

Van Andel Institute	Number:	COM-POL-009
	Issuing Office:	Compliance Office
	Effective Date:	July 11, 2012
TITLE: Institutional Conflict of Interest Policy	Approved By:	David S. Whitescarver Vice President and Chief Legal Officer
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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 must have policies that both encourage interactions with outside entities, and at the same time define clear boundaries. Conflict of interest (COI) may become a concern as the number of interactions and complexity of relationships with outside entities increase. An institutional conflict of interest describes a situation in which the financial interests of an institution or institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, or other activities of the institution. The intent of this policy is to assure that the design, conducting and reporting of research is free from bias, and to assure that the Institute continues to meet federal requirements as a non-profit entity.

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

Individual conflict of interest, conflict of commitment, and nepotism are addressed in other policies and procedures.

2.0 HISTORY / REVISIONS FROM PREVIOUS VERSIONS

This is the initial written Institutional Conflict of Interest policy and is based on the revised COM-POL-006 Financial Conflicts of Interest Policy, effective July 11, 2012, which revised the April 26, 2011 version of the Conflicts and Commitment Policy.

3.0 DEFINITIONS

3.1 Institutional Conflict of Interest in Research: An Institutional COI may occur whenever the financial interests of the institution, or of an institutional official who has the authority to act on behalf of the institution, might affect – or reasonably appear to affect – institutional processes for the design, conduct, reporting, review, or oversight of research.

3.2 Financial Interest: Anything of monetary value or potential monetary value received or owned by the individual, their spouse, and their dependent children, that reasonably appears to be related to the individual’s 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);

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- An intellectual property right (e.g., a patent, copyright, or royalty from such right); and
- Reimbursed or sponsored travel related to institutional responsibilities, except if funded by any U.S. government agency or institution of higher learning, including academic teaching hospitals;
- A gift (e.g., money, hospitality, or a physical item over \$100).

The term does *not* include:

- Salary or other remuneration for services from VAI, from a U.S. institution of higher education, or from a government agency within the U.S. Services can include, for example, giving seminars or lectures, teaching engagements, being on advisory committees, or 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.
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3.3 Significant Financial Interest (SFI) (individual): A financial interest that exceeds the thresholds defined in 42 CFR 50.603:

- Any remuneration received from a publicly traded entity in past 12 months and value of current equity exceeds \$5,000
- Any remuneration received from a non-publicly traded entity in past 12 months exceeds \$5,000, OR an equity interest is held.

3.4 Significant Financial Interest (institutional):

- Royalties: Institutional COI may be present when the institution has agreements to receive milestone payments and/or royalties from the sales of an investigational product that is the subject of the research;
- Non-publicly traded equity: When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is the sponsor of research or the manufacturer of a product to be studied or tested at the institution; and
- Publicly traded equity: When the institution has obtained an ownership interest exceeding \$100,000 in value in a publicly-traded company that is the sponsor of research or the manufacturer of a product to be studied.

3.5 Financial Conflict of Interest (FCOI): A financial interest that could directly and significantly affect the design, conduct, or reporting of funded research, or the performance of duties and

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responsibilities on behalf of VAI. An FCOI may be an individual or institutional SFI defined above, or an FI.

3.6 PHS: Public Health System.

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

3.8 Covered Officials: Board of Trustees, President, Vice Presidents and other institutional administrators, insofar as they have oversight of research, with special attention to human subjects research.

3.9 Non-Compliance: Situations in which this Institutional COI policy is not followed including but not limited to: failure of a covered official to disclose an individual or institutional SFI timely, failure of the Institution to review or manage an institutional FCOI in a timely manner.

4.0 APPLICABILITY

This policy is applicable to all the covered officials defined above.

5.0 POLICY STATEMENT

5.1 Disclosure of Financial Interests

Covered Officials of VAI must report all financial interests (and those of his/her spouse and dependent children) with an outside entity which does, or contemplates doing business with VAI and whose activities are related in any way to their own or VAI's research or clinical activities, patent or licensing activities, purchasing activities or any other job responsibilities; or operates within VAI's field and may be considered competing with or complementing VAI's mission. These disclosures must be made at the time of hire, contract, or appointment and updated annually, updated within 30 days of discovering or acquiring a new significant financial interest, and no later than the time of the individual's application for PHS funded research.

