



Number:	LEG-POL-001.10
Issuing Office:	Legal
Effective Date:	5/1/2023
Approved By:	Thomas Curran, General Counsel
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## 1.0 PURPOSE

Van Andel Institute, Van Andel Research Institute, and Van Andel Education Institute (collectively, "VAI") are committed to fostering and maintaining the highest standard of integrity and ethical conduct in all VAI activities. To that end, VAI has policies that define clear boundaries regarding interactions with outside entities. It is in this context that Conflicts of Interest (COI) may become a concern as the number of interactions and complexity of relationships with outside entities increase. Clear policy and guidance on this important topic is needed and mandated by the Federal government regulations applicable to VAI activities.

The intent of this policy therefore is to:

- Assure that the design, conduct, review, analysis, oversight, and reporting of Research at VAI is free from bias.
- Inform Covered Persons about situations that generate Conflicts of Interest related to Research.
- Provide mechanisms for VAI to manage Conflicts of Interest that arise.
- Ensure VAI policies and practices are consistent with Federal and state law and regulations, and funding agency guidance.

## 2.0 APPLICABILITY

This policy is applicable to all Covered Persons as defined in Section 4 below. Every Covered Person has an obligation to become familiar with, and abide by, the provisions of this policy. This policy does not apply to contract employees (e.g., individuals in security, IT, cafe, or housekeeping roles) or students.

Insofar as it relates to Research, this policy is primarily written to ensure VAI complies with the Public Health Service's "Promoting Objectivity in Research" regulations at 42 CFR 50.601 through 42 CFR 50.607. However, other Research sponsors also maintain policies regarding Conflicts of Interest. To the maximum extent possible, therefore, this policy and any references to PHS or PHS Awarding Components should be flexibly interpreted and implemented in such a way to enable VAI's compliance with all other COI policies, as applicable.

As described in Section 3.8, all subrecipients of PHS funding, where VAI is a pass-through entity to the subrecipient, are required to follow this policy or submit a certification that its policy complies with Federal regulations regarding Financial Conflicts of Interests (FCOIs).

Where there is a discrepancy between (a) this policy and either (b) applicable Federal or state law and regulations, or (c) funding agency guidance, the requirements of the latter two will take precedence, unless the requirements thereunder are less restrictive and VAI's requirements are more stringent.

Situations giving rise to questions about Conflicts of Interest (COIs) related to a Covered Person's Research should be discussed with the Institutional Official (IO). Situations giving rise to questions about Conflicts of Interest (COIs) unrelated to a Covered Person's Research should be discussed with the IO and/or VAI's General Counsel (GC).



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### 3.0 POLICY STATEMENT

#### 3.1 Disclosure of Financial Interests

Covered Persons are encouraged to contact the GC or IO, or their designees, prior to engaging in, or agreeing to engage in, an activity that would result in a required Disclosure of a Financial Interest.


Covered Officials are required to disclose Financial Interests that are both related to their Institutional Responsibilities and with outside entities that: (a) do business with VAI or contemplate doing business with VAI, (b) are or may be perceived to be a significant institutional financial interest as set forth in VAI’s *Institutional Conflict of Interest Policy* (COI-POL-003.02), or (c) operate within VAI’s field and may be considered competing with or complementing VAI’s mission. Covered Officials’ Disclosures must be made at the time of hire, contract, or appointment and within 30 calendar days from the date on which a new Financial Interest is discovered or acquired.

Covered Researchers are required to disclose all new, or update existing, Financial Interests related to their Institutional Responsibilities. Covered Researchers’ Disclosures must be made at the time of hire, contract, or appointment; within 30 calendar days from the date on which a new Financial Interest is discovered or acquired; on an annual basis (at a time determined by VAI) for the previous twelve (12) month period; and at the time of application to a PHS Awarding Component for funding.

As part of the Disclosures described above, Covered Researchers must disclose Travel that is related to their Institutional Responsibilities and reimbursed or sponsored by an entity other than VAI. Such Disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. Excluded from this definition is travel paid for by VAI, a U.S. Federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital or medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education, teaching hospital or medical center.

