



Financial Conflict of Interest in Sponsored Research Policy

Brigham Young University is committed to preserving public trust in the objectivity of research. Pursuant to the standards of the [Church Educational System Honor Code](#), all research should be conducted with the highest scientific and ethical standards, which requires the disclosure and management of financial conflicts of interest. Generally, the effects of financial conflicts of interest can be eliminated or substantially reduced by early and full disclosure of personal financial interest in the potential outcomes of sponsored research. Standards in this policy are to be administered with discretion and judgment in compliance with federal regulatory requirements.

Definitions

Financial Conflict of Interest (FCOI) exists when the AAVP – research and graduate studies (AAVP – R) determines that an Investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the sponsored research.

Immediate Family Member includes an investigator's spouse and dependent children.

Investigator is 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, including collaborators or consultants.

Key Personnel is the project director or principal Investigator and any other personnel considered to be essential to work performance and identified as Key Personnel in a contract proposal and contract.

Management Plan is a written plan describing how an FCOI will be managed.

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the Investigator and those of the Investigator's Immediate Family Members that reasonably appear to be related to the Investigator's institutional responsibilities:

- For any publicly traded entity (PTE), an SFI exists if the value of any remuneration received from the PTE in the 12 months preceding the disclosure and the value of any equity interest in the PTE as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; or



- For any non-publicly traded entity, an SFI 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's Immediate Family Members hold any equity interest (e.g., stock, stock option, or other ownership interest); or
- For intellectual property rights and interests (e.g., patents, copyrights), an SFI exists upon receipt of income related to these rights and interests.

SFI does *not* include the following:

- Salary, royalties, or other remuneration paid by the university to the Investigator if the Investigator is currently employed or appointed by the university, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights.
- Income from seminars, lectures, or teaching engagements sponsored by and/or service on advisory or review panels for a U.S. federal, state, or local government agency or a U.S. institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education.
- Income from investment entities, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these entities.

Sponsor is an agency, foundation, or institution that funds the research that is subject to this policy.

Potential Conflicts of Interest in Sponsored Research Activities

Conflicts of interest in sponsored research activities are most likely to occur when faculty and other university personnel are involved in commercial pursuits. These may include, but are not limited to, the following:

- Serving outside interests – Conducting research when any of the participants or their Immediate Family Members have an equity ownership, managerial or consulting role, or SFI in the Sponsor whose product, process, or device is under study.
- Accepting gifts and gratuities – Accepting gifts of more than nominal value, gratuities, or special favors from outside entities supporting sponsored research.
- Consulting – Entering into paid consulting agreements that may affect research in a material way (direction, focus, timing, reporting, etc.).
- Use of university employees – Using university employees (e.g., students or staff) to perform services for an outside entity in which the Investigator or the Investigator's Immediate Family has an equity ownership, managerial or consulting role, or SFI.
- Use of university resources – Using non-reimbursed or otherwise unauthorized institutional resources such as equipment, supplies, facilities, or space to support the



interests or activities of an outside entity in which an Investigator or the Investigator's Immediate Family has an equity ownership, managerial or consulting role, or SFI.

- Access to research information – Providing unauthorized privileged access to research information or other intellectual property developed with university resources or support to an outside entity in which the Investigator or the Investigator's Immediate Family has an equity ownership, managerial or consulting role, or SFI.

Disclosure Requirements

Prior to submitting a research application to an external Sponsor, Investigators must submit a [Financial Conflict of Interest Disclosure Form \(Disclosure Form\)](#) to their department chair. For internally funded research that has a potential SFI, Investigators must submit a Disclosure Form to their department chair before funds are expended. During the period of award, Investigators must submit an updated Disclosure Form within 30 days of discovering or acquiring a new SFI. The AAVP – R has been designated by the university to solicit, review, and approve financial disclosures.

Annual Disclosure

Annually, faculty disclose all conflicts of interest through the Faculty Profile system. In addition to this disclosure, faculty will use the Disclosure Form to update previously disclosed SFIs and to disclose any new SFIs.

