**Financial Conflict of Interest Management Plan Example**

**Management Plan**

**Conflicted Investigator:** <Add Conflicted Investigator Name>

**Conflicting Organization:** <Entity Name> (hereafter “the entity”)

**Project Title:** <Add Research Study Titles>

# Principle Investigator: <Add PI Name>

**Role and Principal Duties on Project**

**Role:** ☐Principal Investigator ☐ Co-Investigator ☐ Study Team Member

**Duties Description:** <Provide a description of duties, i.e. Acting as a co-investigator in developing the research plan, conducting data analysis of resulting data, and drafting/editing resulting publication.>

**Conditions of Management Plan**

Check boxes as appropriate for you, your Spouse, and/or your Dependents.

## I. Modifications of Roles

The following changes to my responsibilities have been made to mitigate the FCOI:

☐ **Licensing.** I will refrain from participating in any licensing discussions between TAMU-CC and <entity name> except within normal inventor role.

☐ **Financial Transactions.** I will recuse myself from the final approval or authorization of any financial transaction or relationship between TAMU-CC and <entity name> in which I have a SFI.

☐ **Purchases.** I will not be directly involved in making decisions involving the purchase of items from the entity using funding under my control. Any such contractual arrangements are to be delegated to an impartial party, <add title>, who is not under my supervision or control.

☐ **Data Analysis.** I will not be involved in the analysis of research data. Analysis of research data will be performed by non-conflicted investigators.

☐ **Human Subjects Research:** I will not be involved in the recruitment or consenting of human subjects.

☐ **Human Subjects Research:** I will not be involved in the evaluation adverse events in human subjects research.

☐ **Use of University Facilities and Services:** Any activity involving the use of University facilities or services for the benefit of the entity must be conducted in accordance with all relevant University policies pertaining to the use of University facilities. If I wish to use University facilities for the benefit of the entity, I will make arrangements through my department chair and your dean. I will ensure a written and approved facilities use agreement is in place before the activity begins.

☐ **Research Support from the Entity.** Before accepting any research support (e.g., grants, contracts, unrestricted gifts, or materials) from the entity, I will specifically disclose details of the award to my dean or director’s office for approval, including the scope of the work and any award conditions. I will update Maestro to assign the related research project to the conflict disclosed with entity.

☐ **Subagreements with Entity.** If I anticipate engaging in a project for which the entity will be a subawardee or subcontractor, I will contact your dean or director’s office for approval prior

to submitting a proposal. Additional clearance from the <role> may be necessary for any contracts resulting from such a collaboration.

☐ **Other**: <specify>

## II. Modification of Significant Financial Interest (SFI)

☐ Reduction of SFI

☐Elimination of SFI

☐ End the relationship that created the FCOI

☐ Change my relationship with <entity name> to <describe change to reduce or eliminate FCOI>

☐ Any resulting intellectual property developed from this grant/research project has been assigned to <add party name>.

## III. Interaction with Studies, Staff and Colleagues

TAMU-CC has a duty to ensure that the entrepreneurial activities of its faculty and staff do not have a negative impact on students or research staff, especially on the academic progress of students. To fulfill this obligation, you should provide information on potential conflicts of interest to all students, fellows, trainees, and other research workers whom you supervise in the course of your research (hereafter students and staff). See Appendix B: Informing students and staff of potential conflicts of interest.

☐I will disclose in writing my FCOIs to students, staffs and colleagues who are a part of the study.

☐ I have, or will, provide this information on an annual basis and to all new hires/students.

☐ Included in the notification, I will provide/have provided instruction to students, staff, and/or colleagues that if they have concern about the influence of the FCOI on potential findings, they may inform the VP of Research & Innovation without repercussion.

You must also notify all your co-investigators on federal grants of potential conflicts of interest.

☐I will disclose in writing my FCOIs to the following:

☐ Co-Investigators.

☐ Subrecipients

☐ Other: <specify>

## IV. Public Disclosure

☐ **Public Posting**: I have posted information on my website, faculty page, pertaining to my FCOI.

☐ This information outlines the value, type, etc. of the FCOI and how it creates a FCOI.

☐ This information includes my participation in a company as a founder, consultant, etc.

☐ This information includes a summary of my reimbursed/sponsored travel

☐ **Human Subjects Research**: Conflict will be disclosed to all potential research participants in the consent process and in the consent documents when human participants are involved.

