

THE UNIVERSITY OF ALABAMA IN HUNTSVILLE
RESEARCH CONFLICTS OF INTEREST AND CONFLICTS OF COMMITMENT POLICY
INTERIM

Number 07.01.03

Division Office of the Vice President for Research and Economic Development

Date Effective April 19, 2023

Purpose This Policy sets forth the expectation that any individual, regardless of title, position, or employment, who is responsible for the design, conduct, or reporting of proposed or active research (Investigator/Responsible Personnel), conduct their activities for The University of Alabama in Huntsville (UAH or University) in ways that promote and maintain public trust, including acknowledging and appropriately managing Conflicts of Interest (COI), including Financial Conflicts of Interest (FCOI) and Conflicts of Commitment (COC).

This Policy makes a reasonable effort to identify, review, and manage actual or apparent COI and COC of Investigators/Responsible Personnel that engage in research on behalf of UAH.

This Policy ensures that the design, conduct, and reporting of research, including research funded under contracts, grants or cooperative agreements, will be objective and free from bias resulting from FCOI and provides the foundation for the Office of the Vice President for Research and Economic Development (OVPRED) to certify that UAH research grants and contracts proposals submitted on behalf of research grant or contract eligible employees to external funding agencies are submitted after full disclosure and consideration of potential matters relating to FCOI.

This Policy creates and sets forth the duties of the Research Conflicts of Interest Review Board (RCIRB).

Scope This Policy applies to all Investigators/Responsible Personnel, whether faculty, staff, or students, who engage in research on behalf of UAH, as well as their Unit Heads as that term is defined in this Policy.

Definitions

Approved Management Plan – A Management Plan, as defined in this Policy, that has been approved by the Vice President of Research and Economic Development.

Conflicts of Commitment (COC)- A circumstance in which an Investigator/Responsible Personnel's engagement in External Activity or Professional Public Service Activities compromises the ability to carry out their

primary obligations and commitments to UAH. Because conflicts of commitment generally arise from allocation of time, the primary commitment of employees' time should be toward their primary Institutional Responsibilities.

Conflicts of Interest (COI) – A circumstance in which an Investigator/Responsible Personnel's financial, professional, familial or personal relationships or interests affect, or have the appearance of affecting, judgment in exercising a duty or responsibility owed to UAH. Financial Conflict of Interest related to the design, conduct, or reporting of research is defined separately below.

Dependent – Any individual, regardless of that individual's legal residence or domicile, who receives 50% or more of the individual's support from an Investigator/Responsible Personnel or the Investigator/Responsible Personnel's spouse or who resided with the Investigator/Responsible Personnel for more than 180 days during a calendar year.

Entity – A company, association, organization, institution, or any other type of entity with a separate legal identity, including a for-profit, not-for-profit, or an organization of higher education. For purposes of reporting Financial Interests under this Policy, it also includes an individual.

External Activity – Activity that draws upon the knowledge, skill, or abilities that Investigators/Responsible Personnel use to fulfill Institutional Responsibilities at UAH and that are performed for an entity other than UAH, whether foreign or domestic, and whether or not for compensation. Examples of External Activity include, but are not limited to, the following:

- external employment;
- consulting;
- lecturing, presenting, performing, or speaking;
- establishing and/or supporting a start-up company;
- serving as an expert witness;
- participating in a board of directors or similar governing body;
- participating in a scientific advisory board; or
- appointments or other commitments to other academic institutions or research institutes (if permitted).

Familial relationship – One's spouse or domestic partner, parents, grandparents, children (biological or adopted), grandchildren, great grandchildren, brothers and sisters (whole or half-blood), spouse of a sibling/child/grandchild/great grandchild or corresponding in-law or "step" relationships as well as any other members of one's household. Note: this list of relationships is not to be considered an exhaustive list; other close, personal relationships between two individuals could be considered on a case-by-case basis to be subject to this Policy.

Financial Conflict of Interest (FCOI) – A reasonable determination that a Significant Financial Interest of an Investigator/Responsible Personnel is related to and could significantly and directly affect the design, conduct, or reporting of research or a sponsored program.

