THE UNIVERSITY OF ALABAMA IN HUNTSVILLE

RESEARCH CONFLICTS OF INTEREST AND CONFLICTS OF COMMITMENT

Number 07.01.03

Division Office of the Vice President for Research and Economic Development

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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 (VPRED) 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.

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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 <u>or</u> 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:

- a. external employment;
- b. consulting;
- c. lecturing, presenting, performing, or speaking;
- d. establishing and/or supporting a start-up company;
- e. serving as an expert witness;
- f. participating in a board of directors or similar governing body;
- g. participating in a scientific advisory board; or
- h. 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:

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

- a. professional studies (e.g., attendance at scientific meetings);
- b. seminars, lectures, performances, presentations, or continuing education sessions:
- c. service on review panels (e.g., participation in manuscript review, grant/contract review, academic program review, etc.);
- d. service on advisory committees; or
- e. service on a Board of Directors or similar governing body provided to:
- f. U.S. federal, state, or local government agencies;
- g. institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education, whether U.S. or abroad;
- h. 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
- j. 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:

- a. Design the development of the strategy and means to test a research question or hypothesis.
- b. 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.
- c. 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.

- a. With regard to any publicly-traded entity, a Significant Financial Interest exists if the value of the Financial Interest received from the entity in
- b. the current or prior calendar year, when aggregated, exceeds \$5,000.
- c. With regard to any non-publicly traded entity, a Significant Financial Interest exists if:
 - o the value of any remuneration received from the entity in the

- current or prior calendar year, when aggregated, exceeds \$5,000; or
- o when the Investigator (or the Investigator's spouse or dependents) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- d. 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.
- e. 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 or 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 RCIRB will be composed of six full-time employees, including the Chair of the Faculty Senate Research Committee, three members appointed by the Faculty Senate from tenured faculty, and two senior research staff members appointed by VPRED who are experienced with the administration of Federal contracts/grants and sponsored programs, and others as deemed appropriate by the VPRED, and will be 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 https://www.uah.edu/ovpr

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.