

Valleywise Health Administrative Policy & Procedure

Effective Date: 10/24

Reviewed Dates: 00/00

Revision Dates: 00/00

Policy #: 42026

Policy Title: Research Conflicts of Interest

Scope: ☐ **District Governance (G)**

☒ **System-Wide (S)**

☐ **Division (D)**

☐ **Multi-Division (MD)**

☐ **Department (T)**

☐ **Multi-Department (MT)**

Purpose:

To identify the expectations and requirements for Principal Investigators and other Research Personnel for identifying and reporting Conflicts of Interest (COIs) in research studies and to describe the management and reporting of COIs by the Department of Research.

Definitions:

Clinical Privileges or Privileges: The authorization granted by the Board to render specific patient care services, for which the Medical Staff leaders and Board have developed eligibility and other privileging criteria and focused and ongoing professional practice evaluation standards.

Conflict of Interest: "Any circumstance that might interfere with an investigator's ability to be objective in the conduct of research". For purposes of this policy, a conflict of interest will be considered to exist when a Valleywise Health researcher participates in a research study and the Valleywise Health Researcher, a family member* or an associated entity** has a business or financial interest that could be enhanced based on the outcome of the study.

* Family member is considered a spouse, domestic partner or child.

** Associated entity is any trust, organization or enterprise over which the Valleywise Health Researcher or family member exerts control.

Disclosure of Significant Financial Interests: An investigator's significant financial interests to an Institution.

Financial Conflict of Interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

FCOI Report: An institution's report of FCOI to a Public Health Service (PHS) Awarding Component.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

House Staff: Includes residents, fellows, and Individuals licensed as appropriate, who are graduates of medical, allopathic and osteopathic, dental, or podiatric schools; who are appointed to a hospital's professional graduate training program that is approved by a nationally recognized accrediting body; and who participate in patient care under the direction of Member of the Medical Staff of the pertinent clinical disciplines with appropriate clinical privileges in the hospital.

Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: 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: The project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

Medical Staff: All physicians, dentists, oral surgeons and podiatrists, who have been appointed to the Medical Staff by the Board. Medical Staff are also referred to as Attendings.

Principal Investigator (PI): The individual(s) designated by Valleywise Health and if applicable, the applicant organization, to have the appropriate level of authority and responsibility to direct the research project. Research projects, whether funded by an applicant organization or not, may designate multiple individuals as PIs, who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PIs are named, each is responsible and accountable to the funding body, if applicable, for the proper conduct of the project or program including the submission of all required reports. The presence of more than one PI on a project diminishes neither the responsibility nor the accountability of any individual PI.

Research Personnel: Any person involved with clinical research involving living or deceased human subjects or their protected health information.

Significant Financial Interest:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. With regard to any publicly traded entity, a significant financial *interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - b. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
3. The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars,

lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Valleywise Health Code of Conduct: Valleywise Health Code of Conduct and Ethics and any subsequent policy amending or superseding such policy

Policy:

The purpose of this policy is to maintain the integrity of research conducted at Valleywise Health and to provide information about identifying, managing, reducing and eliminating, when applicable, conflicts of interest of its PIs and investigators.

Procedure: All personnel involved in research at Valleywise Health must demonstrate knowledge of the basic principles of COI and submit a yearly COI form to IRB staff for review and upload to the online IRB system.

I. Training

- A. All personnel involved in research must demonstrate knowledge of the basic principles involved in identifying and managing research COIs.
 - 1. In order to be included as a member of the research staff for a study, an individual must complete the Biomedical Investigator course in CITI. This is a foundational human subjects protection course, which includes training on COI.
 - 2. Renewal of this certification must take place at intervals no less than three years.
 - 3. If a FCOI is identified for an Investigator, IRB and Research Department staff members will ensure that the Investigator satisfies all federal reporting requirements.
- B. The IRB Coordinator will maintain a file of personnel and dates of completion of competency requirements. No new protocols will be approved without documentation that all study personnel have completed training in protection of human subjects.

