

## **CONFLICT OF INTEREST MANAGEMENT PLAN (COIMP)**

Pursuant to Appalachian State University's Conflict of Interest and Commitment Policy (ASU Policy Manual 604.6), an actual or a potential Conflict of Interest (COI) has been identified that must be mitigated through a Conflict of Interest Management Plan (COIMP). This document, developed in accordance with Policy 604.6, Section 4.8, sets forth the steps agreed upon by the signatories below in order to manage the conflict(s). In particular, **the Covered Person(s) agree(s) to cooperate with officials of ASU in managing actual or potential COIs identified in this document.**

<b>SECTION I: GENERAL INFORMATION</b>
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**1. NAME OF COVERED PERSON(S):**

**2. SPONSOR/ENTITY OR INDIVIDUAL WITH WHOM COI EXISTS:**

**3. UNIVERSITY AND/OR EXTERNAL PROJECT IDENTIFIERS**

AIR Disclosure #	AGrants Project #	Award #	Project Name

**Other, if applicable (e.g., Internal Review Board, NSF Award Number, etc.):**

**4. TITLE AND BRIEF DESCRIPTION OF FUNDED PROJECT(S) (if applicable):**

**5. PRINCIPAL INVESTIGATOR(S) (if applicable):**

**6. PROJECT DIRECTOR(S) (if applicable):**

**7. NATURE OF CONFLICT OF INTEREST (check all that apply):**

- |   |  |
|---|--|
| <input type="checkbox"/> Equity interest      | <input type="checkbox"/> Relationship (e.g., colleague, family member, etc.) |
| <input type="checkbox"/> Consulting fee       | <input type="checkbox"/> Other (please describe):                            |
| <input type="checkbox"/> Travel reimbursement |  |
| <input type="checkbox"/> Honorarium           |  |

**8. VALUE OF FINANCIAL INTEREST (check one):**

- |   |   |
|---|---|
| <input type="checkbox"/> Not applicable to this project/disclosure. |   |
| <input type="checkbox"/> \$0-\$4,999                                | <input type="checkbox"/> \$20,000-\$100,000 _____ |
| <input type="checkbox"/> \$5,000-9,999                              | (indicate increment of \$20,000)                  |
| <input type="checkbox"/> \$10,000-\$19,999                          | <input type="checkbox"/> Over \$100,000 _____     |
|   | (indicate increment of \$50,000)                  |

\_\_\_ The value of this financial interest cannot be readily determined through reasonable measures of fair market value.

**9. RELATIONSHIP OF FINANCIAL INTEREST TO ANY FUNDED PROJECT(S) AND BASIS FOR DETERMINATION THAT COI EXISTS (if applicable):**

**10. ROLE AND PRINCIPAL DUTIES OF COVERED PERSON(S) IN EACH FUNDED PROJECT (if applicable):**

<b>SECTION II: MANAGEMENT PLAN REQUIREMENTS</b>
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The following items indicate elements that may be appropriate for the COIMP. For each item, indicate specific requirements, if the item applies; or indicate that the item does not apply. *[See attached guidance document for examples of possible provisions.]*

**1. PUBLIC DISCLOSURE OF FINANCIAL INTERESTS.**

\_\_\_ This item is not applicable to this COIMP.

Requirements:

**2. MONITORING OF RESEARCH OR OTHER ACTIVITY BY NEUTRAL, INDEPENDENT REVIEWER(S).**

\_\_\_ This item is not applicable to this COIMP.

Requirements:

**3. MODIFICATION OF RESEARCH PLAN OR WORK PLAN.**

This item is not applicable to this COIMP.

**Requirements:**

**4. DISQUALIFICATION OF COVERED PERSON FROM PARTICIPATION IN PROJECT OR ACTIVITY, OR PARTS THEREOF.**

This item is not applicable to this COIMP.

**Requirements:**

**5. DIVESTITURE OR SEVERANCE OF SIGNIFICANT FINANCIAL OR OTHER INTERESTS WHICH CREATE A COI WITH UNIVERSITY EMPLOYMENT RESPONSIBILITIES (see Policy Manual 604.6, Section 3.19) OR PHS RESPONSIBILITIES.**

This item is not applicable to this COIMP.

**Requirements:**

**6. RELATIONSHIP MANAGEMENT (SPOUSE, PARTNER, COLLEAGUE, ETC.)**

This item is not applicable to this COIMP.

