**UNT HEALTH SCIENCE CENTER**

**RESEARCH CONFLICT OF INTEREST**

**(RCOI)**

**MANAGEMENT PLAN DOCUMENTS**

Revised 12/09/2019

**UNT HEALTH SCIENCE CENTER**

**RESEARCH CONFLICT OF INTEREST (RCOI) MANAGEMENT PLAN**

**Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**RCOI-MP Number: \_\_\_\_\_\_\_**

This Research Conflict of Interest Management Plan (“Management Plan”) is required pursuant to applicable laws and regulations, and/or the policies of UNT Health Science Center (“UNTHSC”), in order to provide assurances to the University, external entities (as applicable) and the public that the conflict described herein will be appropriately managed to avoid improprieties, including any potential bias, inappropriate use of institutional resources, or self-dealing, or the appearance of any of these.

At the time of a Management Plan being required of an investigator, one or more members of the Research Conflict of Interest Committee or staff of the Office of Research Compliance will meet with the relevant Principal Investigator (PI), Research Monitor and PI Supervisor to discuss the plan, required annual report(s) and audit process. It is anticipated that this Management Plan meeting and training of all relevant parties will facilitate adherence to the Management Plan and all subsequent related activities associated with managing that specific Research Conflict of Interest.

# A. DEFINITIONS

## Research Conflict of Interest:

A research conflict of interest (“RCOI”) occurs when there is a divergence between an individual's private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal financial gain, rather than the best interests of the institution. A research conflict of interest depends on the facts and circumstances of the particular situation, and not on the character or actions of the individual. A research conflict of interest is not improper if it is disclosed as required by law, regulation and policy, and is appropriately managed to avoid harm (or the appearance of harm) to the University.

# B. IDENTIFICATION OF INVESTIGATOR AND SUPERVISORS INVOLVED IN MANAGING THE RESEARCH CONFLICT

1. Investigator whose conflict or potential research conflict of interest is involved (name, email):

 Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Outside Organization: (hereinafter, “Entity”) involving the potential conflict of interest.

 Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 URL (if any): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Investigator’s title/role with Entity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Extent of Investigator’s control, ownership and interest in Entity:

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

3. Research Monitor (“RM”) who will have primary responsibility for overseeing implementation of this Management Plan:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The Research Monitor (RM) will assure that safeguards are in place to prevent graduate students from being harmed through delayed graduation, reduction in research time, lessened commitment to coursework, compromised publication abilities or any other adverse (to the student) action caused by the relationship of Investigator with Entity. Examples of an adequate process include but are not limited to naming an academic co-advisor, utilizing the graduate advisory committee, considering appropriate supervisory roles and responsibilities, etc.

# C. BACKGROUND

# Background: Information about the relationship between the UNTHSC Investigator and the Entity:

* Describe the Entity and the relationship of the employee to the Entity.

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

Some points that may be relevant here:

* Is the disclosure due to involvement in the formation of a start-up Entity? (if so, explain)

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

* Who are the founders of the Entity?

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

* What is the intellectual property on which the Entity is based?

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

* Describe the anticipated relationship of the Entity to UNTHSC.

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# D. MANAGEMENT PLAN AND OVERSIGHT RESPONSIBILITIES

## 1. Research Conflict of Interest Management Oversight:

In association with the Appropriate Supervisor (Department Chair, Center/Institute Director, etc.) the responsibilities of the Research Monitor include: initial plan implementation, monitoring and reporting as specified in this plan, and modification of the plan as needed.

The Investigator will submit to the Research Monitor and Appropriate Supervisor for signature an annual report containing a summary of the documented activities in each of the areas outlined in Section 2 below [a template annual report is available for use by the Investigator]. If necessary, the Research Monitor will initiate a revised Management Plan. [It is recognized that there are multiple roles that employees have at UNTHSC, and it is difficult to specify in advance all possible situations. The purpose of this management plan is to assure that the Investigator will follow the guidelines in the Research Conflict of Interest Policy 12.101, as applicable].

## 2. RCOI Management Plan Outline:

This Management Plan requires that steps that will be taken to assure that Investigator’s external activities do not involve the inappropriate use of state and university resources, misuse of University personnel or students, misuse of the University name or trademarks, or cause confusion as to the Investigator acting on behalf of the University. Such steps will include:

**Appropriate Disclosures:** The Investigator will coordinate with Office of Sponsored Programs and the Office of Research Compliance to appropriately disclose his/her affiliation with Entity on individual UNTHSC regulatory compliance protocols, sponsored proposal submissions and grants/contracts that also involve the procurement of materials from and/or collaboration with the Entity.

