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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 Institute activities. To that end, the Institute has policies that both encourage interactions with outside entities, and at the same time define clear boundaries. Conflict of commitments may become a concern as the number of interactions and complexity of relationships with outside entities increase. A conflict of commitment occurs where there is a divergence between an individual’s outside activities and his or 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.

Financial conflict of interest, institutional conflict of interest, and nepotism 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).

3.0 DEFINITIONS

Conflict of Commitment: Engagement in outside activities that compromise commitments to VAI.

Consulting: An Outside Activity that is intended to further the interests of a third-party entity or person, generally in the provision of a service.

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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; and
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 FCOIs as required by 42 CFR 50.604(c).

This policy does not apply to:

- Contract employees (e.g., security, the Café, or housekeeping); or
- Students (including 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 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.


Institutional Official (IO): The General Counsel is the designated IO responsible for the solicitation and review of conflict of commitment disclosures and prior approvals.

Non-Compliance: Situations in which the 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: Any 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.

Outside Activity: Outside Activities are defined as professional services, paid or unpaid, that are in the general area of expertise for which the faculty member is employed by the Institute, but are beyond the scope of the individual's employment responsibilities. A faculty member's area of expertise shall be as defined by his/her department chair.

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

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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 and Approval of Outside Activities

No covered person may engage in an outside activity related to his/her role at VAI if prior approval is required from his/her immediate supervisor and/or the IO, or designee. These disclosures must be:

- Made at the time of hire or contract;
- Updated annually;
- Updated within 30 days of change,
- Sufficiently in advance of finalizing a binding agreement or commitment to allow the disclosure to be reviewed and acted upon prior to finalization.

Covered persons may not utilize VAI resources for outside activities, including facilities, intellectual property, personnel, equipment or confidential information, unless prior approval has been obtained.

4.1.1 Outside Consulting Activities


For any proposed consulting related to VAI technology, research or the covered person's institutional responsibilities, any consulting agreements must be sent in advance to the Legal Department for review to ensure compliance with VAI policies and government regulations, which must be approved before the consultation may begin.

4.1.2 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.

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4.1.3 Required Prior Approval

A faculty member must request and obtain prior written approval from his/her Department Chair working with the Legal Department prior to engaging in the following Outside Activities:

- Conducting actual research as defined by the Common Rule as the “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (§ 46.102(d));
- Engaging as a consultant that requires the faculty member to be an employee of the outside entity;
- Exceeding the monthly or annual time limits;
- Involving students, or Institute staff, in outside activities;
- Starting a company;
- Teaching for an entity other than the Institute during the appointment period;
- Assuming an executive or management position for a third-party entity (e.g., as President, Chief Scientific Officer, etc.).

4.2 Time Limitations:


A full-time faculty member may engage in Outside Activities up to an equivalent of one day/week and limited to 4 days per month at any one time; exceptions require prior approval.

4.3 Review of Disclosures

The Legal Department will review any disclosure or request for approval for outside activity and determine if it represents a potential conflict of commitment. Potential financial conflicts of interest or commitment will be referred to the IO, the Conflicts Committee (CC), or the Institutional Conflicts of Interest Committee (ICOIC), as applicable, for evaluation.

4.4 Conflicts Committee (CC)

The CC members are appointed by the IO in consultation, as appropriate, with the Compliance Department, Chief Scientific Officer and the Chief Operations Officer. The CC meets as needed to review and evaluate disclosures of potential COI and to determine appropriate management plans.

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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 institutional conflicts of interest or commitment and to determine appropriate management plans.

4.6 Management Plans

The CC or ICOIC will determine an appropriate management plan for conflicts of commitment. Management plans may include, but are not limited to, the following: Internal or external disclosures;

- Divestiture;
- Severance of relationships that create actual or potential COI;
- 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 Non-Compliance

If VAI is made aware of non-compliance with this policy, the IO, or designee, must conduct a retrospective review of the covered person's and/or VAI's activities within 60 days to determine whether it is related to PHS funded research, whether a financial conflict of interest (FCOI) exists, and, if so, implement an interim management plan. Within 120 days of VAI's determination of noncompliance, VAI must complete the retrospective review including a determination whether bias in the design, conduct or reporting of research has 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.

4.8 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.

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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 as 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-001 Financial Conflict of Interest Policy
- COI-POL-003 Institutional Conflict of Interest Policy

6.0 POLICY REVISIONS/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	July 1, 2021
Version 07	December 20, 2021