

I. POLICY AND GENERAL STATEMENT

PolyVascular Corp ("the institution") is committed to ensuring that financial interests of the institution and individuals involved in research do not affect, or appear to affect, the design, conduct, or reporting of research or compromise the protection of human subjects. Therefore, employees, contractors, or other associates that conduct research for the institution using public or private funding from any source must disclose potential conflicts of interest and, when appropriate, work cooperatively with the Financial Conflict of Interest Official ("FCOI Official") to develop and implement plans to manage, reduce or eliminate conflicts of interest.

This policy does not necessarily preclude the conduct of research where a conflict of interest, or potential conflict of interest, is present. However, for such research to be initiated, it must be approved in accordance with this policy.

When a covered individual or the institution has a significant financial interest related to the research, neither the institution nor the covered individual may expend research funds unless the FCOI Official has determined that no financial conflict of interest exists or that any financial conflict of interest is manageable in accordance with the terms of a management plan that has been adopted and implemented.

If a specific federal law or regulation provides different requirements than this policy, the more stringent requirement applies.

II. DEFINITIONS

Financial Conflict of Interest Official: A Financial Conflict of Interest Official ("FCOI Official") will be designated by the institution's Board of Directors or other designee to perform the duties required by this policy.

Covered Family Member: For purposes of disclosure, a covered family member includes (1) a spouse; (2) a dependent child or stepchild; (3) any other person financially dependent on the covered individual; and (4) any other person with whom the covered individual has joint financial interests such that an objective third party could reasonably conclude that the covered individual's decisions or other exercise of professional responsibilities at the institution could be influenced by the effect of that action on the person's financial interest. A person described by Subdivision (3) or (4) is a covered family member without regard to whether a legal or biological family relationship exists with the covered individual. If the covered individual is in doubt, the covered individual should resolve the doubt in favor of disclosure.

With regard to the definition above, in disclosing financial interests, the interest of any legal entity, including a foundation or a trust, that is controlled or directed by the individual and/or covered family members is considered to be the interest of the covered individual or covered family member as if the separate legal entity did not exist.

Covered Individual: An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research, including a principal investigator, co-investigator, project director, any other person identified as senior/key personnel in a grant application, research protocol, or report, and others who direct or can materially influence the research. The principal investigator is responsible for determining if other research staff meet the definition of being responsible for the design, conduct, or reporting of the research.

With regard to the definition above, in disclosing financial interests, the interest of any legal entity, including a foundation or a trust, that is controlled or directed by the individual and/or covered family members is considered to be the interest of the covered individual or covered family member as if the separate legal entity did not exist.

Covered Institutional Officials: Individuals whose research related financial interests are considered “institutional” interests include institutional officials who have research oversight authority, act on behalf of the institution, or have immediate oversight of human subjects research.

Fiduciary Position: a position the covered individual held in a for-profit or non-profit entity in the preceding twelve months, including a position as a member of the board of directors, an officer or other executive or management position, for which the individual received any form of remuneration or reimbursement for expenses.

Financial Conflict of Interest: exists when a significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

Institutional Responsibilities: any professional responsibility performed by the covered individual on behalf of the institution, including conducting research activities, teaching, professional practice, research consultation, institutional committee membership, and service on institutional research committees and panels.

PHS Awarding Component: The organizational unit of the Public Health Service (“PHS”) that funds the research.

Principal Investigator (“PI”): the individual who has primary responsibility for design, management and reporting of applicable research, is responsible for identifying key personnel who must complete the certification and ensures completion of the certifications.

Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

Significant Financial Interests Related to Research:

The following interests are considered to be significant financial interests. Unless specifically excluded below, a covered individual’s disclosure statement must include the following information regarding the covered individual and covered family members, but only regarding interests that reasonably appear to be related to the individual’s institutional responsibilities.

- From a publicly traded entity: the total amount and source of payments received in the preceding twelve months from a publicly traded entity and the value of any equity interest held in the entity on the date of disclosure that, when aggregated, exceed \$5,000, including:
 - salary or other payments for services (e.g., consulting fees, honoraria, paid authorship); and
 - equity interests held, including any stock, stock options, or other ownership interest or entitlement to such an interest, valued by reference to public prices or other reasonable measures of fair market value.

