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## Financial Conflict of Interest in Sponsored Research Policy

### I. Summary

Brigham Young University (BYU) is committed to preserving public trust in the objectivity of research. In accordance with the [Church Educational System Honor Code](#), all research must be conducted with the highest ethical standards. Research programs should never be influenced by the existence of related opportunities for financial gain by principal investigators. The results of the funded research should never be biased by financial or other considerations available to the principal investigators.

Legal requirements arising from university research sponsored by the United States Public Health Service (PHS) and the National Science Foundation (NSF) provide that institutions must have in place a research-specific policy to eliminate, reduce, or manage conflicts of interest. While these legal requirements refer specifically to receipt of federal funding in the establishment of a policy governing financial or other conflicts of interest, compliance with the policy is expected of all university personnel involved in sponsored research activities, regardless of funding source.

This policy document constitutes a general policy by specifically addressing the PHS regulations entitled “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought” and “Responsible Prospective Contractors.” These rules are also known as the financial conflict of interest (FCOI) regulations. See 42 C.F.R. Part 50 and 45 C.F.R Part 94.

The purpose of this policy is to provide guidance to university personnel regarding the disclosure, management, reduction, or elimination of FCOIs. Investigators are responsible for complying with the institution’s written FCOI policy and for disclosing any significant financial interest (SFI) as defined in the procedures.

### II. Managing Conflict of Interest in Sponsored Research

The effects of conflict of interest can be eliminated or substantially reduced by early and full disclosure of relevant or substantial personal financial interest in the potential outcomes of sponsored research. A consistently applied process allows for development of an effective management plan and administrative review. This policy is designed to safeguard individual and institutional reputations by defining and delineating the range of opportunities appropriate for university personnel under specified circumstances. The underlying presumption is that university personnel are well acquainted with and committed to the [Church Educational System Honor Code](#) and exhibit these personal standards in the execution of their duties as university employees.



### III. Application of this Policy

This policy is broadly applicable to all university personnel. Full-time faculty members at the university are those primarily engaged in scholarly activities funded in whole or in part by internal university resources or by external entities. Other university personnel who do not direct but are involved in research activities may also encounter conflicts of interest. These may include administrative or staff personnel providing some level of research support, research associates, post-doctoral fellows, and part-time personnel such as student assistants.

As a general rule, the more comprehensive a responsibility to which an individual is assigned in the university's administrative structure, the more likely that individual may encounter situations presenting potential conflicts of interest. Existing organizational channels provide for supervision of all personnel, and the supervision should include a concern for conflicts of interest at any level of responsibility.

This policy shall be publicly accessible on the website of the Research Administration Office (RAO) and is in effect as of August 24, 2012.

Standards in this policy are to be administered with discretion and judgment based upon the facts and circumstances of any given case.

### IV. Definitions

**Awarding Sponsor**—Agency, foundation, or institution that funds the research that is subject to this policy.

**Conflict of Commitment**—A situation in which the interests and efforts of university personnel are directed toward activities outside the university to the extent that an individual's ability to perform university responsibilities or duties is compromised. University personnel are required to devote their time and energy to assigned teaching, research, institutional citizenship, and administrative responsibilities. (See also [Conflict of Interest and Conflict of Time Commitment Policy](#).)

**Disclosure**—Formal, written reporting of all involvement or situations which constitute, or might appear to constitute, conflicts of interest relative to the assigned responsibilities of principal investigators. Such reporting must occur prior to the submission of a proposal for externally sponsored research and at any time during the conduct of the sponsored research in which a conflict arises. Federal law requires disclosure of the detailed financial aspects of the conflict if the amount of financial gain to the individual exceeds \$5,000.

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



**Institutional Responsibilities**—An Investigator’s professional responsibilities on behalf of the university, which include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels.

**Investigator**—Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research. This definition may include collaborators and consultants.

