

## **ALS Biopharma, LLC CONFLICT OF INTEREST POLICY**

### **INTRODUCTION**

This policy governing financial conflict of interest applies to all Investigators of the Institution including subgrantee/contractor/collaborating Investigators but excludes applications for Phase I support under the SBIR and STTR programs. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest 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.

### **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 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 designated as Kathleen Czupich.

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

*Investigator* means any individual who is responsible for the design, conduct, or reporting of PHS 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.

*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, 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 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).

*SBIR* means any PHS awarded contract awarded under the provisions of U.S. Code- Title 15, Chapter 14A, Aid to Small Business.

## **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 faculty 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.

## **1) 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 March 1 for the previous calendar 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) have 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 Financial Conflict of Interest with the Investigator's research.

## **2) 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 Financial Conflict of

Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate.

A Financial Conflict of Interest 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-supported research. If the Institutional Official determines that there is a Financial Conflict of Interest 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.

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.

Key Elements of a Management Plan include:

- Role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator’s agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

#### 4) REPORTING TO PHS

Should any reported conflict or non-compliance require reporting to PHS, 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.

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE		
REPORT	CONTENT	REQUIRED WHEN?
New FCOI Report (Initial submission)	Grant Number, PI, Name of Entity with FCOI, Nature of 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 (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year 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 or make changes to	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.

	originally submitted FCOI report.	
Mitigation Report	Project Number, Project Title, Contact 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.

## 5) INVESTIGATOR NON-COMPLIANCE

### a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

A Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator, and where applicable, the IRB, and will notify the individual of the right to appeal the decision to an oversight committee, appointed by the Institutional Official for the purpose of the review.

In the event that the PHS-funded project to evaluate a drug, medical device or treatment was conducted by an investigator with a conflict that was not disclosed or managed, the institution requires, through PHS mandate that investigators to disclose the conflict in each public presentation of the results of the research.

### b) Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest 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 Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official will complete a retrospective review 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 the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional official will promptly update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions, including corrective actions, that will be taken to manage the Financial Conflict of Interest 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.

## 6) TRAINING

Each Investigator must complete training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

## **7) RECORD RETENTION**

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee.

## **8) 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 the faculty member, to a requestor of information concerning financial conflict of interest related to PHS 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.

## **9) PUBLIC ACCESSIBILITY**

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Investigator;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS policy.

## **10) 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.