



## SECONDARY INTERESTS STANDARD:

### 10. HealthPartners Institute Research Activities

*This Standard contains important information that you should know. Please review this standard and the corresponding Policy in full and contact your leader, the [HealthPartners Institute](#), or the [Office of Integrity and Compliance](#) with any questions. You may use the links below to navigate within the document.*

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#### **Basic Rules:**

HealthPartners colleagues and external partners who perform research activities with the HealthPartners Institute or elsewhere are expected to follow the guidelines outlined in this standard, associated policy, as well as the HealthPartners Code of Conduct. There are many unique rules related to research activities, so colleagues must carefully review this standard and any associated regulations.

Note: When vendors provide drugs, devices, or other supplies directly to the HealthPartners Institute for research purposes under a written agreement, this does not constitute a secondary interest that requires disclosure under the Secondary Interests policy because the relationship is between the vendor and HealthPartners Institute and is articulated in a written agreement.

#### **Rules that apply to all HealthPartners Institute Research Activities:**

1. Do not use confidential information learned through your role at HealthPartners for your outside activity (direct care services, consulting work, speaking arrangements, etc.). This includes patient and member information, intellectual property, unique processes, patents, trademarks, etc.
2. Don't use HealthPartners resources for your personal benefit.
3. Do not allow the outside activity to influence, or appear to influence, your research activities, care or coverage decisions, or referrals for HealthPartners patients or members.
4. Don't use information about patients, members, research subjects or colleagues for your

outside activity.

5. You should not refer HealthPartners patients or members to the other organization, business or facility of your outside activity.
6. Refrain from any decision-making at HealthPartners that relates to your Secondary Interest.
7. Research-related job duties that may otherwise constitute a conditional or prohibited Secondary Interest under the HealthPartners system-wide Secondary Interest policy may be permitted for Research Activities under certain circumstances and risk factors—see the examples and exceptions section of this Standard.
8. There are research-specific procedures for HealthPartners Institute colleagues related to the disclosure and management of Secondary Interests. Please see the appropriate HealthPartners Institute Work Standard for Secondary Interests.



If the Secondary Interest activity does not relate in any way to Health Care, does not relate in any way to the work you perform at HealthPartners, and does not conflict with the Code of Conduct, you don't need to tell us about it. This would be considered **Permitted Secondary Interests**, so it does not need to be disclosed or approved through the HealthPartners Institute process.



If the Secondary Interest relates in any way to Health Care, or relates in any way to the work you perform at HealthPartners, it is Conditional, and you must disclose it as a **Conditional Secondary Interest** and it must always be approved through the HealthPartners Institute process. If a Management Plan is put into place, you must follow it.



If the Secondary Interest will interfere with your job performance at HealthPartners in a way that cannot be managed or avoided, or if it conflicts in any way with the Code of Conduct, it is a **Prohibited Secondary Interest**.

### **Examples:**



The following are examples that fall into the **Permitted Secondary Interest** category. This means that you don't need to tell us about them or disclose them.

1. Outside Employment: You are a researcher with a green thumb who works at a garden center on weekends.
2. Consulting Services: You are an Institutional Review Board (IRB) member who provides advertising consulting services to local small businesses.
3. Service on Boards of Directors: You serve as a community board member at your local YMCA.
4. Financial: You hold ownership or investment interests in a publicly-traded security or mutual fund.
5. Travel/Lodging/Conferences:

- a. Federally funded research: Colleagues conducting federally funded research on behalf of the Institute may accept reimbursement for travel and lodging expenses associated with the federally funded research, as part of the research contract. This does not need to be disclosed as a secondary interest.
- b. Commercially funded research: Colleagues conducting commercially funded research on behalf of the Institute and do not work on federally sponsored projects do not need to disclose travel expenses if these expenses are part of a research contract.
- c. Investigators conducting **federally funded research** and **travel on behalf of a commercial entity** should review the conditional section below.



The following are examples of **Conditional Secondary Interests**. This means that they must be disclosed and follow the appropriate review process through the HealthPartners Institute, which may include a Management Plan.