Financial Interest(s) – Anything of monetary value, whether or not the value is readily ascertainable, accepted or owned by Investigators/Responsible Personnel, their spouses, or their dependents, not held in an investment vehicle such as a mutual fund or retirement account in which the owner does not directly control investment decisions. Examples of Financial Interests include, but are not limited to:

- remuneration for participation in External Activities (e.g., salary, consulting and other fees, gifts, honoraria, etc.);
- acquisition or ownership of (or an option to acquire or own) stock, shares, or other types of equity interests;
- income arising from stock, shares and other types of equity interests;
- income received from royalties (e.g., for sale by volume of products, textbooks, etc.);
- income received from commercialization of intellectual property (e.g., for licenses, options, or other revenue generating activity); or
- sponsored or reimbursed travel.

Institutional Responsibilities – All activities, duties, and responsibilities performed by an employee of UAH in the course of their employment or other relationship with UAH, including, but not limited to, scholarship, research, research consultation, teaching, professional practice, administration, contracting or procurement responsibilities, or Professional Public Service Activities.

Investigator/Responsible Personnel – Any individual, regardless of title, position, or employment, who is responsible for the design, conduct, or reporting of proposed or active research.

Management Plan – A plan developed by the Unit Head with assistance from the Investigator/Responsible Personnel that outlines and implements measures that actively reduce, mitigate or eliminate an actual, potential or perceived COI, COC, or FCOI. This plan is considered a Management Plan when it is signed by the Unit Head and the Investigator/Responsible Personnel and uploaded to UAH's Electronic Research Administration System for review.

Personal relationship – Romantic or intimate relationship.

Professional Public Service Activities (PPSA) – Those activities specifically enumerated below for the groups specifically enumerated below, which are considered part of an Investigator/Responsible Personnel's Institutional Responsibilities, whether or not separately compensated:

- professional studies (e.g., attendance at scientific meetings);
- seminars, lectures, performances, presentations, or continuing education sessions;
- service on review panels (e.g., participation in manuscript review, grant/contract review, academic program review, etc.);
- service on advisory committees; or

- service on a Board of Directors or similar governing body

provided to:

- U.S. federal, state, or local government agencies;
- institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education, whether U.S. or abroad;
- nonprofit/philanthropic entities, professional societies, or professional associations, that are not affiliates of or affiliated with industry or other for profit entities;
- organizations accredited or approved by the appropriate independent boards or bodies governing oversight of continuing professional education activities; or
- civic groups.

Research Conflict of Interest Review Board (RCIRB) – The RCIRB is the UAH board whose main purpose is to review and make recommendations to the VPRED regarding Management Plans that address COI, COC, and FCOI including Investigator/Responsible Personnel-disclosed Financial Interests meeting the criteria (i.e., thresholds and types) for Significant Financial Interests for the current and past calendar year. The RCIRB has other responsibilities as set forth in this Policy.

Research – A systematic investigation or inquiry adding to the general body or application of knowledge. For purposes of this Policy, research also includes any activity for which funding is sought and/or received through a grant or cooperative agreement, regardless of funding source, such as a research grant, career development award, center grant, individual fellowship award, contract, infrastructure award (construction, renovation, equipment, etc.) institutional training grant, program project, or research resources award. The term also includes all work involving human subjects requiring Institutional Review Board approval.

Responsible for the design, conduct, or reporting of research – A person who is responsible for the design, conduct, or reporting of research as follows:

- Design - the development of the strategy and means to test a research question or hypothesis.
- Conduct - 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 other project personnel, such as postdoctoral fellows, graduate students, or other junior researchers. 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 Form FDA-1572 or device agreement, and/or must complete a sponsor's conflict of interest form.

- Reporting - the authorship of publications or reports that describe the results of the study. Such reports may be made to the sponsor of the research or to academic or scientific meetings.

Significant Financial Interest (SFI) – Thresholds (i.e., types and amounts) of Financial Interests of Investigator/Responsible Personnel (or their spouse or dependents) that reasonably appear to be related to (or is in the same field of expertise as) the Investigator/Responsible Personnel's Institutional Responsibilities as set forth below.

- With regard to any publicly-traded entity, a Significant Financial Interest exists if the value of the Financial Interest received from the entity in the current or prior calendar year, 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 current or prior calendar year, when aggregated, exceeds \$5,000; or
 - when the Investigator (or the Investigator's spouse or dependents) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- With regard to intellectual property rights and interests (e.g., patents, copyrights), a Significant Financial Interest exists for any intellectual property licensed, optioned, or that has generated income/revenue.
- Significant Financial Interest does NOT include remuneration for Professional Public Service Activity with U.S. entities, textbook royalties, peer reviewed journal editorship activities for publishing companies, or other related items as determined by the Research Conflict of Interest Review Board in accordance with federal regulations.