**Requirements:**

**7. OTHER. (If applicable, insert any other conditions necessary to manage the conflicts identified in connection with this project.)**

## SECTION III: REQUIREMENTS APPLICABLE TO ALL MANAGEMENT PLANS

### **1. Policy Compliance, Including Human/Animal Subjects Protections**

All research activity must comply with all applicable University policies, including but not limited to:

- Review of Research Involving Human Subjects (ASU Policy 209)
- Payments to Human Subjects (ASU Policy 210)
- Human Subject Research Recruitment (ASU Policy 216)
- Care and Use of Animals for Research Teaching or Demonstration (ASU Policy 213)
- Use of Recombinant DNA in Research and Teaching Laboratories (ASU Policy 212)
- Integrity in Scholarship and Scientific Research (ASU Policy 211)
- Export Control Management Plan (ASU Policy 208)

Specific conditions may be indicated above under Management Plan Requirements. Full IRB approval must be sought and obtained prior to conducting any research involving human subjects.

### **2. Legal and Regulatory Compliance**

All research activity must comply with all applicable laws and regulations, including but not limited to those governing research funded by the Public Health Service.

### **3. Intellectual Property**

Inventorship and ownership of any new intellectual property arising from the project(s) described in this COIMP will be determined in accordance with the University's Policy on Intellectual Property Transfer (ASU Policy 207), subject to third party rights; or per the research agreement between ASU and SPONSOR (on record at the Office of Research and Sponsored Programs and AGrants). Financial arrangements related to new inventions or discoveries will be negotiated at fair market value.

#### **4. Personnel**

All personnel directly involved in the conduct of projects supported by SPONSOR will be made aware of the associated potential or actual conflicts of interest and the manner in which they will be managed. With respect to the project(s) and COIs identified in this document, personnel who have concerns or questions related to possible COIs may speak with \_\_\_\_\_, who is not affiliated with the project(s) and can provide objective guidance.

#### **5. Publications**

Scholarly publications will be submitted in accordance with Appalachian and UNC policies, and in accordance with sponsoring research agreement(s). (See respective AGrants files listed on page 1).

#### **6. Reporting and Review of Conflict of Interest Management**

COVERED PERSON(S) will prepare an annual report updating all information relevant to this management plan, which will be reviewed and approved by \_\_\_\_\_ and forwarded to the dean of the \_\_\_\_\_ for administrative review and approval on at least an annual basis. Additional projects submitted to SPONSOR(S) will be attached and subject to this management plan prior to submission to SPONSOR(S) or managed separately under a new plan approved prior to proposal submission.

#### **7. Use of University Resources**

No University facilities, equipment, or staff will be utilized for the direct benefit of the SPONSOR unless such work is covered by a Research Agreement or other appropriate agreement. All uses of University resources by or on behalf of SPONSOR will be appropriately reimbursed (as summarized in the previously listed agreements). Should ASU facilities, equipment, or staff be used, ASU must be compensated fully for direct and indirect expenses incurred by ASU in support of these projects. Use of ASU resources in such projects must be well documented and charged to the SPONSOR.

**[End of text. See next page for signatures.]**

**Management Plan Committee:**

<b>Role</b>	<b>Name/Title (Print)</b>	<b>Signature</b>	<b>Date</b>

Submit the approved plan and a copy of the most recent Conflict of Interest Disclosure form to all relevant individuals and offices – e.g., Management Plan Committee members, Officer of Research, and Sponsored Programs, Institutional Review Board, department chair, dean, etc.

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**Institutional Conflict of Interest Management Plan Approval:**

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COI Coordinator (or Designee)

Date: \_\_\_\_\_

## **CONFLICT OF INTEREST MANAGEMENT PLAN (COIMP) GUIDANCE FOR COMPLETION**

### **General Information**

This document provides a template for preparing a Conflict of Interest Management Plan (COIMP) when a Conflict of Interest (COI) has been identified that requires management under the terms of the University's Policy on Conflict of Interest and Commitment, ASU Policy Manual 604.6 ("Policy 604.6"). Among the key definitions in that Policy are the following:

Conflict of Interest Coordinator: General Counsel or the General Counsel's designee.

Covered Person (or Covered Individual): see Policy 604.6, Section 3.5. For present purposes, stated briefly, an individual for whom a conflict has been identified.

Designated University Official (DUO): Dean of the individual's college or other appropriate unit head.

Conflict of Interest and Commitment Council: A standing committee, with membership and responsibilities as described in Policy 604.6, Section 4.5. Among other things, the Council will review COI management plans upon the request of any dean, vice chancellor, or chancellor and make recommendations to the referring official.

