The Valley Hospital
Valley Health System

POLICY AND PROCEDURE

POLICY # 23.01
SUBJECT: CONFLICTS OF INTEREST IN RESEARCH

POLICY:

This Policy is in accordance with 42 CFR 50 Subpart F and 45 CFR 94. It is the policy of the Hospital to promote objectivity in research. To that effect, each Investigator shall disclose real or potential conflicts of interest in research. As described below, any such conflicts that could directly and significantly affect the design, conduct or reporting of Hospital research will be eliminated, reduced or managed. All Investigators engaged in research at the Hospital must comply with this Policy.

PURPOSE:

Consistent with its mission of patient focused care, the Hospital seeks to advance medical knowledge through research and, where appropriate, to transfer the outcomes of research to clinical practice for the benefit of the public. Actual or apparent conflicts of interest may arise when an Investigator has a financial or other interest directly or indirectly related to research or a sponsor of research. The purpose of this Policy is to ensure that Investigators avoid or minimize conflicts of interest in research, and respond appropriately when conflicts of interest arise.

DEFINITIONS:

Annual Compliance Statement: IRB member attestation of compliance with IRB policy (Exhibit A).

Conflicts of Interest Committee ("COI Committee"): Committee that advises on conflict of interest in research matters. The COI Committee is comprised of the Chief Corporate Compliance Officer; Institutional Official; Vice President, Medical Affairs; Vice President, Administration; and others as deemed appropriate by the Chief Corporate Compliance Officer.

Family: Any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest: Anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property

rights and interests.

The term "Financial Interest" does NOT include:

a) salary, royalties, or other remuneration from the Hospital;

b) income from the authorship of academic or scholarly works;

c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or

d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

"Financial Interest" also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his or her Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest: A Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds $5,000; or

b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds $5,000; or

c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or

d) is income related to intellectual property rights and interests not reimbursed through the Hospital.

Financial Conflict of Interest: A Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that the

Hospital reasonably determines could directly and significantly affect the design, conduct or reporting of Hospital research.

Financial Disclosure Form: An attestation of current financial status of an Investigator that is required for all Investigators participating in a government-funded or Investigator initiated research study **(**Exhibit B**)**.

Hospital: All Departments that comprise The Valley Hospital, including the Office of Clinical Trials.

Institutional Official: The individual within the Hospital responsible for the solicitation and review of disclosures of significant financial interests, including those of the Investigator's Family, related to the Investigator's Institutional Responsibilities. For the purposes of this policy, the Institutional Official is designated as the Director, Research Administration.

Institutional Responsibilities: The Investigator's professional responsibilities on behalf of the Hospital, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator: Any individual who is responsible for the design, conduct, or reporting of sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator, sub-investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

PHS: U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services ("HHS"), and any components of the PHS to which the authority involved may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research: A systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Sponsor(s): Entities which provide support to Hospital Investigator(s) in research projects of mutual interest or in studies involving said entity's products or services to which applications for support of such studies are made.

PROCEDURE:

1) Disclosure of Interests in Research

All Investigators must disclose any real or perceived conflict of interest in research, including any Financial Interest, as set forth in this Policy.

When applying for IRB approval of a research project, each Investigator must submit to the IRB the appropriate financial disclosure form(s). For industry-sponsored research, the Investigator must complete the financial disclosure form provided by the sponsor. In addition, if the contemplated research is PHS-funded or Investigator initiated, each Investigator must complete the Hospital's Financial Disclosure Form (Exhibit B). The IRB will not consider a research proposal unless and until all Investigators participating in the research project have submitted the appropriate disclosure form(s).

Each Investigator must submit initial financial disclosure forms when seeking IRB approval, updated financial disclosure forms when applying for annual renewal of a study, and, as needed, within thirty (30) days of discovering or acquiring any Significant Financial Interest during the course of a study that was not previously disclosed.

Investigators whose research is PHS-funded must also disclose reimbursed or sponsored travel related to their Institutional Responsibilities. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official and/or Chief Corporate Compliance Officer will determine if additional information is needed to ascertain whether the travel constitutes a Financial Conflict of Interest with the Investigator's PHS-funded research.