Unit Head(s) – Applicable Dean, Chair, Director, Provost, Associate or Assistant Vice President, Vice President, or President, who has executive management responsibilities for supervising an employee.

Policy

This Policy supersedes any prior or current University policy addressing conflict of interest or commitment in research and other sponsored programs. This Policy is subject to all applicable laws, including, but not limited to: Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F - Promoting Objectivity in Research; Title 45 CFR Part 94 - Public Health Service (PHS) Responsible Prospective Contractors; National Science Foundation "Award and Administrative Guide" Chapter IV.A; Ethics Act of the State of Alabama – Chapter 25 of Title 36; Conflict of Interest Statutes – 18 U.S.C §§ 202-209, as amended.

Violation of this Policy constitutes grounds for disciplinary action up to and including termination of employment and/or referral for criminal prosecution.

Conflicts of Interest and Commitment Disclosure and Management

Investigators/Responsible Personnel have an ongoing responsibility to fully disclose any and all financial, professional, familial or personal relationships and activities that have the potential to create an actual or apparent COI with respect to UAH research activities.

Investigators/Responsible Personnel must annually complete a Conflicts of Interest and Commitment disclosure form online in UAH's Electronic Research Administration System software program (Kuali).

New Investigators/Responsible Personnel are required to complete the Conflicts of Interest and Commitment disclosure form within thirty (30) days of hire.

When Investigators/Responsible Personnel become aware of any significant change in circumstances or with respect to a Financial Interest, they must update their Conflicts of Interest and Commitment disclosure form.

An identified COI or COC may require development of a Management Plan as set forth in the Procedures, which may include, but is not limited to, reducing or eliminating the COI or COC. All Management Plans must be reviewed by the RCIRB and approved by the VPRED at which time the plan becomes an Approved Management Plan.

If a Unit Head becomes aware of a COI or COC that an Investigator/Responsible Personnel has not disclosed, the Unit Head shall discuss the situation with that individual and require that a disclosure immediately be made or updated via the Conflicts of Interest and Commitment disclosure form.

Financial Conflict of Interest Disclosure and Management

All Investigators/Responsible Personnel must annually complete a FCOI certification. This requirement is in addition to the Conflicts of Interest and Commitment disclosure. In addition, this certification must be completed by Investigator/Responsible Personnel prior to submitting a proposal for external funding.

FCOI Certification is completed in Kuali as part of the Conflicts of Interest and Commitment online disclosure form.

FCOI certification must be updated within thirty (30) days of discovering or acquiring a new Significant Financial Interest.

Identification of a FCOI requires development and implementation of a Management Plan as set forth in the Procedures, which may include, but is not limited to, reducing or eliminating the FCOI. All FCOI Management Plans must be reviewed by the RCIRB and approved by the VPRED at which time they become an Approved Management Plan.

If a Unit Head becomes aware of a FCOI that an Investigator/Responsible Personnel has not disclosed, the Unit Head shall require that a disclosure

immediately be made or updated via the Conflict of Interest and Commitment disclosure form.

Whenever a FCOI is not identified or managed in a timely manner due to nondisclosure by the Investigator/Responsible Personnel, lack of institutional review or management of the FCOI, or failure by the Investigator/Responsible Personnel to comply with an Approved Management Plan, the RCIRB must conduct a retrospective non-compliance review and recommend corrective actions as indicated by federal regulations.

Conflicts of Interest and Commitment Training

All Investigators/Responsible Personnel must complete training during the onboarding process and at least once every year after hire.

External Activity and PPSA

Investigators/Responsible Personnel may not engage in any External Activity and certain PPSA (as set forth below) prior to disclosing and receiving approval at least two (2) weeks before engaging in same. Investigators/Responsible Personnel seeking approval must complete the online [Request for Permission to Engage in External Activity](#) as set forth in the Procedures.

