

 VAN ANDEL INSTITUTE®	Conflict of Interest Policies and Procedures	
	Number	COI-POL-001.08
	Issuing Department	Legal
FINANCIAL CONFLICT OF INTEREST	Effective Date	July 1, 2021
	Page	1 of 8

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 encourage interactions with outside entities, as well as define clear boundaries. A Financial Conflict of interest (FCOI) may become a concern as the number of interactions and complexity of relationships with outside entities increase. An FCOI occurs when 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 for VAI appear to be or are materially influenced by considerations of personal gain, financial or otherwise. The intent of this policy is to assure that the design, conduct, and reporting of research is free from bias.

This policy is intended to be consistent with federal and state law. Where there is a discrepancy, the applicable federal or state law or requirements of the funding agency will take precedence, unless the law is or requirements are less restrictive and VAI’s requirements are more stringent.

Conflict of commitment, nepotism, and institutional COI are addressed in other policies and procedures.

2.0 APPLICABILITY

This policy is applicable to the following individuals affiliated with VAI, identified as “covered persons:”

1. Employees and non-employees who are eligible to apply for PHS funding;
2. Scientists with academic appointments at any level, key personnel, and research fellows;
3. Manager positions and above;
4. Officers, Board Members;
5. Consultants (limited to consultants working on a PHS funded project);
6. Persons with the authority to make or influence purchasing decisions as part of their routine job duties.

All sub-recipients of PHS funding where VAI is prime awardee institution, or pass-through institution, are required to follow this policy and/or submit certification that its policy complies with regulations and report financial conflict of interests (FCOIs) as required by 42 CFR 50.604(c).

This policy does not apply to:

- Contract employees (e.g., individuals in security, café, or housekeeping roles); or
- Students (e.g., guest students, and student interns).

 VAN ANDEL INSTITUTE®	Conflict of Interest Policies and Procedures		
	Number	COI-POL-001.08	
	Issuing Department	Legal	
FINANCIAL CONFLICT OF INTEREST		Effective Date	July 1, 2021
		Page	2 of 8

3.0 DEFINITIONS

Covered Persons: The following individuals affiliated with VAI:

1. Employees, non-employees who are eligible to apply for PHS funding;
2. Scientists with academic appointments at any level, key personnel, and research fellows;
3. Manager positions and above;
4. Officers and Board Members;
5. Consultants working on a PHS funded project;
6. Persons with the authority to make or influence purchasing decisions as part of their routine job duties

All sub-recipients of PHS funding where VAI is prime awardee institution, or pass-through institution, are required to follow this policy and/or submit certification that its policy complies with regulations and report FCOI's as required by 42 CFR 50.604(c).

This policy does not apply to:

- Contract employees (e.g., individuals in security, the Café, or housekeeping); or
- Students (e.g., guest students, and student interns).

Disclosure (or Disclose): The covered person's communication of specific information about financial interests or potential conflicts of commitment to VAI.

1. **Prior Approval** means disclosing and obtaining approval for a financial interest (FI) or potential conflict of commitment before it is acquired.
2. **Timely Disclosure** means disclosing a financial interest as soon as possible and no later than 30 days from its acquisition or discovery.

Family Members: The spouse, individuals of the same household, and dependent children of the Covered Person.

Financial Conflict of Interest (FCOI): A financial interest that 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. An FCOI may be a significant financial interest (SFI) or a financial interest (FI).

Financial Interest (FI): Anything of monetary value or potential monetary value received or owned by the individual, their spouse, and/or their dependent children, that reasonably appears to be related to the individual's 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;
- A gift (e.g., money, hospitality, or a physical item).

 VAN ANDEL INSTITUTE®	Conflict of Interest Policies and Procedures		
	Number	COI-POL-001.08	
	Issuing Department	Legal	
FINANCIAL CONFLICT OF INTEREST		Effective Date	July 1, 2021
		Page	3 of 8

The term significant 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, an institution of higher education, an academic teaching hospital or medical center, or U.S. research institute affiliated with a U.S. institution of higher education for the following services: giving seminars or lectures, teaching engagements, being on advisory committees, or study section review panels.
- 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.

Institutional Official (IO): The General Counsel is the designated (IO) responsible for the solicitation and review of disclosures as required at 42 CFR 50.604(d).

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the Institution. This may include 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: Principal Investigators (PI) and any other person, who is responsible for, or has material input into, the design, conduct, review, analysis, oversight or reporting of research.

Management Plan: Definition of the action(s) taken by VAI to address a financial conflict of interest (FCOI). Management Plans may include, but are not limited to, the following:

1. Internal or external disclosures;
2. Divestiture;
3. Severance of relationships that create actual or potential FCOI;
4. Disclosure to the IRB or IACUC;
5. Restriction from participation in designated research activities or other job responsibilities; or
6. Notification requirements (e.g., notifying the Manager of Technology Transfer for intellectual property issues or notifying the Director of the Office of Grants and Contracts for PHS reporting).

