

OBJECTIVITY IN SPONSORED RESEARCH: FINANCIAL CONFLICTS OF INTEREST

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PURPOSE AND SCOPE

This policy applies to all Investigators participating in Sponsored Research and/or research involving human or animal subjects conducted at or sponsored by the Laboratory. For such Investigators, the requirements of this policy apply in addition to the requirements of the Laboratory’s Conflict of Interest and Conflict of Commitment for Research, Administrative and Management Staffs policy ([POL.ORG.029](#)), which addresses Investigators’ responsibilities to the Laboratory as employees. For the purposes of this policy, Investigators are responsible for disclosing his or her immediate family’s Significant Financial Interests (SFI) pursuant to this policy.

The Laboratory seeks to ensure that the design, conduct and reporting of research, whether funded by the Federal government, a private sponsor or internally, is not biased by any potential Financial Conflict of Interest.

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The policy requires Investigators to disclose to the Laboratory any Significant Financial Interest that reasonably appears to be related to their Institutional Responsibilities. The Laboratory is then required to review any disclosures and determine whether any of the reported Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the research, and, if so, prior to the expenditure of awarded funds, take measures to protect such funded research from bias due to a potential Financial Conflict of Interest and disclose all managed Significant Financial Interest to the Awarding Agency and the public, if required.

Further, this policy requires Investigators to disclose to the Laboratory any Significant Financial Interest that reasonably appears to be capable of being influenced by, or of influencing, proposed research involving humans or animals. The Laboratory reviews any such disclosures and implement management plans, as appropriate.

POLICY STATEMENT

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. SFIs held by those conducting the research may 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 subjects 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, conflict of interest review will be coordinated with the Laboratory Institutional Review Board (see [POL.RES.017](#) and [POL.RES.018](#)).

DISCLOSURE

Investigators must disclose their Significant Financial Interests and those of their immediate family as follows:

- Upon becoming affiliated with the Laboratory and annually thereafter.
- Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, inheritance, etc.) a new Significant Financial Interest.

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Each Investigator named in an IRB protocol application must complete a separate disclosure in accordance the Laboratory's IRB Review of Financial Conflicts of Interest policy ([POL.RES.017](#)).

SUBRECIPIENT REQUIREMENTS

If a subrecipient carries out a portion of the work, the Laboratory takes reasonable steps to ensure that they have a FCOI policy that complies with respective regulations and reports identified FCOIs for its Investigators within a time frame that allows the Laboratory to report them to the Awarding Agency.

REVIEW AND MANAGEMENT FOR SPONSORED RESEARCH COMPLIANCE

Sponsored Research Administration (SRA) does not submit any research proposal unless all named Investigators have a current SFI disclosure on file. Furthermore, SRA obtains affirmation from Investigators as to the accuracy of their disclosures upon receipt of a notice of award. Investigators must identify if any SFI could reasonably influence or be influenced by the proposed research activity.

"RELATED TO THE RESEARCH" REVIEW

Upon receipt of a notice of award and prior to the expenditure of any funds, a member of SRA's Leadership (director or senior managers) reviews the financial disclosures made by the named Investigators to determine if any disclosed interest represents a SFI for that Sponsored Research. The SRA Leadership reviewer will make an initial determination if the SFI is related to a sponsored research project. An SFI is related to a sponsored research project when it is determined that the SFI (1) could be affected by the funded research or (2) is in an Entity whose financial interest could be affected by the research. The SRA Leadership reviewer may request the Investigator to provide supplemental information to inform the review. If it is determined that the SFI is related to the sponsored research project, the Designated Institutional Official further assesses whether the SFI might be deemed a FCOI.

FCOI DETERMINATION

To determine whether a SFI might be deemed a FCOI, the SRA Leadership reviewer will perform a review of the Investigator's external financial interests to the project described in the proposed research activity. If the SFI could directly and significantly affect the design, conduct or reporting of the proposed research, then it is a FCOI that must be managed, reduced, or eliminated.

Among the factors that should be taken into consideration in the determination of whether an SFI is an FCOI include the role of the Investigator and the opportunity to bias the results, the nature of the research being proposed, whether the work is funded by an entity in which the Investigator holds a SFI, and consideration of the value of the SFI in relation to the size and value of the entity. The factors that should be considered include:

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1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Investigator's technology, the amount of commercialization payments received by the faculty member from that technology, both currently or in the future; or
8. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which the Investigator has a SFI; or
13. Whether the project involves a subaward to an entity in which the Investigator has a SFI.

