



# NIH Project Financial Conflict of Interest Requirements

## Summary

The National Institutes of Health (NIH) state it is committed to preserving the public's trust in research. Therefore, NIH-supported research needs to be conducted without bias and with the highest scientific and ethical standards. Their Financial Conflict of Interest Policy is a regulation that promotes objectivity in research and establishes the standards to provide a reasonable expectation that the design, conduct and reporting of NIH research will be free from bias resulting from investigators' financial conflict of interest (FCOI). Through its policies and procedures, BI also seeks to ensure that any researcher engaged in NIH research complies with the expectations of the NIH Financial Conflict of Interest Policy.

BI acknowledges the use of the *University of Melbourne PHS/NIH Project Financial Conflict of Interest (FCOI) Requirements Guidance* and the *Public Health Services/National Institutes of Health Project Financial Conflict of Interest Procedure of James Cook University*.

The full NIH Financial Conflict of Interest (FCOI) policy and associated detailed guidance (including FAQs) are available on the NIH website.

## Purpose

This Procedure provides guidance to support compliance with the NIH Financial Conflicts of Interest Policy. This Procedure explains the expectations of the management and disclosure of financial conflicts of interest of BI personnel who are investigators on any NIH proposal or project.

These requirements differ from, and are in addition to, BI's general requirements relating to managing conflicts of interest. The FCOI requirements must be addressed by all BI investigators on any NIH proposal/project. Of particular note is that the disclosure requirements relate to ALL significant sources of funding, including those relating to investigators' other activities at BI.

## Scope

This guidance applies to:

- Any person identified as senior or key personnel in a NIH grant application or progress report who can directly or materially influence the research, or who is responsible for the design, conduct, and reporting of such research.
- When BI is a Prime Awardee or a Sub-awardee.
- The Company Secretary acts as BI's Designated Official to determine whether an FCOI exists and implement and monitor management plans.

## Definitions and Abbreviations

Term/Abbreviation	Definition
BI	Bionics Institute
SFI	Significant Financial Interest (full definition below)
FCOI	Financial Conflict of Interest (full definition below)

Term/Abbreviation	Definition
NIH	National Institutes of Health
Pass-through Entity	Entity that provides a subaward to a subrecipient to carry out a portion of the prime award.
PD/PI	A project director or principal Investigator of a NIH-funded research project.
Senior/Key Personnel	The PD/PI and any other person identified as senior/key personnel by BI in the grant application, progress report, or any other report submitted to the NIH
Awarding IC	The NIH Institute/Center (IC) responsible for the award, administration, and monitoring of grant supported activities.

## Definition of Significant Financial Interest (SFI)

### A significant financial interest (SFI) is defined as:

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

**Travel:** Investigators also 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), related to their institutional responsibilities. The following details should be provided in the disclosure: the purpose of the trip, the identity of the sponsor/organiser, the destination, and the duration. The Company Secretary will determine if further information is needed, in order to determine whether the travel constitutes and FCOI with the NIH-funded research.

This disclosure requirement **does not** apply to travel that is reimbursed or sponsored by a US 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 centre or a research institute that is affiliated with an institution of higher education.

**Foreign financial interests:** Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on

advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity. This includes foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

### **The term SFI does not include the following types of financial interests:**

(i) salary, royalties, or other remuneration paid by BI to the Investigator if the Investigator is currently employed or otherwise appointed by BI, including intellectual property rights assigned to BI and agreements to share in royalties related to such rights.

(ii) 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.

(iii) income from seminars, lectures, or teaching engagements sponsored by a US 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 centre, or a research institute that is affiliated with an institution of higher education located in the US; or

(iv) income from service on advisory committees or review panels for a US 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 centre, or a research institute that is affiliated with an institution of higher education located in the US.

## **Responsibilities**

### **Investigators**

Prior to commencing any NIH funded research at BI, Investigators must undertake FCOI training available through the [NIH FCOI Online Tutorial](#). This must be undertaken at least every four years.

- Assist BI's Principal Investigator to complete BI's FCOI Disclosure Form at the **pre-award stage (no later than the time of application)**.

