Benaroya Research Institute

POLICY
ADM POL 016.04

Title: Research Conflicts of Interest

Effective Date	3/1/2025	Responsible Department:	ADM
Next Review Date	4/1/2030	Author(s):	Cheryl Weaver

This policy will remain in effect until the next version is reviewed and approved.

Reviewed by:	**Date**
BRI Policy Coordination Committee	6/16/17, 1/11/2023, 2/19/2025
Approval Signature: Executive Director	
Margaret McCormick boxSIGN R1VWQZ24-4Y2397ZL	

PURPOSE

This policy establishes guidelines and mechanisms for identifying and managing potential or actual Conflicts of Interest (COI) involving individuals related to the conduct of research at, for, or under the auspices of Benaroya Research Institute at Virginia Mason ("BRI") who are responsible for the design, conduct, or reporting of basic, translational, or clinical research, including the evaluation, approval, or oversight of such research.

BRI intends, by this policy, to meet or exceed applicable federal and state requirements, to ensure all stages of research are protected, and to provide a reasonable expectation that the design, conduct, reporting, monitoring, expenditure of funds, or reporting and oversight of research conducted at or under the auspices of BRI will be free from bias of any conflicting Financial or Positional / Relationship Interest of an Investigator or other Covered Person, as defined herein.

This policy is designed to reflect the values of BRI and is based on the following principles:

- The protection of human research subjects is our foremost concern.
- The integrity of research depends on the management, reduction, or elimination of COI's.

SCOPE

This policy applies to all Covered Persons.

DEFINITIONS

The following definitions, listed alphabetically in **bold**, apply to terms used in this policy:

"**Academic"** entity means 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.

"Conflict of Commitment" refers to a situation where an individual engages in external activities, either paid or unpaid, that interferes with his/her primary obligation and commitment to the Institution.

"Conflict of Interest (COI)" occurs when a Covered Person or Family Member of such individual has, directly or indirectly, a Financial or Positional / Relationship Interest that could affect the design, conduct, reporting, evaluation, approval, monitoring, expenditure of funds or oversight of a research study. In addition, the following may apply:

- BRI itself, a Research Leader, a member of a Research Protections Committee, or other BRI official with the authority to make decisions related to research, has a Financial or Positional Interest with an outside entity that may influence the evaluation, approval, or oversight of research conducted at or under the auspices of BRI.
- An Investigator's Financial or Positional Interest in a technology transfer arrangement may present a potential or actual research COI.

"Conflict of Interest (COI) Committee Member" means the individual assigned to review and assess disclosures of Financial or Positional/Relationship Interests. A COI is also considered an actual COI where referenced. Committee members are comprised of the following.

- Executive Director & Chief Operating Officer
- Director, Grants & Contracts Administration
- Director, Research Integrity & Safety
- Director, Business Development

"Conflict of Interest Oversight Committee (COIOC)" means the Committee that provides Institutional oversight to review and assess disclosures of Financial or Positional/Relationship Interests and any Management Plans. Individual Committee Members manage areas within their expertise or Department and do not conduct research at BRI. This eliminates the potential for conflicts.

"Covered Persons" means:

- Investigators (as defined below) who conduct research at, for, or under the auspices of BRI, whether funded by the government or the private sector, including Investigator-initiated studies.
- Key Personnel directly involved with Human Subjects, e.g., Study Coordinator.
- Voting members of Research Protections Committees who have responsibility for evaluating, approving, or overseeing research activities, e.g., Institutional Review Board; and
- Research Leaders (as defined below).

"Family Member" includes a Person's relative by blood or marriage, including husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in- law; grandparent, or grandchild, and spouse of a grandparent or grandchild.

"Financial Interest" means anything of monetary value, whether the value is readily ascertainable, held directly or indirectly by a Covered Person and/or a Family Member, including but not limited to the following.

- Equity Interest – means any interest in the profits of or other ownership interest in any entity or enterprise, whether public or private, including stock and other equity securities, and any right to acquire any of the foregoing such as an option, warrant or other convertible security.
- Compensation – Income or other payments for services, including, but not limited to salary, gifts, consulting fees, honoraria, paid authorship, dividends, loan, or other consideration with value, such as significant product discounts.
- Intellectual Property Interest – Any personal (i.e., non-BRI) propriety interest or right held or claimed directly or indirectly by a Covered Person or a Family member, including but not limited to, a proprietary interest or right in an invention, technology, know-how, a patent, patent application, trademark, licensing agreement, trade secret, or copyright.
- Reimbursed Travel – Any reimbursed or sponsored travel to the Covered Person as defined below.

