**COVER SHEET/Instructions**

**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”). Use this template when an Institutional Conflict of Interest is present; when financial interest is of a value greater than $5,000; or when project is PHS funded.

## **Management Plan Elements**

The items set forth in Section II, “Management Plan Elements,” 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 negation between the Office of Research and the FUNDER and incorporated in the research agreement.

## 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.

## 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.

## 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.

## 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.
	+ Add a supervisor section for students and employees.

**Note: Significant Conflicts of Interest should be reviewed by the COI Council prior to being fully executed. Per the COI Policy, Deans or the equivalent position have the authority to request COI Council Review by emailing coi@appstate.edu; or the COI Coordinator may request review. Individuals who are disclosing a Conflict of Interest using this form are encouraged to work with their Department Chair directly to develop this plan.**

**If you need assistance please contact the Office of Research Protections at coi@appstate.edu.**

**These cover pages can be removed from the completed Management Plan.**

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

Institutional/Significant Financial Conflict of Interest

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).

Use this template when an Institutional Conflict of Interest is present; when Interest is of a value greater than $5,000; or when project is PHS funded.

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**.

## **SECTION I: GENERAL INFORMATION**

1. **Name of covered person(s)** (individual(s) with the conflict)**:**
2. **Sponsor, entity, or individual with whom COI exists**:
3. **University and/or external project** **identifiers**

|  |  |  |  |
| --- | --- | --- | --- |
| **AIR Disclosure #** | **AGRANTS Project #** | **Award #** | **Project name** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Brief description of funded project(s) (if applicable)**:
2. **Principal Investigator(s) (if applicable)**:
3. **Project Director(s) (if applicable)**:
4. **Nature of Conflict of Interest (check all that apply)**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Equity interest |  |  | Relationship (e.g. colleague, family member, etc.) |
|  | Consulting fee |  |  | Travel reimbursement |
|  | Honorarium |  |  | Other (please describe):  |
|  |  |

1. **Value of financial interest (check one)**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Not applicable to this project/disclosure |  |  |  |
|  | $5,000 - $9,999 |  |  | $10,000 - $19,999 |
|  | $20,000 - $100,000 |  |  | Over $100,000 |
| (Indicate increment of $20,000):  |  | (Indicate increment of $50,000):  |
|  | The value of this financial interest cannot be readily determined through reasonable measures of fair market value.  |

1. **Relationship of financial interest to any funded project(s) and basis for determination that COI exists (if applicable)**:
2. **Role and principal duties of covered person(s) in each funded project (if applicable)**:

## **SECTION II: MANAGEMENT PLAN ELEMENTS**

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. For requirements, describe specific steps that will be taken to meet the requirement. The cover pages provide some examples.

1. **Public disclosure of financial interests**.

|  |  |
| --- | --- |
|  | This item is not applicable to this COIMP |

 Requirements:

**All personnel directly involved in the conduct of this project must be made aware of the associated potential or actual conflicts of interest and the manner in which they will be managed. Appalachian has a letter template on our COI Forms webpage for disclosing to research staff, and one for disclosing to students.**

1. **Monitoring of research or other activity by neutral, independent reviewer(s)**.

|  |  |
| --- | --- |
|  | This item is not applicable to this COIMP |

 Requirements:

1. **Modification of research plan or work plan**.

|  |  |
| --- | --- |
|  | This item is not applicable to this COIMP |

 Requirements:

1. **Disqualification of covered person from participation in project or activity, or parts thereof**.

|  |  |
| --- | --- |
|  | This item is not applicable to this COIMP |

 Requirements:

1. **Divestiture of severance of significant financial or other interest 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:

1. **Relationship management (spouse, partner, colleague, etc.)**.

|  |  |
| --- | --- |
|  | This item is not applicable to this COIMP |

 Requirements:

1. **Disclosure of conflict to students**

|  |  |
| --- | --- |
|  | This item is not applicable to this COIMP |

 Requirements:

**Appalachian has a letter template on our COI Forms webpage for disclosing to research staff, and one for disclosing to students.**

**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:

Applies Does not Apply

|  |  |  |
| --- | --- | --- |
|  |  | 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) |

Please initial below.

1. **Legal and Regulatory** **Compliance**
\_\_\_\_\_\_\_ All research activity will comply with all applicable laws and regulations, including but not limited to those governing research funded by the Public Health Service.
2. **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
3. **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.
4. **Publications**
\_\_\_\_\_ Scholarly publications will be submitted in accordance with Appalachian and UNC policies, and in accordance with sponsoring research agreement(s).
5. **Reporting and Review of Conflict of Interest** **Management**

\_\_\_\_\_ COVERED PERSON(S) will prepare a report updating all information relevant to this management plan, which will be reviewed and approved by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and forwarded to the Dean of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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.

1. **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.

**SECTION IV: MANAGEMENT PLAN SIGNATURES**

Please add rows as needed. The covered person (the one with the conflict) should be listed and sign. Personnel who have a named role in this plan should be listed and sign. The covered person’s supervisor/Chair and Dean should also be listed and sign. The Dean may request a review of this plan by the COI Council prior to signing. Requests should be in writing to coi@appstate.edu.

After all signatures are obtained, please route to the Office of Research for COI Coordinator signature.

|  |  |  |  |
| --- | --- | --- | --- |
| Role | Name/Title (Print) | Signature | Date |
|  |  |  |  |
|  |  |  |  |
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**Institutional Conflict of Interest Management Plan Approval**:

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COI Coordinator (or Designee) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of next review