



Procedure Title: Financial Conflict of Interest Procedure - Intermountain (Research)	
Effective Date: 07/29/2025	Last Review Date: 07/29/2025
Document Owner: Shelby Moench (Director Research-Administration IRB and HRPP)	Next Review Date: 11/28/2028
Executive Approver(s): Samuel Brown (Chief Academic and Research Officer)	

Purpose:

To define the minimum requirements for identifying and managing financial conflicts of interest. These requirements apply to all research conducted at Intermountain Healthcare.

Scope:

Intermountain Health

Definitions:

Conflict of Interest — a circumstance in which professional judgement regarding a primary interest (e.g. patient care or welfare, research integrity) could be compromised by a secondary interest (e.g. financial gain, personal or profession reputation) resulting in real or perceived bias. Conflicts of Interest include Financial Interests and Leadership Roles, which could directly and significantly affect the design, conduct or reporting of a research study.

Domestic Partner — an individual permanently residing with a researcher, both considering themselves life partners and who can show financial interdependence and joint responsibility for each other's common welfare.

Financial Conflict of Interest (FCOI) — a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

Financial Interest — includes anything of monetary value, whether or not the value is readily ascertainable.

Immediate Family — for the purpose of Research Conflict of Interest disclosures immediate family is defined as spouse/Domestic Partner, dependent and/or minor children.

Institutional Official — the official(s) assigned by Intermountain to solicit and review disclosures of Significant Financial Interests from Investigators who are planning to participate in, or are participating in research. The Official (or designee) reviews disclosures and determines whether any Significant Financial Interest is related to research and if a Financial Conflict of Interest exists by making a reasonable determination that the Significant Financial Interest could be affected by the research, or is in an entity whose Financial Interest could be affected by the research.

Investigator — the project director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include collaborators or consultants.

Public Health Service (PHS) — a service of the U.S. Department of Health and Human Services, and includes any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Remuneration — includes salary and payment of services not otherwise identified as salary (e.g. honoraria, consulting fees, paid authorship) from any person or entity other than Intermountain. Equity interest includes any stock, stock option, or other ownership interest, as determined through

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reference to public prices or other reasonable measure of fair market value. This does not include income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

Senior / Key Study Personnel — the Principal Investigator/program director and any other person identified as senior/key personnel by Intermountain in a grant application, progress report or any other report related to the Research. This also includes individuals responsible for the design, conduct, or reporting of Research, regardless of title or position or research funding source.

Significant Financial Interest (SFI) — a Financial Interest consisting of one or more of the following interests of the Investigator (and those of the immediate family) that reasonably appears to be related to the Investigator's institutional responsibilities:

- With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any Remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity, as of the date of disclosure, when aggregated, exceeds \$5,000.
- With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any Remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's immediate family) holds any equity interest (e.g., stock, stock option, or other ownership interest); or intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Procedure:

1. Intermountain Healthcare is committed to conducting research in a manner that ensures the integrity of the research process and of Intermountain research programs. Intermountain requires all Investigators and Key Study Personnel to promptly disclose Financial Interests and other situations that present a conflict of interest or an appearance of a conflict of interest. Intermountain Healthcare identifies financial conflicts of interest (FCOI) and other situations that may give rise to conflicts of interest and addresses such situations to ensure research decisions are made in the best interests of research participants and Intermountain Healthcare.

2. Investigator and Key Study Personnel Responsibilities

a. All Investigators and Key Study Personnel have an obligation to:

- i. Read, understand and abide by this procedure and be aware of institutional policies related to Conflict of Interest.
- ii. Consider in advance whether any contemplated actions might create a conflict of interest.
- iii. Report conflicts of interest through the appropriate channels.
- iv. Work with the Research Conflict of Interest Committee and IRB to avoid, eliminate, minimize or manage conflicts of interest.
- v. Abide by the final decisions of the IRB and Research Conflict of Interest Committee.
- vi. Not begin research until any real or perceived conflicts have been minimized, managed or eliminated.
- vii. Complete annual and study-specific disclosure forms to the best of their knowledge.