II. Review Process

- A. All Investigators working on a Valleywise Health research study, will disclose any Significant Financial Interests while listed as study staff on a research study.
- B. PHS-funded research: If the Investigator is participating in a PHS-funded research study, the Investigator must disclose this to the Institution's designated officials no later than the time of application for PHS-funded research.

- C. NIH-funded research: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education and foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000). Institutions are strongly encouraged to review their FCOI policy and make any necessary changes to ensure Investigators fully understand their disclosure responsibilities.
- D. The Valleywise Health Department of Compliance, in conjunction with the Valleywise Health Research Department and the Chief Clinical Officer (CCO), will review the Investigator's Detailed Disclosure Form to ensure completeness and consistency with prior disclosures (if applicable). The Valleywise Health IRB and Research Departments, in conjunction with the Valleywise Health Compliance Department and the CCO, will consider whether any of the disclosed Significant Financial Interests of the Investigator are related to the project and whether the financial interest could directly and significantly affect the design, conduct, or reporting of the project.

For example, a direct effect would occur when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the entity in which the Investigator has a Significant Financial Interest, or when the entity is a proposed subcontractor or participant in the project. A significant effect on the financial interest is one that will materially affect the value of the entity, its earnings, or sales of its products. The following are examples of when an Investigator would be deemed to have a financial conflict of interest (FCOI): (i) if the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that could be affected by the research results from a proposed PHS-funded grant or contract, or an industry sponsored contract, based on an analysis of the scope and subject matter of the proposed project described in the application, or (ii) the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that licenses technology from Valleywise Health which has resulted in license income and that technology is the subject of a proposed PHS-funded award, or other funded award. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.

For disclosures of Significant Financial Interest greater than \$5,000 but less than \$10,000 the information will be reviewed and a determination of whether a conflict exists will be made. Disclosures of Significant Financial Interests of amounts in excess of \$10,000 shall be submitted to the

Valleywise Health Compliance Department, for review and approval, or continuing management.

If the Valleywise Health Research Department, IRB, or Compliance Department identifies a FCOI, a mitigation plan may be implemented for the FCOI. The staff member with the FCOI will be alerted to this fact and the proposed mitigation plan. If the plan is accepted by the reviewers and the staff member, the staff member will submit a revised COI form with the mitigation plan included.

III. FCOI Mitigation Plan

A. Disclosure of Significant Financial Interest.

If the Valleywise Health Research Department, IRB, or Compliance Department identifies a FCOI, a mitigation plan may be implemented for the FCOI.

- a. The mitigation plan will be developed and agreed upon by representatives of the Valleywise Health Research Department, IRB, or Compliance Department identifies a FCOI
- b. The staff member with the FCOI will be alerted to this fact and the determination that a mitigation plan is warranted and the specifics of the proposed plan. If the plan is accepted by the reviewers and the staff member, the staff member will submit a revised COI form, which includes the mitigation plan and his/her intention to follow the plan.
- c. The completed COI form will be uploaded to the Valleywise Health IRB system.
- d. COI forms must be updated at least annually, if the individual remains on a research study, or if the following circumstances apply:
 - i. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - ii. An Investigator is new to an Institution; or
 - iii. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.
- e. Annual Reporting. FCOIs for federally funded grants must be reported annually within a competitive segment or until the FCOI no longer exists. The annual FCOI report will include:
 - i. Status of the FCOI
 - ii. Any changes to the management plan, if applicable
 - iii. For PHS-funded research, updates to COI forms must be completed within 30 days of discovering and acquiring the (e.g.,

through purchase, marriage, or inheritance) a new significant financial interest.