Investigators must disclose all identified Significant Financial Interests (and those of the Investigator's spouse/common law partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities. This is done by notifying the Company Secretary (copy in [rgo@bionicsinstitute.org](mailto:rgo@bionicsinstitute.org)) using the FCOI Disclosure Form at the **post-award stage**:

- prior to expenditure of NIH funding;
- annually post-award;
- within 30 days of a new SFIs arising during the course of an NIH project; and
- within 30 days of new investigators joining the project.

Investigators must assist with the development of a management plan for any identified FCOIs.

Investigators must comply with this Guidance and with any management plan developed to manage any identified FCOIs.

Investigators must assist with completing any reports that are required to be provided to the NIH or Pass-Through Entities; and

Comply with any other obligations under the NIH policy.

### **Principal Investigator**

The Principal Investigator is BI's first named investigator on the NIH grant.

The Principal Investigator must comply with all Investigator Responsibilities and in addition:

#### **Pre-award**

- complete the FCOI Disclosure Form with respect to all BI Investigators and submit the FCOI Disclosure Form to the Company Secretary (copy in [rgo@bionicsinstitute.org](mailto:rgo@bionicsinstitute.org)) at the pre-award stage **(no later than the time of application)**.

### **Post-award**

- confirm that the information disclosed in the FCOI Disclosure Form is still current and, if not, update the Form;

and

- ensure that all BI Investigators involved in the NIH project are aware of, comply with and make any disclosures required under this Guidance, including completing the FCOI Disclosure Form for any Significant Financial Interests identified in the FCOI Disclosure Form.

### **Company Secretary**

The Company Secretary must review disclosures of Significant Financial Interests and determine if a FCOI exists.

The Company Secretary must manage FCOIs. This includes developing and implementing management plans and monitoring compliance.

The Company Secretary must maintain the following records for at least three years from the date of the final expenditures report is submitted to NIH, or, where applicable, from other dates specified in NIH policy:

- All Investigator disclosures of financial interests;
- Review of and actions taken related to such disclosures.

The Company Secretary must comply with any other obligations under the NIH policy.

### **Bionics Institute Responsibilities**

BI must provide annual and ad hoc FCOI reports to NIH.

BI must address non-compliance in accordance with this Guidance.

BI must take relevant corrective actions.

BI must receive, review and register changes to FCOIs.

BI must develop and implement Institutional-level processes to comply with NIH policy.

BI must report to NIH within 60 days of changes to FCOIs arising.

If BI is a sub-recipient of NIH-funded research, BI must comply with reporting time periods specified in the agreement with the awardee Institution.

BI must provide Institutional-level monitoring and assurance.

BI must record completion of training by all Investigators.

### **Training Requirements**

Each Investigator must understand their responsibilities under this Guidance (including the responsibilities regarding disclosure of SFIs) and the NIH policy.

Each Investigator must complete the NIH on-line tutorial:

- prior to engaging in NIH-Funded Research;
- at least once every 4 years; and
- immediately when any of the following circumstances apply:

(i) this supplemental guidance or procedures relating to FCOI policies are revised in any manner that affects the requirements of Investigators;

- (ii) An Investigator is new to BI, even if the /NIH Funded Research has already begun; or
- (iii) An Investigator is not in compliance with this supplemental guidance or a management plan, as determined by the Designated Official.

When the NIH on-line tutorial has been completed, the Investigator must save an electronic copy of the certificate generated through the system and provide a copy to the Research Governance Office.

## Determination of Financial Conflict of Interest (FCOI)

The Company Secretary determines, on behalf of BI, whether an FCOI exists for the purposes of the NIH policy.

The Company Secretary must determine whether the SFI declared by the Investigator may reasonably be said to be related to the NIH research. This is done by assessing whether the SFI:

- could be affected by the NIH research; or
- is in an entity whose financial interest could be affected by the NIH research.

If the SFI is determined by the Company Secretary to be related to the NIH research, the Company Secretary must then determine whether the SFI could directly and significantly affect the design, conduct, or reporting of the NIH research.

If the SFI is determined by the Company Secretary to both:

- relate to the NIH research; and
- affect the design, conduct or reporting of the NIH research,

**it is an FCOI**, and must be managed (see below).

The Investigator may be involved in the determination of whether a SFI is related to NIH research. If required, the Company Secretary may seek guidance from a representative of the BI Board. However, the determination of whether an FCOI exists must ultimately be made by the Company Secretary.