PPSA, whether or not compensated, does not require completion of a Request for Permission to Engage in External Activity *unless*:

- a. It requires international travel paid for or reimbursed through a UAH account, any UAH education abroad, or undertaken for conducting UAH business or fulfilling Institutional Responsibilities; or
- b. It involves Investigator/Responsible Personnel who
 - i. have a resulting Financial Interest (which includes sponsored or reimbursed travel) exceeding \$5,000 acquired from any one entity in the previous 12 months for their participation in PPSA; or

Exception: Investigators/Responsible Personnel do not have to submit a form for such Financial Interest if the Financial Interest is acquired in return for providing seminars, lectures, presentations, or service on advisory committees or review panels for U.S. federal, state, or local government agencies, U.S. institutions of higher education as defined at 20 U.S.C. 1001(a), U.S. academic teaching hospitals, U.S. medical centers, or U.S. research institutes that are affiliated with a U.S. institution of higher education.

- ii. receive any Financial Interest in any amount from a foreign person or entity (governmental, non-profit, for profit, etc.).

Investigators/Responsible Personnel must still properly account for time spent on PPSA, whether disclosed or not, in accordance with UAH policies, including those regarding leave time.

The Unit Head is required to handle review of External Activity and PPSA in accordance with the Procedures.

Contracts and Purchases

Investigator/Responsible Personnel on research projects or sponsored programs at UAH may not participate in the selection, award, or administration of a contract (i.e., vendor transaction or subaward) supported by a federal award if that person has a real or apparent COI, and may not solicit or accept gratuities, favors, or anything of monetary value, from contractors or parties to subcontracts.

When Investigators/Responsible Personnel, Unit Head, or Unit Head's designee becomes aware of an instance where an Investigator/Responsible Personnel (or someone with whom an employee has a financial, familial or personal relationship) has a Financial Interest, whether existing or proposed, related to a specific procurement transaction or set of transactions with which the employee has some involvement in their official capacity as an employee of UAH, the Unit Head (or designee) must consult with Business Services prior to any final action on the purchase or contract.

Gifts, Gratuities, Benefits, Services, or Awards, etc.

Solicitation or acceptance of personal gifts, food/beverages, services, gratuities, or other things of value is prohibited if such solicitation or acceptance influences, or has the appearance of influencing, education, research, purchasing, or other official business decisions.

If Investigators/Responsible Personnel are concerned that a personal gift, gratuity, benefit, service, or award, etc. may be perceived as unethical, that employee should consult with the Unit Head. It is the duty of the Unit Head to oversee and manage situations where even the perception of impropriety may occur.

In analyzing this situation, the Unit Head should determine whether the proposed gift, gratuity, benefit, service, or award:

- a. Serves a legitimate University business purpose and provides a net benefit to UAH;
- b. Meets customary industry practices and conventions;
- c. Puts the faculty or staff member in a questionable ethical position; and
- d. Its acceptance is otherwise allowed by this Policy and all other University policies as well as the Alabama Ethics Law.

Research Conflict of Interest Review Board

The OVPRED will appoint the RCIRB, which will be composed of fulltime employees and chaired by the Assistant VP for Contracts and Grants (AVPCG).

The appointed members of the board shall serve three-year, staggered terms. A member of the University's Office of Counsel will serve as a liaison (non-voting) member.

The RCIRB serves as an advisory board for identified COI, COC, and FCOI. The RCIRB shall:

- a. Review Management Plans outlining and implementing measures to actively reduce, mitigate or eliminate an apparent, potential, or perceived COI, COC, or FCOI by Investigator/Responsible Personnel and make a recommendation to the VPRED. The VPRED may accept the recommendations of the RCIRB or return the Management Plan to the RCIRB with stated concerns. The VPRED is responsible for granting final approval of the Management Plan at which time it becomes an Approved Management Plan.
- b. Review amendments to an Approved Management Plan and, if necessary, make recommendations on a different course of action to be taken in the management, reduction, or elimination of the COI, COC, or FCOI.
- c. Conduct retroactive non-compliance reviews and recommend corrective actions.
- d. Provide assistance in the implementation of the Conflict of Interest Financial Disclosure in Research and other Sponsored Programs Policy.
- e. Maintain an ongoing awareness of procedures, practices, and standards with regard to COI, COC, and FCOI with a view to assuring consistency with the terms of this Policy.
- f. Ensure that a proper balance is maintained between confidentiality and RCIRB operations and standards.
- g. Disclose any potential COI posed by serving on the RCIRB. If the AVPCG has any reservations about proceeding with the conflict disclosed, the VPRED will make a final decision on abstention from participation.
- h. Oversee the ongoing review of all Approved Management Plans to ensure compliance with this Policy