Management Positions

Investigators must disclose if they or their Immediate Family Members hold a management position with a sponsor, vendor, or subcontractor of the sponsored program activity. A management position includes serving as a board member, director, officer, partner, trustee, employee, or consultant. These Investigators must disclose the following information:

- Name of the Investigator
- Name of the person holding the management position
- Name of the entity
- Position held

Significant Financial Interests

Investigators must report if they or their Immediate Family Members have an SFI. These Investigators must disclose the following information:

- Grant or contract number
- Project Director (PD)/Principal Investigator (PI) or Contact PD/PI
- Name of Investigator



- Name of the person with the SFI
- Name of the entity associated with the SFI
- Nature of SFI (e.g., equity interest, consulting fees)
- Value of the financial interest, or a statement that the value of a financial interest cannot be readily determined
- A description how the financial interest relates to the sponsored research

Travel

Investigators must disclose the occurrence of any directly reimbursed travel or sponsored travel related to the Investigator's institutional responsibilities that is paid on behalf of the Investigator and not reimbursed to the Investigator. Because the Investigator is not reimbursed, the exact monetary value of the travel may not be readily available. The disclosure must include the purpose, Sponsor or organizer, destination, and duration of the trip. The director of the Research Administration Office (RAO) will determine if the disclosure of reimbursed or sponsored travel requires further investigation, including a determination or disclosure of monetary value.

Individuals are not required to disclose travel that is reimbursed or sponsored by the university; a federal, state, or local government agency; another U.S. institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with a U.S. institution of higher education.

Management Plans

If a potential FCOI appears likely, or at the university's request, the Investigator must submit a proposed Management Plan with the Disclosure Form. The Investigator works in consultation with the RAO to develop the Management Plan. The AAVP – R has been designated by the university to solicit, review, and approve Management Plans.

Conditions or restrictions that might be required in a Management Plan include, but are not limited to, the following:

- public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research)
- for research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants
- appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest
- modification of the research plan



- change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research
- reduction or elimination of the financial interest (e.g., sale of an equity interest)
- severance of relationships that create financial conflicts

The department chair is responsible for monitoring Investigator compliance with the Management Plan through the completion of the project.

Review of Disclosures and Standards for Determining an FCOI

Disclosure Forms will be reviewed by the department chair, the Dean's Office, the RAO director, and the AAVP – R to determine whether a disclosed SFI is related to the Investigator's research and whether it constitutes an FCOI.

An Investigator's SFI is related to his or her research when the university, through the AAVP – R, determines that the SFI could affect the research. An FCOI exists when the university, through the AAVP – R, determines that the SFI could directly and significantly affect the design, conduct, or reporting of the sponsored research.

Review of Disclosures for New Investigators and New SFIs

For ongoing research, if an Investigator who is new to the sponsored research discloses an SFI or an existing Investigator discloses a new SFI to the department chair, the department chair will advise the associate dean and RAO director and forward the disclosure to the AAVP – R, who, within sixty days, will

- review the disclosure of the SFI,
- determine whether it is related to the proposed or existing funded research, and
- determine whether an FCOI exists.

If an FCOI exists, the AAVP – R will require the Investigator to submit a Management Plan for approval. Depending on the nature of the SFI, the AAVP – R may determine that it is necessary to take interim measures between the date of disclosure and the completion of the review.

Undisclosed or Unreviewed SFIs and FCOIs

Whenever an SFI is identified that was not disclosed in a timely fashion by an Investigator or, for whatever reason, was not previously reviewed by the AAVP – R during an ongoing sponsored research project (e.g., was not timely reviewed or reported by a subrecipient), the AAVP – R must, within sixty days, review the SFI with the Investigator, department chair, associate dean, and RAO director and determine whether it is related to the research and if an FCOI exists. If necessary, the AAVP – R will require the implementation of a Management Plan.



Retrospective Review

A review panel, consisting of the AAVP – R, RAO director, the department chair, and the associate dean, will conduct a retrospective review whenever

- an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI;
- the department chair fails to review, identify, or monitor an FCOI; or
- an Investigator fails to comply with an FCOI Management Plan.

The retrospective review will include a review of the Investigator’s activities and the research project to determine whether any research, or portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct, or reporting. The retrospective review will be conducted within 120 days of the university’s determination of noncompliance.

The retrospective review will document the following information:

- project number
- project title
- PD/PI, or contact PD/PI if a multiple PD/PI model is used
- name of the person with the FCOI
- name of the entity associated with the FCOI
- reason for the retrospective review
- detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
- findings of the review
- conclusions of the review

Based on the results of the retrospective review, if appropriate, the AAVP – R will update the information provided to the Sponsor and specify the actions that will be taken to manage the FCOI going forward. Depending on the nature of the FCOI, the university may take additional interim measures between the date that the FCOI or the Investigator’s noncompliance is identified and the completion of the institution’s retrospective review.

