

Policy for Managing Financial Conflicts of Interest

I. INTRODUCTION

A. Policy Purpose

The United States Public Health Service (“PHS”) 2011 regulations have unique requirements regarding financial conflict of interest (“FCOI”) reporting and conflict management. All PHS agencies require awardee institutions to ensure objectivity in research through compliance with its comprehensive FCOI regulations (Responsibility of Applicants for Promoting Objectivity in Research (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94)).

The PHS 2011 regulations, located at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>, amend the 1995 regulations by expanding and adding transparency to investigators’ disclosure of significant financial interests, enhancing regulatory compliance and effective institutional oversight, managing investigators’ FCOI, and increasing PHS compliance oversight.

United States PHS agencies required to follow the PHS 2011 regulations include the National Institutes of Health (“NIH”).

Astero Erado Inc. and its subsidiaries and affiliates (collectively, the “Company”) must ensure that the integrity of research grants, cooperative agreements, and contracts, and the safety and welfare of research subjects, are never subordinate to, or compromised by, financial interests or the pursuit of personal gain. The principles articulated herein are intended to provide guidance in the management of formal relationships between employees of the Company and their external constituencies in order to ensure that the design, conduct, and reporting of sponsored research will not be biased by any conflicting financial interests. Each investigator is required to disclose a listing of his or her significant financial interests, as well as those of his or her spouse and dependent children, that would reasonably appear to be affected by the research proposed for funding by PHS. If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, the Company will report the existence of such conflicting interests to the sponsor and act to protect the resulting research from bias due to the conflict of interest. This policy statement is intended to satisfy current federal regulations for disclosure with regard to projects funded by the PHS.

B. Scope

This policy is applicable immediately to all PHS-funded program activities at the Company carried out by Company employees, consultants, scientists, trainees, technicians, and other agents or research collaborators. In addition, this policy applies to non-PHS-funded program activities for which the sponsor has adopted the PHS 2011 FCOI regulations. The requirements of the FCOI regulations do not apply to PHS-funded Phase I Small Business Innovation Research Grant or Small Business Technology Transfer Grant funding.

II. DEFINITIONS

- A. **Investigator** is 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.
- B. **Institutional responsibilities** means an Investigator's professional responsibilities on behalf of the Company, including research, research consultation, teaching, professional practice, Company committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- C. A **financial conflict of interest (FCOI)** exists when the Company's designated official(s) reasonably determines that an Investigator's significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The Company will review each Investigator's SFI disclosure to determine if an SFI:
 - 1. is related to the PHS-funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research), and
 - 2. could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- D. **Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.
- E. **Significant financial interest (SFI)** means:
 - 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:
 - a. With regard to any publicly traded entity, an SFI 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;
 - b. With regard to any non-publicly traded entity, an SFI 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
 - c. 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 disclosure will include the purpose of the trip, the identity of the

sponsor/organizer, the destination, and the duration. The Company's designated 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.

3. SFI 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 Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; any ownership interest in the Company held by the Investigator; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; 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.

III. POLICY STATEMENT

A. Investigator Training

In accordance with relevant federal regulations, the Company is required to manage, eliminate, or reduce any potential FCOI that may be inherent in the personal financial interest of an Investigator. The Company, therefore, will be responsible for ensuring that each Investigator is informed about:

1. the Company's FCOI policy,
2. the Investigator's responsibilities regarding disclosure of SFIs relating to the Investigator's institutional responsibilities, and
3. PHS FCOI regulations.

In accordance with FCOI regulations, the Company requires each Investigator to complete a mandatory training module prior to engaging in research related to any PHS-funded grant, cooperative agreement, or contract, at least every four years thereafter, and immediately when any of the following applies:

1. the Company revises this FCOI policy or related procedures in any manner that affects the requirements of the Investigators,
2. an Investigator is newly appointed at the Company, or
3. the Company finds that an Investigator is not in compliance with this FCOI policy or management plan (see Section III, Part E).

B. Investigator Disclosure of Significant Financial Interests

The Company requires Investigators to disclose to the Company any SFI, including those of his or her spouse and dependent children, which would reasonably appear to be affected by the project being funded by the PHS. The Company will provide an efficient and effective method for soliciting and reviewing timely disclosures from Investigators through a written and signed disclosure statement (SFIs

Disclosure Form). Investigators are required to provide updated disclosure information no later than the time the respective application is submitted to PHS, at least annually during the period of the award, and within 30 days of discovering or acquiring a new SFI. The Company will review disclosures of SFIs of the Investigator and those of the Investigator's spouse or dependent children.

C. Identification of Financial Conflicts of Interest

In conjunction with the administrative review of applications for grants, contracts, or cooperative research agreements, the Company's designated official(s) will review each financial disclosure submitted and shall make the determination of whether an FCOI exists.

In making an FCOI determination, the Company's designated official(s) may consult with all appropriate Company officials. If the Company's designated official(s) determines that no FCOI exists, the resulting negative finding will be filed in the Company's Human Resources files. No further review is required for negative findings. Positive findings (i.e., findings of existence of FCOI) can be managed (see Section III, Part D) via a management plan.