**Significant Financial Interest (SFI)**—Any equity interest in, or payment for services rendered to, a business, non-profit entity, or another institution that exceeds \$5,000 in a 12-month period. This definition includes any salary, consulting fees, honoraria, paid authorships, and any other payment of any kind for services rendered. This definition also includes any stock, stock options, or other ownership interests, and it includes any type of equity interest in non-publicly traded entities. Intellectual property rights and interests, such as patents and copyrights, also constitute SFIs upon receipt of income related to these rights or interests.

Once the dollar threshold is met by an individual for a single SFI, all SFIs must be disclosed.

SFIs excluded from disclosure include the following:

- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or research institute that is affiliated with an institution of higher education.
- Income from service on advisory or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or research institute that is affiliated with an institution of higher education.
- 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.

**Public Health Service**—The Public Health Service Act of 1944 created the PHS as the primary division of the Department of Health, Education and Welfare (HEW), which later became the United States Department of Health and Human Services. The PHS comprises all agency divisions of Health and Human Services and the Commissioned Corps.

Agencies within the PHS include the following:

- Administration for Children and Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)



- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Federal Occupational Health (FOH)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

#### **V. Potential Financial Conflicts of Interest in Sponsored Research Activities**

Financial conflicts of interest in sponsored research activities are most likely to occur when faculty and other personnel have commercial interests with outside entities. Such interests may include, but are not limited to, the following:

**Serving Outside Interests**—Conducting research when any of the participants in the externally- or university-sponsored activity, or their immediate families, have an equity ownership or a managerial, consulting, or other significant financial interest in the sponsoring outside entity whose product, process, or device is under study.

**Accepting Gifts and Gratuities**—Accepting gratuities, gifts of more than nominal value, or special favors from outside entities supporting sponsored research.

**Consulting**—Entering into paid consulting agreements with outside entities whose influence may affect in a material way (such as in direction, focus, timing, or reporting) research at the university sponsored either by the outside entity, or any other sponsor, institutional or external, of related work.

**Use of University Employees**—Using university employees (e.g., students or secretarial, clerical, or technical staff) to perform services for an outside entity in which the principal investigator, or his or her immediate family, has an equity ownership or a managerial, consulting, or other significant financial interest.

**Use of University Resources**—Using non-reimbursed or otherwise unauthorized substantial or continuing use or purchase of institutional resources such as equipment, supplies, facilities, or space to support the interests or activities of an outside entity in which a principal investigator, or his or her immediate family, has an equity ownership or a managerial, consulting, or other significant financial interest.

**Access to Research Information**—Providing privileged access to research information or other intellectual property that was developed with university resources or support from an external



source to an outside entity in which the principal investigator, or his or her immediate family, has an equity ownership or a managerial, consulting, or other significant financial interest.

## VI. Disclosure

**Investigator Disclosures**—Disclosure forms are available from RAO. Investigators must disclose to the director of ROA any SFI held by the investigator or the investigator's spouse or dependent children. Each investigator must make this disclosure through his or her department chair and dean's office to the director of RAO by the time a research application is submitted to an external sponsor. Investigators must submit to the director of RAO an updated disclosure statement at least annually and within thirty days of discovering or acquiring a new SFI.

Each investigator must also disclose the occurrence of any reimbursed travel or sponsored travel related to his or her institutional responsibilities (including purpose of trip, sponsor or organizer, destination, and duration). Individuals are not required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency; another institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education. The director of RAO will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

Following investigator disclosure of an SFI, the university, through the department chair, associate dean, dean, or director of RAO, must review each disclosure and determine whether the SFI is related to externally-funded research and whether the SFI constitutes an FCOI. An SFI is related to externally-funded research if the department chair, associate dean, dean, or director of RAO reasonably determines that the SFI could be affected by the externally-funded research or is in an entity whose financial interest could be affected by the research. An SFI constitutes an FCOI if the department chair, associate dean, dean, or director of RAO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the externally-funded research.

