



Subject <b>Secondary/Significant Financial Interest and the Objectivity in Research</b>	Attachments X Yes No
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Manual HealthPartners Institute Research Policy Book	Last Review Date 4/2016
Issued By HealthPartners Institute	Next Review Date 3 <sup>rd</sup> Quarter 2018
Applicable This Policy will apply to any Covered Person (as that term is defined in this Policy).	Origination Date 09/98
	Retired Date NA
Review Responsibility HealthPartners Institute Board of Directors	Contact HealthPartners Compliance Committee

**I. PURPOSE**

The purpose of this Policy is to facilitate the open disclosure and review of any real or potential Secondary/Significant Financial Interests between a Covered Person's Research obligations or Institutional Responsibilities and their personal or financial interests or obligations, and to establish a process to eliminate, manage or reduce such interests and to protect the rights and interests of research participants. The elimination, management, or reduction of Secondary/Significant Financial Interests as specified in this Policy is undertaken to preserve objectivity in the (1) design, conduct, or reporting and (2) review, administration and oversight of Research. This Policy is catalyzed by, and consistent with, the Public Health Service (PHS) regulations on "Objectivity in Research," 42 CFR Part 50 and Department of Health and Human Services (DHS) draft Guidance on "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" (45 CFR Part 46 and 21 CFR Parts 50 and 56).

This Policy has been developed to also assure compliance with the HealthPartners and Park Nicollet Federal-Wide Assurance, and assure compliance with the International Committee of Medical Journals Editors ("ICJME") disclosure requirements, found at <http://www.icmje.org/icmje-recommendations.pdf>, for competing interest in journals that are members of the ICMJE. This Policy supplements but does not replace applicable Minnesota state laws governing conflicts of interest applicable to non-profit charitable corporations or other applicable HealthPartners policies or practices relating to the activities of Covered Persons, such as the Code of Conduct, Work for Hire or Intellectual Property policies.

**II. POLICY**

It is the policy of HealthPartners Institute that any person engaged in the (1) review, administration or oversight of Research conducted under the auspices of HealthPartners Institute or (2) design, conduct or reporting of a Research Project must disclose Secondary/Significant Financial Interests related to Research, or the Project, or to the sponsor of the Project, or of the Sponsor's affiliated entity or entities. If HealthPartners Institute determines that such an interest might reasonably appear to directly affect Research or a particular Research Project, HealthPartners Institute will take steps either to

eliminate, manage or reduce the personal and/or financial interest, pursuant to Section III of this Policy.

### **III. PROCEDURE(S)**

#### **3.1 Disclosures.**

Annual Disclosures. Administrators shall disclose all Secondary/Significant Financial Interests by submitting a completed Disclosure Form and all required supporting documentation to HealthPartners Institute's Executive Director, Research, or designee, who will review this information with the Conflict of Interest Committee, as necessary. All Disclosure Forms must be updated by the Administrator who submitted the initial Disclosure Form and as new reportable Secondary/Significant Financial Interests are obtained. Administrators have a continuing obligation to scrutinize any transactions in which they are involved for potential Secondary/Significant Financial Interests and must make full disclosure to HealthPartners Institute's Executive Director, Research, or designee within 30 days of acquisition or discovery.

- b. Project Specific Disclosures. The Project Team shall disclose all Secondary/Significant Financial Interests by including a completed project Disclosure Form and all required supporting documentation in the Research Project application package when it is initially submitted. The completed Disclosure Form shall be forwarded by HealthPartners Institute's Executive Director, Research, or designee, to the Conflict of Interest Committee. All Disclosure Forms must be updated by the Project Team member who submitted the initial Disclosure Form during the period that the applicable Research Project is active as new reportable Secondary/Significant Financial Interests are obtained. The Project Team has a continuing obligation to scrutinize any transactions in which they are involved for potential Secondary/Significant Financial Interests and must make full disclosure to the Conflict of Interest Committee, through the Office of Research Subjects within 30 days of acquisition or discovery.