Failure to Comply with this Policy

Failure to file a complete and truthful disclosure as required by this Policy, or to comply with the conditions or restrictions imposed in the resolution, management, or elimination of interests required to be disclosed, constitutes a violation of University policy and may violate state and/or federal law. In such cases, the Investigator/Responsible Personnel will be subject to appropriate sanctions consistent with University policies relating to faculty, staff, or other applicable disciplinary policies. In addition, the University may suspend an ongoing research project or technology transfer activity to prevent continued violation of this policy. In any case in which the Investigator/Responsible Personnel does not comply with any applicable conditions or restrictions imposed pursuant to this Policy, the University shall withdraw any affected applications for funding if the project cannot otherwise be completed without the services of the Investigator/Responsible Personnel.

Procedures

Conflicts of Interest and Commitment Disclosure and Management

- All Investigator/Responsible Personnel must annually complete the Conflicts of Interest and Commitment disclosure form online in the UAH's Electronic Research Administration System software program (Kuali).
- New Investigators/Responsible Personnel are required to complete the Conflicts of Interest and Commitment disclosure form within thirty (30) days of hire.
- If applicable, an approved/effective Permission to Engage in Outside Activities document must be completed in myUAH located under the Human Resources Table.
- All Investigator/Responsible Personnel must annotate for **each sponsored project** list, if there "is" or "is no" conflict with the outside engagement.
- The Assistant Vice President for Contracts and Grants (AVPCG) will review all COI/COC disclosure forms.
- If a COI/COC is identified, the AVPCG will notify the appropriate Unit Head.
- Within 30 days of being notified by the AVPCG of an identified COI/COC, Unit Heads, or their designee(s), are required to review any disclosed COI/COC in their areas and, if necessary, develop, with the assistance of the Investigator/Responsible Personnel, a Management Plan. The Unit Head may contact Assistant Vice President of Contracts and Grants (AVPCG) if guidance is needed in developing a Management Plan.
- The Unit Head must complete the Management Plan in myUAH under the Research Tab.
- The key elements of an Approved Management Plan for COI or COC include:
 1. Role and principal duties of the Investigator/Responsible Personnel in the research project and/or at UAH.
 2. Explanation as to why the funding cannot come through UAH.
 3. Conditions of the management plan, which may include documentation of disclosure, strategies to eliminate the conflictual elements of the activity, and/or prohibition of the activity.
 4. Confirmation of the Investigator/Responsible Personnel's agreement to the management plan.
 5. How the management plan will be monitored to ensure Investigator/ Responsible Personnel compliance, if necessary; and
 6. Other information as needed.

- Once the Management Plan has been completed, signed and submitted, the AVPCG will refer the plan and the Investigator/Responsible Personnel's disclosure materials to the Research Conflict of Interest Review Board (RCIRB) for further review.
- The RCIRB will make a recommendation to the Vice President of Research and Economic Development (VPRED).
- The VPRED may accept the recommendations of the RCIRB or return the Management Plan to the RCIRB with stated concerns.
- The VPRED shall be responsible for deciding whether to grant final approval of the Management Plan, at which time it will become an Approved Management Plan.
- This process will be followed for requested or necessary amendments to an Approved Management Plan.

Financial Conflict of Interest Disclosure and Management

- This certification must be completed by Investigator/Responsible Personnel annually and prior to submitting a proposal for external funding. Financial Conflict of Interest (FCOI) Certification is completed in Kuali as part of the Conflicts of Interest and Commitment online disclosure form.
- The AVPCG will review all FCOI Certifications and, if a possible FCOI is identified, the AVPCG will notify the appropriate Unit Head.
- Within 30 days of being notified by the AVPCG of a FCOI, the Unit Head is required to develop, with the assistance of the Investigator/Responsible Personnel, a Management Plan. The Unit Head may contact the AVPCG if guidance is needed in developing a Management Plan.
- The Unit Head must complete the Management Plan in Kuali Build under the OVPRED Tab.
- Once the Management Plan has been completed and signed, the AVPCG will refer the plan and the Investigator/Responsible Personnel's disclosure materials to the RCIRB.
- The RCIRB will make a recommendation to the VPRED.
- The VPRED may accept the recommendations of the RCIRB or return the Management Plan to the RCIRB with stated concerns.
- The VPRED shall be responsible for deciding whether to grant final approval of the Management Plan, at which time it will become an Approved Management Plan.
- This process will be followed for requested or necessary amendments to an Approved Management Plan.
- The key elements of an Approved Management Plan for FCOI include:

