

OVPRED 07.01.03 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 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 order to meet the disclosure requirements stated in CRF, Title 42, Section 53.605(a)(5)(i)-(iv), the information concerning any significant financial interest disclosed will be provided to the requesting individual in writing within 5 business days by 'name of the responsible individual' or the Institution shall ensure public accessibility, via a publicly accessible Web site prior to the Institution's expenditure of any funds under a PHS-funded research project.
- In accordance with 42 CFR 50.605 (a)(1)(i)-(iv), <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F/section-50.605>. 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. See 50.605 (5)(i) thru (iv) for additional institution reporting requirements.

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