#### **3.2 Review Process Applicable to All Disclosures.**

- a. The determination of whether a potential for a Conflict of Interest exists is made by the Conflict of Interest Committee.
- b. The Conflict of Interest Committee will review all relevant information, including the Forms, and make a final determination to the President of HealthPartners Institute and the Executive Director, Research, indicating one of the outcomes specified in Section 3.2.b.i and ii below. The Conflict of Interest Committee shall document its findings, including the basis for any recommendation to permit or recommend management, reduction or elimination of the Conflict of Interest in the Summary Report:
  - i. The Conflict of Interest is so remote that there is little or no probability for bias in objectivity in a Research Project or with respect to an individual's obligations to HealthPartners Institute the Institute to review, administer and oversee Research; or
  - ii. The Conflict of Interest requires management, elimination or reduction and the Conflict of Interest Committee will develop a specific Management Plan which shall be included in a Memorandum of Understanding between the Covered Person and the President of HealthPartners Institute. The following are examples of conditions or restrictions that may be included in a Management Plan:
    - (a) Public disclosure of the related Conflict of Interest(s)/Significant Financial Interest (e.g. when presenting or publishing the research);
    - (b) Recommend to the Institutional Review Board or Animal Care and Use Committee monitoring of the Research Project by independent reviewers appointed by the President of HealthPartners Institute. The Conflict of Interest Committee shall specify any monitoring procedures to be imposed, such as when a Covered Person will be permitted to review contracts related to

- a Research Project, where applicable, or conduct Research, if applicable;
- (c) Recommend modification of the Research plan to the Institutional Review Board or, Animal Care and Use Committee if applicable;
- (d) Disqualification of the Covered Person from participation in all or a portion of a Research Project;
- (e) Partial or complete divestiture of the related Secondary/Significant Financial Interest(s);
- (f) Severance of relationships that create actual or potential Conflict of Interests;
- (g) Disqualification of the Covered Person from reviewing any contract related to a Research Project or HealthPartners Institute Responsibilities;
- (h) Allowing the Covered Person to review any contract related to a Research Project or HealthPartners Institute only together with a third party designated by the Executive Director, Research; or
- (i) Any other action that the Conflict of Interest Committee deems appropriate.

When a Project Team member has a Secondary/Significant Financial Interest that would reasonably appear to directly or indirectly and significantly affect a Research Project, the Conflict of Interest Committee may recommend to the President of HealthPartners Institute that the Research Project not proceed. Alternatively, under certain circumstances the Conflict of Interest Committee may recommend that the President of HealthPartners Institute establish a Management Plan for the conduct of the Research Project.

When an Administrator has a Secondary/Significant Financial interest that would reasonably appear to directly or indirectly and significantly affect his or her obligations to HealthPartners Institute, the Conflict of Interest Committee may recommend to the President of HealthPartners Institute that this person's role be altered or managed through establishment of a Management Plan.,

- c. The President of HealthPartners Institute and Executive Director, Research, shall have the authority to accept, reject or modify the Management Plan recommended by the Conflict of Interest Committee and shall notify the Conflict of Interest Committee of their decision to accept, reject or modify the Conflict of Interest Committee's recommended Management Plan and such decision must be incorporated into a Summary Report.
- d. The review of the Disclosure Form(s) and adoption of conditions or restrictions to manage or eliminate the conflict must be finalized and incorporated into a Memorandum of Understanding between the Covered Person and the President of HealthPartners Institute prior to the expenditure of funds under the award.
- e. The President of HealthPartners Institute, through the Conflict of Interest Committee, shall submit the Summary Report to the Institutional Review Board or Animal Care and Use Committee. The Institutional Review Board or Animal Care and Use Committee has the final authority to decide whether the conflict of interest and the Management Plan, if any, allow the Research Project to be approved. When there is a Conflict of Interest, the Institutional Review Board or Animal Care and Use Committee shall not review the applicable Research Project until it has reviewed the interest and Management Plan, if any, unless there has been divestment of financial interests to the point where there is no longer any Conflict of Interest.

- f. The President of HealthPartners Institute shall advise the HealthPartners Institute Board of Directors of the Covered Person's Conflict of Interests and the President of HealthPartners Institute and Executive Director, Research, decision to accept, reject or modify the Conflict of Interest Committee's recommended Management Plan.
- g. The Conflict of Interest Committee will monitor the Covered Person's compliance with the Management Plan by obtaining progress reports from the Covered Person no less than annually. Sanctions for noncompliance may include, but are not limited to, termination of employment, ineligibility of Covered Persons to submit research applications, seek approval of the human research protection program, or supervise research staff.

