

**INTRA-CELLULAR THERAPIES, INC.**  
**APPENDIX TO FINANCIAL CONFLICTS OF INTEREST POLICY**

**Financial Conflict of Interest Policies and Procedures Applicable to PHS Funding**

This Appendix to the Company's Conflicts of Interest Policy set forth in the Company's Corporate Code of Conduct and Ethics and Whistleblower Policy, documents the Company's policies and procedures for compliance with the Public Health Service regulations, entitled *Promoting Objectivity in Research*, 42 CFR Part 50 Subpart F ("PHS Regulations"). These regulations describe the actions an individual and the Company must take in order to promote objectivity in PHS-funded research. The PHS Regulations apply to organizations that apply for, or receive, PHS research funding by means of a grant or cooperative agreement, and to each Investigator (defined below) who is planning to participate in, or is participating in, such research.

The Public Health Service ("PHS") includes the following agencies:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

This Appendix will be publicly available on the Company's website.

**1. Definitions**

This Appendix uses the following Definitions:

- a. **Financial interest:** anything of monetary value, whether or not the value is readily ascertainable.
- b. **Institutional responsibilities:** all professional activity on behalf of the Company (e.g., research, administration).
- c. **Investigator:** the project director, principal investigator or any other individual, 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.

- d. **Research:** any 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). The term includes any such activity for which research funding is available from PHS through a grant or cooperative agreement.
- e. **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 appear 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) **With regard to intellectual property rights and interests** (e.g., *patents, copyrights*), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests.
- (2) **Any reimbursed or sponsored travel** (i.e., that which is reimbursed to or paid on behalf of the Investigator, the Investigator's spouse or dependent children), **related to the Investigator's responsibilities**, if the cost or value received from a single entity exceeds \$5,000 for the preceding twelve (12) months. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a U.S. federal, U.S. state, or U.S. local government agency, a U.S. institution of higher education as defined at 20 U.S.C. § 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

- (3) The term *significant financial interest* does not include the following types of financial interests:
- (i) 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;
  - (ii) Ownership interest in the Company held by the Investigator;
  - (iii) 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;
  - (iv) Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, U.S. state, or U.S. local government agency, a U.S. institution of higher education as defined at 20 U.S.C. § 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education; or
  - (v) Income from service on advisory committees or review panels for a U.S. federal, U.S. state, or U.S. local government agency, a U.S. institution of higher education as defined at 20 U.S.C. § 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

## **2. Training**

Each Investigator must complete training on this Appendix and the PHS Regulations prior to engaging in research related to any PHS-funded activity and at least every four years, and immediately when any of the following circumstances apply:

- a. The Company revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators (training will be completed in the manner and within the time frame specified in communications announcing such changes);
- b. An Investigator is new to the Company (training must be completed within 30 days of joining the Company); or
- c. The Company finds that an Investigator is not in compliance with this Appendix or with a management plan issued under this Appendix (training must be completed within 30 days).

## **3. Disclosure**

- a. **Initial Disclosure:** Each Investigator who is planning to participate in PHS-funded research must disclose to the Company's designated official an up-to-date listing of the Investigator's Significant financial interests (and those of their spouse and dependent children) no later than the time of application for PHS-funded research. Each new Investigator, who, subsequent to the submission of an application for PHS funding, or during the course of the PHS-funded research project, plans to participate in the project, must similarly disclose their Significant financial interests to the Company's designated official prior to participation in the project.
- b. **Annual updates:** Each Investigator who is participating in PHS-funded research must submit an updated disclosure of Significant financial interests at least annually during the period of the award. Such disclosure must include any information that was not disclosed initially to the Company pursuant to paragraph 3(a) above or in a subsequent disclosure of Significant financial interests, and must include updated information regarding any previously disclosed Significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- c. **Updates within 30 days:** Each Investigator who is participating in PHS-funded research must submit an updated disclosure of Significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant financial interest.
- d. **Sponsored travel disclosure:** Significant financial interest disclosures related to reimbursed or sponsored travel will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Company may request additional information on a case-by-case basis.

#### **4. Guidelines for Determining Relatedness and Financial Conflicts of Interest**

The Company's designated official will review all disclosures. The objective of the review is to determine whether an Investigator's Significant financial interest is related to the PHS-funded research and, if so, whether the Significant financial interest is a financial conflict of interest.

An Investigator's Significant financial interest is related to PHS-funded research when the designated official 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 designated official may involve the Investigator in the determination of whether a Significant financial interest is related to the PHS-funded research.

A financial conflict of interest exists when the designated official reasonably determines that the Significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

In determining if an Investigator's Significant financial interest is related to PHS-funded research,

and if so, whether the relationship creates a financial conflict of interest, the designated official will consider the Investigator's role on the project and the following factors:

- The nature of the PHS-funded research project and whether it relates to basic or fundamental research directed at understanding basic scientific processes;
- The possibility for prompt commercialization or clinical application of research results;
- Whether the research involves intellectual property (e.g., an invention) linked to the Significant financial interest;
- Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board;
- Where the Significant financial interest is in another company, whether the Investigator's Significant financial interest could result in the Investigator influencing company decisions, or whether the research could have a significant impact on the company's business or financial outlook;
- The amount of the Significant financial interest;
- Whether the Significant financial interest is in an entity that funds the PHS research in whole or in part, whether through a research agreement, gift, or other arrangement;
- Whether the research could affect the value of the Significant financial interest;
- Whether the project involves a contract (including a subaward) to an entity in which the Investigator has a Significant financial interest.