Investigator disclosures should include the following information:

- Grant/contract number
- Name of project director or principal investigator (PD/PI), or contact PD/PI if a multiple PD/PI model is used
- Name of investigator with SFI
- Name of the entity with which the investigator has an SFI
- Nature of the SFI (e.g., equity, consulting fees, travel reimbursement, honoraria)
- Approximate dollar value of the SFI or a statement that a value cannot be readily determined. The value may be stated within the following ranges: \$0–\$4,999; \$5,000–



\$9,999; \$10,000–\$19,999; \$20,000–\$100,000 by increments of \$20,000; \$100,000 and above by increments of \$50,000.

The university must maintain all records related to investigator disclosures of SFIs for at least three years from the date that the research is complete or the date that a final expenditures report is submitted to the external sponsor, whichever is later.

**Management Plan**—The department chair, associate dean, dean, or director of RAO must review all investigator SFI disclosures and determine whether any SFI constitutes an FCOI. If the SFI is determined to be an FCOI, then, before any funds are spent, the department chair, associate dean, dean, or director of RAO must review the FCOI with the investigator and develop a formal, written FCOI management plan. Conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- Public disclosure of the FCOI (e.g., when presenting or publishing the research)
- Disclosure of the FCOI directly to participants in research projects involving human subjects
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI
- 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 FCOI (e.g., sale of an equity interest)
- Severance of relationships that create the FCOI

Whenever, in the course of an ongoing research project, an investigator who is new to participating in the research project discloses an SFI or an existing investigator discloses a new SFI, the department chair will advise the college dean or associate dean and forward the disclosure to the director of RAO, who shall within sixty days:

- Review the disclosure of the SFI
- Determine whether it is related to the proposed or existing funded research
- Determine whether an FCOI exists, and, if so, implement a management plan that specifies the actions that have been and will be taken to manage the FCOI

Depending on the nature of the SFI, the director of RAO may determine that interim measures are necessary. These interim measures may limit the investigator's participation in funded research between the date of disclosure and the completion of the university's review of the SFI.



Whenever the university implements a management plan pursuant to this policy, the department chair shall monitor investigator compliance with the management plan on an ongoing basis until the completion of the research project.

**Retrospective Review**—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 director of RAO during an ongoing research project (e.g., an untimely report by a subrecipient), the director of RAO shall within sixty days review the SFI with the investigator, chair, and associate dean or dean; determine whether it is related to the funded research; and determine whether an FCOI exists. If an FCOI exists, the director of RAO shall implement, on at least an interim basis, a management plan that specifies the actions that have been and will be taken to manage the FCOI going forward.

Whenever an FCOI is not identified or managed in a timely manner—including failure by the investigator to disclose an SFI that is determined by the director of RAO to constitute an FCOI, failure by the department chair to review or manage such FCOI, or failure by the investigator to comply with an FCOI management plan—the director of RAO, the department chair, and the associate dean or dean shall within 120 days of the institution’s determination of noncompliance complete a retrospective review of the investigator’s activities and the research project. The purpose of the retrospective review is to determine whether any research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

RAO will document the retrospective review. The documentation shall include, but not necessarily be limited to, all of the following key elements:

- Project number
- Project title
- Name of 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 with which the investigator has the FCOI
- Reason(s) 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 director of RAO shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found in a PHS-funded project, the university, through the director of RAO, will promptly notify and submit a mitigation report to the PHS awarding





sponsor. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project. It must also include the institution's plan of action or 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). Thereafter, the director of RAO will submit FCOI reports annually, as specified elsewhere in this policy. (See Part VIII below.) Depending on the nature of the FCOI, the university may determine that additional interim measures are necessary to limit the investigator's participation in the externally funded research project between the date that the FCOI or the investigator's noncompliance is identified and the completion of the institution's retrospective review.

**Disagreement on Resolution of FCOI**—In the event that the principal investigator, or other personnel involved, and direct line officers are unable to agree on resolution of an FCOI either prior to proposal submission during the approval request stage or during the execution of a research contract, the dean shall render a decision regarding strategy for managing the FCOI. The dean will notify the associate academic vice president – Research and Graduate Studies (AAVP – Research and Graduate Studies) of the FCOI and his or her decision regarding its management. The university will take steps necessary to safeguard the affected research and to protect the university and its personnel. In the event that the university finds university personnel to be out of compliance with this policy, the dean may also recommend appropriate sanctions to the AAVP – Research and Graduate Studies.