1. Employment: You are a clinician who works for another healthcare organization a few hours a month.
2. Financial: Financial interests less than reportable amount.
3. Personal Relationships: Your family member works for a vendor who is also sponsoring a study that you are leading on behalf of the HealthPartners Institute.
4. Travel/Lodging/Conferences: Colleagues conducting **federally funded research** must report **travel funded by commercial entities** that are related to institutional responsibilities.
  - a. This includes:
    - i. Reimbursed or sponsored travel (paid on behalf of colleague so the exact monetary value may not be readily available)
    - ii. Local, national, and international travel
    - iii. Meals, travel (any mode), lodging, per diem expenses
  - b. This does not include travel sponsored by:
    - i. Federal, State, or local government agencies
    - ii. An institute of higher education as defined at 20 USC 1001(a)
    - iii. Academic teaching hospital
    - iv. Medical center
    - v. Research Institute that is affiliated with an Institution of higher education.
5. Consulting: You are an investigator who provides expert consulting services for a federal agency or commercial entity, with arrangements managed by and compensation paid to the HealthPartners Institute. This is considered a Secondary Interest that must be disclosed; however, a management plan may not be required.
6. Advisory/Boards of Directors: You are a Research Study Steering Committee or Data Safety Monitoring Board (DSMB) member for commercial vendor.
7. **Litigation Support Services:** Any outside activity involving litigation, such as expert witness testimony, must be disclosed per the Policy and must also be disclosed in writing to the HealthPartners Law Department. The Law Department, in consultation with appropriate leaders, will review, approve or deny, and impose Management Plans on such arrangements.



The following are examples of **Prohibited Secondary Interests**. This means that you may not hold these interests while working for or on behalf of HealthPartners.

1. You receive payment or other benefits intended to influence prescribing practices or medical decision-making, or based on an agreement to consider or use a specific product or service.
2. You receive payment or other benefit for arrangements in which you agree to change the use of a product or service from the current/competing product or service to another specific product or service.
3. You receive payment or other benefits for recruiting patients for clinical research activities, except for recruitment activities approved by the appropriate Institutional Review Board (IRB).

#### **Exceptions:**

- If you're asked to participate in an activity as part of your assigned work responsibilities and/or as a representative of HealthPartners, those activities are not considered Secondary Interests and do not require disclosure, review and approval. However, remember that you must still always follow the Code of Conduct when participating in those activities. For research-specific situations, please see the above "Examples" section.
  - An example would be assignment by HealthPartners of a Medical Directorship at a rural clinic affiliated with HealthPartners.

#### **Practical Tips:**

1. If you are not sure if your activity constitutes a Secondary Interest, you should disclose.
2. Members of MMCORC and the IRB should disclose.
3. Members of any Data Safety Monitoring Board (DSMB) set up for investigator-initiated studies at HealthPartners Institute should disclose.
4. HealthPartners liability insurance does not cover your activities outside HealthPartners, so make sure you understand your options for proper insurance coverage.
5. Be aware of how your participation in any outside activity could compromise your independent judgment, interfere with your professional responsibilities, or embarrass or damage the organization's reputation.
6. Participation in conferences and educational events often involve interactions with vendors who do business with HealthPartners or competitors of HealthPartners. Colleagues should not have or appear to have, a personal stake in relationships with vendors or competitors of HealthPartners.

#### **Important Reminder:**

These are important standards for you to follow. If you don't follow them, you may be subject to

discipline, which could impact the status of your employment, contract, clinical, or research privileges.

HealthPartners may maintain additional policies and procedures related to the Secondary Interests and/or Conflicts of Interest of Colleagues who are in leadership, governance, research or medical staff roles. Colleagues who are in those roles must meet the requirements of this standard, the Policy, and those of any applicable additional policies and procedures.

### **Definitions:**

Terms or phrases used in this Standard that are not defined below are defined in the Secondary Interests, Vendor Relationships and Other Arrangements that May Present Conflicts of Interest Policy (the “Policy”) or the Code of Conduct.

**“Affiliated Entity”** means (1) 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.

**“Commercial entity”** is any non-governmental entity, however organized, which furnishes goods or services to the general public.

**“Conflict of Interest”** means a Secondary Interest that interferes with – or appears to interfere with – your ability to perform your work for HealthPartners objectively, without inappropriate influence, and in the best interests of the organization and the people we serve. The standard for determining whether a Conflict of Interest exists is not whether you think there is a Conflict of Interest, but whether another reasonable and objective person would consider it a conflict.

**“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. 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.

**“Covered Person”** means:

1. **“Administrators”**. Any person identified below engaged in the review, administration, or oversight of Research
  - a. Members of the Institutional Review Board, Animal Care and Use Committee,

Administrative Review Committee, Research Review Committee, Data Safety/Data Monitoring Boards and the Compliance Committee.

- b. The HealthPartners Institute staff responsible for the review, administration, and oversight of Research on behalf of HealthPartners Institute; and
- c. Any other person who acts on behalf of HealthPartners Institute and who is in a position to influence organizational decision-making.