1. Role and principal duties of the conflicted Investigator/Responsible Personnel in the research project.
2. Conditions of the management plan.
3. How the management plan is designed to safeguard objectivity in the research project.
4. Confirmation of the Investigator/Responsible Personnel's agreement to the management plan.
5. How the management plan will be monitored to ensure Investigator/ Responsible Personnel compliance; and
6. Other information as needed.

Annual Training for COI, COC, and FCOI

The training courses are administered through the CITI Program, which is accessible via [myUAH](#). Please [click here](#) for course enrollment instructions.

External Activity and Professional Public Service Activities (PPSA)

- A copy of the Request for Permission to Engage in External Activity will be completed in [MyUAH](#) located under the Human Resources Tab and submitted to the Unit Head for review/approval. The authority for approval to engage in External Activity rests with the Investigator/Responsible Personnel's Unit Head.
- In considering whether to grant the Request for Permission to Engage in External Activity, the Unit Head must:
 1. Ensure adequate controls and monitoring procedures are in place to review and approve External Activity, such that the External Activity:
 - does not interfere, or appear to interfere, with the Investigator/Responsible Personnel's primary obligations to UAH so as to constitute a COC;
 - is compatible with the interests of UAH as a public academic and research institution; and
 - does not violate federal and state laws and UAH policies related to the use of UAH resources or facilities.
 2. Ensure proper accounting of time away of Investigator/Responsible Personnel for External Activity and PPSA.
 3. Ensure use of UAH information and resources, including facilities, personnel, equipment, patents, copyrights, technology, and work product in approved External Activity, is contracted, and approved for in writing by UAH and reimbursement is made to UAH at fair market value for such use where the use exceeds thresholds allowed by law or policy.
 4. Ensure written financial arrangements among affected UAH organizations are in place for portions of Investigator/Responsible Personnel salaries attributable to shared appointments/ assignments/work projects performed for the federal government or an external entity.

Contracts and Purchases

When mandated by Board Rule 106 and Alabama Code § 41-16-82, Business Services will require the submission of a Vendor Disclosure statement.

<https://uasystem.edu/images/documents/departments/Vendor-Disclosure-Form.pdf>.

Gifts, Gratuities, Benefits, Services, or Awards, etc.

Any gift, gratuity, benefit, service, or award, etc. received by Investigator/Responsible Personnel as a result of their work for UAH should be reportable in the annual Conflicts of Interest and Commitment online disclosure.

Research Conflict of Interest Review Board (RCIRB)

- The VPRED will appoint a RCIRB chaired by the AVPCG.
- Initial appointments will be for 24 months.
- The RCIRB will consider the nature of the research, the magnitude of the interest and the degree to which the conflict is related to the research, the extent to which the interest could be directly and substantially affected by the research, and any conflict management strategies proposed or already in place. The RCIRB may recommend a revised management plan, which may involve elimination of the conflict prior to initiating the activity and notify the VPRED of its recommendation.
- The VPRED will review the recommendations of the RCIRB and make a final determination regarding the management plan. This final determination will be forwarded to the Investigator/Responsible Personnel and copied to the Unit Head. In the case of research involving human participants, a copy of the determination will be forwarded to the Institutional Review Board (IRB) as well.
- The investigator must agree in writing to accept the management plan prior to initiating the research.
- No individual who holds a significant financial interest in a project may participate in the review of its management strategy.
- RCIRB meetings are closed to the public and documentation/records are confidential personnel records.
- Any investigator may appeal the decision of the RCIRB regarding the Approved Management Plan to OVPRED
- Records of all disclosures made pursuant to this procedure, OVPRED Interim Policy 07.01.03, and of any action taken to resolve, manage, or eliminate any interest disclosed under this policy shall be retained for at least three years from the submission of the final expenditures report, in the case of grants or cooperative agreements; at least three years from the final payment, in the case of research contracts; or until the resolution of any sponsor agency action involving those records, whichever is longer.
- In the event the University discovers that a failure to comply with this policy has biased the design, conduct, or reporting of the research, the University's AVPCG will promptly notify the sponsor of the research and describe the corrective action(s) taken or to be taken, consistent with applicable law and/or policy.
- Institutional officials holding a significant financial interest in an externally sponsored research project may not participate in the solicitation, negotiation of terms and conditions, oversight of the research (unless named as a member of the research team), or management of any conflict of interest held by members of the research team.
- Any collaborator from another institution or organization who will share responsibility for the design, conduct, or reporting of research results must comply with the policies and