☐ The IRB has been provided notice of the FCOI Management Plan.

☐ The IRB has reviewed and approved language to be provided to research participants.

☐ I will include detailed information, as approved by the IRB, to all human research participants in the study.

**V. Publications and Presentations.** See Appendix A: Disclosing in publications

☐ I have an obligation to my employer, TAMU-CC, to publish all findings, even if they would damage my potential financial benefit.

☐ My relationship with entity may not restrict publication or presentation, although publication may be delayed for the purpose of pre-publication review for a period consistent with Texas A&M University-Corpus Christi (TAMU-CC) (hereafter “TAMU-CC”) policies.

☐ **Disclosure:** I will disclose the relationship with the entity in publications and academic presentations, if:

1. the entity supports research reported in the publication; or
2. the publication or presentation is related to the entity’s commercial interests or intellectual property.

☐ **Disclosure:** I will publicly disclose the FCOI when presenting or publishing with the following language (See FCOI Public Disclosure Examples):

 <add disclosure language to be used in publications/presentations>

## VI. Independent Monitor

☐An oversight monitor will advise and consent to all major research decisions

☐ Oversight Monitor will review the research and results every <enter interval‐not to exceed 6 Months>

☐ I will provide continuous updates on research to VP of Research & Innovation, including the option to provide access to research findings and/or have a delegate of the BCCA VP of Research sit in on research study meetings.

☐ I will provide, every 6 months, a written summary regarding data analysis and interpretation.

☐ I will provide access to the raw data involved in research, including instrument output and notebooks.

## VII. Oversight and Reporting

☐ **Updates.** I will comply with the requirement to submit annually the FCOI disclosure. If I have relevant changes, I will report these changes in my outside activities within 30 days of the change.

☐ **Annual Review.** I will meet annually with your department chair, center director, or, if you are the department chair or center director, with your dean or director, or his or her designee, to review information related to your relationship with the entity or entities, its influence on University activities and compliance with the terms of this management plan

☐ **Amendments.** I understand TAMU-CC reserves the right to modify this management plan and to impose new or additional conditions. Such modifications, conditions, and additional terms will be effective immediately and incorporated into this management plan. TAMU-CC will notify me of these changes in advance by sending an email message to the email account used for my annual Outside Activities Report notifications. I will be deemed to have accepted these terms and conditions unless I appeal my management plan, which must be done in writing and sent to TAMU-CC’s Conflict of Interest Committee.

## VIII. Other

<add other elements to the plan>

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| --- | --- | --- |
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| Investigator      |   | Date  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |   | \_\_\_\_\_\_\_\_\_\_\_\_\_  |
| Investigator’s Supervisor      |   | Date  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |   | \_\_\_\_\_\_\_\_\_\_\_\_\_  |
| Dr. Ahmed Mahdy  |   | Date  |

Vice President for Research & Innovation

# Appendix A: Disclosing in publications

The following examples are to guide investigators disclosing their significant financial interests in publications and presentations. Investigators may use alternative approaches that meet the requirements laid out in the body of this management plan.

Journals and entities sponsoring meeting, symposia or conferences have varying standards for reporting financial relationships relating to your institutional responsibilities. However, you should always acknowledge those relationships when publishing or presenting data from your research or relating to the topic of your publication of presentation. The following are examples of disclosure statements. If you use one of the examples, you should modify it to fit your specific relationship.

## Example 1

The author(s) of this [publication, presentation or poster] has research support from [Source of research funding] and also [holds stock in; serves on an advisory board for; serves on the Board of Directors of, received an honorarium from] [name of entity]. The terms of this arrangement have been reviewed and approved by Texas A&M University-Corpus Christi in accordance with its policy on objectivity in research.

## Example 2

The author(s) of this [publication, presentation or poster] consults for [Entity(ies)] on [subject of consultation]. The author(s) also conducts research in areas of interest similar to the business interests of [Entity(ies)]. The terms of this arrangement have been reviewed and approved by Texas A&M University-Corpus Christi in accordance with its policy on objectivity in research.

## Example 3

The author(s) of this [publication, presentation or poster] was a [speaker for, consultant to, received an honorarium from] [Entity(ies)]. The terms of this arrangement have been reviewed and approved by Texas A&M University-Corpus Christi in accordance with its policy on objectivity in research.