Prior to entering into externally sponsored projects or applications for externally sponsored projects with an outside entity, where the Covered Researcher has a Significant Financial Interest (SFI), the Covered Researcher must affirm the currency of their annual Disclosure or submit an ad hoc updated Disclosure of their Financial Interests with the outside entity. VAI will not submit an application for an externally sponsored project unless all Covered Researchers participating in the proposed project have submitted such annual or ad hoc Disclosures as required.

Disclosures should be made sufficiently in advance of finalizing any binding agreement or commitment related to a Financial Interest to allow VAI time to review the Disclosure and implement an appropriate Management Plan, if needed.

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### 3.2 Initial Receipt and Triage of Disclosures

The Institutional Officer (IO), in coordination with the GC, is responsible for ensuring Disclosures made by Covered Persons are properly processed and triaged under the policy. The IO will review each Disclosure and make an initial determination of whether it constitutes a Conflict of Interest (COI).

The IO may at any time meet with the Covered Person who submitted the Disclosure, or with any other individual, if the information provided in the Disclosure is not sufficient for the IO to carry out their responsibilities under this policy.

If the IO determines that the Financial Interest described in the Disclosure does not constitute a COI, the IO will make a note of said determination for the IO's records and the review will be considered complete unless additional information should come to light later that would warrant a reconsideration of the IO's determination.

If the IO determines that the Financial Interest described in the Disclosure constitutes a COI, the IO will determine whether the COI is a Significant Financial Interest (SFI).

If the IO determines that the COI is not a SFI, the IO will make a note of their determination for the IO's records, and the review will be considered complete unless additional information should come to light later that would warrant a reconsideration of the IO's determination.

If the IO determines that the COI is a SFI, and the Disclosure under review is from a Covered Official, or a Covered Researcher acting in the capacity of a Covered Official, the IO will refer the matter for review and management as described in 3.3 below.


If the IO determines that the COI is a SFI, and the Disclosure under review is from a Covered Researcher, or a Covered Official acting in the capacity of a Covered Researcher, the IO will review and manage the SFI, as described in 3.4 below.

### 3.3 Review of the Significant Financial Interests of Covered Officials and Covered Researchers Acting in the Capacity of a Covered Official

The GC will manage the review and institutional handling of the SFIs of Covered Officials and Covered Researchers acting in the capacity of a Covered Official.

The GC may at their discretion require that a Management Plan be put into place for a SFI handled under this Section (e.g., when a Covered Official could benefit from materially participating in a major procurement or Purchasing Decision).

The GC may also choose to refer the matter to the Institutional Conflict of Interest (ICOI) Committee for further handling under VAI's *Institutional Conflict of Interest Policy* (LEG-POL-003).

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### **3.4 Review of the Significant Financial Interests Covered Researchers and Covered Officials Acting in the Capacity of a Covered Researcher**

VAI’s Institutional Official (IO) will manage the review and institutional handling of the SFIs of Covered Researchers and Covered Officials acting in the capacity of a Covered Researcher.

The IO may at any time meet with the Covered Person who submitted the Disclosure, or with any other individual, if the information provided in the Disclosure is not sufficient for the IO to carry out their responsibilities under this policy.

The IO will first determine whether the SFI is a Financial Conflict of Interest (FCOI). In making their determination, the IO may refer to Attachment A, “Factors for Determining the Existence of a FCOI” for guidance.

If the IO determines that the SFI is not a FCOI, the IO will make a note of their determination for the IO’s records, and the review will be considered complete unless additional information should come to light later that would warrant a reconsideration of the IO’s determination.

If the IO determines that the SFI is a FCOI, the IO will make a note of their determination for the IO’s records. The IO will take action to manage the FCOI, including the reduction or elimination of the conflict, as appropriate, through a written Management Plan. The affected Covered Person must formally agree to the proposed management strategies and sign the written Management Plan before any sponsored activity may proceed.

The IO will periodically review the activity subject to the Management Plan to ensure compliance with the Management Plan.

### **3.5 The Conflict of Interest Committee**

The VAI Conflict of Interest Committee (CC) will meet on an as-needed basis to serve as a resource and sounding board for the IO and GC in the execution of their responsibilities under this policy, including when the IO or GC request guidance on specific cases or the application of this policy to particular situations. The CC is also responsible for ensuring that FCOIs and related Management Plans are communicated to all VAI stakeholders (other than the Covered Person affected by a Management Plan) with a need to know. CC members are appointed by the GC in consultation with the IO and, as appropriate, the Chief Scientific Officer and the Chief Operations Officer.