For example, conducting federally funded research that could materially affect the financial interests of an Entity in which the Investigator has a personal financial interest presents a conflict that must be managed, reduced, or eliminated. More specific examples of potential FCOI include:

1. **An Investigator holds equity over a certain dollar amount or percentage of an Entity that stands to benefit from the research study at JAX.** In this situation, good research results that benefit the Entity, may also benefit the Investigator financially. Research results that negatively impact the Entity would also reduce the value of the Investigator's equity. This does not necessarily mean an Investigator would conduct research unethically, however, the likelihood of

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that occurring and the public perception that the research is tainted are increased when Investigators hold significant equity in an Entity that can benefit from his or her research.

2. **An Investigator receives significant financial compensation in the form of consulting payments or payment for services on an Entity's advisory board from an Entity that will be affected by the research study.** As in the previous example, this situation involves financial benefits to the Investigator. He or she could easily feel pressured to report only positive results if his or her future income from the Entity might be affected.

3. **Involving students or post-doctoral students and trainees in work that could directly benefit a company in which the faculty member supervising the students has a personal financial interest.** While presenting a conflict of interest, this situation may be acceptable as long as certain approval and oversight steps are taken to ensure that the interests of the students/trainees are adequately protected.

4. **Giving an Entity preferential access to results of JAX-conducted research while providing personal consulting services to that Entity.** This presents a conflict that is always unacceptable.

5. **Receiving licensing milestone payments for licensed technology while performing clinical research on that licensed technology.** While presenting a conflict of interest, this may be acceptable if the amount of the payments does not exceed specific thresholds. Exceptions may be allowed under limited conditions even if payments exceed the thresholds, with appropriate management.

6. **Holding a JAX Faculty appointment while having an executive or board position at a for-profit company.** For full-time JAX Faculty, this is always prohibited.

If the determination is made that an FCOI may exist, the matter is referred to the Sponsored Research COI Committee comprised of the Designated Institutional Official, a representative from the Office of the General Counsel and the Senior Vice President for Research.

The Sponsored Research COI Committee, with the cooperation of the Investigator and the respective Scientific Director, develops a management plan which will be outlined in a Memorandum of Understanding (MOU). In formulating the MOU, the Sponsored Research COI Committee should consider that it has a range of options available to it when a conflict of interest needs to be managed. Each situation will have its own unique aspects that should be considered. Therefore, the COI Committee must carefully review each situation and ensure that the problems or potential problems are adequately addressed. At the same time, it is important that the COI Committee not over-manage the situation so that the research is not impeded unnecessarily. Some of the options available to the COI Committee include:

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- Require that the Investigator disclose his or her conflicting financial interests to all collaborators, laboratory staff members, and any proposed trainees;
- Require that the Investigator disclose financial interests in any public release of study results (this is a common requirement in many professional journals);
- Require that the Investigator have a person unaffiliated with his or her research provide an objective review of data, results and any manuscripts intended for publication;
- Require that the Investigator revise aspects of the research project so as to mitigate any real or potential conflicts;
- Prohibit the Investigator from participating in certain proposed research activities; and,
- Require that the Investigator reduce or divest the significant financial interest.

When the MOU detailing the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the Entity is complete, it must be signed by the Investigator and countersigned by the Laboratory’s General Counsel or the Designated Institutional Official.

The Laboratory takes steps to monitor Investigator’s compliance with the management plan outlined in the MOU for as long as the Investigator carries out the Sponsored Research.

Records of all SFI disclosures and of actions taken to manage actual or potential FCOIs is retained by the Designated Institutional Official until three years after the latter of: (i) the date of submission of the final expenditure report of the award to which they relate or, (ii) for Federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report or, (iii) the resolution of any government action involving those records.

TRAINING REQUIREMENTS

Each Investigator must be informed of this policy and complete FCOI training prior to engaging in Sponsored Research and at least every four years thereafter, and immediately when this policy is revised, the Investigator is new to the Laboratory, or the Laboratory finds that the Investigator is not in compliance with this policy or an applicable management plan. SRA, on behalf of the Laboratory, is responsible for communicating this policy to the Investigators and ensuring that the FCOI training is completed and maintained.

AGENCY SPECIFIC REPORTING REQUIREMENTS

The Designated Institutional Official, on behalf of the Laboratory, reports any identified FCOI to the Awarding Agency in accordance with their regulations or provide a written response to any requestor within five (5) business days of a request.

