

# POLICY

## NIH Financial conflict of interest policy

### Purpose

The purpose of this policy is to set out Hearing Australia's requirements in relation to the behaviours and ethical standards it expects from employee(s) who receives/receive a National Institutes of Health (NIH) grant.

### Audience

The audience for this policy is every person who receives an NIH grant and works for Hearing Australia. This includes:

- Employees, whether permanent or temporary.
- Consultants and contractors.

They are collectively referred to as "employees and contractors" in this policy.

**Effective Date:**

**February 2021**

**Effective Until / Review Date: February 2023**

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## 1 BACKGROUND

As individuals striving to make Hearing Australia (HA) a successful organisation, employees and contractors share a common goal:

***We are committed to providing world leading research and hearing services for the wellbeing of all Australians.***

To achieve this goal, each employee and contractor must earn and keep the trust of Hearing Australia's clients, shareholders, regulators, suppliers, colleagues and the communities in which they operate.

The document sets out HA's policy around the identification and management of any significant financial interests that an investigator has. The policy aims to ensure that any financial interest does not adversely affect the design and execution of a project funded by the National Institutes of Health .

## 2 DEFINITIONS

### 2.1 INVESTIGATORS

Any staff involved in the design, conduct or reporting of a project funded by the NIH. This includes, but is not limited to the Principle Investigator (PI), Co-Investigators (CIs), other HA researchers and Subcontractors who are engaged in an NIH grant awarded to HA.

### 2.2 SIGNIFICANT FINANCIAL INTEREST (SFI)

(1) A financial interest of the Investigator, their spouse or dependent children that reasonably appears to be related to the Investigator's institutional responsibilities:

Remuneration from public company > \$5,000 over the last 12 months

Remuneration from non-public company > \$5,000 over the last 12 months

Income from intellectual property rights

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;

(2) Investigators must declare reimbursed or sponsored travel related to their institutional responsibilities. This does not include reimbursement or sponsorship from Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical centre, or a research institute that is affiliated with an Institution of higher education

#### 2.2.1 Significant Financial Interest does not mean

Any form of remuneration paid by the institute at which the investigator is employed including income from seminars, lectures, teaching engagements, review panes or scientific advisory boards sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical centre, or a research institute that is affiliated with an Institution of higher education.

### 2.3 A FINANCIAL CONFLICT OF INTEREST (FCOI) MEANS

Where, after investigation, it is determined that an SFI could affect directly and significantly the design, conduct and reporting of an NIH-funded project.

### 2.4 SUBCONTRACTOR

External parties (researchers or institutions) that HA has engaged to perform part of the NIH funded project.

## 3 REQUIREMENTS

### 3.1 RESPONSIBILITIES OF THE INVESTIGATORS AT HEARING AUSTRALIA

#### 3.1.1 Disclosure

The PI, on behalf of the project team engaged in an NIH grant, must disclose any SFIs they may have within the mandated timeframe (See Appendix 1 for Declaration). They must do this:

- Before applying for NIH funding
- At least annually
- Within 30 days of acquiring a new SFI
- Within 60 days of a new Investigator on the grant

The PI is responsible for collecting the SFIs completed by the other Investigators and giving them to the Funding Coordinator.

#### 3.1.2 Training

All Investigators and Other external collaborators and consultants are required to complete the NIH FCOI training prior to engaging in NIH-supported research, and at least every 4 years. More details can be located at: <https://nexus.od.nih.gov/all/2018/12/03/new-financial-conflict-of-interest-training-module-available/>.

Training should be completed when:

- A new investigator joins Hearing Australia who will work on an NIH funded research activities
- An Investigator is found to be non-compliant with this policy or as an FCOI
- Before an Investigator applies for an NIH grant

Training records will be maintained by the Funding Coordinator. It is the PI's responsibility to ensure that, within 10 business days, the Funding Coordinator be notified of the completion of the training .

#### 3.1.3 Other sub-contractors on the grant

If there are other sub-contractors that are not defined in this policy but will make contributions to the NIH funded project in any other form (where required, the Funding Coordinator will support in seeking NIH's approval). the PI must collect SFIs from these parties, regardless of whether they are internal or external to HA.