### **3.6 Financial Interests Requiring Special Handling**

Financial Interests disclosed by Covered Officials, at the discretion of the GC, may be handled as described in this policy with the following exceptions:

- A specially constituted Conflict of Interest Committee will review the Financial Interest Disclosures and formally approve all determinations of SFIs, FCOIs, and related Management Plans.



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- Appointments to specially constituted Conflict of Interest Committees will be made by the GC in consultation with the IO and, as appropriate, the Chief Scientific Officer, Chief Operations Officer and the VAI Board of Trustees. Specially constituted Conflict of Interest Committees may include individuals not affiliated with VAI when deemed warranted by the GC.
- Appointments to specially constituted Conflict of Interest Committees and any procedures of said committee will be implemented to minimize to the greatest extent possible any real or perceived authority or influence individual disclosers may have over the work of the committee or its members.

### 3.7 Reporting to PHS

Prior to the expenditure of any funds awarded by PHS:

- The IO or their designee will review the FCOIs of Covered Persons involved in the PHS funded activity and ensure that Management Plans are implemented when required, and
- The Director of Sponsored Research or their designee will report FCOIs to the PHS Awarding Component as required pursuant to 42 CFR 50.605, including sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI, and to assess the appropriateness of VAI's Management Plan.


If VAI identifies a new FCOI (whether of a Covered Person engaged in an existing PHS funded project who has already disclosed their Financial Interests or upon the participation of a Covered Person who is new to a PHS funded project) after the initial report to the PHS Awarding Component, within sixty (60) calendar days of the date on which the SFI was disclosed:

- VAI will implement, on at least an interim basis, a Management Plan that specifies the actions that have been, and will be, taken to manage the FCOI, and
- The Director of Sponsored Research or their designee will submit an FCOI report to the PHS Awarding Component.

Depending on the nature of the SFI, the IO may determine that additional interim measures are necessary with regard to the Covered Person's participation in the PHS funded project between the date of disclosure and the completion of VAI's review.

For any FCOI previously reported by VAI regarding an ongoing PHS funded project, the Director of Sponsored Research or their designee shall provide to 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 project. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. FCOI reports shall be provided annually to the PHS Awarding Component for the duration of the project period (including extensions with or without funds).

If funding for PHS research project is made available to VAI from a pass-through entity, such FCOI reports as described in this Section shall be made to the pass-through entity prior to the expenditure of any PHS funds and within sixty (60) calendar days of any subsequently identified FCOI such that the pass-through entity may fulfill their reporting obligations to PHS.

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### 3.8 Subrecipients of PHS Funds Awarded to VAI

Whenever VAI carries out a PHS-funded research through a subrecipient (i.e., VAI is a pass-through entity), VAI shall:


- Incorporate as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of VAI or that of the subrecipient will apply to the subrecipient's investigators.
  - If the subrecipient's investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced in this Section that its policy complies with PHS regulations. The agreement shall specify a time period for the subrecipient to report all identified FCOIs to VAI sufficiently in advance to enable VAI to provide timely FCOI reports to the PHS Awarding Component as required by PHS regulations.
  - If the subrecipient cannot certify it has an FCOI policy that complies with PHS regulations, the agreement shall state that subrecipient investigators are subject to this policy for disclosing SFIs that are directly related to the subrecipient's work for VAI. The agreement shall specify a time period for the subrecipient to submit all Investigator Disclosures of SFIs to VAI sufficiently in advance to enable VAI to comply timely with its review, management, and reporting obligations as required by PHS regulations.
- Provide FCOI reports to the PHS Awarding Component regarding FCOIs of subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

### 3.9 Non-Compliance with PHS Policy

Whenever an FCOI related to a PHS funded project is not identified or managed in a timely manner (including failure of a Covered Person to disclose an SFI that is determined by VAI to constitute a FCOI or failure by VAI to review or manage an FCOI) or a Covered Person fails to comply with a Management Plan related to a PHS funded project, the IO will, within 120 calendar days of VAI's determination of noncompliance, complete a retrospective review of the Covered Person's activities and the PHS-funded project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in its design, conduct, or reporting.