Investigators are encouraged to discuss any other potential conflicts of interest in research with the Institutional Official and/or Chief Corporate Compliance Officer, even in situations that are not covered by the disclosure procedures in this Policy.

2) Review of Potential Conflicts of Interest in Research

The IRB will track and report to the Institutional Official any disclosed Financial Interest or other outside interest in research. The Institutional Official will determine whether the disclosed Financial Interest constitutes a Significant Financial Interest, and whether any other disclosed outside interest requires further review. If there is no Significant Financial Interest or further review required, the Institutional Official will send written documentation (Exhibit C) to that effect to the IRB to be placed in the research project file. If there is a Significant Financial Interest or further review required, the Institutional Official will promptly report the Significant Financial Interest or other outside interest to the Chief Corporate Compliance Officer.

The Chief Corporate Compliance Officer will promptly review any Significant Financial Interest or other outside interest in research reported by the Institutional Official. If the Chief Corporate Compliance Officer determines that there is no Financial Conflict of Interest or other conflict of

interest, she will send written documentation (Exhibit C) to that effect to the Institutional Official and IRB to be placed in the research project file (Exhibit C). If there is a potential Financial Conflict of Interest or other conflict of interest, the Chief Corporate Compliance Officer will refer the matter to the COI Committee for a final determination.

The Chief Corporate Compliance Officer will provide written notice to the Institutional Official and IRB of the COI Committee's decision and any action that should be taken with respect to an identified Financial Conflict of Interest or other conflict of interest in research. The IRB will place a copy of this written documentation (Exhibit C) in the research project file.

If there is a Financial Conflict of Interest or other conflict that can be managed, the COI Committee will recommend a management plan in writing. The IRB may require additional action (but may not remove a management plan requirement) to ensure that a Financial Conflict of Interest or other conflict of interest in research does not adversely affect the rights and welfare of human subjects in the study, and any new requirements will be communicated by the IRB Chairman (or his or her designee) to the Chief Corporate Compliance Officer and Institutional Official for consideration by the COI Committee.

The management plan may, as appropriate, include the following requirements or any other strategies as determined by the COI Committee and/or IRB:

- Public disclosure of the conflict of interest in research (e.g., in the informed consent/authorization and/or research publications;
- Monitoring of the research by independent reviewers and/or a data safety monitoring board;
- Modification of the research plan;
- Divestiture of the Investigators conflict of interest or placement in a blind trust;
- Escrow of an equity interest until certain triggering conditions are met;
- Prohibition of the Investigator's involvement in the research;
- Prohibition of the Investigator's consenting of study subjects;
- Prohibition of the Investigator from serving as the Principal Investigator;
- Prohibition of the Investigator's participation in contract negotiations for the research; or
- Severance of the Investigator's relationship(s) that create the conflict of interest in research.

The management plan will state who is responsible for overseeing the implementation of the plan, and for reporting on compliance at stated intervals to the COI Committee. If the

management plan prescribes monitoring of the research, it will describe specifically how the monitoring plan shall be performed, who shall perform it, what records are to be kept, and what reports are made to the COI Committee.

The Chief Corporate Compliance Officer will notify the Investigator of the COI determination, as well as the Investigator's right to appeal the decision and the appeals procedure. (Exhibit D) Within two weeks of notification of the decision, the affected Investigator must agree in writing to the proposed management plan or submit a written request to appeal the determination to the Chief Corporation Compliance Officer. The appeal will be reviewed by an appeals committee comprised of the Chair of the COI Committee, Chair of the IRB and President of The Valley Hospital Foundation ("Appeals COI Committee"). The Investigator may appeal the COI determination only upon the following grounds: (1) inaccurate or incomplete information was relied upon, (2) improper procedures were applied, or (3) bias influenced the decision. The decision of the Appeals COI Committee is final and the Investigator will be notified of the determination. The Investigator must sign the final approved written management plan before any related research goes forward.