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- viii. Complete COI training prior to engaging in any research activities and at least every four years or as often as the organization determines.

3. Disclosure of Financial Interest

- a. All Investigators and Key Study Personnel must report all their Financial Interests at least annually by submitting the Annual Research Conflict of Interest Disclosure form in the IRB's electronic system. Intermountain will request further information as needed.
- b. All Investigators and Key Study Personnel are required to report any reimbursed or sponsored travel when the travel is related to their institutional responsibilities and is being reimbursed or sponsored by a non-Intermountain entity. The disclosure should specify the purpose of the trip, the identity of the sponsor/organizer, the destination, and duration. Note this does not apply to travel that is reimbursed or sponsored by a Federal, state or local government agency, or institution of higher education (as defined at 20 U.S.C. 1001(a)), which includes academic teaching hospitals, medical centers, or a research institute affiliated with an institution of higher education.
- c. No externally sponsored project application will be approved for submission to a sponsor by the Pre-Award Office unless each Investigator has completed the Annual disclosure form and COI Training.
- d. Prior to conducting human subjects research, each Investigator and all Key Study Personnel on the proposal must have a current Annual disclosure form on file. In addition, each Investigator and all Key Study Personnel must disclose his/her Financial Interests related to specific research projects through the Study Specific Conflict of Interest Disclosure Form in the electronic IRB system.
- e. Each Investigator and all Key Study Personnel must update their Annual COI disclosure form within 30 days of discovering or acquiring a new Financial Interest.

4. Responsibilities of the Institution

- a. Intermountain will comply with all applicable federal and state laws, regulations and policies promoting objectivity in research. These include, but are not limited to:
 - i. Maintaining an up-to-date, written and enforced FCOI policy that complies with the Public Health Service (PHS) requirements (42 CFR 50.601) and making the policy available publicly.
 - ii. Informing each Investigator and all Key Study Personnel of this policy on FCOI and responsibilities regarding the disclosure of Significant Financial Interests (as required in regulations at 42 CFR 50.601).
 - iii. Requiring each Investigator and all Key Study Personnel to complete COI Training.
 - iv. Taking reasonable steps to ensure the sub-recipient's institutional FCOI policy is followed for any sub-recipient's research receiving PHS funding. If there is no FCOI policy, then reasonable steps are taken to comply with the PHS requirements.
 - v. Providing guidelines to the Research Conflict of Interest Committee to determine whether a Significant Financial Interest is related to research, and if so, whether or not the Significant Financial Interest is a FCOI.
 - vi. Taking actions as necessary to manage FCOI.
 - vii. For PHS-funded projects, completing appropriate reporting as required under 42 CFR 50.601.

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- viii. Maintaining records relating to Investigators' disclosures of Financial Interests.
- ix. Establishing adequate enforcement mechanisms and provide for sanctions and other administrative actions to ensure Investigator compliance as appropriate.