Documentation of the retrospective review will include the award number, project title, name of the Principal Investigator, name of Covered Person with the FCOI, name of the entity with which the Covered Person has a FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

If the retrospective review reveals bias in PHS funded research, the IO will notify the PHS Awarding Component promptly and submit to the PHS Awarding Component a mitigation report that meets the requirements at 42 CFR 50.605(a)(3). The mitigation report will include, at a minimum, the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and VAI's plan of action or

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actions taken to eliminate or mitigate the effect of the bias. If a Covered Person is found to be non-compliant, they will be required to complete COI training as part of a mitigation plan. Thereafter, the Director of Sponsored Research or their designee will submit FCOI reports annually, as specified elsewhere in this policy.

If funding for a PHS funded project is made available to VAI from a pass-through entity, such notifications and reports as described in this Section shall be submitted to the pass-through entity.

### 3.10 Non-Compliance with VAI Policy

A Covered Person’s failure to fully and accurately disclose Financial Interests, to maintain current and accurate Disclosures, or to follow Federal, state, funding agency, or VAI requirements may result in disciplinary action, up to and including termination.

Depending on the nature of the FCOI, VAI may determine that additional interim measures are necessary with regard to the Covered Person’s participation in PHS-funded projects between the date that the FCOI or the Covered Person’s noncompliance is determined and the completion of VAI’s retrospective review (e.g., the IO may suspend all relevant activities or take other disciplinary action until the matter is resolved). The Institute may implement other actions as it may deem appropriate.

### 3.11 Training


Covered Researchers must complete training regarding this Policy, the PHS “Promoting Objectivity in Research” regulations, and their responsibilities regarding Disclosure prior to engaging in PHS funded Research, and at least every four (4) years thereafter.

Covered Researchers must also complete training within a reasonable period of time as determined by the Institute in the event that this Policy is substantively amended in a manner that affects the requirements of Covered Researchers, if a Covered Researcher is new to VAI, or if VAI determines that a Covered Researcher has not complied with this policy or with a Management Plan related to their activities.

### 3.12 Record Retention

Records of individual Disclosures of Financial Interests and training, VAI's review of, and response to Disclosures (whether or not a Disclosure resulted in the determination of an FCOI), CC minutes, and any actions taken by VAI under this policy, including Management Plans and retrospective reviews, will be retained for the longer of:

- Three (3) years past the end of VAI’s relationship of the Covered Person,
- Three (3) years from the date the final expenditures report is submitted to the PHS Awarding Component for Covered Persons on PHS Research projects, or
- Other dates as may be specified pursuant to [45 CFR 75.361](#) (i.e., if any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken).

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The GC will retain records regarding the Financial Interests of Covered Officials, Covered Researchers acting in the capacity of a Covered Official, and Covered Researchers when their Financial Interests are unrelated to their Research. The IO will retain records regarding the Financial Interests of Covered Researchers that are related to their Research.

Records retained under this policy will be made accessible as needed to other VAI administrative units, such as the CC, the Office of Sponsored Research, and the Finance Office.

### 3.13 PUBLIC ACCESSIBILITY

To ensure public accessibility regarding expenditure of any funds under a PHS funded project, the Director of Sponsored Research will provide a written response to any requester within five business days of a request that meets the criteria at 41 CFR 50.605(a)(5). The information to be made available shall be consistent with the requirements of the PHS regulations.

## 4.0 DEFINITIONS

CONFLICT OF INTEREST (COI) means a situation where there is a divergence between an individual's private interests and his/her professional obligations to VAI, such that an independent observer might reasonably question whether the individual's professional actions or decisions appear to be or are materially influenced by considerations of personal gain, financial or otherwise.


CONFLICT OF INTEREST COMMITTEE (CC) means VAI's committee that serves as a resource and sounding board for the General Counsel and Institutional Official in the execution of their responsibilities under this policy; provides guidance upon request on specific cases or the application of this policy to particular situations; and ensures that FCOIs and related Management Plans are communicated to all VAI stakeholders (other than the Covered Person affected by a Management Plan) with a need to know.

COVERED OFFICIALS means the following individuals affiliated with VAI

- Board Members;
- Officers;
- Executives and Vice Presidents;
- Employees in manager positions and above;
- Employees with responsibility for the supervision of faculty and staff participating in Research conducted at or under the auspices of VAI; and
- Persons with the authority to make or influence Purchasing Decisions as part of their routine job duties.