3) IRB Compliance

All IRB members will sign an Annual Compliance Statement (Exhibit A). IRB members may not participate in the initial or continuing review of any research project in which the member has a conflict except to provide information as requested by the IRB. If at any time during the review of a particular research project an IRB member has a real or perceived conflict of interest or a Significant Financial Interest, the IRB member will recuse himself/herself from the voting process. The minutes will reflect the abstention from deliberations and voting.

4) Training

All Investigators must complete training on this Policy prior to engaging in research, and at least every four years thereafter. Investigators may fulfill this requirement by completing the National Institute of Health's Financial Conflict of Interest tutorial (located at http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm), and submitting the certification of completion to the IRB.

All Investigators must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this Policy or with a management plan related research.

5) Reporting Requirements

Should any conflict of interest or non-compliance require reporting to a government sponsor, the Institutional Official will submit a report in accordance with applicable law. If funding for the research project is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee prior to the expenditure of any funds and such that the prime

awardee may fulfill its reporting obligations to PHS.

6) Investigator Non-Compliance

a) Disciplinary Action

The Chief Corporate Compliance Officer and the Institutional Official have the authority to impose and enforce disciplinary action in the event of non-compliance with this Policy or a management plan related to research. Disciplinary action may include suspension of all relevant research activities until the matter is resolved or other appropriate action is implemented.

A decision to impose disciplinary action will be described in a written explanation to the Investigator, COI Committee and where applicable, to the IRB. The explanation will also inform the Investigator of his or her right to appeal the decision and the appeals procedure.

b) Retrospective Review

If it is determined that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, a retrospective review will be conducted of the Investigator's activities and the research project to determine whether the research done during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

If the affected research requires reporting of the Financial Conflict of Interest or non-compliance, the Institutional Official will submit a report in accordance with any applicable law.

For PHS-funded research, the Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the Institutional Official will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description

of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

7) Records Retention

The Hospital will retain all disclosure forms, conflict management plans, and related documents for a period of three (3) years from the date of termination or completion of the research project or, if applicable, three (3) years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee. If any litigation, claim, financial management review, or audit is started before the expiration of the three year period, however, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

8) Public Accessibility

For any PHS-funded research project, the Institutional Official will publish on a publicly-accessible website or respond within five (5) business days to any request for information concerning any Significant Financial Interest that meets the following criteria:

a) The Significant Financial Interest was disclosed and is still held by the Investigator;

b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and

c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The Institutional Official (or his/her designee) shall maintain a log of requests and responses pursuant to this Section 8.

9) Confidentiality

As far as practicable and consistent with legal obligations, all disclosure forms, conflict management plans, and related information will be confidential and shared internally on a need-to-know basis. However, the Hospital may be required to make such information externally available to the PHS Awarding Component and/or HHS, any other sponsor or agency funding research of an Investigator, to a requestor of information concerning any Significant Financial Interest, or to the primary entity who made the funding available to the Hospital, if requested or required. If the Hospital provides disclosure forms, conflict management plans, and related information to an outside entity, the affected Investigator will be informed of this disclosure.

RESPONSIBILITY: **President, The Valley Hospital Foundation**

Revised: 5/16/2013

Audrey Meyers
President and Chief Executive Officer

EFFECTIVE: 12-18-01
REVISED: 6-20-13
Approved: IRB Committee, 12/13/01; 4/22/03
Supersedes: Policy #23.01, 05/02/03; 05/15/06; 08/18/09; 8/16/10
Attachments: **Exhibit A** - Annual Compliance Statement
Exhibit B - Financial Disclosure Form
Exhibit C - COI Tracking Form
Exhibit D – COI Appeal Form

References: 42 CFR, Part 50
45 CFR, Part 94
21 CFR, Part 54
Guidance for Clinical Investigators, Industry, and FDA Staff, Financial Disclosure by Clinical Investigators (Draft Guidance, May 2011)
Guidance for Industry, Financial Disclosure by Clinical Investigators (March 2001)
National Science Foundation, Awards and Administration Guide Chapter IV (Jan. 2010)