

OBJECTIVITY IN SPONSORED RESEARCH: FINANCIAL CONFLICTS OF INTEREST

1.0 PURPOSE AND SCOPE

The Jackson Laboratory's Policy on objectivity in Sponsored Research establishes requirements related to the disclosure and management of significant financial interests by The Jackson Laboratory (the "Laboratory") faculty members and other Investigators involved in applying for and carrying out Sponsored Research. This policy will be modified as necessary to maintain compliance with the requirements of external agencies. The Laboratory's policies on conflict of commitment reside in [POL.ORG.044](#) and [SLP.ORG.009](#).

Certain federal agencies have specific requirements for the disclosure, management, and reporting of outside interests related to their Institutional Responsibilities, including carrying out Sponsored Research projects. The focus of these requirements is to ensure responsible stewardship of Sponsored Research funds and to promote research free from bias resulting from the Investigator's real or perceived Financial Conflict of Interest ("FCOI"). Agencies with such requirements include the Public Health Service ("PHS") and related components such as the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), and the Food and Drug Administration ("FDA"). The National Science Foundation ("NSF") also has its own requirements, and other sponsors may apply unique requirements in their awards, which shall apply. Contact Sponsored Research Administration with any questions about specific sponsor terms.

2.0 ADMINISTRATIVE CONTROLS

2.1 ACCOUNTABILITY AND SANCTIONS

You are expected to read and understand this Policy and seek answers or clarification whenever needed. Instances of noncompliance or subversion of this Policy may result in disciplinary action up to and including loss of facility and systems access privileges and termination of employment.

2.2 RESPONSIBILITY

The Laboratory requires Investigators to disclose financial interests and professional relationships in outside entities that would reasonably appear to be related to their Institutional Responsibilities in accordance with this policy and applicable sponsor policies.

2.3 EXCEPTIONS PROCEDURE

N/A

3.0 POLICY STATEMENT

3.1 COORDINATION WITH IRB FOR CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH

As noted above, this policy applies to all research, including research involving human subjects. The Laboratory and its researchers have ethical obligations to honor the rights and protect the safety of persons who participate in research conducted at the Laboratory. Significant Financial interests ("SFIs") held by those conducting the research may

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compromise the fulfillment of those ethical obligations and the well-being of the research subjects, as well as the integrity of the related research. Accordingly, any person with an unmanaged conflict of interest is prohibited from participating in the conduct of such research. In addition, research involving human subjects where there is a financial conflict of interest may only go forward if the design and circumstances of the human subject research are such that they serve to protect **both** the human subjects **and** the objectivity of the data obtained. For example, research that includes multiple independent sites, or where the intervention or choice of device is blinded to the investigators, has an independent data and safety monitoring board or has other such protective elements, may be allowed to proceed with an appropriate conflict of interest management plan. In order to address these special concerns when human subjects are involved in the research, a conflict of interest review will be coordinated with the Laboratory Institutional Review Board (see [POL.RES.017](#) and [POL.RES.018](#)).

3.2 INVESTIGATOR TRAINING

All Investigators are required to take the Laboratory's PHS-compliant FCOI training, which includes reviewing the Laboratory's policy, the Investigator's responsibilities, and federal requirements. Training must be completed before engaging in research and refreshed at least every four years. In addition, Investigators may need to complete training when:

- (1) FCOI policies are revised in a manner that changes Investigator requirements;
- (2) An Investigator is new to the Laboratory; and
- (3) An Investigator is non-compliant with FCOI policies and procedures.

3.3 DISCLOSURE

Who Must Disclose

The following individuals are considered Investigators on Sponsored Research projects and must disclose:

- The Principal Investigator (PI);
- All Laboratory faculty contributing effort to the Sponsored Research project; and
- Any other person that the PI or a contributing faculty member designates as responsible for the design, conduct, or reporting of research.

When to Disclose

All Laboratory Investigators participating or planning to participate in Sponsored Research at the Laboratory must disclose all financial interests, including those of their spouse and dependent children, that could reasonably be related to the Investigator's Institutional Responsibilities, as follows:

- When an Investigator is new to the Laboratory;
- On an annual basis;
- Within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI;
- Within thirty days of a significant change in an already disclosed interest; and

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- When submitting proposals for funding and when submitting annual progress reports, as required by sponsors.

3.4 REVIEW AND DETERMINATION OF AN FCOI

The Designated Official (“DO”) is responsible for reviewing all disclosures submitted by Laboratory Investigators to identify SFIs and activities that may reasonably appear to be related to the Investigator’s Institutional Responsibilities. The DO will determine whether there is a FCOI and, if so, whether it can be managed. Where the FCOI cannot be managed, it must be eliminated. All FCOIs must be managed or eliminated prior to the expenditure of Sponsored Research funds.

