



Financial Conflict of Interest (FCOI) Policy

Policy Statement

Jacaranda Biosciences, Inc. (JBI) is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. JBI has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

This policy has been developed to address and comply with Public Health Service (PHS) requirements as defined in 42 CFR Part 50 Subpart F, Promoting Objectivity in Research. This regulation was developed to promote objectivity in research by establishing standards that ensure a reasonable expectation that the design, conduct and reporting of research funded under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. The regulation can be found at <https://ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>.

Key Definitions

The following definitions are provided as a reference for the purpose of understanding this policy. A complete list of official definitions which apply to this policy can be found at 42 CFR 50.603.

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

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

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, 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.

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

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant financial interest means:

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

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities according to federal guidelines.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Responsibilities

The Designated Official (or designee) shall be responsible for the following:

- Informing JBI Investigators of their obligations under this policy and any related regulations;
- Reviewing disclosures of significant financial interest with heads of department to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest;
- Screening and managing potential financial conflicts of interest;
- Maintaining all records relating to disclosures of financial interests, and any related actions under this policy;
- Ensuring inclusion of any required certifications in applications for funding or contract proposals; and
- Reporting and disclosure as required under this policy and applicable regulations.

For PHS/NIH-funded research, the Designated Official shall also have the following responsibility:

- Taking reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this policy or provide JBI with sufficient assurances to enable JBI's compliance with all applicable laws or regulations. To this end, the written agreement between JBI and the subrecipient will specify whether JBI's or the subrecipient's financial conflicts of interest policy will apply to the subrecipient's Investigators and, if the subrecipient's policy will apply, the Designated Official will:
 - Obtain certification from the subrecipient that its policy complies with JBI's policy and the applicable regulations (absent such certification, JBI's policy will apply to the subrecipient's Investigators), and
 - Establish time periods for subrecipient reporting of financial conflicts of interest to JBI that enable JBI to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If JBI's policy will apply to subrecipient Investigators, JBI will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations.

Training

The NIH Financial Conflict of Interest tutorial was designed by the NIH to provide education training on what constitutes financial conflict of interest. This course is required for Investigators involved with an PHS/NIH-funded project.

FCOI training will be completed by Investigators (at minimum):

- Prior to engaging in research related to any PHS/NIH-funded grant
- At least every four (4) years
- Immediately, if:
 - JBI revises its FCOI policy in any manner that affects requirements of Investigators
 - Investigator is new to JBI
 - An Investigator is not in compliance with the policy or management plan

The NIH course is accessible at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. Upon completion of the training, a certificate of completion must be turned into the Designated Official and will

be stored on the SPI internal server with other staff training qualifications. The Investigator should also retain a copy of the certificate for their records.

Disclosure, Review, and Monitoring

Disclosure of Significant Financial Interests (SFI) shall be via the *Financial Interest Disclosure Form* (Exhibit 1), which is completed by an Investigator prior to engaging in research related to any PHS/NIH-funded grant, and when an SFI arises during the course of research.

At minimum, disclosure of SFI must occur:

- No later than at the time of application for PHS/NIH-funded research
- At least annually during the period of the award
- Within thirty (30) days of discovering or acquiring a new SFI

When an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, the Designated Official shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and, 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 FCOI.

The Designated Official shall determine whether an Investigator's SFI is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If JBI determines that a financial conflict of interest exists, a financial conflicts of interest management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, JBI may require the management of conflicting financial interests in other ways as it deems appropriate.

Reporting

The Designated Official will report disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:

- i. Initial report – prior to the Company’s expenditure of any funds under a NIH-funded research project, the Company must provide to the NIH an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the regulation.
- ii. During on-going NIH-funded research projects – the Company shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, the Company shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.
- iii. Annual FCOI report – For any FCOI previously reported to the NIH, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

The Designated Official will notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation. The Designated Official will notify NIH promptly if an Investigator fails to comply with the Institution’s FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research. The Designated Official and Investigator will develop and undergo a corrective action plan for noncompliance with the JBI FCOI policy or the management plan.

Reporting to NIH will include reporting elements (e.g., entity name, name of the investigator with the FCOI, nature of SFI(s), value of the SFI(s), etc.) as required by the regulation.

Documentation of any retrospective reviews shall include at a minimum the following key elements: Project Number; Project Title; PD/PI or contact PD/PI if multiple PD/PI model is used; Name of the Investigator with the FCOI; Name of the entity with which the Investigator has an FCOI; Reasons for the retrospective review; Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed); Findings of the review; and Conclusions of the review.

Investigator Noncompliance

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), JBI may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator’s participation in the research.

Per federal regulations, JBI will conduct a retrospective review within 120 days of the JBI’s determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a significant financial interest that is determined by JBI to constitute a financial conflict of interest;
- Failure by JBI to review or manage such a financial conflict of interest;
- Failure by the Investigator to comply with the financial conflict of interest management plan;

For PHS/NIH-funded research, failure to comply with this policy or the applicable regulations shall result in the following:

- If the Investigator’s failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS/NIH -funded research,

JBI shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;

- JBI will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts; and
- If HHS determines that a clinical PHS-funded 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 neither disclosed nor managed, JBI shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

Retention of Records

The Designated Official will retain financial conflicts of interest disclosure forms and other supporting information including actions taken to manage actual or potential conflicts of interest. For PHS/NIH-funded research, these records shall be retained for at least 3 years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

Disclosure

JBI will make the following information publicly available:

- This FCOI policy
- Any information concerning identified FCOIs held by senior/key personnel (as defined by federal regulations) participating in PHS/NIH-funded research. The publicly accessible information will:
 - Be made available prior to the expenditure of funds
 - Include the minimum elements as provided in the regulation
 - Be made available within five (5) business days of a written request to JBI
 - Be updated, at least annually and/or within sixty (60) days of a newly identified FCOI
 - Remain available for three (3) years from the date the information was most recently updated

Jacaranda Biosciences, Inc. (JBI)

Financial Interest Disclosure

Name:
Role:
Award:

Check reason for submittal:

New Disclosure	
Updated Disclosure	
Annual Reporting/Non-Competing Continuation	
Competing Continuation	
No-cost Extension	
Addition of Investigator	
Change in PI	

Answer the following questions providing explanations as needed (if yes, please explain).

Do you, your spouse, your registered domestic partner and/or your dependent child(ren) have any of the following financial interests related to your institutional responsibilities:

• Financial compensation from consulting, employment, managerial, and fiduciary relationships (including travel) from an entity other than JBI that, when aggregated over the preceding twelve months exceeds \$5,000?
No___ Yes___

• Equity and other financial interests above \$5,000 in an entity other than JBI?
No___ Yes___

• Any equity interest(s), or entitlement to the same, in a non-publicly traded for profit entity other than JBI?
No___ Yes___

• Receipt of payments for any intellectual property rights and interests (e.g., from patents, copyrights assigned to any entity other JBI)?
No___ Yes___

Signature and Date

Print name