Under the Policy, when a potential COI is identified, the Conflict of Interest Coordinator is required to confer with the Covered Person and the Covered Person's department chair or supervisor, dean, vice chancellor, or chancellor as appropriate. Ultimately, the Designated University Official is responsible for determining whether a COI exists. Policy 604.6, Section 4.7.

Once it is determined that a COI exists, the Designated University Official (in consultation with the Conflict of Interest and Commitment Council, if applicable) is responsible for drafting, approving, and implementing a Conflict of Interest Management Plan. Policy 604.6, Section 4.8.4. The COI Coordinator approves all such plans at an institutional level and reports all identified COIs and COIMPs to the Provost. Policy 604.6, Section 4.8.7.

The template set forth above is based on the requirements and guidelines set forth in Policy 604.6, Sections 4.7 and 4.8, and is intended to provide a starting point for Designated University Officials who are responsible for developing COIMPs. Additional guidance appears below. **The COI Coordinator (Office of University Counsel, 262-2751) and the Office of Research (262-2130) are available for assistance.**



## **Management Plan Requirements**

The items set forth in the section labeled “Management Plan Requirements” are drawn from Policy 604.6, Section 4.8.5. Examples of text that could be relevant in a particular situation appear below. If the item is not applicable in a given situation, simply check the statement to that effect so that it will be clear the item has been considered.

Note that for externally funded research, provisions addressing certain of these items may be the subject of negotiation between the Office of Research and the FUNDER and incorporated in the research agreement.

### **1. PUBLIC DISCLOSURE OF FINANCIAL INTERESTS**

*Examples* could include, but are not limited to:

- Disclosure in IRB documentation provided to human subjects.
- Annotations to publications submitted to journals.
- Other measures as appropriate.

### **2. MONITORING OF RESEARCH OR OTHER ACTIVITY BY NEUTRAL, INDEPENDENT REVIEWER(S)**

*Examples* could include, but are not limited to:

- Monitoring by a colleague (within the department or in another department or unit on campus) with appropriate expertise.
- Monitoring by an impartial external third party.
- Monitoring by a small ad hoc committee formed specifically for this purpose.
- Other measures as appropriate.

### **3. MODIFICATION OF RESEARCH PLAN OR WORK PLAN**

*Examples* could include, but are not limited to:

- Requiring that random samples of biomaterials be sent to an alternative lab to support findings.
- Requiring supplements to be purchased from a non-conflicted vendor.
- Mandating a change in procedures or statistical analysis.
- Assigning an objective third party to manage or review finances on a regular schedule.
- Other measures as appropriate.

#### **4. DISQUALIFICATION OF COVERED PERSON FROM PARTICIPATION IN PROJECT OR ACTIVITY, OR PARTS THEREOF**

May be relevant especially for small business technology development and small business innovation awards, where Principal Investigators are both the campus PI and the owner of a spinoff company.

*Examples* could include, but are not limited to:

- Conflicted individual is disqualified as serving as the campus PI and a campus collaborator appointed to that role.
- PI divests her- or himself of the administrative role in the external business.
- Other measures as appropriate.

#### **5. DIVESTITURE OR SEVERANCE OF SIGNIFICANT FINANCIAL OR OTHER INTERESTS WHICH CREATE A COI WITH UNIVERSITY EMPLOYMENT RESPONSIBILITIES (see Policy Manual 604.6, Section 3.19) OR PHS RESPONSIBILITIES**

*Examples* could include, but are not limited to:

- Service on board of directors or scientific advisory board of enterprise that provides financial support for University research, where Covered Person or Immediate Family member receives such financial support: COIMP could require disclosure, recusal, or resignation.
- Departmental and Financial Oversight: To ensure that a conflicted investigator does not have sole control of finances, it may be appropriate to designate an individual who has no relationship to the SPONSOR to approve annual project budgets, any budget amendments, human subjects payments, etc.

#### **6. RELATIONSHIP MANAGEMENT (SPOUSE, PARTNER, COLLEAGUE, ETC.)**

*Examples* could include, but are not limited to:

- Measures to ensure neutral decision-making about formulation and passage of recommendations (e.g., ensuring that there are safeguards in place to eliminate any chance of bias toward outcomes that favor either or both of your disciplines).
- Budgetary controls (e.g., designating who approves money for any activities to ensure no favoritism toward you or the related person).
- Other measures as appropriate.

***Please contact the COI Coordinator (Office of University Counsel, 262-2751) or the Office of Research and Sponsored Programs (262-2130) if you have questions, comments, and need assistance.***