3.5 FCOI MANAGEMENT AND MONITORING

The DO will develop and implement a plan to manage the FCOI. Examples of conditions or restrictions that the Laboratory may impose to manage an FCOI include, but are not limited to:

- (1) Public disclosure of FCOI (e.g., when presenting or publishing the research);
- (2) For research projects involving human subjects research, disclosure of FCOI directly to participants;
- (3) 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;
- (4) Modification of the research plan;
- (5) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (6) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (7) Severance of relationships that create financial conflicts.

The management plan should include:

- (1) A description of the SFI and the FCOI;
- (2) Role and principal duties of the conflicted Investigator in the research project;
- (3) Specific conditions of the management plan;
- (4) A description of how the management plan is designed to safeguard objectivity in the research project;
- (5) Confirmation of the Investigator’s agreement to the management plan;
- (6) How the management plan will be monitored to ensure Investigator compliance. The appropriate Investigator shall sign and certify each management plan, along with the DO.

The Investigator will provide an update on the details of the management plan at least annually and when circumstances related to the SFI change. Such plans shall remain in effect until the completion of the research project or until the FCOI is eliminated, whichever comes first.

3.6 REPORTING CONFLICTS TO SPONSORS

The Laboratory will report FCOIs to sponsors in accordance with sponsor policy. Where the sponsor does not have a policy that requires reporting, the Laboratory may report the existence of the FCOI on an information-only basis after the FCOI has been managed.

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3.7 SUBAWARDS

When the Laboratory carries out Sponsored Research through subawardees where the sponsor requires contractors or collaborators to follow the same policy, the Laboratory, as the awardee Institution, will take reasonable steps to ensure that all subawardees, contractors, or collaborator Investigators comply with the sponsor's COI requirements. The Laboratory will incorporate, as part of a written agreement with the subawardees, contractors, or collaborators, terms that establish that (1) their conflicts of interest policy is compliant with the sponsor's COI requirements, (2) all their Investigators must comply with their conflicts of interest policy.

3.8 REMEDIES FOR NON-COMPLIANCE

The Senior Vice President for Research and the Director of Sponsored Research Administration are responsible for the interpretation, coordination, and enforcement of the policy. Violation of any part of this policy, including failure to appropriately manage an FCOI, may result in sanctions or other administrative actions against the Investigator in accordance with the Laboratory's policy on Employee Conduct Disciplinary Administration ([POL.HRS.022](#)). In such cases, the DO will coordinate with sponsors in accordance with their regulatory requirements.

3.9 RECORDS

The Laboratory will maintain records relating to all Investigator disclosures of financial interests and the Laboratory's review of and response to such disclosures (whether or not a disclosure resulted in a determination of an FCOI) and all actions under the Laboratory's policy, for at least three years from the date the final expenditures report is submitted to the sponsor or, where applicable, from other dates specified in the sponsor's regulations.

3.10 PHS-SPECIFIC REQUIREMENTS

All FCOIs must be managed or eliminated in accordance with this policy prior to the expenditure of PHS funds.

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses an SFI or an existing Investigator discloses a new SFI to the Laboratory, the DO shall, within sixty days:

1. review the disclosure of the significant financial interest;
2. determine whether it is related to PHS-funded research;
3. determine whether a financial conflict of interest exists; and
4. 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.

Depending on the nature of the SFI, the Laboratory 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 Laboratory's review.

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3.11 PHS SIGNIFICANT FINANCIAL INTERESTS

In addition to the definition of Significant Financial Interest above, PHS considers Sponsored Travel of \$5,000 or more paid by a single Organization over a 12-month period to be an SFI when the travel is related to an Investigator's Institutional Responsibilities.

Sponsored Travel means travel expenses paid for directly or reimbursed to you for travel by you, your spouse, or immediate family when the travel or the sponsoring Organization could be related to your Institutional Responsibilities.

Investigators 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) of \$5,000 or more received over a 12-month period. The disclosure must take place within 30 days of completion of the trip. Sponsored travel does not include travel reimbursed or sponsored by a Federal, state, or local government agency in the United States, or a United States public or non-profit institution of higher education (as defined at 20 U.S.C. 1001(a)) or its affiliated hospital, medical center, or research institute. The Investigator's disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

3.12 FCOI REPORTS TO PHS

Prior to the expenditure of any PHS funds, the Laboratory shall provide to the PHS awarding component through the NIH eRA Commons an FCOI report regarding an Investigator's SFI found to be an FCOI, describing the SFI and the management plan in accordance with the PHS regulations. This shall apply to FCOIs related to Laboratory and subrecipient Investigators. In cases in which the Laboratory identifies an FCOI and eliminates the conflict prior to the expenditure of PHS-awarded funds, the Laboratory will not submit an FCOI report.