- The term Financial Interest does not include:
  - Salary or other remuneration received from the BRI, including royalties paid to the Covered Person by the BRI, other Intellectual Property Interests assigned to the BRI, and agreements to share in royalties related to such Interests.

- Income from service on advisory committees or review panels for Government, Academic or non-profit entities.
- Reimbursement of travel that is reimbursed or sponsored by a government, Academic or non-profit entity;
- Holding US federal financial instruments (such as federal savings bonds); or
- Income from or an equity investment in a blind trust, mutual fund, pension fund or other investment vehicle over which neither the Covered Person nor a Family Member have decision-making power concerning the purchase or sale of investments in those vehicles.

"Government" entity shall mean a federal, state or local government agency.

"Human Subject Research" A 'human subject' is a living individual about whom an investigator obtains either (1) data or samples (e.g., blood, tissue) through intervention or interaction with the individual, or (2) identifiable private information.

"Insider Trading" refers to the federal laws making it illegal to trade stocks while in possession of information not available to the general public or to inform other traders of such information. (Public announcements and publishing render research information available to the general public.) The Securities and Exchange Commission has prosecuted researchers who have tipped off friends, relatives, and business associates regarding initial results of clinical trials prior to publication.

"Investigator" means any individual who, regardless of title or position, is an employee or agent of BRI, is affiliated by contract or agreement with BRI, or otherwise conducts research through or under the auspices of BRI, and who is responsible for the design, conduct, or reporting of research, proposals for such funding, research protocol, progress or other report, and when competitive and non-competitive renewals are granted. Investigators may include the principal, co- or sub-investigator, project director, any person identified as senior/key personnel in a grant application sub-recipients, collaborators, consultants, research and regulatory faculty, staff scientists, postdoctoral fellow, graduate students, staff clinicians, surgeons or hospitalists.

"Perceived Conflict of Interest" occurs when an individual or institution may reasonably be understood as having two competing interests which interfere or undermine an Investigator's, Institution's or Committee Member's ability to fulfill their responsibilities. Examples of a perceived conflict may be voting on a study that includes a family member as Key Personnel or voting on a study where the Committee Member is an active participant (in the past 12 months). It is not a perceived conflict to donate money to an Institution for general research purposes.

"Positional / Relationship Interest" means that a Covered Person or a Family Member is an officer, director or trustee, consultant (including a medical director), or employee of an entity with which the BRI has or is considering a transaction or arrangement.

"Reimbursed or Sponsored Travel" means paid by an entity, including non-profit organizations, but excluding travel sponsored or reimbursed by a US government agency, a US institution of higher education, or one of the following US institutions affiliated with a US institution of higher education: a research institute, a medical center, or an academic teaching hospital or a non-profit. The specific details required for disclosure are the name of an entity sponsoring the travel and purpose, destination, and duration of the travel.

"Research" is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

"Research Leaders" means Executive Leaders, Directors, and/or Medical Directors of BRI who have responsibility for or make decisions regarding the conduct or oversight of research conflicts of interest at BRI.

"Research Protection Committees" means voting members of a committee responsible for evaluating, approving, monitoring, or overseeing research conducted at BRI. This includes the Institutional Review Board (Human Subjects Protection), Institutional Biosafety Committee and the Institutional Animal Care and Use Committee.

"Significant Financial Interest" means one or more of the following Financial Interests received, held, or owned directly or indirectly by a Covered Person and/or a Family Member, that when aggregated, exceeds the following thresholds:

- For Human Subjects Research, any Financial Interest is significant.
- For all Research other than Human Subjects Research, any Financial Interest (including Compensation, an Equity Interest, Intellectual Property Interest or Reimbursed Travel), which alone or in the aggregate, exceeds the following thresholds:
  - Publicly Traded Entity:
    - Equity Interest: Any Equity Interest in a publicly traded company exceeding $5,000, valued as of the date of disclosure.
    - Compensation: Any compensation from a publicly traded company exceeding $5,000 received in the 12 months preceding the date of disclosure.
  - Non-Publicly Traded Entity:
    - Equity Interest: Any Equity Interest in a non-publicly traded company, valued as of the date of disclosure.
    - Compensation: Any Compensation from a non-publicly traded company exceeding $5,000 received in the 12 months preceding the date of disclosure.
- Intellectual Property Interests: Any Intellectual Property Interest upon receipt of income from such Interest, regardless of value.
- Reimbursed Travel: Any amount of Reimbursed Travel received in the 12 months preceding the date of disclosure.

POLICY STATEMENT

A. Disclosure of Financial or Positional Interests: All Financial or Positional Interests must be disclosed, managed, and/or eliminated in accordance with state and federal laws and regulations (including, but not limited to Insider Trading regulations), as well as Virginia Mason Franciscan Health System or CommonSpirit Health System policies. BRI will follow the Significant Financial Interests regulations for assessing any mitigation plan.