### 3.3 Responsibilities of HealthPartners Institute.

- a. If a Conflict of Interest exists, and if required by the Sponsor, the Executive Director, Research, must notify the Sponsor of the existence of the Conflict of Interest and submit the following reports to the Sponsor:
  - i. Initial Report. The Executive Director, Research, shall provide a report prior to the expenditure of Research funds ("Initial Report"), which shall include the information specified in Section 3.3.a.iv below.
  - ii. Interim Report. During the period of the award, the Executive Director, Research, shall provide a report within 60 days of identifying a new Conflict of Interest ("Interim Report"), which shall include the information specified in Section 3.3.a.iv below.
  - iii. Annual Report. The Executive Director, Research, shall provide an annual report ("Annual Report") at the same time as when the grantee submits the annual progress report to the Research funder, including multi-year progress report, or at the time of the funding extension of the Research Project, which report shall include the following information in addition to the information specified in Section 3.3.a.iv below:
    - (a) The status of the Conflict of Interest; and
    - (b) Changes to the Management Plan, if any.
  - iv. The Initial Report, Interim Report and Annual Report shall include the following information:
    - (a) the grant/contract number;
    - (b) the name of the project director/principal Investigator ("PD"/"PI") or contact PD/PI;
    - (c) the name of the covered person with the Conflict of Interest;
    - (d) the name of the entity with which the Investigator has a Conflict of Interest;
    - (e) the nature of the Conflict of Interest; (e.g., equity interest, consulting fees, travel reimbursement; honoraria);
    - (f) the value of the Financial of Interest, if any, in the following categories: \$0 - \$4,999; \$5,000-\$9,999; \$10,000- \$19,999; amount 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 be determined;
    - (g) a description of how the Conflict of Interest relates to the Sponsor-funded Research and the basis for HealthPartners Institute's determination that the Conflict of Interest conflicts with the Research;
    - (h) whether the Conflict of Interest was managed, reduced or eliminated; and
    - (i) the key elements of the Management Plan, if applicable.

- b. Sub-recipient Reporting Requirements. HealthPartners Institute shall incorporate as part of a written agreement with all sub-recipients, terms that (i) establish whether this Policy or the Conflict of Interest policy of the sub-recipient will apply to sub-recipient Investigators and (ii) include time periods to meet disclosure and/or Conflict of Interest reporting requirements. Sub recipient institutions that rely on their Conflict of Interests policy shall report identified Conflict of Interests to HealthPartners Institute in sufficient time to allow HealthPartners Institute to report the Conflict of Interest to the Sponsor (e.g., to NIH through the eRA Commons Financial Conflict of Interest Module) to allow HealthPartners Institute to meet its reporting obligations.
- c. Public Accessibility. HealthPartners Institute shall make available the following information concerning identified Significant Financial Interests held by Covered Persons via a publicly accessible website or by a written response to any requestor within five (5) business days of a request. If the following information is made available via a publicly accessible website, then HealthPartners Institute shall update the website annually and within 60 days of identifying any new Significant Financial Interest when posting to the Website.
- Covered Persons;
  - Covered Person's title and role with respect to the Research Project;
  - Name of the entity in which the Significant Financial Interest is held;
  - Nature of the Significant Financial Interest; and
  - The value of the Significant Financial Interest (\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,000; amount between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000 or statement that a value cannot be readily determined.
- d. Record Retention. HealthPartners Institute must retain the information above for three years following the termination or completion of the Research Project to which the records relate, or the resolution of any Sponsor action involving the records, whichever occurs last. If the Research Project is funded by PHS, the information must be retained at least three (3) years from the date of final expenditures report submitted to the PHS.
- e. Conflict of Interest Training. Each Investigator shall complete training prior to engaging in Research related to any Sponsor-funded grant or contract and at least every four (4) Years, and immediately under the following circumstances:
- i. where any institutional conflict of interest policy applicable to Investigators changes in a manner that affects Investigator requirements;
  - ii. where an Investigator is new to HealthPartners Institute; and
  - iii. where HealthPartners Institute finds that an Investigator is noncompliant with this Policy or the Management Plan.
- f. Retrospective Review and Mitigation Report. HealthPartners Institute shall complete and document a retrospective review of the Covered Person's activities within 120 days of HealthPartners Institute's determination of non-compliance with this Policy to determine bias in the design, conduct or reporting of Research. HealthPartners Institute shall notify the Sponsor promptly and submit a mitigation report ("Mitigation Report") to the Sponsor only in cases where bias is found as a result of a retrospective review. The Mitigation Report shall address the impact of the bias on the Research Project and the actions HealthPartners Institute has taken, or will take, to eliminate or mitigate the effect of the bias. In addition, the Mitigation Report shall include the Project number, Project title, contract principal Investigator, name of the Covered Person with the Significant Financial Interest, name of the entity with the Significant Financial Interest, the reason for the review, the details of methodology used to identify a Significant Financial Interest, findings, and conclusion.
- g. Reports to NIH. In cases where NIH is the Sponsor of the Research Project, the Initial Report,