- From a non-publicly traded entity: the total amount and source of payments received in the preceding twelve months from a non-publicly traded entity that, when aggregated, exceed \$5,000, or a description of any equity interest held in the entity on the date of disclosure, including:
 - salary or other payments for services (e.g., consulting fees, honoraria, paid authorship); or
 - equity interest held in any amount, including stock, stock options or other ownership interest or entitlement to such an interest.
- Intellectual property rights held and any agreements to share in royalties related to those rights, and the amount and source of royalty income that the covered individual or covered family member received or had the right to receive in the preceding twelve months, if when aggregated exceed \$5,000.
- Gifts received in the preceding twelve months that exceed \$5,000 in value, or multiple gifts from a single entity that in the aggregate exceed \$5,000 in value, other than gifts from a covered family member, and the value and source of the gifts.
- Reimbursed or sponsored travel in the preceding twelve months (see exclusions noted below). The disclosure of this travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the value of the travel, if the aggregated value of all payments from the sponsor/organizer (such as salary, consulting fees, honoraria, paid authorship and travel) exceeds \$5,000.

The following items do not have to be reported:

- Salary, royalties, or other remuneration paid by the institution to the covered individual, if the covered individual is currently employed or otherwise appointed by the institution.
- Income from seminars, lectures or teaching engagements sponsored by a federal, state, or local government, an institution of higher education as defined by 20 U.S.C. §1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.
- Income from service on advisory committees or review panels for a federal, state, or local government, an institution of higher education as defined by 20 U.S.C. §1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.
- Income from investment vehicles, such as mutual funds or retirement accounts, as long as the covered individual does not directly control the investment decisions made in those vehicles.
- Travel reimbursed or sponsored by a federal, state, or local government, an institution of higher education as defined by 20 U.S.C. §1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

The FCOI Official may request further information about a covered individual's travel, including the monetary value of the travel, in order to determine whether the travel constitutes a financial conflict of interest.

Covered individuals should also disclose other significant financial interests not specifically required by this policy if they have concerns the interests would reasonably appear to be affected by the proposed research (e.g., significant financial interests of family members other than a spouse or dependent children).

III. Procedures Related to FCOI

A. Education

A covered individual must complete training related to this policy and applicable policies, regulations, and laws at least once every four years. A covered individual who is new to the institution must satisfy this training requirement before beginning research at the institution. Our institution will use the NIH FOCI Training Website (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) or an equivalent and will maintain training records for all covered individuals.

A covered individual must complete the training immediately if the institution finds that the individual is not in compliance with this policy or the individual's management plan, or if the institution revises this policy in a manner that affects the individual's duties.

The FCOI Official or designee is responsible for ensuring that appropriate faculty, staff, trainees, and other persons participate in training related to this policy and applicable laws, and informing each investigator of the institution's policy, disclosure responsibilities, and federal regulations.

Each covered individual must acknowledge annually that the individual is aware of and has read this policy and is aware of the covered individual's responsibilities regarding disclosure of significant financial interests and of applicable federal regulations.

B. Financial Disclosure by Covered Individuals

A covered individual shall submit or update a financial conflict of interest disclosure statement at the time of application for PHS-funded research if a current financial disclosure statement is not on file, and within 30 days of acquiring or discovering an SFI, and on an annual basis.

The FCOI Official or designee may require a covered individual to submit additional disclosures, including a copy of any related agreement, contract, offer letter or other documentation.

C. Review Process

A designated FCOI Official or designee will review Financial Conflict of Interest Disclosure Forms to determine whether any disclosed significant financial interest is related to research in which the covered individual is engaged. A significant financial interest is related to research in which the covered individual is engaged if the FCOI Official or designee reasonably determines that the financial interest appears to be affected by the research or is in an entity whose financial interest appears to be affected by the research.

All significant financial interests related to research are referred to an FCOI committee (FCOIC), designated by the Board of Directors, for review. The FCOIC will determine whether a financial conflict of interest exists and, if so, will propose a management plan to manage, reduce or eliminate the financial conflict of interest, as described in (D) below. When there is a significant outside financial interest of the institution related to the proposed research, the FCOIC will report to the Board of Directors to manage the conflict.

The FCOI Official will make the final determination regarding what actions are required to manage, reduce or eliminate conflicts of interest.