For any SFI identified as conflicting subsequent to the initial FCOI report and during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Laboratory shall provide an FCOI report to the PHS Awarding Component, within sixty days.

After the initial submission of an FCOI report, the Laboratory shall provide the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. The Laboratory shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

The FCOI report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict and to assess the appropriateness of the Laboratory's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:

- (1) Project number;
- (2) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (3) Name of the Investigator with the FCOI;

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- (4) Name of the entity with which the Investigator has an FCOI;
- (5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); (vi) Value of the 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;
- (6) A description of how the financial interest relates to the PHS-funded research and the basis for the Laboratory’s determination that the financial interest conflicts with such research; and
- (7) A description of the key elements of the Laboratory’s management plan, including:
 - a. Role and principal duties of the conflicted Investigator in the research project
 - b. Conditions of the management plan
 - c. How the management plan is designed to safeguard objectivity in the research project
 - d. Confirmation of the Investigator’s agreement to the management plan
 - e. How the management plan will be monitored to ensure Investigator compliance; and
 - f. Other information as needed.

3.13 RETROSPECTIVE REVIEW

Whenever the Laboratory identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Laboratory during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the DO shall, within sixty days:

1. review the significant financial interest;
2. determine whether it is related to PHS-funded research;
3. determine whether a financial conflict of interest exists, and, if so:
4. 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 going forward;

Whenever an FCOI under a PHS-funded research project is not identified or managed in a timely manner, including failure by the Investigator to timely disclose an SFI that is later determined by the Laboratory to constitute an FCOI; failure by the Laboratory to timely review or manage such an FCOI; or failure by the Investigator to comply with an FCOI management plan, the Laboratory shall, within 120 days of the Laboratory’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.

Under PHS policy, the Laboratory is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;

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- (5) Name of the entity with which the Investigator has an FCOI;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the Laboratory shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, the Laboratory must notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. 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 Laboratory'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).

The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, which may include directing the Laboratory on how to maintain appropriate objectivity in the PHS-funded research project, requiring the Laboratory to submit records, submit to on-site review, accept special award conditions, suspension of funding, or other enforcement actions until the matter is resolved.

Thereafter, the Laboratory will submit FCOI reports annually, as specified elsewhere in this policy.

3.14 PHS SUBAWARDS

The Laboratory will take reasonable steps to ensure that all subrecipient Investigators comply with PHS FCOI policy, including those of any subrecipient institutions. The Laboratory will incorporate, as part of a written agreement with the subrecipient, terms that establish that:

- (1) the subrecipient's financial conflicts of interest policy is compliant with the PHS FCOI policy,
- (2) all subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, and
- (3) there is a specified time period for the subrecipient to report all identified conflicts of interest to the Laboratory, where this time period is sufficient to enable the Laboratory to provide timely FCOI reports to the PHS as required.

3.15 PHS RECORDS

The Laboratory will maintain records relating to all Investigator disclosures of financial interests and the Laboratory's review of and response to such disclosures (whether or not a disclosure resulted in a determination of an FCOI) and all actions under the Laboratory's policy for PHS COI review or retrospective review, as applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in PHS regulations.

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3.16 NSF-SPECIFIC REQUIREMENTS

Overview of NSF Specific Review, Management, Reporting, and Remedies for Non-Compliance

When a conflict of interest is identified, efforts must be made to manage, reduce, or eliminate the conflict. Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate conflicts of interest include, but are not limited to:

- (1) Public disclosure of significant financial interests;
- (2) Monitoring of research by independent reviewers;
- (3) Modification of the research plan;
- (4) Disqualification from participation in the portion of the NSF-funded research that would be affected by significant financial interests;
- (5) Divestiture of significant financial interests;
- (6) Severance of relationships that create conflicts.

If the Responsible Representative determines that imposing conditions or restrictions would be either ineffective or inequitable and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

If it is determined that there is no way to manage an FCOI satisfactorily, and if the Laboratory finds that research will proceed without the imposition of conditions or restrictions when an FCOI exists, the Laboratory must notify NSF through their AOR representative using NSF's electronic systems. The responsible representative should also coordinate with the Laboratory's General Counsel to keep NSF's Office of the General Counsel appropriately informed.