Annual Report and Mitigation Report shall be provided to the Sponsor through the eRA Commons Financial Conflict of Interest Module.

#### IV. DEFINITIONS

- 4.1 "Affiliated Entity" means any organization now or hereafter formed (i) which controls HealthPartners Institute; (ii) which is controlled by HealthPartners Institute; (iii) which is controlled by another organization that also controls HealthPartners Institute; or (iv) which is controlled by an organization described above; and (2) any association, joint venture or contractual arrangement entered into by any organization described above, in which said organization can be said to control or have equal right to control the association, joint venture or contractual arrangement.
- 4.2 "Conflict of Interest Committee" is a committee of HealthPartners Institute. The Conflict of Interest Committee shall be comprised of one director from the HealthPartners Institute Board of Directors appointed by the Chair of the HealthPartners Institute Board of Directors, and the Chairs of HealthPartners' Institutional Review Board or his/her designee whose responsibility it is to address Secondary/Significant Financial Interests in Research, as outlined in Section III of this Policy. HealthPartners, Inc.'s General Counsel, or her or his designee, and the Manager of Research Integrity and Compliance shall serve as staff to the Conflict of Interest Committee. If any committee member is the subject of a Secondary/Significant Financial Interest in Research, the Chair of the HealthPartners Institute Board of Directors shall appoint a substitute for such member.
- 4.3 "Covered Person" means:
- I. "Administrators". Any person identified below engaged in the review, administration or oversight of Research
    - i. members of the Institutional Review Board, Animal Care and Use Committee, Research Committee, Health Services Research Subcommittee, Clinical Research Subcommittee, Basic Science Research Subcommittee, Data Safety and Monitoring Boards and the Compliance Committee; and
    - ii. the HealthPartners Institute staff responsible for the review, administration and oversight of Research on behalf of HealthPartners Institute; and
    - iii. any other person who acts on behalf of HealthPartners Institute and who is in a position to influence organizational decision-making.
  - II. "Project Team". Any person identified below who is engaged in the design, conduct or reporting of a Research Project:
    - i. principal Investigators, co-Investigators, physicians, and employees; and
    - ii. any other individual who has responsibility for accomplishing the objectives of a Research Project, whether employed by HealthPartners or not.
- 4.4 "Disclosure Form" means the Secondary Interest Disclosure Form to be completed by Administrators pursuant to Section 3.1.a of this Policy and the Secondary Interest Disclosure Form to be completed by the Project Team pursuant to Section 3.1.b of this Policy and attached to the Research application.
- 4.5 "Immediate Family" means a spouse, parent, child, sibling, step-parent, step-child, step-brother or

sister, grandparent, grandchild, spouse of a grandparent or grandchild.