1. **Investigators:** Subject to the exceptions listed below, Investigators on all National Science Foundation ("NSF"), Public Health Service ("PHS"), FDA applicable or other publicly or privately funded research proposals must complete a *Financial or Positional Interest Disclosure Statement* (a) annually, (b) within 30 days of acquiring or discovering new Financial or Positional Interests, and (c) before each acceptance of award for funds or study approval.

2. **Principal Investigator:** It shall be the responsibility of the Principal Investigator to (a) identify all Covered Persons involved in the study that have a Financial or Positional Interest, (b) ensure that all such Covered Persons prepare and submit a *Financial or Positional Interest Disclosure Statement* annually and before each acceptance of award for funds or study approval, and (c) ensure that disclosure updates occur and material changes in Financial or Positional Interests are appropriately disclosed.

3. **Exceptions to Disclosure:** A *Financial or Positional Disclosure Statement* shall not be required with respect to (a) selected Phase 1 research no matter the funding, or (b) studies solely funded through restricted or unrestricted internal BRI funds, (c) collaborative research agreements when no Human Subjects are involved, or (d) studies where no budget or informed consent are required.

B. Submission of Forms: *Financial or Positional Interest Disclosure Statements* shall be delivered to the assigned COI Oversight Committee Member.

C. COI Oversight Committee (COIOC): COIOC shall receive disclosures and manage potential or actual COI's. The COIOC members do not conduct any research projects therefore further safeguards are not required.

D. Evaluation: The COIOC Member shall review COI disclosures in a timely manner:

1. The COIOC Member determines whether a disclosed Interest represents a Significant COI that requires a management plan or other action. The COIOC Member shall take such actions as necessary to ensure that a perceived or actual COI will be managed, reduced, or eliminated, and shall inform the Covered Person of their conflicts management plan.

2. If at any time the Covered Person has concerns related to the conflicts management plan or feels a different plan is justified under the circumstances, the following levels of review apply:
    - First, the Covered Person must request reconsideration by the full COIOC;
    - Second, the Covered Person may appeal the conflict management plan to the President of BRI, whose determination shall be final;
    - Third, if the Covered Person is the President of Benaroya Research Institute, they may appeal to the Virginia Mason Franciscan Health System (VMFH) General Counsel, whose determination shall be final.

E. Reporting: BRI's designated official shall inform NSF's Office of General Counsel or the PHS Awarding Component, where required, of the existence of or failure to manage a COI.

1. PHS requires institutions, prior to expenditure of funds under an award, and annually thereafter, to report to the PHS Awarding Component the existence of any COI, including (1) the name of the entity with which Investigator has the COI, (2) the nature of the Significant Financial Interest, (3) the value of the Significant Financial Interest, (4) a description of how the Significant Financial Interest relates to the PHS-funded research, (5) the basis for how the Significant Financial Interest conflicts with such research, and (6) key elements of BRI's management plan. Identified financial Conflicts of Interest (FCOI) must be submitted via FCOI Module in eRA Commons.

2. PHS requires BRI to conduct a retrospective review in those cases of non-compliance with this Research COI Policy or any management plan. BRI is required to notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component only in cases where bias is found. If a report is submitted, it will address the impact of the bias on the research project and the actions BRI has taken, or will take, to eliminate or mitigate the effect of the bias.

3. For NSF-funded projects, NSF requires only that COI that have not been managed, reduced, or eliminated prior to the expenditure of funds under an award be reported to the NSF Office of General Counsel.

F. Subrecipient Compliance: BRI shall establish by written agreement with subrecipients funded from NSF or PHS awards whether BRI's Research COI Policy or the subrecipient's research COI policy will apply to the subrecipient's Investigators and include time periods for the subrecipient to meet disclosure and/or COI reporting requirements. Subrecipients who rely on their COI policy must report identified COI to BRI in sufficient time to allow BRI to meet its reporting obligations under law.

G. Procedures for Addressing Conflicts of Interest:

1. No Investigator involved in industry-sponsored Human Subject Research shall be permitted to have an Equity Interest in the sponsor of such research or engage in insider trading activities. There is no minimum level of Equity Interest permitted. (Note: Equity Interest shall not include an interest in or income from a blind trust, mutual fund, pension fund or other investment vehicle over which neither the Investigator nor a Family Member have decision-making power concerning the purchase or sale of investments in those vehicles.)

2. Positional / Relationship and Significant Financial Interests shall generally be disclosed to human research subjects in the informed consent process unless an IRB has agreed to a complete waiver of consent.