3.17 NSF SUBAWARDS

When the Laboratory carries out NSF-funded research through subawardees, contractors, or collaborators, the Laboratory, as the awardee Institution, will take reasonable steps to ensure that all subawardee, contractor, or collaborator Investigators comply with NSF COI requirements. The Laboratory will incorporate, as part of a written agreement with the subawardees, contractors, or collaborators, terms that establish that (1) their conflicts of interest policy is compliant with NSF COI requirements, (2) all their Investigators must comply with their conflicts of interest policy.

4.0 QUESTIONS/GUIDANCE

Questions about this Policy should be directed to documentcontrol@jax.org or the person identified below as responsible for interpretation and administration of this Policy.

The Laboratory employee responsible for interpretation and administration of this Policy is the Director, Sponsored Research Administration.

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5.0 DEFINITIONS AND ACRONYMS

Unless defined differently by a sponsor (see PHS and NSF information below), the following definitions apply to this policy.

Designated Official (DO) means the individual(s) designated by the Laboratory to review disclosures of significant financial interests and determine whether there is an FCOI. The DOs at the Laboratory are the Senior Vice President for Research and the Director, Sponsored Research Administration.

Financial Conflict of Interest (FCOI) means a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of Sponsored Research.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Immediate Family means an Investigator's spouse, partner, or dependent children.

Institutional Responsibilities means all of an Investigator's professional responsibilities on behalf of the Laboratory, including, but not limited to, research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards (IRBs) or Data and Safety Monitoring Boards.

Investigator means the Principal Investigator or project director, co-investigators, key personnel, and any other person at the Laboratory, regardless of title or position, who is responsible for the design, conduct, or reporting of sponsored research or proposed for such funding, designated by the principal investigator/project director.

Laboratory means The Jackson Laboratory.

Manage means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Organization means any domestic or foreign, public, governmental, or private, for-profit or not-for-profit, legally constituted entity other than the Laboratory.

Significant Financial Interest (SFI) means Financial Interests Related to an Investigator's Institutional Responsibilities: A SFI is a Financial Interest consisting of one or more of the following interests of the Investigator. The Investigator (and those of the Investigator's spouse and dependent children) must disclose any such SFI that reasonably appears to be related to the Investigator's institutional responsibilities:

- (1) 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;

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- (2) 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
- (3) Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.

The term SFI does not include the following types of Financial Interests: salary, royalties, or other remuneration paid by the Laboratory to the Investigator if the Investigator is currently employed or otherwise appointed by the Laboratory, including intellectual property rights assigned to the Laboratory and agreements to share in royalties related to such rights.

SFI also does not include 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; and

SFI also does not include income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency in the United States, a United States public or non-profit institution of higher education (as defined at 20 U.S.C. 1001(a)) or its affiliated hospital, medical center or research institute; or income from service on advisory committees or review panels for a Federal, state, or local government agency in the United States, or a United States institution of higher education.

Sponsor means the organizational unit of the Federal government or private sponsor that funds the Sponsored Research subject to this policy, including the Laboratory in cases where the research is funded in whole or in part with Laboratory funds.

Sponsored Research means a systemic investigation, study, or experiment designed to develop or contribute to generalizable knowledge supported by a grant, cooperative agreement, sponsored research agreement, or internal award. The term encompasses basic and applied research, including human subject research and product development.

Subrecipient means an external entity that conducts substantive, programmatic work or an important or significant portion of a Sponsored Research project.

5.1 NSF-SPECIFIC DEFINITIONS

Significant Financial Interest (SFI) In addition to the definition included in the overall policy above, the definition of Significant Financial Interest also includes equity interests in private equity, or other ownership interests, and venture or other capital financing.

*NOTE: Although current NSF regulations specify a higher threshold for SFI than PHS (NIH), the Laboratory policy identifies \$5,000 as the monetary threshold. Similarly, in non-publicly traded companies, PHS and Laboratory policy identify any equity amount as the threshold.

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Responsible Representative means the individual identified and appointed by the Laboratory to assume the review responsibility for its own Investigators. The Responsible Representative is the DO.

6.0 REGULATORY AUTHORITY, RELATED POLICIES, PROCEDURES, AND OTHER DOCUMENTS

Citation	Description
DOC.REC.009	Institutional record retention schedule
POL.HRS.022	Employee conduct and disciplinary administration
POL.ORG.044	Institutional conflicts of interest and commitment
POL.ORG.017	IRB review of financial conflicts of interest
POL.ORG.018	IRB financial conflicts of interest: bonus payments in clinical trial agreements
POL.RES.019	IRB member and consultant conflicts of interest
SLP.ORG.009	Standards for conflicts of interest and commitment for researchers
NIH FCOI Guidance	NIH FCOI guidance
PHS Policy 42 CFR Part 50 Subpart F	DHHS - promoting objectivity in research
NSF PAPPG	NSF proposal & award policies & procedures guide