

Research Compliance	Effective Date: 06/01/2020
OVPR Policies and Procedures	Revised:

**OVPR-02: Policy for Conflicts of Interest in Research and Technology Transfer**

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## **PURPOSE**

Baylor University is committed to basic values of transparency, integrity of scholarship, and independence as it pursues its mission to create, preserve, and disseminate knowledge through teaching, research, and public service. Accordingly, the University allows and encourages research, entrepreneurship, and cooperative activities with agencies, companies, and organizations external to the University, as well as other outside interests that enhance the missions of the University. All faculty and staff members are to act with honesty, integrity, and in the best interest of the University when performing their duties, and to abide by the highest standards of research, educational, professional, and fiscal conduct.

This policy is intended to: (i) educate employees about situations that generate conflicts; (ii) provide means for employees and the University to manage real or apparent conflicts; and (iii) promote the best interests of the University. Principles and procedures, outlined in this policy, assure that University research personnel will report external commitments and financial interests in a timely manner and real and apparent conflicts will be identified and responsibly managed.

## **POLICY STATEMENT**

The University will exercise care in accepting or entering into sponsored agreements, technology transfer agreements, and human subjects and animal research in which the investigators involved (or their family members) have financial or management interests that create conflicts. Such agreements will not be accepted if the conflicts:

- can be expected, with reasonable certainty, to create the opportunity to compromise the integrity or objectivity of those investigations, or undermine the employees' obligations to the University, sponsor, research subjects or students, and
- cannot be satisfactorily managed with appropriate administrative oversight.

To be eligible to receive grants, contracts, or cooperative agreements from external agencies and entities (e.g., federal sponsors, industry sponsors, etc.) that follow PHS, NSF, or other COI disclosure and review requirements, the University has policies and procedures for:

- The disclosure of certain related outside interests held by individuals or their family members
- The institutional review of the relevance of such outside interests to the design, conduct, or reporting of the research
- The management or elimination of those interests deemed to constitute COIs
- Reporting COIs to the sponsoring or gifting agency or entity
- Making information about managed COIs available to the public in the case of PHS funded research and research funded by entities following PHS FCOI regulations

While the University has special requirements for research projects proposed for or receiving funding from PHS and entities explicitly requiring compliance with PHS FCOI regulations, it applies a common set of procedural requirements to all other sponsored research, technology transfer agreements, or human or animal subject projects.

This Policy represents one aspect of the University's commitment to address and manage conflicts of interest and operates in addition to other University policies related to conflicts of interest and conflicts of commitment.

## **APPLICABILITY**

This policy applies to all Baylor University research personnel responsible for the design, conduct, or reporting of research and who are currently participating in, or submitting proposals to participate in, research funded by a) federal, state and/or local government agencies, b) commercial sponsors, and c) other organizations funding research at or on behalf of Baylor University. Principal Investigators of non-funded non-exempt research involving human or animal subjects also fall under this policy. For the purpose of this policy, "research personnel" refers to the following: tenure/tenure track faculty, research faculty, research associates, post-doctoral research fellows, and others identified at the time of proposal submission as having potential for a conflict of interest related to a research activity that involves their University responsibilities. This includes all full-time, part-time, regular FTE, temporary, and contract research personnel and others acting on Baylor's behalf in the performance of University-related research.

## **RESPONSIBILITY**

The Vice Provost for Research is responsible for overseeing the implementation of this Policy. Day-to-day responsibility for such implementation is delegated through the Vice Provost for Research to the Assistant Vice Provost for Research, Research Compliance.

## **REGULATIONS AND RELATED DOCUMENTS**

### Applicable Law

42 CFR Part 50, subpart F – Promoting Objectivity in Research for Which PHS Funding is Sought

45 CFR Part 94 – Responsible Prospective Contractors

### University Policies and Documents

BU-PP 023 Standards of Personal Conduct

BU-PP 024 Code of Ethics

BU-PP 800 Conflict of Interest Policy

### Forms and Tools

University Dual Interest Disclosure Form

Research Conflict of Interest Disclosure Form

## **DEFINITIONS**

A **conflict of interest (COI) in research** exists when the University determines that a financial or management interest could directly and significantly affect, or be affected by, the design, conduct, or reporting of the research.