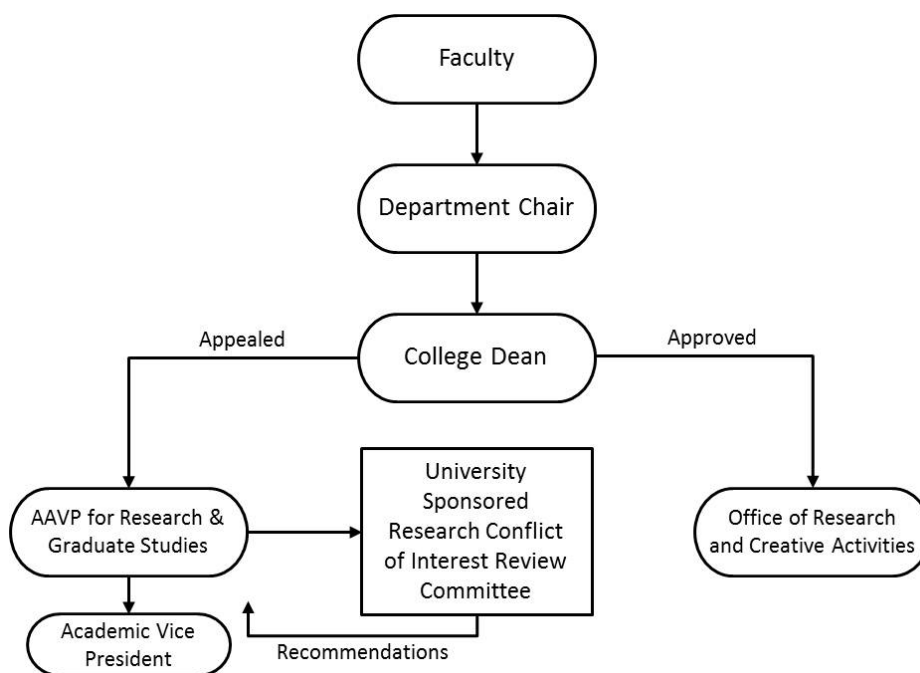
**Appeal Process**—Personnel may appeal the dean's decision or recommended sanctions in writing to the AAVP – Research and Graduate Studies. As shown in the following diagram, the AAVP will then empanel an ad hoc University Sponsored Research Conflict of Interest Review Committee. The committee will be chaired by the director of RAO 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 also be appointed to the committee. Other university personnel with specific and relevant expertise or experience may also be invited to serve on the committee as the case warrants.

The committee will review the SFI disclosure and FCOI management plan and any recommendations of the academic supervisors to resolve the problem. The committee shall have 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 evaluation of conflicting activities. The committee's summary of findings and specific recommendations as to modifications of the management plan to eliminate, reduce, or more effectively manage conflicts of interest will be submitted to the AAVP – Research and Graduate Studies. If the aggrieved faculty member or non-faculty employee is appealing sanctions





recommended as a result of noncompliance, the committee shall also comment on their appropriateness, given the nature and extent of the FCOI.



**Final Determination**—The AAVP – Research and Graduate Studies will review the decision of the dean and the findings and recommendations of the University Sponsored Research Conflict of Interest Review Committee and will then advise the academic vice president (AVP) as to an appropriate disposition of the matter, including possible sanctions. Recommended sanctions for failure to comply with this policy may include, but are not limited to, rescinding contracts involving the funds, freezing funds or accounts, prohibiting participation in future sponsored activities, written warning, formal reprimand, probation, suspension, salary reduction, and other corrective actions as deemed appropriate. The decision of the AVP regarding the resolution of the FCOI and sanctions shall be final. In the case of non-faculty personnel, the AAVP – Research and Graduate Studies will recommend the imposition of sanctions, as permitted, to be implemented in accordance with the applicable administrative and staff personnel policies and procedures of the university.