Non-Compliance: Situations in which this FCOI policy is not followed including but not limited to: failure of a covered person or sub-recipient to disclose an SFI 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.

Non-Profit Organization: An entity that is recognized as being tax-exempt under the U.S. Internal Revenue Code. Examples include the American Association for Clinical Research (AACR), Michael J. Fox Foundation for Parkinson's Research, American Cancer Society, etc.

PHS: Public Health Service.

PHS Awarding Component: The organizational unit(s) of the PHS that has awarded funds to support a project.

 VAN ANDEL INSTITUTE®	Conflict of Interest Policies and Procedures		
	Number	COI-POL-001.08	
	Issuing Department	Legal	
FINANCIAL CONFLICT OF INTEREST		Effective Date	July 1, 2021
		Page	4 of 8

Purchasing Decisions: The selection of vendors or products on behalf of VAI, includes contract negotiation relating to such purchases, or decisions to continue or expand business with a given company.

Research: a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health or agriculture, and encompasses basic and applied research. Research includes any activity for which research funding is available regardless of the source.

Significant Financial Interest (SFI): A financial interest of the covered person (and those of the covered person's spouse and dependent children) that reasonably appears to be related to the covered person's VAI responsibilities and that exceeds the thresholds defined at 42 CFR 50.603:

- Any remuneration received from a publicly traded entity in past 12 months and value of current equity that when aggregated, exceeds \$5,000;
- Any remuneration received from a non-publicly traded entity in past 12 months that when aggregated, exceeds \$5,000 OR an equity interest is held; or
- Intellectual property rights and interests, upon the receipt of income from such rights (e.g., patents, copyrights);
- Any reimbursed or sponsored travel in accordance with the definition below.

Travel: Reimbursed or sponsored travel expenses that are related to a covered person's institutional responsibilities. Disclosure of reimbursed or sponsored travel by for-profit or non-profit organization is required for covered persons.

Excluded from this definition is travel paid for by VAI (domestic only), 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.

U.S.: Any state of the United States of America or any U.S. territory, e.g., Guam, Puerto Rico.

4.0 POLICY STATEMENT

4.1 Disclosure of Financial Interests

Covered persons affiliated with VAI must disclose all financial interests (and those of his/her spouse and/or dependent children) with an outside entity which does, or contemplates conducting business with VAI and whose activities are related in any way to the individual's VAI job responsibilities, e.g.,:

- Research or clinical activities,
- Patent or licensing activities,
- Purchasing activities or
- Any other job responsibilities related to the individual's role at VAI; or who operates within VAI's field and may be considered competing with or complementing VAI's mission.

 VAN ANDEL INSTITUTE®	Conflict of Interest Policies and Procedures		
	Number	COI-POL-001.08	
	Issuing Department	Legal	
FINANCIAL CONFLICT OF INTEREST		Effective Date	July 1, 2021
		Page	5 of 8

Disclosures must be:

- Made at the time of hire or contract;
- Updated annually;
- Updated within 30 days of discovering or acquiring a new SFI;
- Sufficiently in advance of finalizing a binding agreement or commitment (to allow the disclosure to be reviewed and acted upon prior to finalization); and
- Updated no later than the time of application for PHS research funding.

4.2 Reimbursed/Sponsored Travel

Travel expenses that are related to a covered person’s institutional responsibilities that is reimbursed or sponsored by a for-profit or non-profit organization requires disclosure for each instance of travel incurred.

Disclosure of travel must include, at a minimum, the following information: sponsor/organizer; destination; duration; and purpose of the trip.

Excluded from this definition is travel paid for by VAI (domestic only), 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.

4.3 Review of Disclosures – Designation of Responsibilities

The General Counsel is the designated IO responsible for the solicitation and review of disclosures as required at 42 CFR 50.604(d). Under the supervision of the IO, the Legal Department will review any disclosure and determine if it represents a potential conflict of interest related to the disclosing person’s institutional responsibilities. Potential conflicts will be referred to, the Conflicts Committee (CC) or Institutional Conflict of Interest Committee (ICOIC) for evaluation. If a disclosure represents a potential institutional conflict of interest, the disclosure will be referred to the ICOIC. All potential conflicts of interests disclosed by officers, executives, and board members will be referred to the ICOIC. See *Institutional Conflict of Interest Policy* (COI-POL-003).

4.4 Conflicts Committee

The CC members are appointed by the IO in consultation, as appropriate, with the Compliance Department, VARI Research Director/Chief Scientific Officer, and the Chief Operations Officer. The CC meets as needed to review and evaluate disclosures of potential FCOI and to determine appropriate management plans. See *Institutional Conflict of Interest Policy* (COI-POL-003).