3. The COIOC Member may impose additional conditions to manage any COI.

4. The COIOC Member will report all COI which result in a management plan and/or disclosure to human research subjects in the informed consent process. This may include working with external Institutional Review Boards.

H. Training: All "Covered Persons" must complete CITI (Collaborative Institutional Training Initiative) training prior to engaging in any research related to federally funded or privately funded grants or contracts and at least every four years thereafter. Industry sponsored trials are excluded from the training requirement. Training shall also be completed in the following circumstances: (1) BRI's COI policies change in a manner that affects Investigator requirements; (2) an Investigator is new to BRI; or (3) BRI determines the Investigator is noncompliant with this Research COI Policy or a management plan.

I. Enforcement: BRI shall take appropriate disciplinary and corrective action to enforce this Policy including, but not limited to, contract termination or termination of employment.

J. Record Retention: For PHS-funded grants, *Financial Disclosure Statements* and associated management plans will be maintained for a period of three (3) years from the date of the submission of the final expenditures report or from other dates as specified in 45 CFR 74.53(b) and 92.42(b). For studies involving industry sponsors, the *Financial or Positional Disclosure Statements* will be archived along with the other Regulatory Study Documents until acceptable to shred per policy or Sponsor contract and agreement.

K. Public Accessibility Concerning PHS-Funded Projects: This Policy shall be made publicly available on the Benaroya Research Institute website. Information regarding current Financial or Positional COI related to PHS-funded research projects also will be disclosed within five (5) days of a written public information request. Disclosures can be obtained by contacting the Institutional Official. Information required to be disclosed shall at a minimum include: the Investigator's name, title, and role with respect to the research project; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; and the approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 in increments of $50,000), or a statement that the interest is one for which the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

L. Research Protection Committee Conflict Management:

1. At the beginning of each Committee meeting, (e.g., Institutional Review Board, Institutional Biosafety or Institutional Care & Use), the Committee Chair shall request Committee Members disclose an actual or perceived Conflict of Interest.

2. A Committee Member with an actual or perceived COI may answer questions but must leave the room during deliberation and voting on the specific study or project.

3. A disclosable COI includes a Key Personnel on a study under review, or a Family Member with a Positional or Financial Interest in the sponsor of research.

4. It shall not be considered a COI to serve on a governmental research advisory committee.

REFERENCES

- ADM POL 002 Intellectual Property Policy
- ADM POL 004 Outside Employment and Consulting Policy
- ADM POL 024 Conflicts of Interest
- FAC POL 001 Vendor Relations
- CRP POL 001 Clinical Research Administration Policy
- 45 CFR 46 (Subpart A) Common Rule(Protection of Human Subjects – eCFR)
- 42 CFR 50 (Subpart F) – Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought
- 45 CFR 94 0 Responsible Prospective Contractors
- 21 CFR 50 Protections of Human Subjects
- 21 CFR 54 – Financial Disclosures by Clinical Investigators
- 21 CFR 56 Institutional Review Boards
- 45 CFR 94.3-94.5 Responsible Prospective Contractors
- HHS Guidance 68 Fed. Reg. 15,456 (2003), Terms and Conditions of NIH Grant Awards, AAMC Guidelines from the Task Force on Financial Conflicts in Clinical Research
- Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by Clinical Investigators (FDA 2013)Notice Number: NOT-OD-13-004 – NIH policy on travel disclosure

IMPLEMENTATION & TRAINING PLAN

- The policy will be implemented through existing conflict of interest review procedures in the IRB and grants offices at BRI, as well as in Research Oversight Committee procedures.
- The policy will be posted on the BRINet Policy and SOP Center, and on VMMC Intranets.
- The policy will be posted on www.benaroyaresearch.org

Revision History:

Revision Level	Effective Date	Description of Changes
04	3/1/2025	Added scope to align with CSH to include monitoring and expenditure of funds. Administrative revisions and removed COLT review due to elimination of the group.
03	2/1/2023	Created COI Oversight Committee. Clarified 1) travel expenses are reportable, 2) Research Protections Committees do not have COI management for Covered Persons, 3) Research Protections Chair manages any conflicts reported during the meeting and 4) what constitutes a conflict for a Research Protections Committee Member, 5) included perceived, positional and significant interests definitions, 6) Collaborative Research needs to report conflicts, 7) all positive disclosures will be assessed if an informed consent must be revised to

		reflect the disclosure and 8) clarified that less than $5000 is not a concern for any conflict of interest management plan (this still excludes all individual stock ownership).
02	6/16/2017	Converted to BRI policy and updated scope.
01	6/1/2012	Revised to comply with NIH requirements.
00	2001	Initial VM Policy