the Company (the "Designated Official") to solicit and review information regarding potential Financial Conflicts of Interest, including, but not limited to, financial disclosure statements from any Interested Person planning to participate in Research funded by a Public Entity.

VI. REVIEW OF SIGNIFICANT FINANCIAL INTERESTS

- A. Prior to the expenditure of any funds awarded by a Public Entity, including NIH or other PHS Awarding Component funds awarded, the Company's Designated Official

shall review all Investigator SFI Disclosures, determine if any SFIs relate to PHS-funded research, determine if an FCOI exist (SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research), and develop and implement management plans, as needed to manage the FCOIs.

- B. The process to review disclosures of SFIs, make determinations of FCOIs, and implement a management plan when required for an Investigator must be completed when:
 - 1. An Investigator is new to participating in the research project or for an existing Investigator who discloses a new SFI or
 - 2. Within 60 days whenever the Company identifies a SFI that was not disclosed in a timely manner by an Investigator or not previously reviewed by the Company.
- C. The actions required to manage FCOIs, including any financial conflicts of a Subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project are described in Article VII.

VII. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

- A. If the Designated Official determines a Financial Conflict of Interest exists, the Company must 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.
- B. If, during 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 the Institution, the designated official(s) of the Institution shall, within 60 days:
 - 1. Review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research;
 - 2. 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.
- C. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.
- D. Whenever an Institution identifies a significant financial interest that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project, the designated official(s) shall, within 60 days:

1. Review the disclosure of the significant financial interest; and determine whether it is related to PHS-funded research;
 2. 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.
- E. 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 the Institution to constitute a financial conflict of interest; failure by the Institution 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.
1. The Institution will document the retrospective review and the documented review will include the following information at a minimum:
 - (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
 - (ix) Conclusions of the review
- F. Based on the results of the retrospective review, if appropriate, the Institution 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, the Institution will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
1. 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 the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias. Thereafter, the Institution will submit FCOI reports annually.

2. Depending on the nature of the financial conflict of interest, an Institution 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 Institution's retrospective review.
- G. Whenever an Institution implements a FCOI management plan, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.
- H. If the Company carries out the PHS-funded research through a subrecipient, the Company will ensure the subrecipient Investigators comply with this FCOI policy through a written agreement with the subrecipient.

VIII. REPORTING REQUIREMENTS

- A. The Institution will send initial, ongoing, and revised FCOI report to the NIH or other PHS Awarding Component, as required by the regulation, for the Institution and any of its subrecipients, if applicable:
1. Prior to the expenditure of funds
 2. Within 60 days of the identification for an Investigator who is newly participating in the project
 3. At least annually to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 4. Following a retrospective review to update a previously submitted report
- B. The FCOI reports must include, but is not limited to, the following information.
1. Project Number
 2. PD/PI or Contact PD/PI if a multiple PD/PI model is used
 3. The Investigator's name with the financial conflict of interest
 4. The Investigator's title and role with respect to the research project
 5. Name of the entity with which the Investigator has a financial conflict of interest
 6. The nature of the significant financial interest
 7. 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.

8. 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
 9. A description of the key elements of the Institutions Management Plan, including:
 - (i) Role and principal duties of the conflicted Investigator in the research project
 - (ii) Conditions of the management plan
 - (iii) How the management plan is designed to safeguard objectivity in the research project
 - (iv) Confirmation of the Investigator's agreement to the management plan
 - (v) How the management plan will be monitored to ensure Investigator compliance
 - (vi) Other information as needed.
- C. If bias is found in the design, conduct, or reporting of PHS-funded research, the Institution will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
1. The mitigation report must include, at a minimum, the key elements documented in VII.E.1 above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.
- D. If the failure of an Investigator to comply with an Institution's 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, the Institution will notify the PHS Awarding Component of the corrective action taken or to be taken.

IX. ENFORCEMENT MECHANISMS AND REMEDIES FOR NONCOMPLIANCE

- A. If the Company reasonably believe that an Investigator has failed to comply with this Conflict of Interest Policy, it will notify the individual or party of this belief and allow for the opportunity to explain the failure to disclose potential FCOIs to the institution.
- B. If, after the response has been evaluated and any further necessary investigation has been conducted, the Company determines a FCOI exists or an Investigator has failed to meet the requirements in this policy the Company will take appropriate disciplinary action or other administrative actions to ensure Investigator compliance.

- C. In any case that the Company requires a retrospective review of a potential FCOI, the Company will conduct such a review within 120 days of the determination of the non-compliance following the requirements outlined in Article VII Subsection E of this policy.
- D. If in any case 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 the Company as required, the Company will require the Investigator involved to:
 - 1. Disclose the FCOI in each public presentation of the results of the research, and;
 - 2. Request an addendum to previously published presentations.

X. MAINTENANCE OF FCOI-RELATED RECORDS

- A. All FCOI-related records will be retained and maintained in a manner that meets or exceeds all regulatory requirements, including but not limited to, at a minimum:
 - 1. 3 years from the date the final expenditures report is submitted to the PHS
 - 2. From other dates specified in 45 CFR 75.361, where applicable.