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procedures of his or her institution/organization relating to disclosure and review of any significant financial interest(s) held by that collaborator. Whether the collaborator's institution/organization has or lacks an established conflict of interest policy/procedure, that institution or organization must provide the University adequate assurances of its review of a significant financial interest as defined by this policy and its ability to manage, reduce, or eliminate such conflict consistent with this policy.

COI in Research Involving Human Participants

Special consideration will be given to conflicts of interest when the research involves human participants. In addition to the procedures outlined above, the conflict must also be disclosed on the Institutional Review Board application form. In these situations, the IRB will communicate with the AVPCG regarding the elimination, disclosure, and/or management of such conflicts.

Federal Agency Regulations

- Investigators conducting research funded by the Public Health Service, including the National Institutes of Health, or the National Science Foundation, as well as those conducting studies regulated by the Food and Drug Administration, should note that they are, in addition to The University of Alabama in Huntsville policy and procedure, subject to agency-specific conflict-of-interest regulations.
- In accordance with **42 CFR 50.604(a) Responsibilities of Institutions regarding Investigator financial conflicts of interest**: UAH must maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this subpart, and make such policy available via a publicly accessible Web site.

<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F/section-50.604>

- In accordance with 42 CFR 50.605 (a)(1)(i)-(iv), Management and reporting of financial conflicts of interest. Prior to UAH's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with § 50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F/section-50.605>

For access to the UAH COI/COC Management Plan Template [\(click here\)](#)

Review	Office of the Vice President for Research and Economic Development is responsible for the review of this Policy every five (5) years or whenever circumstances require.
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APPENDIX

Conflict of Interest/Conflict of Commitment (COI/C) Management Plan – Template

Employee's Name:	College/Center/Department/Office:
Date:	Oversight Manager/Supervisor:
Outside Entity/Entities and/or Relationship(s):	Plan Reviewer:

Note: The Oversight Manager/Supervisor must complete the Management Plan in [Kuali](#).

A. Description

*[Describe the outside activity, employment, interest, or relationship that creates an actual, potential, or perceived conflict. Include the employee's level of involvement and how or where the situation might impact the employee's university responsibilities. **Provide explanation as to why the same funding cannot come through the University.]***

Provide a statement of understanding/agreement between employee and immediate supervisor:

B. Safeguards

Employee agrees to: [\[use only the paragraphs that apply to the situation\]](#)

1. Disclose the connection to Outside Entity to their Supervisor/Oversight Manager and the university.
2. Disclose the connection to Outside Entity to those involved in making decisions to purchase products or services from Outside Entity in which they have the opportunity to influence.
3. Refrain from substantive discussion and the decision-making process in their university role when services or products are being selected involving or related to Outside Entity.
4. Forward any transactions requiring approval for payments to Outside Entity to Oversight Manager for approval.
5. Enter into an agreement with the University for any use of university facilities, equipment, materials, and/or resources for any activities related to Outside Entity.
6. Refrain from hiring or otherwise engaging (volunteer or otherwise) students or staff whom they supervises or advises at the university to perform work for the Outside Entity (or vice versa) without written approval and oversight from the department chair or dean, and delegate supervisory responsibilities to *[an independent university person]*.

7. Refrain from evaluating the performance or making any changes in the employment or academic status of any university staff or students they supervises or advises, who also has an interest in Outside Entity.
8. Refrain from engaging in Outside Entity business or other outside activities when expected to perform their university responsibilities, and to take approved leave/time-off to engage in outside employment or activities to eliminate a conflict.
9. Refrain from using university equipment, materials, time, and/or resources for the Outside Entity or related activities without an appropriate agreement with the university for such use.
10. Refrain from hiring, supervising, advising or evaluating the performance of any immediate family members or close friends.
11. Remain knowledgeable of all relevant [UAH Policies](#) and diligently follow them including but not limited to the University Intellectual Property Policies and Agreements, Financial Conflict of Interest Policy related to research, the Conflict of Interest Policy, the COI/COC policy and all other relevant university policies and procedures.
12. Disclose to immediate supervisor any and all changes that may affect this Plan and update their university disclosure online within 30 days of any material change in relationships or financial interests.