A **COI in a technology transfer agreement** exists when a University employee (also referred to as an "individual" for purposes of this policy) has an ownership interest or a management interest in an entity proposing to option, license, or be assigned University intellectual property (IP).

**Conflict of Interest Review Committee (COIRC)** is a Baylor University committee designated under BU-PP 800 Conflict of Interest Policy to review actual or perceived conflicts of interest brought forth by Internal Audit or the Office of the Vice Provost for Research, determine whether actual or perceived conflicts exist, and develop management plans for COIs.

**Disclosure** means the reporting of an outside interest, activity, or relationship related to an individual's University responsibilities. The information disclosed includes, but is not limited to, "significant financial interests" as defined in the Public Health Service (PHS) Financial Conflict of Interest (FCOI) Regulation.

**Family member** means the investigator's spouse, domestic partner, and dependents.

**Institutional Conflict of Interest (ICOI)** means investments and relationships developed by Baylor University leadership or administrative units. These situations are considered in cases that are reviewed by the COI Review Committees and incorporated into management conditions as needed.

**Institutional responsibilities** mean an individual's professional responsibilities on behalf of the University, such as research, teaching, conduct of sponsored projects, professional practice, and service on institutional committees.

**Intellectual Property** means inventions, discoveries, processes, methods, compositions, formulae, procedures, protocols, techniques, results of experimentation and testing, information, data, designs, utility models, know how, whether any of the foregoing are patentable or not, patents (whether registered or unregistered), works of authorship, mask works, database rights, copyrights (whether registered or unregistered), moral rights, trademarks, service marks and trade names (whether registered or unregistered), logos, brands and domain names, goodwill, trade secrets, rights in confidential information, rights of publicity, and any other intellectual or industrial property rights of any nature including, without limitation, all applications, registrations, renewals, reissues, extensions, divisions, assignments and continuations of, or licenses, waivers or settlements in connection with, any of the foregoing, together with all similar and analogous rights throughout the world.

An **investigator** means the principal investigator (PI), participating investigators, coinvestigators, and senior/key personnel identified as such by the institution in a proposal or report to the sponsor, and any other investigator who is identified by the PI as responsible for (i.e., not simply working on) the design, conduct, or reporting of a research project. "**Conduct of research**" means the supervision or management of a study's execution. This is typically done by the principal investigator (PI) and co-investigators, but also may be performed by postdoctoral fellows and graduate students who have significant supervisory roles for junior researchers or technicians who are part of the study. For studies involving human subjects, this includes anyone who is responsible for explaining the study, risk-benefit, and/or alternatives to potential participants, is listed on the 1572 or device agreement, and/or must complete a sponsor's conflict of interest disclosure form. "**Design of research**" means the planning of the scientific strategy to test a research proposal. "**Reporting of research**" means the authorship of: publications to journals or otherwise, reports to the research sponsor, or presentation at conferences or scientific meetings related to the research.

**Management or manage** means taking action on financial or management activities to address an actual, potential, or perceived COI, to ensure, to the extent possible, that the design, conduct, and reporting of the research will be free from bias and that the academic success of trainees and junior faculty is maximized.

Examples of management strategies include, but are not limited to:

- Public disclosure of the COI
- Monitoring of the research or research management by independent reviewers
- Assignment of ombudspersons for students/trainees/junior faculty
- Modification of the research plan
- Disqualification from participation in all or in a portion of the research
- Divestiture of the interest
- Severance of the relationship that creates the COI

A **management interest** means holding a position (e.g., officer, trustee, director) in an outside organization that carries a fiduciary (e.g., legal or ethical) obligation to act in the best interest of the outside organization.

An **outside interest, activity, or relationship** (referred to as an “outside interest” for purposes of this policy) with an outside organization that relates to an individual’s institutional responsibilities, and that applies to the individual and his or her family members, may consist of:

- Paid or unpaid activities for, and relationships with, an outside organization for which the individual utilizes the same skills and knowledge as for his or her institutional responsibilities
- Membership in professional societies does not constitute a relationship in this context; however, leadership, paid travel, and paid activity on behalf of the society do represent an outside interest
- Ownership in a company or business, including equity, stock, or stock options (exclusive of 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)
- Intellectual property rights or interests, including license and option agreements made through Technology Commercialization and Industry Engagement (TCIE) for technology developed at the University, and non-University patents, copyrights, and royalties
- Compensation, loans (other than student loans), other payment(s), or items of value received from an outside organization for an activity related to the individual’s institutional responsibilities
- Travel expenses that are reimbursed to an individual or paid directly by an outside organization (disclosure required by either PHS regulations or other COI policy)