#### 3.1.4 Management plan

If an FCOI is found, the relevant Investigator(s) must adhere to any management plan that is put in place, as outlined in Clause 3.2 of this policy.

### 3.2 RESPONSIBILITIES OF THE OPERATIONS AND FINANCE MANAGER, NAL, HA

The Operations and Finance Manager in consultation with the Director, is responsible for reviewing the submitted SFIs to determine if they constitute an FCOI.

If it is deemed that an SFI constitutes an FCOI, a management plan must be developed and implemented to ensure that the research project is not affected, or the impact caused by the FCOI can be mitigated to the minimum level. In the event it is determined that a project's design, conduct or reporting has been affected, the NIH will be notified and corrective actions will be implemented immediately.

The Operations and Finance Manager will also conduct reviews where an Investigator fails to comply with [the NIH FCOI policy](#), the implemented management plan and/or where an SFI is not declared within the correct timeframe.

### 3.3 RESPONSIBILITIES OF THE FUNDING COORDINATOR

The Funding Coordinator is responsible for:

- Submitting any FCOI to the NIH where required in a timely manner
- Maintaining the records pertaining to SFIs and FCOIs including the due dates
- Monitoring compliance amongst the Investigators and any sub-contractors

### 3.4 RECORDS

In the circumstance where an FCOI has been identified, HA shall maintain all records for 3 years from the date of the final expenditure report submitted to the NIH.

### 3.5 ENFORCEMENT MECHANISMS

Investigators employed by HA that do not comply with the requirements as set out in this policy will be deemed in breach of the HA policy. In the instance where a breach occurs, the relevant HA policy and procedure will apply.

## 4 RELATED DOCUMENTS

*MDT-039 Fraud and Corruption Control Plan,*

*HR-102 Business Ethics Policy*

## 5 DOCUMENT CONTROL

Version Number	Author	Owner	Date Effective	Replaces	Review Date
1	Operations and Finance Manager, NAL, HA	Director, NAL	Feb 2021	-	Feb 2023

## 6 APPENDIX 1 – SFI DECLARATION

(Investigators to complete where required).

The complete Declaration(s) must be provided to the PI in the first instance for records.

It is the responsibility of the PI for collecting all the Declarations from other Investigators who may have a SFI, and then providing them (including the PI's Declaration if any) to the Funding Coordinator within 7 business days for HA's records and further process.

Name:	
NIH grant number:	
Project PI:	
Institution of employment:	

### A. Which of the following reasons is this declaration made for:

- i. I am applying for/involved in an application for NIH funding
- ii. I have discovered or acquired (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest (declaration must be made within 30days)
- iii. I am making an annual declaration

### B. Declaration (please select from one of the options below)

- i. I do not have any current financial conflict of interests connected to this project;
- ii. I have a potential financial conflict of interest (please include details below)

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In signing this document, I confirm:

1. I have completed this declaration to the best of my knowledge and have considered all of the potential financial conflicts of interest relating to me, my spouse and dependent children;
2. I have undertaken an NIH online FCOI training within the last four years;
3. I have read and understood the HA's Business Ethics Policy; and
4. I have completed this declaration in accordance with the HA policy

Declaration made by

(Print Name)

Signature

Date

Operations and Finance Manager to complete

If Section 1.B.i has been answered, please consider any potential conflicts and, if satisfied, please sign this form below.

If Section 1.B.ii has been answered, consult with the member of staff to identify the following information

<p><b>Name of the entity with which the Investigator has a potential FCOI</b></p>	
<p><b>Nature of the financial interest</b> (e.g. equity, consulting fee, travel reimbursement, honorarium)</p> <p>For sponsored travel reimbursement, the minimum information to include is the nature of the trip, name of the sponsor/organiser, destination, duration</p>	
<p><b>Estimated value of the financial support</b></p>	

Please provide any additional information here:

Declaration made by

(Print Name)

Signature

Date

Director, NAL to complete

I have reviewed the information provided to me and have met with the Operations and Finance Manager to review the Significant Financial Interest. I can confirm that:

1. There is not a conflict of interest (please provide details below)
2. There is a conflict of interest and the Grants Office will make an FCOI declaration to the NIH on my behalf (within the 60-day deadline or within 30 days for new disclosures)

Declaration made by

(Print Name)

Signature

Date