

Valleywise Health Administrative Policy & Procedure

Effective Date: 10/02

Reviewed Dates: 03/03; 06/12; 08/18; 12/18

Revision Dates: 02/03; 07/03; 12/03; 07/05; 06/08; 05/10; 08/12;
10/12; 06/14; 10/20

Policy #: 42004 S

Policy Title: Research: Research Personnel: Qualifications, Competency, Continuing Education and Conflicts of Interest

Scope: [] District Governance (G)
[X] 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 that will assure the safe and ethical conduct of research involving human subjects.

Definitions:

Allied Health Professional: A health care practitioner other than a Medical Staff member who is authorized to provide patient care services in the Hospital who have been granted clinical privileges.

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: means "A conflict of interest refers to 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."

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

Principal Investigator (PI): means "The individual responsible for the conduct of the research."

Provider: A Medical Staff Member with Clinical Privileges, Resident, or Allied Health Professional.

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

Residents: 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.

Valleywise Health Standard of Conduct: means "Valleywise Health Standard of Conduct Policy consistent with the Maricopa County Ethics Handbook and any subsequent policy amending or superseding such policy.

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

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

Policy:

- A. It is imperative that research personnel maintain a high level of expertise and knowledge that will provide for the safety and protection of human subjects and assure the application of the highest standards of ethical and legal principles to the research conducted at Valleywise Health.
- B. All research projects, including cooperative research and multi-center studies, involving Valleywise Health patients or employees, must identify a PI who is affiliated with Valleywise Health. This person must be a Valleywise Health employee or have an appointment to the Valleywise Health staff, and shall belong to one of the following categories:
 - 1. Member of the Medical Staff or House Staff
 - 2. Professional with a doctoral degree in a science or related discipline
 - 3. Nurse with a bachelor's or higher degree
 - 4. Other Licensed Healthcare Provider
- C. PIs must be operating within the scope of practice for which they have been granted privileges by Valleywise Health. If specialty procedures that are part of the research protocol are not normally included or delineated in the description of the scope of practice or involve specialized training or certification, the investigator must provide evidence of such experience or training or certification.
- D. All research personnel are responsible for assuring that research is conducted in a manner that meets ethical and regulatory standards outlined in the Belmont Report, the Code of Federal Regulations and the Valleywise Health policies and

procedures. The PI on a study will be responsible for the conduct of the study and for assuring that all research personnel on the study are qualified for their roles in the study and will/have obtained the necessary training outlined in section II below.

- E. All research personnel, who are in a position to influence the design, conduct, or reporting of research, must identify any potential conflicts of interest that might be construed to affect the objective conduct of the research. The Institutional Review Board (IRB) will review these on a case-by-case basis to assure that appropriate steps are taken to assure objectivity in the conduct of the research.

Procedure:

I. Identification of the Principal Investigator

A. House Staff

1. Members of the House Staff (Residents) may not serve as principal investigators (PIs), the research project must be carried out under the direction of a Faculty Sponsor, who will serve as PI. The faculty sponsor assumes ultimate responsibility for the scientific and ethical conduct of the study. The resident may serve as a sub-investigator (SubI)
2. For administrative purposes, the resident SubI may be the primary contact person for the IRB. Correspondence will be addressed to the resident SubI and copies will also be sent to the PI/faculty advisor.
3. For research involving procedures and treatments, the Faculty Sponsor (the PI) assumes ultimate responsibility for the medical care provided to the patient as part of the research protocol. The faculty sponsor's name and contact information should be included in the informed consent documents under who to contact with questions about the research study.

B. Non-Physician Members of Valleywise Health Staff

1. If the non-physician staff member is performing this research as part of an educational program to attain an advanced degree, the project will be considered a training project and will be administered similarly to those for house staff. There must be a Faculty Sponsor who is a member of the Valleywise Health staff who will serve as PI. The faculty sponsor must have sufficient research and clinical experience to serve as a PI and to oversee the performance of this research.

C. Medical Staff

1. When a member of the medical staff (attending staff) serves as PI, the IRB accepts the hospital's review and appointment process as evidence that the staff member is competent to perform clinical research in the areas that hospital privileges have been granted.
2. If the research involves procedures, devices, or treatments that are outside the typical scope of clinical practice of the area in which a staff member has privileges, additional evidence of competence must be submitted to the IRB before the research can begin.