4.5 Institutional Conflicts of Interest Committee (ICOIC)

The ICOIC members are appointed by the IO in consultation, as appropriate, with the Chief Operations Officer and the VAI Board of Trustees. The ICOIC meets as needed to review and evaluate disclosures of potential conflicts of interest or commitment and to determine appropriate management plans.

 VAN ANDEL INSTITUTE®	Conflict of Interest Policies and Procedures	
	Number	COI-POL-001.08
	Issuing Department	Legal
FINANCIAL CONFLICT OF INTEREST	Effective Date	July 1, 2021
	Page	6 of 8

4.6 Management Plans

The CC or ICOIC will determine an appropriate management plan for individuals who have FCOI(s) that are FIs or SFIs. Management plans may include, but are not limited to, the following:

- 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 the Manager of Technology Transfer for intellectual property issues or notifying the Director of Sponsored Research/Grants and Contracts for PHS reporting).

4.7 PHS Funded Research

As described in *section 4.1* above, investigators are required to submit updated disclosures no later than at the time of application for PHS research funding. In addition, prior to the expenditure of any funds awarded from PHS, VAI must review all investigator disclosures, *section 4.3* above, and report any PHS research related FCOI(s) to the PHS awarding component as required pursuant to 42 CFR 50.605(b), 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 after the initial report, a conflicting interest is identified, VAI must review and make a report to the PHS awarding component within sixty days of that identification.

To ensure public accessibility regarding expenditure of any funds under a PHS funded research project, VAI will provide a written response to any requestor within five business days of a request that meets the criteria at 41 CFR 50.605(a)(5).

The Director of Sponsored Research/Grants and Contracts is responsible for the required reporting to the PHS awarding component, and to respond to requests for information on SFI(s) related to PHS funded research projects.

4.8 Training

COI training will be provided to covered persons upon hire, and at time of policy revision. Covered persons are required to complete COI training prior to engaging in research related to any PHS funded grant and at least every four years. Covered persons are also required to complete COI training whenever the covered person is found to be in non-compliance with this policy or management plan. VAI will provide training through regularly scheduled orientation training sessions, and/or internet-based training modules. Additional resources will be posted to the COI SharePoint site, <https://sp.vai.org/coi/>.

 VAN ANDEL INSTITUTE®	Conflict of Interest Policies and Procedures		
	Number	COI-POL-001.08	
	Issuing Department	Legal	
FINANCIAL CONFLICT OF INTEREST		Effective Date	July 1, 2021
		Page	7 of 8

4.9 Non-Compliance

If VAI is made aware of non-compliance with this policy, the IO, or designee, must within 60 days, review the financial interest to determine whether it is related to PHS funded research, whether an FCOI exists, and, if so, implement an interim management plan. If FCOI is determined for PHS-funded research, within 120 days of VAI's determination of noncompliance, VAI must conduct a retrospective review of the investigator's activities to determine whether bias in the design, conduct or reporting of research occurred. If bias is found with PHS funded research, the IO or designee must notify the PHS Awarding Component promptly and submit a mitigation report that meets the requirements at 42 CFR 50.605(a)(3). In all cases, such retrospective review must be documented.

If a covered person is found to be non-compliant, he/she is required to complete COI training as part of a mitigation plan.

4.10 Records Maintenance

Records of individual disclosures and training, VAI's review of, and response to the disclosures, and actions taken by VAI, including any management plans or retrospective review, will be retained by the Compliance and/or Legal Department for at least 3 years past the end of the relationship of the individual with VAI, or 3 years from the date the final expenditures report is submitted to NIH for individuals on PHS research projects, whichever is longer. Records will be made accessible as needed to other VAI administrative units, such as the CC, the ICOIC, the Office of Sponsored Research/Grants and Contracts, and the Finance Office.

All disclosures, CC or ICOIC minutes, and management plans, will be maintained by the Legal Department.

5.0 REFERENCES

5.1 Code of Federal Regulations (CFR)

- 42 CFR 50 Subpart F, revised August 25, 2011
- NIH Financial Conflicts of Interest - Frequently Asked Questions http://grants.nih.gov/grants/policy/coi/coi_faqs.htm, (Revised: January 9, 2011)

5.2 VAI Policies and Procedures

- COI-POL-002 Conflict of Commitment Policy
- COI-POL-003 Institutional Conflict of Interest Policy

6.0 POLICY REVISION / VERSION HISTORY

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



**VAN ANDEL
INSTITUTE®**

**Conflict of Interest
Policies and Procedures**

	Number	COI-POL-001.08
	Issuing Department	Legal
	Effective Date	July 1, 2021
FINANCIAL CONFLICT OF INTEREST	Page	8 of 8

Version 06 January 29, 2015
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