D. Management of Financial Conflicts of Interest

Following the determination of the existence of an FCOI, the Company's designated official(s) shall develop and implement a management plan that specifies the actions that have been, and shall be, taken to manage the FCOI. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

1. public disclosure of the identified FCOI,
2. appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI,
3. modification of the research plan,
4. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research,
5. requirement that the Investigator and his or her spouse or dependent children divest certain SFIs related to the positive finding,
6. requirement that the Investigator and his or her spouse or dependent children sever relationships that create the FCOI.

The Company will monitor investigational compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

E. Reporting Requirements to PHS

1. Prior to expending any funds under a PHS-funded grant, cooperative agreement, or contract, the Company must report to the applicable funding agency the existence of any FCOI and ensure that the Company has implemented a management plan in accordance with this policy. If the Company identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, the Company is not required to submit a FCOI report to the respective agency.
2. For any FCOI reported to the respective agency relating to an ongoing PHS-funded research project, the Company will submit an annual report to the applicable funding agency that

conforms to the requirements of the FCOI regulations for the duration of the research project in the time and manner specified by the applicable funding agency.

3. For any FCOI that the Company identifies subsequent to the Company's initial FCOI report during an ongoing PHS-funded research project, a report will be made to the applicable funding agency and a management plan shall be implemented, at least on an interim basis, within 60 days of that identification. If the FCOI is one that was not disclosed by an Investigator in a timely manner or was not previously reviewed or managed by the Company, the Company will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in its design, conduct, or reporting.
4. All reporting shall include, at a minimum, the items enumerated under the FCOI regulations.

F. Compliance

If an Investigator fails to comply with this FCOI policy or an FCOI management plan and the noncompliance appears to have biased the design, conduct, or reporting of the PHS-funded research, or if the Company fails to review or manage an FCOI, the Company shall promptly notify the funding agency of the corrective actions taken or to be taken. The Company shall complete a retrospective review and prepare a mitigation report within 120 days of the determination of noncompliance. If bias is found, this report will be submitted to the applicable funding agency.

All persons subject to this FCOI policy are expected to comply with it fully and promptly. If an Investigator has violated this FCOI policy, for example, by failure to disclose a SFI, the Company may take disciplinary or other appropriate action. Intentional disregard for this policy, including non-adherence to the agreed-upon management plan, shall constitute serious misconduct and may be the basis for further administrative or legal inquiry.

G. Subrecipient Requirements

If the Company carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Company will:

1. incorporate as part of a written agreement with the subrecipient terms that establish whether the Company's FCOI policy or the subrecipient's own FCOI policy will apply to the subrecipient's Investigators.
 - a) If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement that its policy complies with the FCOI regulations. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the Company's FCOI policy for disclosing significant financial interests that are directly related to the subrecipient's work for the Company.
 - b) Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement shall specify time period(s) for the subrecipient to report all identified FCOI to the Company. Such time period(s) shall be sufficient to enable the Company to provide timely FCOI reports, as necessary, to the PHS.
 - c) Alternatively, if the subrecipient's Investigators must comply with the Company's FCOI policy, the agreement shall specify time period(s) for the subrecipient to

submit all Investigator disclosures of SFIs to the Company. Such time period(s) shall be sufficient to enable the Company to comply timely with its review, management, and reporting obligations under the Company's FCOI policy.

2. provide FCOI reports to the PHS funding agency regarding all FCOI of all subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

H. Policy and FCOI Disclosure Procedures

The Company shall ensure public accessibility of the Company's FCOI policy on a publicly accessible website. If a publicly accessible website is not available, for whatever reason, and only in this case, the Company must make the FCOI policy available within five business days of a request. If presence on a publicly accessible website is acquired during the time of the PHS award, the Company must post its FCOI policy within 30 calendar days.

Prior to expending any funds under a PHS-funded grant, cooperative agreement, or contract, the Company shall ensure public accessibility of information about all identified FCOI, via a public website or written response to any requestor within five business days of a request. The information shall consist of the information required to be provided under the FCOI regulations, including:

1. Investigator's name,
2. grant/contract number,
3. project director/principal investigator,
4. Investigator's title and role with respect to the research project,
5. name of the entity in which the SFI is held,
6. nature of the SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.),
7. approximate dollar value of the SFI (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 SFI relates to PHS-funded research and the basis for the FCOI determination, and
9. a description of how the FCOI is being managed, reduced, or eliminated.

I. Maintenance of Records

The Company is required pursuant to the FCOI regulations to maintain all SFIs Disclosure Forms and all related records of actions taken by the Company with respect to disclosures of SFIs for a period of three years from the date of submission of the final expenditures report to the PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

IV. BOARD OF DIRECTORS ADMINISTRATIVE PREROGATIVE

During the course of any inquiry or investigation, the Board of Directors shall have the prerogative to take interim administrative actions, as appropriate, to protect external funds and ensure that the purposes of the external financial assistance are protected.