D. Management Plans

A management plan may impose any condition and prescribe any action necessary to manage a financial conflict of interest, including an action reducing or eliminating the financial conflict of interest, to ensure to the extent possible that the design, conduct, or reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be prescribed include, but are not limited to:

- public disclosure of the conflict of interest in presentations and publications;
- for human subjects research, direct disclosure of the conflict of interest to research participants;
- appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
- modification of the research plan;
- change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- divestiture or reduction of the financial interest; or
- severance of relationships that create an actual or potential financial conflict of interest.

The management plan must be in the form of a written agreement; must provide that the covered individual acknowledges receipt of the plan and understands the requirements of this policy and the required actions and other terms of the plan, including the time frames for required actions; and must clearly identify each specific person responsible for monitoring compliance with the management plan. Each person conducting research under a management plan shall comply fully and promptly with the plan, and each person identified in the management plan as having responsibility for monitoring compliance with the plan shall carefully and fully monitor that compliance.

If research is ongoing and a new covered individual discloses a significant financial interest related to that research or any other covered individual discloses a new significant financial interest related to that research, the FCOI Official shall, not later than the 30th day after the filing of the disclosure statement: (1) review the disclosure statement to determine if a financial conflict of interest exists; and (2) if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research.

The FCOIC will review existing management plans on an annual basis to ensure that conflicts continue to be managed appropriately.

E. Noncompliance with Research Conflicts of Interest Policies

The institution anticipates that covered individuals will comply fully and promptly with this policy. The FCOI Official is responsible for investigating instances of non-compliance and determining whether to impose sanctions and what sanctions will be applied.

Examples of non-compliance include, but are not limited to:

- failure to submit required statements or updates;
- failure to provide additional information requested by the FCOI Official or FCOIC;
- knowingly filing an incomplete, erroneous or misleading statement;
- failing to comply with conflict of interest management plans; or
- knowingly violating applicable laws or regulations.

If the FCOI Official learns of a significant financial interest that was not timely disclosed or reviewed, the FCOI Official shall, not later than the 60th day after learning of the interest: (1) determine whether the significant financial interest is a financial conflict of interest; and (2) if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research going forward.

In addition, if a financial conflict of interest was not timely identified or managed, or if a covered individual fails to comply with a management plan, the FCOI Official shall, not later than the 120th day after determining noncompliance: 1) complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct or reporting of the research; and 2) implement any measures necessary regarding the covered individual's participation in the research between the date that the noncompliance is identified and the date the retrospective review is completed.

The Institution shall document the retrospective review which must include at least the following key elements: (a) Project number; (b) Project title; (c) PD/PI or contact PD/PI if a multiple PD/PI model is used; (d) Name of the Investigator with the FCOI; (e) Name of the entity with which the Investigator has a financial conflict of interest; (f) Reason(s) for the retrospective review; (g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.); (h) Findings of the review; and (i) Conclusions of the review.

Failure on the part of a covered individual to comply with this policy may result in disciplinary action and/or sanctions. Examples of possible sanctions include formal reprimand; termination of appointment for good cause; and/or any other enforcement action mandated by the applicable government granting agency.

For a covered individual who is not an employee of the institution, compliance with this policy is a condition of participating with the institution in the capacity that qualifies the person as a covered individual. The institution may require the individual to execute a document certifying that the individual knows that compliance with this policy is a condition of participation.

For PHS-covered research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating the financial conflict of interest report, notifying the PHS, and submitting a mitigation report as required by federal regulations.

If the failure to comply has resulted in a bias of the design, conduct or reporting of research, the FCOI Official will take appropriate corrective actions and promptly notify the PHS Awarding Component of corrective actions to be taken.

If the U.S. Department of Health and Human Services ("HHS") determines that clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a covered individual with a financial conflict of interest that was not managed or reported by the institution as required by federal regulations,

the institution will require the covered individual involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

F. Reporting for PHS-Sponsored Projects

Federal regulations require that each application for funding to the PHS include specific certifications and agreements related to this policy and financial conflicts of interest. Federal regulations also require that the institution file the reports required by this policy for PHS-funded research.

For PHS-sponsored projects, the FCOI Official must notify the PHS Awarding Component prior to expending any funds that a conflict of interest exists by submitting a financial conflict of interest report in compliance with 42 CFR Part 50, Subpart F, and 45 CFR Part 94. All FCOI reports must include sufficient information to enable the NIH to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the Institution's management plan.

