

	POLICY	Policy No.	ADM POL-016
		Revision No.	02
		Effective Date	7/1/2017
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Title: Research Conflicts of Interest

PURPOSE

This policy establishes guidelines and mechanisms for identifying and managing potential or actual Conflicts of Interest involving individuals involved in 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 that human subjects are protected at all stages of research, and to provide a reasonable expectation that the design, conduct, reporting, and oversight of research conducted at or under the auspices of BRI will be free from bias of any conflicting financial interest of an Investigator or other Covered Person, as defined herein.

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

- The well-being of human research subjects is our foremost concern;
- The integrity of research depends on the management, reduction or elimination of Conflicts of Interests.

SCOPE

This policy applies to all Covered Persons, as defined below.

POLICY STATEMENT

A. Disclosure of Financial or Positional Interests: All Significant 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 Health System policies.

1. **Investigators:** Subject to the exceptions listed below, Investigators on all National Science Foundation (“NSF”), Public Health Service (“PHS”), 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 a new Significant Financial Interest, and (c) before each submission of application for funds or study approval. This form shall be part of the package submitted for review and approval.
2. **Principal Investigator:** It shall be the responsibility of the Principal Investigator to (a) identify all Investigators involved in the study that have a Significant Financial or Positional Interest, (b)

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ensure that all such Investigators prepare and submit a *Financial or Positional Interest Disclosure Statement* annually and before each submission of application for funds or study approval, and (c) ensure that disclosure updates occur and material changes in Investigator Significant Financial or Positional Interests are appropriately disclosed.

3. **Exceptions to Disclosure:** A *Financial Disclosure Statement* shall not be required with respect to (i) Phase 1 research conducted with funds from SBIR or STTR grants, or (ii) studies solely funded through restricted or unrestricted internal BRI funds, (iii) collaborative research agreements with industry, or (iv) studies where no budget is required.

B. Submission of Forms: *Financial or Positional Interest Disclosure Statements* shall be delivered to the Conflict of Interest Institutional Official.

C. Research Oversight Committees (“ROCs”): ROCs shall manage potential or actual Conflicts of Interest by implementing the following safeguards:

1. At the beginning of each meeting the ROC Chair shall request that any reviewer with any actual or perceived Positional or Significant Financial Interest in a study under consideration declare that potential or actual Conflict of Interest.
2. A member with a stated potential or actual Conflict of Interest may answer questions but must recuse him or herself from the room during deliberation and voting on the specific study that may constitute the actual or perceived Conflict of Interest.
3. An ROC member shall be considered to have a disclosable Conflict of Interest if he or she is an Investigator on a study under review, or if he or she (or a Family Member) has a Positional or Financial Interest in the sponsor of research.
4. It shall not be considered to be a Conflict of Interest to serve on a governmental research advisory committee.

D. Evaluation: The Conflict of Interest Institutional Official shall review Conflict of Interest disclosures in a timely manner:

1. The Conflict of Interest Institutional Official determines whether a disclosed Significant Financial Interest represents a Conflict of Interest that requires a management plan or other action. The Conflict of Interest Institutional Official shall take such actions as necessary to ensure that a perceived or actual Conflict of Interest will be managed, reduced, or eliminated, and shall inform the Covered Person of his or her 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 Conflict of Interest Institutional Official;

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- Second, the Covered Person may appeal the conflict management plan to the Executive Director of BRI, whose determination shall be final;
- Third, if the Covered Person is the President of Benaroya Research Institute, he or she may appeal to the Virginia Mason Health System 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 Conflict of Interest.

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 Conflicts of Interest, including (1) the name of the entity with which Investigator has the Conflict of Interest, (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.
2. PHS requires BRI to conduct a retrospective review in those cases of non-compliance with this Research Conflict of Interest 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 Conflicts of Interest 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 PHS awards whether BRI's Research Conflict of Interest Policy or the subrecipient's research conflict of interest policy will apply to the subrecipient's Investigators and include time periods for the subrecipient to meet disclosure and/or conflict of interest reporting requirements. Subrecipients who rely on their conflict of interest policy must report identified conflicts of interest 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.)

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2. Positional and Significant Financial Interests shall generally be disclosed to human research subjects in the informed consent process.
3. The Conflict of Interest Institutional Official may impose additional conditions to manage any Conflict of Interest.
4. The Conflict of Interest Institutional Official will report all Conflicts of Interest which result in a management plan and/or disclosure to human research subjects in the informed consent process to the Executive Director of BRI.