2. **“Project Team”**. Any person identified below who is engaged in the design, conduct, or reporting of a Research Project:
  - a. Principal investigators, co-investigators, physicians, and employees; and
  - b. Any other individual who has responsibility for accomplishing the objectives of a Research Project, whether employed by HealthPartners or not.

**“Financial Interest Related to Research”** means financial interest in the sponsor, product, or service being tested.

**“HealthPartners”** means HealthPartners, Inc. and its subsidiary organizations.

**“Immediate Family Member”** means:

1. Spouse or Significant Other
2. Parent, child or sibling
3. Stepparent, stepchild, stepbrother or stepsister
4. Father-in-law, mother-in-law, daughter-in-law, son-in-law, brother-in-law, or sister-in-law
5. Grandparent, grandchild, spouse of a grandparent or grandchild.
6. Spouse of grandparent or grandchild

**“Institution of Higher Education”** has the meaning ascribed to it in 20 U.S.C. 1001(a).

**“Institutional Responsibilities”** means a Covered Person’s responsibilities on behalf of HealthPartners Institute for the review, administration and oversight of Research.

**“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 such funding, including persons who are sub-grantees, contractors, consortium participants, collaborators or consultants.

**“Management Plan”** means a documented plan that includes special conditions or restrictions to ensure that an outside activity or relationship does not interfere with a Colleague’s professional judgment, objectivity, decision-making and conduct in their work for or on behalf of HealthPartners. For Colleagues who conduct research, a management plan is used to manage, reduce or eliminate the effect of Secondary/Significant Financial Interests on the design, conduct or reporting of a Research Study or the review, administration or oversight of Research conducted on behalf of the HealthPartners Institute.

**“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 encompassed basic and applied research and product development.

**“Secondary Interest”** means a Colleague’s professional, community, personal, financial interests, relationships or activities outside the scope of their work for or on behalf of HealthPartners. Colleagues must disclose any Secondary Interests that could interfere, or a reasonable person believes could interfere, with professional judgment, objectivity, decision-making and conduct in their work for or on behalf of HealthPartners. 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.

**“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:

1. Ownership interest, stock options, or other financial interest related to a Research Project or Institutional Responsibilities, unless it meets the following four tests:
  - a. The value of the interest when aggregated for the Immediate Family does not exceed \$5,000;
  - b. The interest is publicly traded on a stock exchange;
  - c. The value of the interest does not exceed 5% interest in any one single entity when aggregated for the Immediate Family; and
  - d. No arrangement has been entered into where the value of the ownership interest will be affected by the outcome of the Research.
2. Compensation related to Research other than Research Project reimbursement, unless it meets the following two tests:
  - a. The value of the compensation when aggregated with the Immediate Family does not exceed \$5,000 in the past year; and
  - b. No arrangement has been entered into where the amount of the compensation will be affected by the outcome of the Research
3. Proprietary interest related to Research including, but not limited to, a patent, trademark, copyright, or licensing.
4. Board or executive relationship related to Research regardless of compensation.
5. 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.
6. 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).
7. Significant Financial Interest does not include:
  - a. Salary, royalties and remuneration from HealthPartners, or a mutual fund and retirement account over which the Covered Person and his/her Immediate Family

member do not exercise any significant direct control over the investment decisions made in these instruments.

- b. 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, and Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.
- c. Income from service on advisory committees/review panels for public or non-profit entities.
- d. 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.
- e. 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.

**“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.

**“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.

### **References and Other Resources:**

- Code of Conduct
- HealthPartners Policy on Secondary Interests, Vendor Relationships and Other Arrangements that May Present Conflicts of Interest
- HealthPartners Institute Work Standard for Secondary Interests
- Secondary Interest/Conflict of Interest Disclosure Form
- Secondary Interest Leader Toolkit
- Secondary Interest Organizational Standards
  - Appropriate Relationships with Vendors
  - Community Engagement & Charitable Activities
  - Financial Interests
  - Gifts, Meals, Entertainment and Hospitality
  - Non-Care Services or Expertise
  - Open Payments
  - Personal Relationships
  - Travel, Lodging and Conferences
- HPI-BP-02.03 Secondary Interest Disclosure Work Standard

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

**Review History:**

- 2024/06 HealthPartners Institute Board of Directors; HealthPartners Institute Compliance Committee
- 2024/08 – HealthPartners Enterprise Integrity Steering Committee
- 2024/06 – Office of Integrity and Compliance; HealthPartners Institute

For help, contact your leader, the HealthPartners Institute, or the Office of Integrity and Compliance at [integrityandcompliance@healthpartners.com](mailto:integrityandcompliance@healthpartners.com) or 1-866-444-3493.

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