In conducting its review, the designated official may call upon subject-matter experts as needed with respect to any particular project, such as division management and others with relevant expertise.

## **5. Management of Financial Conflicts of Interest**

Where the designated official determines that a financial conflict of interest exists, it will determine the means to avoid or manage the financial conflict of interest. Examples of conditions or restrictions (i.e., management plan) that might be imposed to avoid or manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts;
- Written disclosure of the conflict to all individuals working on the research project;
- Reporting on research progress to the designated official.

The designated official will communicate its determination to the Investigator in writing. No expenditure of funds under any PHS-funded research project will be permitted until the Investigator complies with this Appendix and agrees to comply with any management plan imposed to manage a financial conflict of interest. The designated official will monitor an Investigator's compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

## **6. Public Disclosure**

Prior to the expenditure of any funds under a PHS-funded research project, the Company will ensure public accessibility by written response to any requestor within five (5) business days of a request, of information concerning any Significant financial interest disclosed to the Company that meets the following three criteria:

- (i) The Significant financial interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the principal investigator, project director, and any other person identified as senior key personnel by the Company in the grant application, progress report or any other report the Company submits to PHS;
- (ii) The Company has determined that the Significant financial interest is related to the PHS-funded research; and
- (iii) The Company has determined that the Significant financial interest is a financial conflict of interest.

The information that the Company will make available in a written response to any requestor within five (5) business days of request will include, at a minimum, the following:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;
- (iii) The name of the entity in which the Significant financial interest is held;
- (iv) The nature of the Significant financial interest; and
- (v) The approximate dollar value of the Significant financial interest in the following ranges: \$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 Company will confirm with the Investigator that the information provided is current as of the date of the correspondence and note the same in its written response to the requestor, and the Company will also note in its written response that the information is subject to updates, on at least an annual basis and within sixty (60) days of the Company's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the Significant financial interest will remain available, for responses to written requests, for at least three years from the date that the information was most recently updated.

## **7. Reporting Financial Conflicts of Interest to PHS**

Prior to the Company's expenditure of any funds under a PHS-funded research project, the Company will provide to the PHS Awarding Component a financial conflict of interest report (containing all elements that the PHS Regulations require) regarding any Investigator's Significant financial interest that the Company finds to be a financial conflict of interest and ensure that the Company has implemented a management plan in accordance with this Appendix. In cases in which the Company identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Company will not submit a financial conflict of interest report to the PHS Awarding Component.

For any Significant financial interest that the Company identifies as conflicting subsequent to the Company's initial financial conflict of interest report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Company will provide to the PHS Awarding Component, within sixty (60) days, a financial conflict of interest report (containing all elements that the PHS Regulations require) regarding any Investigator's Significant financial interest found by the Company to be a financial conflict

of interest, and ensure that the Company has implemented a management plan in accordance with this Appendix.

## **8. Noncompliance and Retrospective Review for Bias**

Whenever the Company identifies a Significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Company during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official will, within sixty (60) days, review the Significant financial interest, determine whether it is related to PHS-funded research, and determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that specifies 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 (for example) failure by the Investigator to disclose a Significant financial interest that is determined by the Company to constitute a financial conflict of interest; failure by the Company 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 Company will, within 120 days of the Company'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. The Company will document the retrospective review consistent with elements required by the PHS Regulations.

Based on the results of the retrospective review, if appropriate, the Company will update the previously submitted financial conflict of interest report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Company 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 and a description of the impact of the bias on the research project and the Company'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, the Company will submit financial conflict of interest reports annually, as specified in this Appendix.

Failure by any individual to adhere to this Appendix may be cause for disciplinary action, including termination.

## **9. PHS Award Subrecipients**

For any PHS prime award to the Company that includes a subaward to another institution, the

written agreement between the Company and subrecipient will establish whether the financial conflicts of interest policy of the Company or that of the subrecipient will apply to the subrecipient's investigator(s). If the subrecipient relies on its conflicts of interest policy, the subrecipient must certify as part of the subrecipient agreement, that its policy complies with the PHS Regulations, as appropriate. In either case, the subrecipient agreement will include time periods to meet the Company's disclosure and/or financial conflict of interest reporting requirements to PHS.

**10. Record Retention**

The Company will maintain records relating to all Investigator disclosures of financial interests and the Company's review of and response to such disclosures (whether or not such disclosure resulted in a determination of a financial conflict of interest) and all actions under this Appendix for at least three (3) years after the date a project's final expenditure report is submitted to the PHS or such other date as is required by law.

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