COVERED PERSONS means Covered Officials and Covered Researchers.



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COVERED RESEARCHERS means the following individuals affiliated with VAI:

- Employees and non-employees who are eligible to apply for Research funding;
- Scientists with academic appointments at any level, key personnel, and research fellows;
- Investigators; and
- Consultants working on Federally funded Research projects.

DISCLOSURE means a Covered Person's communication of specific information about Financial Interests or potential conflicts of commitment to VAI.

FAMILY MEMBER means the spouse, or a significant other living in the same household, or dependent child of the Covered Person.

FINANCIAL INTEREST means anything of monetary value or potential monetary value received or held by a Covered Person or their Family Member, whether or not the value is readily ascertainable, that reasonably appears to be related to the Covered Persons VAI duties and responsibilities, including, but not limited to:

- Salary, commissions, consulting fees, or other payment for services (e.g., lecture payment, other honoraria);
- An equity interest (e.g., stock, stock option, security, or other ownership interest);
- An intellectual property right (e.g., a patent, copyright, or royalty from such right);
- Reimbursed or sponsored travel related to VAI responsibilities, except if funded by any U.S. Federal, state or local government agency, an institution of higher education as defined in 20 U.S.C. 1001 (a), an academic teaching hospital or medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education, academic teaching hospital or medical center; and
- A gift (e.g., money, hospitality, or a physical item).

The term Financial Interest does not include:

- Salary or other remuneration for services from VAI, or remuneration from a U.S. Federal, state or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital or medical center, or U.S. research institute affiliated with a U.S. institution of higher education.
- Income from, or ownership of shares of a mutual fund, pension, or other investment fund where the individual does not exercise control over the management and investments of such fund.

FINANCIAL CONFLICT OF INTEREST (FCOI) means a Financial Interest of a Covered Person or a Family Member of a Covered Person that VAI reasonably determines could directly and significantly affect the design, conduct, review, analysis, oversight or reporting of research, or the performance of duties and responsibilities on behalf of VAI.

INSTITUTIONAL OFFICIAL (IO) means the individual within VAI who is responsible for the review of Significant Financial Interests of Covered Persons (including those of a Family Member of a Covered Person) that are related to the Covered Person's Research and for the determination and management of Financial Conflicts of Interest, as required by the PHS regulations. For the purposes of this policy, the Institutional Official is VAI's Vice President for Research Protections.



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INSTITUTIONAL RESPONSIBILITIES means a Covered Person’s professional responsibilities on behalf of VAI. This may include activities such as research, research consultation, teaching, administration, institutional committee memberships, and service on panels such as the Institutional Review Board.

INVESTIGATOR means any individual who is responsible for, or has material input into, the design, conduct, review, analysis, oversight, or reporting of Research, or proposals for funding such Research. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

MANAGEMENT PLAN means the defined action(s) taken by VAI to address a Financial Interest (FI), Significant Financial Interest (SFI), or a Financial Conflict of Interest (FCOI). Management Plans may include, but are not limited to:

- Internal or external Disclosures;
- Divestiture;
- Severance of relationships that create actual or potential FCOI;
- Disclosure to the IRB or IACUC;
- Restriction from participation in designated research activities or other job responsibilities; or
- Notification requirements (e.g., notifying lab staff and trainees, the Director of Technology Transfer, the Director of Sponsored Research, etc.).

NON-COMPLIANCE means a situation in which this policy is not followed, including but not limited to: failure of a Covered Person or subrecipient to disclose a Financial Interest in a timely manner, failure of a Covered Person to follow a Management Plan, failure of VAI to review or manage an FCOI in a timely manner.


PHS AWARDING COMPONENT means the organizational unit(s) of the PHS that has awarded funds to support a project.

PRIOR APPROVAL means VAI’s grant of permission to either acquire, or engage in an activity related to, a Financial Interest, Significant Financial Interest, Financial Conflict of Interest, or potential conflict of commitment before it is acquired or engaged in.

PUBLIC HEALTH SERVICE OR PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

PURCHASING DECISIONS means the selection of vendors or products on behalf of VAI, including contract negotiation relating to such purchases, or decisions to continue or expand business with a given company.

RESEARCH means systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, and encompasses basic and applied research. Research includes any activity for which research funding is available regardless of the source.