A **principal investigator** (PI), for the purposes of this policy, is the person so designated on records including, but not limited to, proposal submissions, Proposal Award Notice, unfunded agreement (e.g., Material Transfer Agreements), Institutional Review Board (IRB) research proposal, subcontract agreement, Institutional Animal Care and Use Committee (IACUC) proposal, internally sponsored project proposal, etc., as the investigator having the responsibility, including the necessary background and training in scientific and administrative oversight, to conduct and manage the research or sponsored project.

An outside interest is **related** to an individual’s institutional responsibilities when it relies upon the same expertise that an individual uses to carry out his or her institutional responsibilities or when it has the

potential to influence the duties that the University considers part of the work it pays or otherwise engages the individual to do.

An entity is **related** to a sponsored research agreement or technology transfer agreement if:

- the entity is sponsoring the research
- the entity is the supplier of equipment, materials, or services for the project or agreement
- the entity is a business commercializing a product that the research is intended to evaluate or further develop
- the entity's financial interests would reasonably appear to be affected by the research or technology transfer agreement

A **significant financial interest (SFI)** exists when a financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's family members) reasonably appears to be related to the investigator's institutional responsibilities:

- Remuneration received from any publicly traded entity in the previous 12 months and the value of any equity interest in the entity that, when aggregated, exceeds \$5,000 (lesser amounts must still be reported to the University)
- Remuneration received from any non-publicly traded entity (including non-profit organizations) in the previous 12 months that, when aggregated, exceeds \$5,000 (lesser amounts must still be reported to the University)
- Any equity interest in a non-publicly traded entity
- Any income received from intellectual property (IP) rights and interests (e.g., patents, copyrights, and royalties from such rights)
- Certain reimbursed or sponsored travel paid to or on behalf of the investigator, except that paid for by a federal, state, or local government agency, a domestic nonprofit institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education

Exceptions 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
- Income from service on advisory committees or review panels, and/or 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
  - a research institute that is affiliated with an institution of higher education
- Income from sponsored projects or agreements processed through and paid by the University

## **DISCLOSURE RESPONSIBILITIES & REQUIREMENTS**

All individuals meeting the definition of research personnel as defined in this policy must certify their knowledge of and compliance with this policy by completing a Research Conflict of Interest Disclosure Form at least annually. Certifications and associated disclosures must also be actively updated:

- At the time of submission for new funding.
- If unrelated to proposals for funding, at the time of submission of non-exempt human or animal protocols if conflicts of interest related to the research exist (Principal Investigators only).
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

All potential conflicts of interests of research personnel and their immediate family members must be disclosed. An annual disclosure must be submitted even if the research personnel has no outside interests.

Disclosure requirements apply for the duration of the research. Research personnel must disclose any of the following, among other things, that occur during the research:

- A new SFI that would reasonably appear to be affected by the research;
- A new SFI in an entity whose financial interested would reasonably appear to be affected by the research;
- A new situation that could call into question the investigator's professional commitments in undertaking the research; or
- A significant change to a previously reported disclosure.

Updated disclosures must be submitted within 30 days after the disclosable situation arises.

All newly-added research personnel must submit disclosures within 30 days after beginning work on the research. The principal investigator is responsible for informing newly-added research personnel of this requirement and ensuring that they submit disclosure forms. Newly-added research personnel are subject to the ongoing disclosure requirements.

## **DISCLOSING FOREIGN INTERESTS**

All research personnel are required to completely and accurately disclose all external financial interests and support, affiliations, activities, and relationships with any foreign entities in accordance with this policy. This includes, but is not limited to:

- Collaborations with investigators at a foreign site anticipated to result in co-authorship;
- Use of facilities or instrumentation at a foreign site;
- Receipt of financial support or resources from a foreign entity;
- Faculty or research appointments at a foreign entity (even if uncompensated);
- Directorships of labs, centers, or programs at a foreign entity (even if uncompensated);
- Any payment, reimbursement, travel support, or other compensation, of any amount, that you have received or will receive, from a foreign entity;
- Any significant scientific element or segment of a project conducted at or by a foreign entity

## **DISCLOSURE REVIEW & MANAGEMENT**

BU-PP 800 Conflict of Interest Policy authorizes a conflict of interest review committee (COIRC) to review individual disclosures and disclosures: (1) submitted through the annual disclosure process; or (2) referred from OVPR. A research project (regardless of funding source) may not commence until the review of the disclosure is finalized, and the research is approved to commence. For disclosures made during an active research project, the research may continue unless otherwise directed.