Resolving Disagreements on the Determination or Management of FCOIs

If the Investigator (and other involved personnel), the department chair, and associate dean are unable to agree on the determination or management of an FCOI either prior to proposal submission, during the approval request stage, or during the execution of a research contract, the RAO director will render a decision regarding the FCOI.



The RAO director will notify the AAVP – R of the FCOI and the decision regarding its management and will take steps to safeguard the affected research and protect the university and its personnel. If it is determined that personnel are out of compliance with this policy, the RAO director may recommend appropriate sanctions to the AAVP – R. Recommended sanctions may include, but are not limited to, rescinding contracts involving the funds; freezing funds or accounts; prohibiting participation in future sponsored activities; and imposing corrective actions such as suspension, probation, or termination as deemed appropriate and in compliance with the [Faculty Discipline and Termination Policy](#) and the [Administrative and Staff Employee Discipline Policy](#). The resolution process is depicted in Appendix A – Conflict of Interest Management Plan Approval and Appeal Process.

Appeal Process

Personnel may appeal the RAO director's decision and/or recommended sanctions in writing to the AAVP – R. As shown in Appendix A, the AAVP – R will then empanel an ad hoc University Sponsored Research Conflict of Interest Review Committee (Committee).

The Committee will be chaired by the AAVP – R and will generally be composed of senior faculty. If the FCOI involves administrative or staff personnel engaged in the research activity, a representative of the administrative reporting line will be appointed to the Committee. Other university personnel with specific and relevant expertise and/or experience may also be invited to serve on the Committee as the case warrants. The Committee has authority to further investigate the applicable facts and circumstances as it deems advisable and will generally evaluate the matter in relation to the standards previously outlined for the evaluation of conflicts.

The Committee will review the disclosure and Management Plan and any recommendations of the academic supervisors to manage the FCOI. If the aggrieved faculty member/personnel are appealing sanctions recommended as a result of noncompliance, the Committee will also comment on the appropriateness of the sanctions, given the nature and extent of the FCOI. The Committee's summary of findings and specific recommendations as to modifications of the Management Plan to eliminate, reduce, or more effectively manage the FCOI will be submitted to the academic vice president (AVP).

Final Determination

The AVP will review the findings and recommendations of the Committee and make a determination on the appealed issues. The decision of the AVP regarding the resolution of the FCOI and sanctions is final. In the case of faculty, any sanctions will be imposed in accordance with the [Faculty Discipline and Termination Policy](#). In the case of non-faculty administrative and staff personnel, any sanctions will be imposed in accordance with the [Administrative and Staff Employee Discipline Policy](#). The AVP may advise the president on the matter.



The AVP or designee will promptly advise the Office of the General Counsel and notify the Sponsor, including appropriate federal agencies, of instances of noncompliance and of corrective action taken.

Public Disclosure for Research Funded by the Public Health Service

Prior to the expenditure of any funds for research funded by the Public Health Service (PHS), the university will respond within 5 business days to requests from members of the public to provide information concerning any SFI disclosed to the university that meets the following criteria:

- the SFI was disclosed and is still held by Key Personnel,
- the university has determined that the SFI is related to the PHS-funded research, and
- the university has determined that the SFI interest is an FCOI.

The university's response will include the following:

- Investigator's name
- Investigator's title and role with respect to the research project
- the name of the person with the SFI
- the name of the entity associated with the SFI
- the nature of the SFI
- the approximate dollar value of the SFI

In its response, the university will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the university's identification of a new FCOI.

If the Department of Health and Human Services determines that a PHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported to the university, BYU will require the Investigator to disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.

Subrecipients

BYU will take reasonable steps to ensure that subrecipients comply with applicable federal regulations by establishing, in a written agreement, whether the subrecipient will follow its own FCOI policy or BYU's FCOI policy. As applicable, BYU will



- obtain a certification from the subrecipient that its FCOI policy complies with applicable federal regulations;
- state in its written agreement that BYU's FCOI policy applies and identify a period in which subrecipients must report FCOIs to BYU to allow sufficient time for BYU to report identified FCOIs as required; or
- state in its written agreement that BYU will solicit and review subrecipient Investigator disclosures to enable BYU to identify, manage, and report identified FCOIs to the Sponsor, as required.