5. Research Conflict of Interest Review and Determination

- a. When notice of a potential conflict of interest is received in the electronic IRB system, the Research Conflict of Interest staff will notify the Research Conflict of Interest (RCOI) Committee Chair (or designee) of the disclosure.
- b. The Research Conflict of Interest Committee has set the following thresholds and constraints for all research conducted at Intermountain Health:
 - i. Any Significant Financial Interest greater than \$5,000/year that is related to a research project (deemed related if the Significant Financial Interest could be affected by the research or is in an Entity or individual whose Financial Interests could be affected by the research) will be reviewed by the Research Conflict of Interest Committee and a Management Plan will be implemented.
 - ii. Any Significant Financial Interest greater than \$25,000/year that is related to a research project will not be allowed unless the Research Conflict of Interest Committee determines there are compelling circumstances to overcome the presumption against participating in the research. This activity would also require a Management Plan.
 - iii. Individuals subject to this policy are prohibited from directly owning equity interest in the company sponsoring the research, but may hold shares in diversified, indexed mutual funds that may include holdings in that company, provided that such funds are not actively managed and do not have a stated investment strategy to concentrate holdings in that company or related companies.
 - iv. Investigators requiring a Management Plan will be invited to meet with the Research Conflict of Interest Committee.
 - v. An Investigator may not participate in research with a sponsor where they also participate (either currently or within the Washout Period) in marketing activities with the sponsor. Marketing activities might include, but are not limited to, paid speaker's bureaus (i.e., talks or presentations where the content is provided by the sponsor and or/is not at arms-length from the sponsor) or paid review of trial results with the sponsor where the Investigator is not participating in the trial or its design.
 - vi. Washout Period: Should an Investigator wish to cease the external financial relationship with a sponsor in order to participate in research, the Research COI Committee will require a pre- and post-washout period of twelve (12) months. In other words, the Investigator's marketing activities with a company must cease entirely (for marketing activities) for one year before initiating the research and for one year following the closure of the research at Intermountain Health.
- c. The Chair (or designee) will review the disclosure and determine if the conflict is:
 - i. A: Significant (greater than \$5,000/year)
 - ii. B: Related to the research
- d. If both A and B apply, the RCOI committee will review the disclosure to determine whether the Significant Financial Interest could directly or significantly affect the design, conduct or

reporting related to the research. If the committee determines that a FCOI exists they will create a FCOI Management Plan, which could include any of following actions:

- i. Public disclosure of the FCOI (e.g. in public presentations or publications related to the research)
 - ii. Disclosure of the FCOI to potential study participants (within the informed consent document)
 - iii. Appointment of an independent monitor who is capable and willing to take appropriate measures to protect the design conduct and reporting of the research against potential biased resulting from the FCOI
 - iv. Modification of the research plan
 - v. Change of personnel or responsibilities or disqualification of personnel from participation in all or certain portions of the research
 - vi. Reduction or elimination of the significant FCOI (e.g., sale of an equity interest)
 - vii. Severance of the relationship generating the FCOI
- e. The Management Plan will be communicated to the individual and the Research team.
- i. Investigators requiring a Management Plan will be invited to meet with the Research Conflict of Interest Committee. The Investigator may request changes to the plan for review by the Research Conflict of Interest Committee.
 - ii. The Management Plan will also be submitted to the IRB.
 - iii. The IRB has final authority on whether the proposed research should be approved; the IRB shall consider the Management Plan and may also add additional protections if deemed necessary for the protection of human participants.
 - iv. To the extent possible and as allowed by law, all Conflict of Interest Disclosure Forms and related information shall be kept confidential and may only be shared with other individuals on a case-by-case and need-to-know basis (e.g., Institutional Conflict of Interest Committee, IRB).

6. Monitoring Management Plans

- a. Intermountain will conduct random and for-cause monitoring to ensure Investigator compliance with Management Plans.

7. Non-Compliance

- a. Failure by the Investigator or Key Study Personnel to comply with a FCOI Management Plan requires a retrospective review of the individual's activities and the research project to determine whether any conduct during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.
- b. For PHS-funded research, a report to the PHS Awarding Component will be completed within 120 days of the institution's determination of noncompliance.
- c. In the event an Investigator is found to be noncompliant with a Management Plan and the noncompliance was determined to have biased the design conduct or reporting of PHS-funded research, the institution will notify the PHS Awarding Component of the corrective action to be taken.

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- d. Failure to comply with this procedure (including failure to comply with regulation or terms outlined in any approved Management Plan) requires NIH notification for PHS-funded research and may result in disciplinary action up to and including termination.

References and/or Primary Sources:

- [Frequently Asked Questions](#)
- [Information Specific to PHS Grants and Cooperative Agreements](#)
- [Mandatory Training](#)
- [NIH Office of Extramural Research Tutorial](#)
- Researcher Disclosure form
- Title 21 CFR Part 54
- Title 42 Code of Federal Regulation (CFR) Part 50 Subpart F for grants and cooperative agreements
- Title 45 CFR Part 94 for research contracts

Related Policies and/or Guidelines:

- [Conflict of Interest - Intermountain \(Research\)](#)

Supporting Documents:

- None