**Research Program:** The Investigator will provide the Research Conflict of Interest (RCOI) Committee with information about the research program that the Investigator will pursue. Investigator will take steps to ensure that to the extent he/she identifies research areas to pursue that these decisions are not driven by a desire to benefit an Entity. It is understood that Investigator’s research by its nature may benefit the Entity and that it may be difficult to determine whether research is being driven by a desire to benefit a specific Entity or the entire industry. Investigator may be asked to address this question with the RCOI Committee.

* In addition, the Investigator will notify students and staff, where relevant, regarding possible relationship between Investigator and Entity.

***Investigator:*** *Complete all applicable sections; place N/A in sections that are not applicable during drafting and review.*

* Describe the Investigator’s time commitment to the Entity.

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

* Describe any potential relationship of GRADUATE STUDENTS to the Entity. This includes work done on behalf of the investigator’s relationship to the Entity.

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

* Describe any potential relationship of RESEARCH STAFF to the Entity. This includes work done on behalf of the investigator’s relationship to the Entity.

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

* Discuss the potential use of UNTHSC equipment and/or facilities by the Entity. University resources, including but not limited to space, personnel, equipment, etc.

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

* What steps will be taken to assure that the Investigator’s external activities do not involve inappropriate use of state and university resources, personnel/students, misuse of the University name or trademarks?

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

* How will student(s) and/or laboratory staff personnel be notified of the Principal Investigator’s relationship with the entity that resulted in the need for an RCOI Management Plan?

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

**Signature Page and Attestation**

This management plan shall be effective from the date of original review/approval by the RCOI Committee for a period of one year after which time it must be reviewed and updated annually.

This management plan shall automatically be terminated when: a superseding management plan is executed; the Research Conflict of Interest Committee determines this management plan is no longer necessary; and/or the investigator fails to comply with the terms of this management plan. This management plan will be attached to and supplement the Investigator’s conflict of interest disclosure.

All of the undersigned hereby acknowledge and agree to abide by the University’s Research Conflict of Interest Policy (Research Conflict of Interest Policy 12.101).

Signatures below indicate acceptance and agreement to the research conflict of interest disclosure and confirm the accuracy of all statements in this management plan for the specific conflict of interest listed in this plan.

**Principal Investigator:**

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

 Print Name of Investigator

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

 Signature of Investigator Date

**Research Monitor:**

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

 Print Name of Research Monitor

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

 Signature of Research Monitor Date

**Supervisor:**

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

 Print Name of Appropriate Supervisor

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

 Signature of Appropriate Supervisor Date

**Reviewed and Acknowledged by the Research Conflict of Interest Committee:**

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

Signature of RCOI Committee Chairperson or Designee Date

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

Signature of VP for Research & Innovation Date

**UNT HEALTH SCIENCE CENTER**

**LETTER REGARDING STUDENT – STAFF INVOLVEMENT**

**IN RCOI MANAGEMENT PLAN**

RCOI-MP Number:

Date:

Management Plan Principal Investigator:

Department/Institute:

Entity:

As part of a Research Conflict of Interest Management Plan, Dr.       is required to inform all faculty/staff/students working in their research program of the related significant financial interest involving the entity named above.

 *Please complete the following information:*

I have been informed by Dr.       of his/her significant personal financial interest involving the entity named above. I understand that any problems or concerns I have about any aspect of work on the research program can be communicated to the Office of Research Compliance or to the Institutional Compliance Officer for UNTHSC. I may also call the EthicsPoint Trust Line at 844-692-6025 to report Ethical Issues or the Internet at <http://www.unthsc.ethicspoint.com>.

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

Signature of Faculty/Student/Laboratory Staff Date

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

Printed Name of Faculty/Student/Laboratory Staff

If you have any questions or concerns, please feel free to contact Ms. Tania Ghani or the Office of Research Compliance.

**Please return completed form to:**

Office of Research Compliance

susan.harlin@unthsc.edu

(817) 735-2742

**UNT HEALTH SCIENCE CENTER**

# RCOI MANAGEMENT PLAN ANNUAL REPORT

RCOI-MP

To:       (Name of Research Monitor)

      (Name of Appropriate Supervisor)

RCOI Committee

From:       (Name of Investigator)

Re: Research Conflict of Interest (RCOI) Management Plan Annual Report –       to       (insert Dates) involving       (Name of Entity)

1. During the past year (reporting period), I have engaged in the following outside consulting activities that relate to my relationship with the above Entity:

[ ]  There are no changes since the last annual report.