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**SIGNIFICANT FINANCIAL INTEREST (SFI)** means a Financial Interest of a Covered Person (or a Family Member of the Covered Person) that reasonably appears to be related to the Covered Person's Institutional Responsibilities and that exceeds the thresholds below (per 42 CFR 50.603):

- Any remuneration received from a publicly traded entity in the 12 months preceding the Disclosure and the value of any equity interest in the entity as of the date of Disclosure that, when aggregated, exceeds \$5,000;
- Any remuneration received from a non-publicly traded entity in the 12 months preceding the Disclosure that, when aggregated, exceeds \$5,000 or, when the Covered Person (or a Family Member of the Covered Person) holds any equity interest in the entity;
- Intellectual property rights and interests, upon the receipt of income from such rights (e.g., patents, copyrights); or
- Any reimbursed or sponsored Travel in accordance with the definition below.

**TIMELY DISCLOSURE** means disclosing a Financial Interest as soon as possible and no later than 30 days from its acquisition or discovery.

**TRAVEL** means reimbursed or sponsored travel expenses that are related to a Covered Researcher's Institutional Responsibilities. Disclosure of reimbursed or sponsored travel by for-profit or Non-Profit Organizations is required for Covered Researchers. Excluded from this definition is travel paid for by VAI, a U.S. Federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital or medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education, teaching hospital or medical center.

**5.0 PERFORMANCE MATERIALS –ADDITIONAL POLICIES, PROCEDURES, GUIDELINES, TEMPLATES AND FORMS**

**5.1 Related Institutional Policies**

- 5.1.1 Faculty Outside and Professional Activities
- 5.1.2 Conflict of Commitment
- 5.1.3 Institutional Conflict of Interest

**6.0 HIGH LEVEL PROCEDURES – N/A**

**7.0 REFERENCES – N/A**

**8.0 HISTORY / REVISIONS FROM PREVIOUS VERSIONS**

- Version 01 January 16, 2003
- Version 02 January 14, 2011
- Version 03 April 26, 2011
- Version 04 July 11, 2012
- Version 05 April 29, 2014
- Version 06 January 29, 2015
- Version 07 November 1, 2020
- Version 08 July 1, 2021
- Version 09 October 31, 2022
- Version 10 May 1, 2023



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### ATTACHMENT A: Factors for Determining the Existence of an FCOI

VAI's Institutional Official may refer to these factors in determining whether a Significant Financial Interest is a Financial Conflict of Interest (FCOI). Note that the existence of one factor alone is likely not sufficient to make a determination. For this reason, multiple factors and a sound judgment based on the preponderance of applicable factors should be used when determining the existence of an FCOI.

Factor
1. Role of Discloser and opportunity to bias results.
2. Nature of the research being proposed.
3. Degree of overlap between aims of research and company orientation/goals.
4. Whether research is funded by an entity in which Discloser holds an SFI.
5. Value of SFI in relation to the size and value of the entity.
6. Whether research is of a fundamental nature directed at understanding basic scientific processes.
7. Whether degree of replication and verification of research results is such that immediate commercialization or clinical application is likely.
8. Whether goal of research is to evaluate an invention linked to SFI (such as when SFI is a patent, or an interest in a company that has licensed invention).
9. Where research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board.
10. Where SFI is in a company, whether SFI could result in researcher having influence over company decisions.
11. Where SFI is in a company, whether research could have a significant impact on company's business or financial outlook.
12. Magnitude, nature, and type of entity in which SFI is held (e.g., size and type of company, number and variety of products, and number of competitors in the area of research).
13. Magnitude of SFI (e.g., amount of consulting, or percentage or value of equity).
14. Where SFI is in sponsor of the research, and sponsor licenses Discloser's technology, amount of commercialization payments received by Discloser from that technology, both retrospective and prospective.
15. Number and nature of relationships Discloser has with outside entity. Multiple entanglements can create a relationship that is stronger than the sum of its parts.
16. Whether goal of research is to validate or invalidate a particular approach or methodology that could affect value of SFI.
17. Whether other scientific groups are independently pursuing similar questions.
18. Whether sufficient external review of conduct and reporting of research exist to mitigate undue bias.
19. Whether goal of project is a comparative evaluation of a technology in which Discloser has SFI.