II. Educational requirements

- A. All personnel involved in research must demonstrate knowledge of the basic principles guiding the ethical design and conduct of research. This must be accomplished by completing the Group 1 Biomedical course offered by the CITI program at www.citiprogram.org.
 - 1. Initial certification must take place prior to participation in any research study.
 - 2. Renewal of this certification must take place at intervals no less than three years. Recertification may be obtained by appropriate continuing education courses on research topics but does not include attendance at the investigator meetings held by a study sponsor for training for the specific study.

- 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.

III. Clinicaltrials.gov

- A. If the research project in question is a clinical trial that is **not** sponsored by an outside agency or company, the PI is responsible for reporting the study to clinicaltrials.gov **before** data collection begins.

IV. Conflicts of Interest

- A. This policy applies to ALL Valleywise Health Researchers. This policy complements the Valleywise Health Standard of Conduct Policy and Policy 0129 S (Compliance: Conflicts of Interest and Gift Policy), as well as other Valleywise Health research policies.

- B. Disclosure of Significant Financial Interest. All individuals responsible for the design, conduct, or reporting of the results of work performed or to be performed under a Public Health Service (PHS) sponsored project, an industry sponsored research study, or other research activity, referred to as "**Investigator**," must disclose their Significant Financial Interests. "Investigator" includes, but is not limited to, the PI, other investigators, Research Assistants or Coordinators, and any other individuals who are involved in accomplishing project objectives. It may include students (graduate and undergraduate) and other personnel listed as authors on project results, even if they are not paid from the project.

- C. What is a "Significant Financial Interest"?
 - 2. With regard to **Publicly-Traded Entities**, Payments or value exceeding \$5,000 (when aggregated for an Investigator and the Investigator's spouse and dependent children) from a single entity during the prior 12 months. This includes any salary, consultant payments, honoraria, paid authorship, equity interest (stock, stock option or other ownership interest).
 - 3. With regard to **Privately Held Entities**, Payments or value exceeding \$5,000 (when aggregated for an Investigator and the Investigator's spouse and dependent children) from a single entity during the prior 12 months or when the Investigator and the investigator's spouse/domestic partner and

dependent children hold **any** equity interest (stock, stock option, or other ownership interest).

4. With regard to **Intellectual Property**, Intellectual property rights and interests (patents, copyrights) **upon receipt of income** related to such rights and interests.
5. With regard to **Travel Reimbursements**, Any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities during the prior 12 months (with the exception of travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education).
6. The term "Significant Financial Interest" **does not include**: salary, royalties, or other remuneration paid by Valleywise Health or District Medical Group to the Investigator if the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to the Institution and agreements to share royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute 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, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.
7. Incentives for Referral or Recruitment: Payments to professionals in exchange for referrals of potential subjects to research studies or for recruitment of subjects into research studies, regardless of the size or nature of the payment, constitute a conflict of interest and are prohibited.

D. What are "Institutional Responsibilities"? An Investigator's Institutional Responsibilities means the Investigator's professional responsibilities on behalf of the Institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

E. Review Process and Guidelines. The Valleywise Health Department of Compliance in conjunction with the Valleywise Health Research Department 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, 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.

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

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.

References: 42 CFR 50, 45 CFR 94, 21 CFR Parts 312 & 812

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

POLICY RESPONSIBLE PARTY: Carla Pauley

DEVELOPMENT TEAM(S): Carla Pauley, Lora Nordstrom

Policy #: 42004 S

Policy Title: Research: Research Personnel: Qualifications, Competency, Continuing Education and 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 -

Retire -

Reviewed -

Revised with Minor Changes - X

Revised with Major Changes -

Please list revisions made below: Name change from MIHS to Valleywise Health, changed owner. Changes to reflect current standard procedures, (Residents cannot be PIs, training requirements have had some slight changes, OCCI doesn't exist)

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

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|--------------------------------------|--------------|
| Committee: Systemwide P&P | 11/20 |
| Committee: MEC | 11/20 |
| Committee: | 00/00 |
| Reviewed for EPIC: | N/A |
| Other: | 00/00 |
| Other: | 00/00 |
| Other: | 00/00 |
| Other: | 00/00 |