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NON-COMPLIANCE

Whenever a FCOI is not identified or managed in a timely manner, whether through the failure of the Investigator to disclose the SFI, the Laboratory to manage the interest or the Investigator to comply with the management plan, the Sponsored Research COI Committee conducts a retrospective review of the Investigator's activities within 120 days of the Laboratory's determination of noncompliance in relation to Sponsored Research. The review determines whether any research, or portion thereof, conducted during the period of noncompliance, was biased in design, conduct or reporting. Whenever an Investigator has been found to have violated this policy or the terms of the management plan, the Sponsored Research COI Committee reports the violation to the President of the Laboratory, who imposes appropriate disciplinary action. The Laboratory, if appropriate, updates the previously submitted FCOI report and if bias is found, submit a mitigation report to the relevant Awarding Agency.

In any case where the Sponsored Research COI Committee determines that a clinical research project 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 Financial Conflict of Interest that was not managed or reported by the Laboratory, the Laboratory requires the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

QUESTIONS AND ADDITIONAL INFORMATION

Contact the Designated Institutional Official.

PROCEDURE

N/A

DEFINITIONS AND ACRONYMS

- **Awarding Agency:** Organizational unit of the Federal government or private sponsor that funds the research that is subject to this policy, including the Laboratory in cases where the research is being funded in whole or in part with Laboratory funds.
- **Designated Institutional Official:** The Director of Sponsored Research Administration is the institutional official designated to solicit and review disclosures of Significant Financial Interests from each Investigator under this policy.
- **Entity:** Any domestic or foreign, public or private, for profit or not-for-profit, legally constituted organization other than the Laboratory or for members of the immediate family, their employers; a U.S. Federal, state, or local government agency; a U.S. institution of higher education, academic teaching hospital, medical center, or research institute affiliated with a U.S.

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institution of higher education. **Entity** includes but is not limited to companies, medical centers or research institutes not affiliated with a U.S. institution of higher education, non-profit foundations, voluntary health organizations (e.g. American Cancer Society), independent research institutions and any foreign Entities or foreign government agencies.

- **Financial Conflict of Interest (FCOI):** A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of research.
- **Immediate Family:** An Investigator's spouse, partner or dependent children.
- **Institutional Responsibilities:** 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:** 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. Additionally, collaborating subrecipient Investigators and consultants are included in this definition.
- **Laboratory:** The Jackson Laboratory.
- **Significant Financial Interest (SFI):** A financial interest that Investigator or their immediate family received during the 12 months preceding the disclosure or as of the date of the disclosure from an Entity that may be seen as having an interest in Investigator's institutional responsibilities and that meets one or more of the following thresholds:
 - Publicly traded Entity: \$5,000 or more in aggregated remuneration (e.g. salary, consulting fees, honoraria, payment for services) and equity interest (stock, stock option or other ownership interests).
 - Non-publicly traded Entity: \$5,000 or more in aggregated remuneration or equity interest of any value.
 - Any income from intellectual property rights and interests.
 - An appointment to serve in either a personal or representative capacity with an Entity.
 - For NIH-funded investigator: reimbursed or sponsored Travel worth \$5,000 or more.
 - The term Significant Financial Interest excludes:
 - Salary in connection with a joint/adjunct appointment held at another institution (foreign or domestic) with whom the Laboratory has an inter-institutional affiliation.
 - Income from seminars, lectures, teaching engagements, advisory committees, review panels or travel paid by a U.S. Federal, state, or local government agency, a U.S. institution of higher education, academic teaching hospital, medical center, or research institute affiliated with a U.S. institution of higher education.
 - Equity interests in, or 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.

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- **Sponsored Research:** 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:** An external entity who conducts substantive, programmatic work or an important or significant portion of a Sponsored Research project.

REFERENCES

- Code of Federal Regulations: [2 C.F.R. § 200.112](#)
- Public Health Service (PHS) regulation on Responsibility of Applicants for Promoting Objectivity in Research: [42 C.F.R. Part 50, Subpart F](#)
- Public Health Service (PHS) regulation for Responsible Prospective Contractors: [45 C.F.R. Part 94](#)
- [NIH Conflict of Interest Policy](#)
- [POL.ORG.029](#)
- [POL.RES.017](#)
- [POL.RES.018](#)
- [POL.RES.019](#)