The regulation provides key elements that must be included in the FCOI report to NIH. These include but are not necessarily limited to the following: (i) Project number; (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used; (iii) Name of the Investigator with the Financial Conflict of Interest; (iv) Name of the entity with which the Investigator has a Financial Conflict of Interest; (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); (vi) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000- \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value; (vii) A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research; (viii) A description of the key elements of the Institution's management plan, including:

- (A) Role and principal duties of the conflicted Investigator in the research project;
- (B) Conditions of the management plan
- (C) How the management plan is designed to safeguard objectivity in the research project;
- (D) Confirmation of the Investigator's agreement to the management plan;
- (E) How the management plan will be monitored to ensure Investigator compliance; and
- (F) Other information as needed.

NIH grant and cooperative agreement award recipients should continue to submit FCOI reports using the electronic Research Administration (eRA) Commons FCOI Module. Once the institution is required to be in full compliance with the regulatory requirements, the additional reporting requirements must be met. Therefore, if the eRA Commons FCOI Module is not updated by the time this occurs, the FCOI report should include an attachment that addresses the minimum elements of the FCOI report as stated above and provided in 42 CFR 50.605(b)(3).

The institution must make information available to HHS or the PHS Awarding Component as required by federal regulation. Reporting is not required for applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

If conflicts are identified after the initial award is made, the FCOI Official must notify the PHS within 60 days of identifying the conflict by filing a financial conflict of interest report as required by federal regulation.

The FCOI Official must also promptly notify the PHS Awarding Component of corrective actions taken if an investigator has biased the PHS funded research, and submit a mitigation report.

G. Web Posting of Financial Conflict of Interest Information and Policy

For each covered individual for whom a financial conflict of interest is found to exist by the FCOI Official and who contributes to the scientific development or execution of the research project in a substantive, measurable way, the institution will make information publicly available through a disclosure upon request within 5 business days. The information will include items specified on the [NIH Financial Conflict of Interest](#) link.

This policy and each update of this policy must be publicly accessible on the Internet.

H. Appeals Process

A covered individual may appeal to the institution's Chair of the Board of Directors if he/she does not concur with the proposed plan for managing/eliminating research conflicts of interest, or if the research is not permitted to be conducted. A written appeal should be submitted within 30 calendar days of notice of the proposed management plan or denial and include evidence detailing the investigator's concerns which support his/her claim that the management plan should be revised and/or the research should go forward. The Chair of the Board or his or her designee will review the appeal and may request the review/advice of the FCOIC. It is the responsibility of the Chair to approve, modify or reject any proposed revisions to the conflict of interest management plan.

I. Contractors and Collaborators

If research is carried out in cooperation with or through a subcontractor, contractor, or collaborator, including a person identified under federal regulations as a "sub-recipient," the institution must enter into a written agreement with the contracting party that provides legally enforceable terms that establish whether this policy or the financial conflicts of interest policy of the contracting party applies to the researchers of the contracting party.

If the policy of the contracting party applies to its researchers, the contracting party must certify that its policy is consistent with the requirements of any applicable federal regulations. If the contracting party cannot so certify, the agreement must state that the researchers are subject to this policy as covered individuals for disclosing significant financial interests that are directly related to the researcher's work at the institution.

If the policy of the contracting party applies to its researchers, the agreement must specify the time periods for the contracting party to report identified financial conflicts of interest to the institution. The time periods must be sufficient for the institution to make any reports required by federal regulations.

If the policy of the institution applies to the researchers of the contracting party, the agreement must specify the time periods for the researchers to submit a financial disclosure statement to

the institution. The time periods must be sufficient for the institution to comply with its review, management, and reporting obligations under federal regulations.

J. Records

Records regarding the disclosure of financial interests and the management of a conflict of interest, including financial disclosure statements, a reviewing official's determinations, and other records of institutional actions, shall be retained for at least 3 years from the date that the final expenditures report is submitted to the PHS (NIH), or as otherwise specified in 45 CFR 75.361, where applicable.

The institution will provide a centralized repository for financial disclosure statements, management plans, and related records.

K. Reviews

The institution, through its Conflict of Interest Office will provide regular reviews, at least annually, of financial disclosure statements to determine individual and institutional compliance with this policy.

L. Contacts

Contact info@polyvascular.com to direct questions to the FCOI Official.