5.2 Review of Disclosures – Designation of responsibilities

The Vice President and Chief Legal Officer is the designated Institutional Official responsible for the solicitation and review of disclosures as required under 42 CFR 50.604(d). Under the

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supervision of the Institutional Official, the Compliance Office will review any disclosure and determine if it represents a potential conflict of interest. Potential conflicts of individuals who are not covered officials will be referred to the Conflicts Committee for evaluation. If a potential conflict may represent an Institutional conflict of interest, the disclosure will be referred to the Institutional Conflict of Interest Committee. All potential conflicts of covered officials (officers, executives, and board members) will be referred to the Institutional Conflicts of Interest Committee.

5.3 Conflicts Committee

The Conflicts Committee (CC) is appointed by the Vice President and Chief Legal Officer in consultation, as appropriate, with the Director of Compliance, Director of VAEI and the Research Director of VARI. The committee meets as needed to review and evaluate disclosures of potential conflicts of interest and to determine appropriate management plans.

The Institutional Conflicts of Interest Committee (ICOIC) is appointed by the Vice President and Chief Legal Officer in consultation, as appropriate, with the Director of Compliance, and the VAI Board of Trustees. The committee meets as needed to review and evaluate disclosures of potential conflicts of interest or commitment and determine appropriate management plans.

5.4 Management Plans

The CC or ICOIC will determine an appropriate management plan for conflicts of interest. Management plans may include, but are not limited to, the following: internal or external disclosure of significant financial interests, divestiture of significant financial interests, severance of relationships that create actual or potential conflicts, disclosure to the IRB or IACUC, restriction from participating in designated research activities or other job responsibilities or notification requirements (e.g. notifying the Director of Technology Transfer for intellectual property issues or notifying the Director of the Office of Grants and Contracts for PHS reporting).

The CC or ICOIC will use the COI Committee Recommendations Form to guide their deliberations and determinations.

5.5 PHS Funded Research

Prior to the expenditure of any funds awarded from PHS, VAI must review all investigator disclosures and report any PHS research related FCOIs 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 financial conflict, and to assess the appropriateness of the Institution's management plan. If after the initial report, a

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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, the institution will provide a written response to any requestor within five business days of a request that meets the criteria of 41 CFR 50.605(a)(5).

The Director of the Office of Grants and Contracts is responsible for reporting as required to the PHS awarding component and to requests for significant financial interests related to PHS funded research projects.

5.6 Training

COI training will be provided to all individuals affiliated with VAI immediately upon policy revision, and on hire or appointment. If a covered official is a VARI investigator, he/she is required to complete COI training prior to engaging in research related to any PHS funded grant, and at least every 4 years. Investigators are also required to complete COI training immediately whenever VAI's FCOI policy (COM-POL-006) is revised regarding investigator requirements, and whenever the individual is found to be in non-compliance with this policy, the FCOI 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/default.aspx>.

5.7 Non-Compliance

If the Institution is made aware of non-compliance with this policy, the Vice President and Chief Legal Officer, or designee, must conduct a retrospective review of the investigator's and/or institution's activities within 60 days to determine whether it is related to PHS-funded research, whether an FCOI exists, and, if so, implement an interim management plan. If the non-compliance is found to be related to PHS-funded research, the process described in COM-POL-006, Financial Conflicts of Interest Policy, Section 5.8 must be followed. If the non-compliance is not related to PHS-funded research, the Vice President and Chief Legal Officer, or designee, in consultation, as appropriate, with the Director of Compliance and Board of Trustees, will determine the requirement for additional review and/or mitigation.

5.8 Records Maintenance

Records of covered official's disclosures and, if applicable, investigator training, the Institution's review of, and response to the disclosures, and actions taken by the Institution including any management plans or retrospective review, will be retained by the Compliance and/or Law

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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 Conflicts Committee, the Institutional Conflicts of Interest Committee, the Office of Grants and Contracts, and the Finance Office.

6.0 PERFORMANCE MATERIALS –ADDITIONAL POLICIES, PROCEDURES, GUIDELINES, TEMPLATES AND FORMS

- 6.1 Conflict of Interest and Commitment Form
- 6.2 COM-FOR-003 Request for Approval of Outside Activities Form
- 6.3 COM-POL-006 Financial Conflict of Interest Policy
- 6.4 COM-POL-008 Conflict of Commitment Policy
- 6.5 Conflict of Interest – Committee Recommendations Form

7.0 HIGH LEVEL PROCEDURES

N/A

8.0 REFERENCES

- 8.1 42 CFR 50 Subpart F as revised August 25, 2011