## Management Plans

Where a FCOI is identified, the Company Secretary must develop and implement a management plan within **60 days** of the FCOI being identified. The management plan will specify the actions that have been, and shall be, taken to manage such FCOI.

Examples of conditions or restrictions that might be imposed to manage a FCOI include:

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

The Company Secretary must appropriately monitor compliance with any management plan until the completion of the NIH project.

## Non-Compliance and Remedies

If BI identifies a SFI was not disclosed by an Investigator, or was not reviewed during an ongoing NIH-funded project, the Company Secretary shall within sixty days:

- Review the SFI;
- Determine if the SFI is related to NIH-funded research;
- Determine whether a FCOI exists.

If a FCOI does exist, the Company Secretary shall:

- 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 going forward.

In addition, when there is non-compliance, specifically:

- A FCOI is not identified or managed in a timely manner;
- An Investigator does not disclose a SFI that is determined by BI to constitute a FCOI;
- Failure by BI to review or manage such a FCOI;
- Failure by the Investigator to comply with a FCOI management plan.

BI shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the NIH-funded research project. The review will determine whether any NIH research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct, or reporting of such research. Investigators must fully and promptly cooperate with this review.

The following minimum information will be documented in the retrospective review:

- Project number.
- Project title.
- PD/PI or contact PD/PI if a multiple PD/PI model is used.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has a financial conflict of interest.
- Reason(s) for the retrospective review.
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed).
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, BI shall update the previously submitted FCOI report. The update will specify the actions required to manage the FCOI going forward.

If bias is found, BI will notify the awarding IC promptly and submit a mitigation report. The mitigation report must include, at a minimum:

- the key elements documented in the retrospective review above.
- A description of the impact of the bias on the research project.
- BI'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).

Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

Where non-compliance relates to NIH research investigating the safety or effectiveness of a drug or device, BI may require the Investigators to disclose the FCOI in each public presentation and request an addendum to previously published outcomes relating to the research, and the Investigators must comply with this requirement.

In the event of non-compliance with any requirements under this Guidance, BI may take corrective actions. These could include withholding access to NIH funds and/or suspending project activity.

Non-compliance with this Guidance, including failure to disclose SFIs or failure to comply with any management plan, may constitute research misconduct. BI will follow the Process for Managing Potential Breaches of the Code to determine if research misconduct may have occurred.

## Record Keeping

Principal Investigators, Investigators and the Company Secretary must create, maintain and store all records relating to implementation of this Guidance for at least 3 years following the submission of the final report to the NIH (or such other period as required under the NIH policy, or BI's Record Retention Schedule).

## Public Accessibility Requirements

This Guidance must be published on BI's public-facing website.

If a request for information is made concerning an FCOI, BI will, disclose requisite details within 5 calendar days.

Requests should be made to [researchintegrity@bionicsinstitute.org](mailto:researchintegrity@bionicsinstitute.org)

BI will provide a written response, within 5 calendar days, to any requestor, for SFIs that meet the following criteria:

- The SFI was disclosed and is still held by senior/key personnel.
- BI has determined that the SFI is related to the NIH-funded research.
- BI has determined that the SFI is a FCOI.

The information provided to the requestor, shall include, at a minimum:

- The Investigator's Name.
- The Investigator's title and role with respect to the research project.
- The name of the entity in which the SFI is held.
- The nature of the SFI.
- The approximate dollar value of the SFI (dollar ranges: \$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.

## Requirements regarding Subrecipients

If BI is the prime awardee, responsibility for compliance with the NIH FCOI will be delegated to each sub-awardee. Sub-awardee agreements will specify matters necessary to implement 42 CFR 50.604, including that the sub-awardee must:

- comply with the requirements of the NIH FCOI policy;
- submit all requisite details of FCOIs to BI:

(i) prior to the expenditure of funds; and

(ii) within 60 days of any subsequently identified FCOI;

- promptly notify BI of any management plan and suspected non-compliance; and
- provide a declaration that all FCOIs have been identified, disclosed and managed in accordance with NIH requirements.

## Internal References

ORG\_FRM\_FCOI Disclosure

RGV\_PRO Managing Breaches

## External References

[NIH FCOI Policy](#)

[NIH FCOI FAQs](#)

[FCOI Training](#)

Process Information					
Version	Approved by	Version Date	Doc ID	Review Date	Contact
1.0	COO	15/08/2023	1101	15/05/2026	Company Secretary