### Initial Screening

Research Compliance is responsible for initial screening of research disclosures. Research Compliance will refer all disclosure forms that indicate a potential COI to the COIRC through Internal Audit, unless otherwise specified in any screening guidelines provided by the COIRC. If the referred disclosure was submitted by research personnel other than the principal investigator, Research Compliance will notify the PI of the general nature of the referral without divulging the particulars of the disclosed information.

### Determination and Management of COIs

The COIRC will regularly review and assess referred disclosures per its policies and procedures. If the COIRC determines that a COI exists and is related to the research, it will decide how the COI should be managed so the research may proceed if at all possible. The COIRC may impose conditions or restrictions to control, reduce, or eliminate the possibility that a COI will affect the objectivity of the research. Examples of COI management options included, but are not limited to:

- Public disclosure of the COI;
- Monitoring of the research by independent reviewers;
- Modification of the research plan;
- Divestiture of the conflicting interests or placement in a blind trust;
- Escrow of an equity interest until certain triggering conditions are met;
- Prohibition on the research personnel's involvement in contract negotiations for the research;
- Severance of the research personnel's relationships that create the conflict; and/or
- Disqualification of the research personnel from participation in all or part of the research.

All COIs must be managed to the satisfaction of the COIRC for the research to proceed and for funding, if any, to be accepted. This applies to all research that is subject to the disclosure requirements of this policy, regardless of whether the research is funded. No COIs may be waived. If the COI cannot be managed, the research personnel must withdraw from the research and Baylor University may need to decline acceptance of the award, terminate a sponsored agreement, or disapprove the research.

COIRC determinations and management plans will be provided in writing according to its policies and procedures.

## **APPEAL**

Appeals of the COIRC determinations may be made according to its policies and procedures. No research expenditures will be made pending appeal.



## **SUBRECIPIENT REQUIREMENTS**

When the University carries out PHS or NSF funded grants or cooperative agreements through subawards, contracts, or collaborators, it must assure that the FCOIs of all subrecipients are reviewed and eliminated or managed properly. During the proposal stage and during the negotiation of a subaward, all subrecipients/potential subrecipients of PHS/NSF funding will be required to certify the following in writing via a Letter of Compliance:

- The subrecipient Institution has a policy in place to review and manage FCOIs that meets regulatory requirements.
- The subrecipient's policy applies to the subawarded portion of the research project, and
- The subrecipient must agree that the identification of and management plan of any FCOI identified will be submitted to the awardee Institution for required reporting purposes.

If the subrecipient Institution does not have a compliant FCOI program in place, the agreement must indicate that the subrecipient will follow Baylor University's policy, including the pre-award and annual submission of a Certification (and disclosure, if applicable) to OVPR within 30 days of the submission of the proposal.

## **TRAINING**

Research personnel proposing or conducting research sponsored by an agency, organization, or other entity that follows the PHS FCOI regulations must complete University-provided training prior to engaging in any PHS funded award and at least every four (4) years thereafter. Such training will cover the University's policy, the investigator's disclosure responsibilities, and the applicable federal regulation. Investigators conducting research following PHS FCOI regulations will also be instructed to complete training if:

- The University revises its FCOI policy that affects requirements of investigators
- An investigator is new to the University
- An investigator is not in compliance with the policy or management plan.

## **REPORTING SUSPECTED CONFLICTS OF OTHERS**

Members of the University community who become aware of any undocumented conflict of interest subject to this policy, not just their own, should report it through the University's Ethics Line (EthicsPoint). Supervisors who become aware of undisclosed conflicts of interest subject to this policy should instruct the personnel to immediately disclose. Any failure to disclose in a timely fashion should be reported to OVPR - Research Compliance.

