

TALUS BIOSCIENCE, INC.
POLICY ON FINANCIAL CONFLICTS OF
INTEREST

I. INTRODUCTION

The Public Health Service (PHS/NIH) has recently implemented new regulations (see <http://grants.nih.gov/grants/policy/coi/index.html>) governing the disclosure and administration of financial conflicts of interest (FCOI) related to PHS-funded research. This policy describes Talus Bioscience Inc.'s (hereinafter referred to as "Talus Bio", the "Company", or the "Institution") implementation of this new regulatory requirement, and its program for training investigators, reviewing disclosures, and carrying out any necessary enforcement and reporting actions.

This policy governing FCOI applies to all Investigators (as defined below) of the Institution. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the FCOI is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

II. DEFINITIONS

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid for on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests not reimbursed through the Institution.

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of Institutional research.

Institutional Official means the individual within the Institution that is responsible for the solicitation and review of disclosures of Significant Financial Interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this Policy, the Institutional Official is the Institution's Chief Operating Officer.

Institutional responsibilities mean the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, teaching, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is independently responsible for the design, conduct, or reporting of PHS/NIH sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate. It is the responsibility of the Principal Investigator on any PHS/NIH-funded research project to identify any individuals meeting this definition who are participating in that project, and to provide that information to the Institutional Official. Any such identified individual will then become subject to all of the requirements of this Policy.

Public Health Service or *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 of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health ("NIH"), and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to 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).

III. CONFLICT OF INTEREST

This Policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this Policy informs the Institution's employees about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this Policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

IV. DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests to the Institution on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms. Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

A. Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional official or designee by July 1 for the previous fiscal year.

B. Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into sponsored projects or applications for sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) has submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

C. Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a FCOI with the Investigator's research.

V. REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a FCOI. If a FCOI exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate. The Institutional Official may, at his or her discretion, convene a committee for guidance in specific cases, or in the application of the Policy to particular situations.

A FCOI will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS/NIH-supported research. If the Institutional Official determines that there is a FCOI that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official.

If an Institution identifies that a Significant Financial Interest was not disclosed or reviewed in a timely manner, the Institutional Officer shall within sixty (60) days review the Significant Financial Interest in coordination with the Chief Executive Officer, determine if a FCOI exists and implement an interim management plan, if needed.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

VI. REPORTING TO PHS/NIH

Should any reported conflict or non-compliance require reporting to PHS/NIH, the Institutional Official will report in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

VII. SUBRECIPIENT REQUIREMENT

The Institution shall incorporate language as part of a written agreement with the subrecipient that establishes whether the FCOI policy of the Institution or that of the subrecipient will apply to the subrecipient's Investigators and include a time period to meet disclosure requirements, if applicable, and FCOI reporting requirements to the Institution. Additionally, if the subrecipient's FCOI policy will apply to subrecipient's Investigators, such subrecipient shall provide a certification to the Institution that its FCOI policy complies with the regulation. Subrecipients who rely on their FCOI policy must report identified FCOIs to the Institution in sufficient time to allow the Institution to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module) to meet FCOI reporting obligations. Alternatively, if applicable, the written agreement shall include a requirement to solicit and review subrecipient Investigator disclosures that enable the Institution to identify, manage and report identified FCOIs to the NIH.

The Institutional Official shall conduct an audit not less than every two years of contracts to subrecipients for FCOI language, document such audit findings, and take corrective actions, if needed.

VIII. INVESTIGATOR NON-COMPLIANCE

A. Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may impose sanctions including but limited to withdrawal of grant funding, termination of employment, suspension of all relevant grant activities, or other disciplinary action until the non-compliance is resolved or other action deemed appropriate by the Institutional Official is implemented.

B. Retrospective Review

In addition, if the Institutional Official determines that a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a FCOI, or failure by an Investigator to materially comply with a management plan for a FCOI, a committee appointed by the Institutional Official will, within 120 days of the Institution's determination of noncompliance, complete and document a retrospective review, consistent with the regulation, of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include all project identifying information, the name of Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review, and any other information required by the regulation.

The Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

In any case in which HHS 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 a FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to: i) Disclose the FCOI in each public presentation of the results of the research, and ii) Request an addendum to previously published presentations.

IX. INVESTIGATOR TRAINING

Each Investigator must complete training prior to engaging in research related to any PHS/NIH-funded grant and at least every four years, and immediately under the designated circumstances:

FCOI training is required of each Investigator:

- A. Prior to engaging in research related to any PHS/NIH-funded project
- B. At least every four years, and
- C. Immediately when any of the following circumstances apply:
 - i) Institution revises its policy in a manner that affects the Investigator;
 - ii) When an Investigator is new to the Institution; or
 - iii) When the Institution finds an Investigator is not in compliance with the Institution's policy or management plan.
- D. The training must inform each Investigator of the:

- i) Regulation;
- ii) Institution's Policy on FCOI; and
- iii) Investigator's responsibilities regarding disclosure of Significant Financial Interests

X. PUBLIC ACCESSIBILITY

The Institution shall post this FCOI policy on its public website.

Prior to the expenditure of funds, the Institution will respond to any requestor with information concerning identified FCOIs held by senior/key personnel (as defined by the regulation). The information will:

- iv) Include all minimum elements required by the regulation;
- v) Be posted on the Institution's public website or made available within five calendar days of a written request;
- vi) Be updated, at least annually (website only but any response to a written request will include the updated information);
- vii) Remain available for three years from the date the information was most recently updated.

The information to be made available shall be consistent with all other applicable requirements of the PHS/NIH regulations and policies.

XI. RECORD RETENTION

The Institutional Official will retain all FCOI-related records for a period of at least three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, and from other dates specified in 45 CFR 75.361, where applicable.

XII. CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding research of Talus Bio, to a requestor of information concerning FCOI related to PHS/NIH funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

XIII. REGULATORY AUTHORITY

This Policy implements the requirements of 42 CFR 50 and 45 CFR 94; where there are substantive differences between this Policy and the requirements, the requirements shall take precedence.