[ ]  Yes: The following change(s) occurred:

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

1. During the past year (reporting period), the following events or changes in activities have occurred that did or may give rise to a potential research conflict of interest in regard to my relationship with the above Entity:

[ ]  There are no changes since the last annual report.

[ ]  Yes: The following change(s) or event(s) have occurred:

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

1. During the past year (reporting period), I have been involved in the following Sponsored Research Agreements that relate to my relationship with the above Entity:

• Sponsored Research Agreement Title:

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

• Parties:

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

• My Role:

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

1. During this past year (reporting period), the following relationship (invention, license, etc.) disclosures have been made by me (whether to UNTHSC or Entity) that relate to my relationship with the above Entity:

[ ]  None

[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. During the past year (reporting period), the following students have been involved in the above Entity related funded sponsored projects or have been employed by the above Entity directly while continuing as a student at UNTHSC: (Attach copy of signed student involvement letter for any not previously submitted.)

[ ]  None

[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. During the past year (reporting period), the following staff personnel have been involved in the above Entity related funded sponsored projects or have been employed by the above Entity directly while continuing as a staff member of UNTHSC: (Attach copy of signed staff involvement letter for any not previously submitted.)

[ ]  None

[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. During the past year (reporting period), the following UNTHSC facilities and/or resources have been involved in the above Entity funded sponsored projects:

[ ]  None

[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Affirmation of Obligations and Limitations in RCOI Management Plan.
* I hereby affirm that I have not disclosed Confidential Information other than as permitted in the RCOI Management Plan during this fiscal Year.
* I hereby affirm that I have notified the students, staff or faculty involved in this research of any relationship between the Investigator and the above Entity.
* I hereby affirm that I have not directed research to be done at UNTHSC with the intent that it benefits the above Entity specifically.
* I hereby affirm that I have not solicited any UNTHSC employee to leave UNTHSC to become an Employee of the above Entity during this past fiscal Year.
* I hereby affirm that during this fiscal Year I have not made use of UNTHSC staff time or resources in support of non-UNTHSC activities.

**or:**

In the alternative, I hereby disclose that I have made use of UNTHSC staff time or resources as follows but have made proper arrangements to compensate UNTHSC for such use:

Clarify/ Information for any of the above items.

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

I hereby affirm that the foregoing is true, correct and complete to the best of my knowledge.

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

Print Name of Investigator

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

Signature of Investigator Date

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

Print Name of Research Monitor

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

Signature of Research Monitor Date

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

Print Name of Appropriate Supervisor

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

Signature of Appropriate Supervisor Date

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

Signature of RCOI Committee Chairperson or Designee Date

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

Signature of VP for Research & Innovation Date

**UNT HEALTH SCIENCE CENTER**

**RESEARCH CONFLICT OF INTEREST (RCOI)**

***AUDITING THE CONFLICT OF INTEREST MANAGEMENT PLAN***

**STANDARD OPERATING PROCEDURES**

At the time of a Management Plan being required of an investigator, one or more members of the Research Conflict of Interest Committee or staff of the Office of Research Compliance will meet with the relevant Principal Investigator (PI), Research Monitor and PI Supervisor to discuss the plan, required annual report(s) and audit process. It is anticipated that this Management Plan meeting and training of all relevant parties will facilitate adherence to the Management Plan and all subsequent related activities associated with managing that specific Research Conflict of Interest.

An annual report (update) is required for all current Research Conflict of Interest (RCOI) Management Plans. For quality control and training purposes, routine reviews (audits) should be conducted on RCOI management plans. The purpose of the audit is to determine if the Principal Investigator is following the approved RCOI Management Plan in place to address the disclosed potential conflict of interest. Note that the management of any disclosed potential Research Conflict of Interest is a joint process with information shared among several offices, notably: Institutional Compliance Office, Office of Sponsored Programs, Office of Research Compliance and the Office of the Vice President for Research and Innovation.

Written notice (email, hard copy, etc.) will be sent from the RCOI Committee representative to the Principal Investigator to schedule a time and place for a meeting to review documentation on how the disclosed potential for research conflict of interest is being addressed as proposed in the RCOI Management Plan.