## **REPORTING COIs TO RESEARCH SPONSORS**

Research Compliance will work to ensure that Baylor University complies with a research sponsor's requirements for reporting COIs. To the extent an SFI or management interest involves sponsored research covered by the PHS FCOI Regulation, the University will report, as appropriate, prior to the expenditure of any funds, the existence of a FCOI and assure that the COI has been managed in accordance with this policy and to protect the research from bias. For SFIs or management interests identified subsequent to the initial PHS award or for an investigator who is newly participating in a PHS project, the University will report all elements of the COI noted above to the PHS agency and assure that the COI has been managed in accordance with this Policy within 60 days of identification. NSF only requires reporting of COIs that have not been managed prior to expenditure of award funds, and the keep the agency informed if a COI cannot be managed successfully.

## **CONFIDENTIALITY OF DISCLOSURES**

All individuals involved in handling a disclosure will exercise care at all times to protect the confidentiality of the disclosed information and the privacy of the individual discloser, to the extent permitted by law. OVPR shall maintain the records pertaining to each research disclosure in strict confidence, to the extent permitted by applicable law and regulation. Access to such records will be limited to the research personnel disclosing, the principal investigator of the research if different from the research personnel disclosing, and representatives from OVPR, the Department's Chair and Dean's Office, University Compliance & Risk Services, the Office of the Provost, and General Counsel, Human Resources and others who have a legal right or business need to review the records.

## **PUBLIC INQUIRIES REGARDING COIs RELATED TO PHS FUNDED RESEARCH**

The University will make available, within five (5) days of a written request, the identified FCOIs in PHS awards held by senior/key investigators in accordance with regulatory requirements. Written requests may be made directly to Research Compliance in OVPR or through [research@baylor.edu](mailto:research@baylor.edu). The information provided upon request will include, at a minimum, the following:

1. Investigator's name
2. Investigator's title and role with respect to the research project
3. Name of the entity in which the SFI is held
4. Nature of the SFI
5. Approximate dollar value of the SFI (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 whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value

## **RECORD RETENTION**

Research COI disclosures, and all actions taken by the University with respect to these interests, will be maintained for at least three years from the termination of the grant, contract, or agreement, unless other state or federal law or University policy requires a longer retention period.

## **NONCOMPLIANCE**

Noncompliance with this policy can occur through the following actions: (1) failure to disclose required information; and/or (2) failure to follow a COI management plan. OVPR will review allegations of violations of this policy and will make recommendations regarding the imposition of disciplinary actions, if any, to the Provost.

The University may conduct retrospective reviews for PHS funded projects within 120 days of a determination that SFIs have not been disclosed appropriately or when a FCOI is not identified or managed in a timely manner.

Flagrant or repeated noncompliance with policy, procedures, or management requirements after notice to an individual is handled through University disciplinary procedures. Failure by an investigator to comply with this policy for reporting a related outside interest which has been determined by the University to have biased the

design, conduct, or reporting of PHS funded research will be promptly reported by the University to PHS, including the corrective action taken or to be taken.

In any case in which the PHS determines that PHS funded clinical research that evaluates the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator who did not disclose, or have under management, a conflicted interest, the University will require the investigator to disclose the COI in each public presentation of the results and to request an addendum to previously published presentations.

### **REPORTING NONCOMPLIANCE**

Anyone who suspect that an individual classified as research personnel has not complied with this policy may bring the matter to the attention of the principal investigator, if different from the PI. If this is not feasible or does not resolve the matter, individuals should report their concerns to OVPR or through EthicsPoint. The COIRC may likewise report its own concerns about a research personnel's compliance.

Baylor encourages good faith reporting of COI concerns. Baylor prohibits retaliation against a person who reports under this policy in good faith. Retaliation for good faith reporting may result in disciplinary action, up to and including dismissal. Similarly, Baylor does not tolerate bad faith reporting. Reporting an individual in bad faith may result in disciplinary action, up to and including dismissal.

### **GOVERNANCE**

This policy will be reviewed and updated, as necessary, on a regular basis by the Office of the Vice Provost for Research. If a federal agency issues rules governing COIs in sponsored research, those rules will govern where applicable. Proposals submitted for funding to PHS or NSF are subject to specific legal requirements concerning FCOIs. This policy is intended to comply with those requirements. Any changes in federal requirements will supersede the relevant provisions of this policy.

### **REVISIONS FROM PREVIOUS VERSION**

N/A