- 4.6 "Institution of Higher Education" has the meaning ascribed to it in 20 U.S.C. 1001(a).
- 4.7 "Institutional Responsibilities" means a Covered Person's responsibilities on behalf of HealthPartners Institute for the review, administration and oversight of Research.
- 4.8 "Investigator" in accordance with 42 CFR 50.603, means the Project Director, or Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research through the auspices of the HealthPartners Institute and funded by PHS or proposed for such funding, including persons who are sub-grantees, contractors, consortium participants, collaborators or consultants.
- 4.9 "Management Plan" means a plan that includes special conditions or restrictions to manage, reduce or eliminate the effect of a Secondary/Significant Financial Interest on the (a) design, conduct or reporting of a Research Project or the review, administration or oversight of Research conducted on behalf of HealthPartners Institute.
- 4.10 "PHS" means the Public Health Service which is an operating division of the U.S. Department of Health and Human Services, and any components thereof to which the authority involved may be delegated. "Research" means the systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research and product development.
- 4.11 "Research Project" or "Project" means Research that is sponsored by the government, private industry or other sponsor and conducted at a HealthPartners entity.
- 4.12 "Secondary Interest" means any personal or financial interest, activity or relationship that the person has outside of their primary role with HealthPartners. Secondary Interests that need to be reported are those that could interfere, or a reasonable person believes could interfere, with professional judgment, or creates the opportunity to influence conduct or outcome of the proposed research. A Secondary Interest is also an interest that gives a person authority or inside information that could be used to benefit the person or their immediate Family.
- 4.13 "Significant Financial Interest" means anything of monetary value, including, but not limited to, when a Covered Person or their Immediate Family member has any of the following:
- a. Ownership interest, stock options, or other financial interest related to a Research Project or Institutional Responsibilities, unless it meets the following four tests:
    - i. The value of the interest when aggregated for the Immediate Family does not exceed \$5,000;
    - ii. The interest is publicly traded on a stock exchange;
    - iii. The value of the interest does not exceed 5% interest in any one single entity when aggregated for the Immediate Family; and
    - iv. No arrangement has been entered into where the value of the ownership interest will be affected by the outcome of the Research.
  - b. Compensation related to Research other than Research Project reimbursement, unless it meets the following two tests:
    - i. The value of the compensation when aggregated with the Immediate Family does not exceed \$5,000 in the past year; and
    - ii. No arrangement has been entered into where the amount of the compensation will be affected by the outcome of the Research.

- c. Proprietary interest related to Research including, but not limited to, a patent, trademark, copyright, or licensing.
- d. Board or executive relationship related to Research regardless of compensation.
- e. Payments for subject enrollment or for referral of patients to research studies if such payments are not reasonably related to costs of a Research Project.
- f. The occurrence of any reimbursed travel or sponsored travel related to the Covered Person's Institutional Responsibilities (including purpose of trip, sponsor/organizer, destination and duration).
- g. Significant Financial Interest does not include:
  - i. Salary, royalties and remuneration from HealthPartners, or a mutual fund and retirement account over which the Covered Person or his/her Immediate Family member do not exercise any significant direct control over the investment decisions made in these instruments;
  - ii. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities and service on advisory 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 that is affiliated with an Institution of Higher Education.
  - iii. Income from service on advisory committees/review panels for public or nonprofit entities;
  - iv. Equity interest that, when aggregated from a Covered Person and the Covered Person's Immediate Family, does not exceed \$5,000 for twelve months, and does not represent more than a 5% ownership interest in any single entity.
  - v. Any 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. Institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

4.14 "Sponsor" means the government (including the organizational unit of the PHS that funds the Research that is subject to 42 CFR Part 50), private industry or other sponsor of a Research Project.

4.15 "Summary Report" means a summary report of information about the nature and amount of a Significant Financial Interest(s), along with the Conflict of Interest Committee's findings and recommended Management Plan.

## **V. COMPLIANCE**

If the Investigator or any of the study staff has failed to comply with the disclosure of conflict interest or to update of that information, or has failed to comply with any conditions or restrictions imposed on the conduct of the research project, the President of HealthPartners Institute and Executive Director, Research, will determine appropriate sanctions, and, if federal funds are involved, conduct a retrospective review and submit a mitigation report as appropriate according 42CFR 50.605(a)(3).

If the failure of Investigator or any of the study staff to comply with this policy has biased the design, conduct or reporting of the research, HealthPartners Institute will promptly notify the sponsor of the research. When clinical research to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator or any of the study staff with a conflicting interest that was not disclosed or managed as required by this policy, HealthPartners Institute will require the Investigator(s) or study staff to disclose the conflicting interest in each public presentation of the results of the research. For previously published presentations, an addendum will be requested.

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination



**VI. ATTACHMENTS**

HealthPartners Institute Disclosure Form – GHI-BP-PPM-02.03 Disclosure Form Att A

**VII. OTHER RESOURCES**

Work Standard 02.03 - explains how to gather secondary interest data

Work Standard 02.03 Att A – Process form takes to collect data prior to review

Work Standard 02.03 Att B – Process data takes once received for review by the IRB staff

42 CFR subpart International Committee of Medical Journals Editors (ICMJE) disclosure requirements

**VIII. APPROVAL/S**

HealthPartners Institute Board of Directors

**IX. ENDORSEMENTS**

HealthPartners Institute Compliance Committee