IV. Reporting

- A. Per federal regulations (42 CFR 50, Subpart F), a copy of this policy will be posted on the Valleywise Health website at: www.valleywisehealth.org
- B. Annual Reporting. FCOIs for federally funded grants must be reported annually within a competitive segment or until the FCOI no longer exists. The annual FCOI report will include:
 - a. Status of the FCOI
 - b. Any changes to the management plan, if applicable
- C. Disclosure of Significant Financial Interest. All Investigators working on a Valleywise Health research study, will disclose any Significant Financial Interests while listed as study staff on a research study.
 - a. PHS-funded research: If the Investigator is participating in a PHS-funded research study, the Investigator must disclose this to the Institution's designated officials no later than the time of application for PHS-funded research.
 - b. Completed COI forms must be uploaded to the online IRB system.
 - c. COI forms must be updated at least annually, if the individual remains on a research study, or if the following circumstances apply:
 - i. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - ii. An Investigator is new to an Institution; or
 - iii. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.
 - iv. For PHS-funded research, updates to COI forms must be completed within 30 days of discovering and acquiring the (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
- D. Federal Agency Reporting of FCOIs.
 - a. Initial FCOI reporting: Any FCOIs for research staff working on a federally funded study (ex. NIH, DHHS, CDC) in which Valleywise Health is the prime recipient, must be reported immediately to the federal agency. If the federal grant is a subaward to Valleywise Health, the FCOI management plan must be reported immediately to the recipient institution, to allow the recipient institution time to report the FCOI to the funding agency. This reporting must occur at least

annually within a competitive grant segment or until the FCOI no longer exists. Initial reporting will be in the form of a FCOI management plan, which will contain the following elements (see COI reporting form).

- i. Grant number and PI or contact PI if the grant is awarded under the multiple PI model;
- ii. Name of investigator (if different than the PI);
- iii. Name of the entity with which the investigator has a FCOI;
- iv. Nature of the FCOI (e.g. consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);
- v. Value of the financial interest \$0 – 4,999; \$5,000 – 9,999; \$10,000 – 19,000; amounts between \$20,000 – 100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000 or a statement that a value cannot readily be determined;
- vi. A description of how the FCOI relates to NIH-funded research and the basis for Valleywise Health's determination that the financial interest conflicts with the research; and
- vii. Key elements of the Valleywise Health management plan to be included:
 1. Role and principal duties of the conflicted Investigator in the research project;
 2. Conditions of the management plan;
 3. How the management plan is designed to safeguard objectivity in the research project;
 4. Confirmation of the Investigator's agreement to the management plan;
 5. How the management plan will be monitored to ensure Investigator compliance; and
 6. Other information as needed.

V. Maintenance of FCOI Documents

A. All FCOI documents will be placed in the Valleywise Health IRB system under the staff member's profile. These documents will be maintained until the individual leaves Valleywise Health or indicates the Valleywise Health IRB that they will no longer be participating in research.

References:

42 CFR 50, Subpart F

NIH grant policy statement, 4.1.10 Financial Conflict of Interest.

The Valleywise Health Code of Conduct and Ethics

Policy # 01291 S Conflicts of Interest and Gift Policy

Valleywise Health Policy & Procedure - Approval Sheet
(Before submitting, fill out COMPLETELY.)

POLICY RESPONSIBLE PARTY: Carla Pauley

DEVELOPMENT TEAM(S): Carla Pauley, Lora Nordstrom

Policy #: 42026 S

Policy Title: Research Conflicts of Interest

e-Signers:

Michael White, MD, MBA, Executive VP & Chief Clinical Officer

Place an X on the right side of applicable description:

New - X

Retire -

Reviewed -

Revised with Minor Changes -

Revised with Major Changes -

Please list revisions made below:

Reviewed and Approved by in Addition to Responsible Party and E-Signer(s):

Committee: Systemwide P&P 11/24

Committee: MEC 11/24

Committee: 00/00

Reviewed for EPIC: N/A

Other: 00/00

Other: 00/00

Other: 00/00

Other: 00/00