Research-Specific Safeguards

13. Apply for or pursue research contracts or grants primarily through the university when within the course of Employee's university responsibilities, and not divert potential grant/contract opportunities from the university to the Outside Entity.
14. Refrain from restricting publication or presentation, although publication may be delayed for appropriate purposes for a reasonable period.
15. Disclose relationship to Outside Entity in publications and presentations if the entity supports research being reported or if the publication/presentation is related to the entity's commercial interests or intellectual property.
16. Disclose in writing the relationship (to Outside Entity or family members) to the sponsor as early as possible.
17. Disclose in writing the relationship (to Outside Entity or family members) to all students, fellows, trainees, and other research workers whom they supervises and that any concerns may be brought to the Assistant Vice President, Contracts and Grants.
18. Notify all co-investigators on federal grants of relationship (to Outside Entity or family members).
19. For human subjects research in which the Outside Entity a) sponsors the study, or b) owns or licenses any intellectual property used in the study:

- a. Report the conflict and provide a copy of this management plan to the IRB;
- b. Disclose the conflict to participants in the study (unless the IRB determines otherwise);
- c. Refrain from participating in the recruitment, enrollment, or consent of participants;
- d. Designate a non-conflicted co-Investigator responsible for acting as an independent reviewer of the data analysis, and/or appoint an external independent reviewer of the raw data and manuscript;
- e. Use double-blind study design and data analysis when possible;
- f. If more than Minimal Risk involved, refrain from serving as the PI or co-PI, unless approved by the Office of The Vice President for Research and Economic Development, Assistant Vice President, Contracts and Grants;
- g. Divest relevant personal interests in or sever the relationship with the Outside Entity research sponsor if necessary.

C. Oversight Plan:

Oversight Manager agrees to: [\[use only the paragraphs that apply to the situation\]](#)

1. Exercise reasonable oversight to verify that Employee's service to or work for Entity, compensated or uncompensated, does not interfere with the Employee's university responsibilities.
2. Exercise reasonable oversight to verify that Employee is not put in the position of discussing or making a decision to purchase products or services from Outside Entity in their University role.
3. Review all invoices from Outside Entity (or assign a designee to do so) and provide final approval of payment to Outside Entity.
4. Review and approve any agreements for use of university facilities, equipment, materials, and/or resources by Employee or the Outside Entity.
5. Exercise reasonable oversight to verify that Employee is not involved in the hiring, supervising, advising, or evaluation process of any immediate family members or close friends.
6. Exercise reasonable oversight to verify that Employee is not involved in making a University employment decision, academic decision, or performance evaluation about any students or staff who also have an interest in Outside Entity.
7. Review this Management Plan with Employee at least on an annual basis to determine progress and what, if any, changes may need to be made to this plan.

[\[Supervisor's Full Name\]](#) acknowledges that the University will monitor and evaluate this plan as well as policies related to it, and, at any time should UAH determine, in its sole discretion, that the plan is not sufficient to guard actual or apparent conflicts of interest or is otherwise not in the interest of UAH, may determine the conflicts as not capable of management and may ask [\[Employee's Full Name\]](#) not to pursue the conflicting activities while an employee of UAH. [\[Employee's Full Name\]](#) further acknowledges their personal duty to ensure their compliance with the Alabama Ethics Law (as applicable) and that this plan is not a substitute for that responsibility.

Acknowledgement and Agreement

By signing below, I, [\[Employee's Full Name,\]](#) acknowledge my agreement and intent to comply with the principles and safeguards of this Conflict of Interest/Commitment Management Plan.

Full Name

Date

Title

College/Center/Department

We approve the above Plan for handling the conflict of interest identified by the employee.

Full Name of Provost/AVP, Human Resources

Date

Vice President for Research & Economic Development
Assistant Vice President, Contracts and Grants

Date

All final and signed Conflict of Interest/Commitment Management Plans will be completed in [Kuali](#).