Whenever an SFI is disclosed by a subrecipient Investigator, the RAO director must, within sixty days, review the SFI with the Investigator, department chair, associate dean, and AAVP – R and determine whether it is related to the research and whether an FCOI exists. If necessary, they will require the implementation of a Management Plan.

Reporting to Sponsors

BYU will make reports to Sponsors as required.

Reporting to the National Institutes of Health

For research funded by the National Institutes of Health (NIH), BYU will send initial, annual, and revised FCOI reports to the NIH.

Reports are sent

- prior to the expenditure of funds;
- within 60 days of the identification of an Investigator who is new to the project;
- within 60 days for new, or newly identified, FCOIs for existing Investigators;
- at least annually to provide the status of the FCOI and any changes to the Management Plan, if applicable, until the completion of the project; reports are submitted simultaneously with BYU's annual progress report, or, if applicable, multi-year progress report or a time of extension; and
- following a retrospective review to update a previously submitted report, if appropriate.

Any FCOI report to the NIH must include sufficient information to enable BYU and the NIH to understand the nature and extent of the financial conflict, and to assess the appropriateness of BYU's Management Plan. Elements of the FCOI report must include, but are not necessarily limited to, the following:

- project number
- PD/PI or contact PD/PI if a multiple PD/PI model is used



- name of the Investigator with the FCOI
- name of the entity associated with the FCOI
- nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
- value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- a description of how the financial interest relates to the PHS-funded research and the basis for the institution's determination that the financial interest conflicts with such research
- a description of the key elements of the university's Management Plan, including
 - role and principal duties of the conflicted Investigator in the research project,
 - conditions of the Management Plan,
 - how the Management Plan is designed to safeguard objectivity in the research project,
 - confirmation of the Investigator's agreement to the Management Plan,
 - how the Management Plan will be monitored to ensure Investigator compliance, and
 - other information as needed.

For any FCOI previously reported by BYU regarding an ongoing PHS-funded research project, the RAO will provide the PHS Sponsor with an annual FCOI report that addresses the status of the FCOI and any changes to the Management Plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. The RAO will provide annual FCOI reports to the PHS Sponsor for the duration of the project period (including extensions with or without funds) in the time and manner specified by the Sponsor.

BYU will promptly notify NIH and take corrective action if an Investigator fails to comply with this policy or the Management Plan. If bias resulting from the FCOI is found in an NIH-funded project, BYU, through the RAO director, will notify the NIH promptly and submit a mitigation report. The mitigation report will include, at a minimum, the information documented in the retrospective review, a description of the impact of the bias on the research project, and the university's actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).



Investigator Training

RAO is responsible for providing training on this policy and applicable federal regulations to each Investigator who conducts externally sponsored research before that Investigator conducts any research. Investigators conducting externally sponsored research must complete the training at least once every four years or immediately if

- the university revises this policy or related procedures in any manner that affects the obligations of Investigators,
- an Investigator is new to the university, or
- an Investigator is found to be out of compliance with this policy or a Management Plan.

Records

The university will maintain records relating to Investigator disclosures and the university's review of and response to those disclosures for at least three years from the date the final expenditures report is submitted to the Sponsor. The university will retain records beyond three years under the following circumstances:

- Records related to the purchase of real property or equipment purchased with federal funds will be retained for three years after final disposition.
- For litigation, claims, or audits started before the expiration of the three-year retention period, the records will be retained by the university until all litigation, claims, or audit findings involving the records have been resolved and final action has been taken.
- At the written request of the Sponsor.

APPROVED: 17 Oct 2022

PRIOR VERSION: 2 Jun 2014

APPLICABILITY: This policy applies to university personnel involved in sponsored research.

POLICY OWNER: Academic Vice President

RESPONSIBLE OFFICE: Associate Academic Vice President – Research and Graduate Studies

RELATED POLICIES:

- [Administrative and Staff Employee Discipline Procedures](#)
- [Church Educational System Honor Code](#)
- [Conflict of Interest Policy](#)



- [Export Control and Fundamental Research Policy](#)
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- [Faculty Discipline and Termination Policy](#)
- [Faculty Grievance Policy](#)
- [Fraud Policy](#)
- [Human Research Protection Policy](#)
- [Personnel Conduct Policy](#)
- [Research Misconduct Policy](#)
- [Supplemental Research Compensation for Externally Sponsored Work Policy](#)
- [Use of Vertebrate Animals as Subjects in Teaching, Testing, or Research Policy](#)



Appendix A

Conflict of Interest Determination Process and Conflict of Interest Appeal Process