The AAVP – Research and Graduate Studies shall promptly notify any research sponsoring entity, including appropriate federal agencies, of instances of noncompliance and of corrective action taken. He or she will also advise the university's Office of the General Counsel. The AVP may advise the university president.



## VII. Subrecipients

The university must take reasonable steps to ensure that colleagues working for subrecipients comply with applicable federal regulations by requiring those investigators to comply with this policy or by requiring the subrecipient entities to provide assurances to the director of RAO that will enable the university to comply with the federal rules. The university should incorporate as part of a written agreement with each subrecipient terms that establish whether the FCOI policy of the awardee institution or that of the subrecipient will apply to subrecipient investigators. The written agreement must also include time periods for subrecipients to meet disclosure and FCOI reporting requirements so that the university may report FCOIs on PHS-funded projects to the awarding sponsor before the expenditure of funds and within sixty days of any subsequently identified FCOI.

## VIII. Reporting to the PHS

Before spending any PHS funds, the university must report any FCOI to the agency awarding the PHS funds. RAO must also submit an annual update report to the awarding sponsor until the FCOI no longer exists. In addition, the university must provide a report within sixty days of learning of any new FCOI on an existing PHS-funded contract or grant.

Any FCOI report required under this section shall include sufficient information to enable the university and, if federally funded, the PHS awarding sponsor to understand the nature and extent of the FCOI and to assess the appropriateness of the university's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:

- Project number
- Name of 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 with which the investigator has the FCOI
- Nature of the FCOI (e.g., equity, consulting fee, travel reimbursement, honorarium)
- Approximate dollar value of the FCOI or a statement that a value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. The value may be stated within the following ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; \$20,000–\$100,000 by increments of \$20,000; \$100,000 and above by increments of \$50,000.
  - A description of how the FCOI relates to the PHS-funded research and the basis for the institution's determination that the SFI conflicts with such research
  - A description of the key elements of the institution'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
- Other information as needed

For any FCOI previously reported by the university for an ongoing PHS-funded research project, RAO shall provide to the PHS awarding sponsor an annual FCOI report that addresses the status of the FCOI and any changes to the management plan. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. RAO shall provide annual FCOI reports to the PHS awarding sponsor for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS awarding sponsor.

#### **IX. Disclosure to the Public**

Within five business days of a request, the university will provide a written disclosure to any requestor of disclosed SFIs held by senior or key personnel at the time of the request that the university has determined are related to PHS-funded research and are FCOIs. This disclosure will include the following information:

- Investigator's name, title, and role with respect to the research project
- Name of the entity in which the SFI is held
- Nature of the SFI
- Approximate dollar value of the SFI or a statement that a value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. The value may be stated within the following ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; \$20,000–\$100,000 by increments of \$20,000; \$100,000 and above by increments of \$50,000.

#### **X. Investigator Training**

Each investigator doing externally sponsored research is required to complete training on this Financial Conflict of Interest in Sponsored Research Policy and the applicable federal regulations before engaging in any sponsored research. RAO is responsible for providing this training. The training must also be provided to all investigators at least once every four years. Training must be provided immediately for any investigator new to the university, for any investigator found to be out of compliance with this policy or the applicable federal regulations, and for all investigators at any time that the university changes this policy.

**APPROVED:** 2 Jun 2014 [Revised 5 Apr 2021]



**PRIOR VERSION:** 25 Aug 2003 (Sponsored Research Activity Conflict of Interest Policy)

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

**POLICY OWNER:** Academic Vice President

**RESPONSIBLE OFFICE:** Research and Graduate Studies

**RELATED POLICIES:**

- [Church Educational System Honor Code](#)
- [Conflict of Interest and Conflict of Time Commitment Policy](#)
- [Research Misconduct Policy](#)
- [Supplemental Research Compensation for Externally Sponsored Work Policy](#)