H. Training: All “Covered Persons” must complete training prior to engaging in any research related to federally-funded or privately-funded grants or contracts and at least every four years thereafter. Training shall also be completed in the following circumstances: (1) BRI’s conflict of interest 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 Conflict of Interest 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).

K. Public Accessibility Concerning PHS-Funded Projects: This Policy shall be made publicly available on the Benaroya Research Institute website. Information regarding current Financial Conflicts of Interest 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 Conflict of Interest 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.

DEFINITIONS

The following definitions 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.

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“**Common Rule**” refers to the Federal Policy for the Protection of Human Research Subjects set forth in 28 CFR Part 46, which outlines the basic provisions for Institutional Review Boards, informed consent, and Assurances of Compliance.

“**Conflict of Interest**” occurs when a Covered Person or a Family Member of such individual has, directly or indirectly, a significant Financial Interest or Positional Interest that could affect the design, conduct, reporting, evaluation, approval or oversight of a research study. For example:

- Individual financial Conflicts of Interest may arise when a personal Financial Interest or a Positional Interest could directly and significantly affect the design, conduct, or reporting, of a research study.
- Other financial Conflicts of Interest may occur when BRI itself, or a Research Leader, or a member of a Research Oversight Committee, or other BRI official with the authority to make decisions related to research, has a Financial Interest 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 Conflict of Interest.

“**Conflict of Interest Institutional Official**” means the individual appointed by the General Counsel for the Virginia Mason Health System to review and assess disclosures of Financial Interests.

“**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.
- Voting members of BRI Oversight Committees who have responsibility for evaluating, approving, or overseeing research activities; and
- Research Leaders (as defined below).

“**Family Member**” includes spouse or domestic partner and dependent children (biological, half, step, or adopted children) of Covered Persons.

“**Financial Interest**” means anything of monetary value, whether or not 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 (i.e., that which is paid on behalf of the Covered Person and not reimbursed to the Covered Person so that the exact monetary value may not be readily available) related to Institutional responsibilities.

The term Financial Interest does not include:

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- 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 or Academic entities;
- Reimbursement of travel that is reimbursed or sponsored by a Government or Academic 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**” shall mean Research governed under the Common Rule that involves a Human Subject. A ‘human subject’ is a living individual about whom an investigator obtains either (1) data 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.

“**Research Leaders**” means Executive Leaders, Administrative Directors, and/or Medical Directors of BRI who have responsibility for or make decisions regarding the conduct or oversight of research conducted at BRI.

“**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, including the principal, co- or sub-investigator, project director, or any person identified as senior/key personnel in a grant application, research protocol, or progress or other report submitted to the Public Health Service (“Key Personnel”), sub-recipients, collaborators, consultants, research and regulatory faculty, staff scientists, and staff clinicians.

“**Positional 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.

“**Research**”, as defined in the Common Rule, means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

“**Research Oversight Committee**” means voting members of a committee responsible for overseeing BRI research, including but not limited to the Institutional Review Board (“IRB”) or any other committee that is responsible for evaluating, approving, monitoring, or overseeing research conducted at BRI.

“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.

“Should/May” indicates that staff may use his/her own judgment regarding compliance with the actions described or defined.

“Staff/Staff Member” refers to individuals employed by BRI.

“Will/Shall” indicates that staff must comply with the action(s) described or defined.

REFERENCES

- ADM POL 002 Intellectual Property Policy
- ADM POL 004 Outside Employment and Consulting Policy
- CRP POL 001 Clinical Research Administration Policy
- Rules and guidelines pertaining to research conflict of interest include the following: 45 CFR 46, 42 CFR 50 and 94, 21 CFR 50, 54, and 56, 45 CFR 94.3-94.5, 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

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RESPONSIBLE DEPARTMENT

The office of the BRI Executive Director is responsible for this policy under the oversight of the BRI Board of Directors.

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

NEXT REVIEW DATE: 7/1/2022

APPROVING BODY and POLICY APPROVAL DATE:

Approved by:	Date:
BRI Policy Coordination Committee	6/16/17
REVIEW ONLY – BOD	6/30/17
REVIEW ONLY – VMHS COLT	6/30/17

Signature: Homer Lane, Executive Director



REVISION HISTORY

Revision Level	Effective Date	Description of Changes
02	6/16/2017	Coverted to BRI policy and updated scope.
01	6/1/2012	Revised to comply with NIH requirements.
00	2001	Initial VM Policy