## Example 4

The studies reported in this [publication, presentation or poster] were supported by a grant from [NIH, NSF, etc]. The [principal investigator, author, speaker] [holds stock in, serves on an advisory board or board of directors for] [Entity]. Although a financial conflict of interest was identified for management based on the overall scope of the project and its potential benefit to [Entity], the research findings included in this [publication, presentation or poster] may not necessarily related to the interests of [Entity]. The terms of this arrangement have been reviewed and approved by Texas A&M UniversityCorpus Christi in accordance with its policy on objectivity in research.

## Example 5

Texas A&M University-Corpus Christi has equity ownership in [Entity], the sponsor who funded the research reported in this [publication, presentation, poster]. Texas A&M University-Corpus Christi may financially benefit from this interest, if [Entity] is successful in marketing products related to this research. The terms of this arrangement have been reviewed and approved by Texas A&M UniversityCorpus Christi in accordance with its policy on objectivity in research.

# Appendix B: Informing students and staff of potential conflicts of interest

The following is guidance to help investigators communicate the details of conflict of interest management plans. Investigators may use alternative approaches, if they meet the requirements laid out in the body of this management plan.

The information should include explanations of:

1. your relationship with the entity, and
2. the right of students and staff to bring concerns about the effect of your relationship with the entity on their work, studies, or progress towards degree to your dean, director, his or her designee, or the FCOI Program.

The process for providing information should meet the following criteria:

* Includes a written summary of the information for each student or staff member
* Provides to the FCOI Program documentation that this process has occurred within 90 days of receipt of this management plan
* Provides any individuals who subsequently join the group comparable information in a timely manner
* Updates documentation to the FCOI Program at least once a year

Students, fellows, trainees, and other research workers whom you supervise in the course of your research a written summary should receive a written summary of your relationship with your managed entities. The following information may be included:

The written summary would be printed on department letterhead and include the following:

1. Date;
2. Description of the investigator's involvement with the entity;
3. Description of the purpose of the entity;
4. Description of the relationship between the investigator’s professional work (research) at the TAMU-CC and the entity;
5. Description of any relationships between the TAMU-CC and the entity, such as sponsored research agreements, facilities use agreements, etc.;
6. Description of any restrictions placed on the design, conduct, and reporting of research by the entity;
7. Description of the ownership of any intellectual property resulting from research connected to the entity;
8. Impartial contacts for students and staff;
9. Investigator’s signature; and
10. Statement of acknowledgment to be signed and dated by the recipient.

You may provide a copy of you notification letter to students and lab personnel via email, making sure to CC the FCOI Program at <email> and listing out each recipient.

Another effective way to communicate the details of your management plan is to hold a meeting to review the provisions of your plan. During this meeting, participants would receive two copies of a written summary signed by the investigator. They would sign and date one copy and return it to the investigator. The investigator would then provide copies of the signed letters to the FCOI Program.

Example Notification:

[Letterhead]

[Date]

To All Personnel in the Laboratory of [PI Name],

This letter is to inform you that I am [List position in company] of a company called [Name of Company], devoted to research in the areas of [Add text explaining the purpose of the company, your involvement with it, and any connections to the lab].

My relationship does not carry with it any restrictions on publication, and any associated intellectual property will be disclosed and processed according to Texas A&M University – Corpus Christi policy.

The purpose of this letter is to inform you of this potential conflict of interest, and, if you feel that at any time your academic pursuits and freedoms are compromised by this relationship.

You have the right to accept or decline work related to this project. If you decide to participate in this work:

1. You will conduct work on behalf of the University, not [Name of Company].
2. You will report to and take direction from your supervisor, no [Name of Company].
3. You have the right to confidential access to the Dean, [Department] or Conflict of Interest Official to discuss any questions or concerns, including the impact of the employee’s relationship with [Name of Company] on your work, advancement, studies, or progress towards a degree. Their contact information is:

Dean:

[Provide contact information for the appropriate dean or director’s designee listed in your management plan]

Conflict of Interest Official:

Dr. Ahmed Mahdy

Vice President for Research and Innovation (361) 825-3881

Ahmed.Mahdy@tamucc.edu.

Sincerely yours,

[Signature]