In general, an audit of the RCOI Management Plan should address the following elements:

1. Potential for data bias:
* Description of Entity and Principal Investigator’s relationship with the Entity that resulted in a need for a management plan. This will provide the background for why the management plan was necessary.
* Was the Principal Investigator involved in the formation of the Entity?
* What is the Principal Investigator’s time commitment to the Entity?
* Has the Principal Investigator forwarded progress reports or data to the Research Monitor for review?
1. Use of UNTHSC resources:
* What UNTHSC equipment and/or facilities is being utilized for this research project?
* What steps are taken to assure that the Investigator’s external activities do not involve inappropriate use of state and university resources, personnel/students, misuse of the University name or trademarks?
1. Involvement and awareness of Principal Investigator and student/laboratory staff
* Do any students or research staff (other than the Principal Investigator) have a relationship with the Entity? (may not apply to all investigators)
* Are student(s) and/or laboratory staff personnel notified of the Principal Investigator’s relationship with the entity that resulted in the need for an RCOI Management Plan?

The RCOI Committee representative(s) conducting the audit will inform the Principal Investigator of the audit process. This visit may include review of records (electronic/hard copy) that indicate the disclosed research conflict of interest is being adequately managed. During the audit, the Principal Investigator will provide the relevant information requested to conduct an appropriate, timely and effective audit. Among these documents (but not limited to) are:

* Copies of any manuscripts related to the project which is being managed
* Copy of disclosures submitted with any journal article submissions
* List of all students/laboratory staff involved in the project.
* A list of student’s degree program and thesis/dissertation committee, if applicable.
* Other documents, as needed.

After meeting with the Principal Investigator, the RCOI Committee representative(s) conducting the audit will schedule one-on-one meetings with any students/laboratory staff involved in the research project.

During the meeting with students/laboratory staff, the RCOIC representative will re-confirm whether the Principal Investigator has disclosed his/her relationship with the Entity that resulted in the need for a management plan. This meeting can be held in the lab or a designated office. Students/laboratory staff will be reminded that any problems or concerns regarding any aspect of the research project can be freely communicated to the Office of Research Compliance as well as UNTHSC Chief Compliance Officer. In addition, suspected improper, unethical conduct or activity can be communicated/reported anonymously by calling the EthicsPoint Trust Line at 844-692-6025 or the Internet at <http://www.unthsc.ethicspoint.com>.

At the end of the audit visit, the Audit/Checklist Form will be forwarded to the Research Monitor and Unit Supervisor to confirm various aspects of the management plan. Then the completed form will be sent via Docu-Sign (or other electronic documentation systems) for signatures.

The signed Audit/Checklist will be presented at the next RCOI Committee Meeting for review and consideration. If further action is needed regarding a corrective action plan or non-compliance, a meeting will be scheduled with the applicable individuals. If the RCOI Committee accepts the Report as submitted, then signatures from the RCOI Committee Chair and Vice President for Research and Innovation are obtained. A copy of the final Report will be distributed as applicable.

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**RESEARCH CONFLICT OF INTEREST (RCOI) MANAGEMENT PLAN RCOI-MP Number: \_\_\_\_\_\_\_**

**Post Approval Monitoring Checklist**

Reviewer(s):       Date of Review:

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

Principal Investigator:

Department/Institute:

Entity:

**Information Provided by Investigator:**

1) Description of Entity and Principal Investigator’s relationship that resulted in a need for a management plan. (This will provide the background for why the management plan was necessary.)

2) Was the Principal Investigator involved in the formation of the start-up Entity?

Yes [ ]  No [ ]  If yes, please provide details.

3) Is there intellectual property involved? Yes [ ]  No [ ]  If yes, please provide details.

4) What was the Principal Investigator’s time commitment to the Entity?      %

5) What steps has the Principal Investigator been taking to manage this potential research conflict of interest?

6) Has the Principal Investigator forwarded progress reports or data related to the Entity to the research monitor for review? Yes [ ]  No [ ]  If yes, please provide copies of the reports. If No, explain:

7) Has the Principal Investigator conducted presentations paid for or on behalf of the Entity?

Yes [ ]  No [ ]  If yes, please provide details.

8) Has the Principal Investigator submitted publications paid for or on behalf of the Entity?

Yes [ ]  No [ ]  If yes, please provide a copy of the publication and disclosure.

9) Do any of the students/laboratory staff have a relationship with the Entity? Yes [ ]  No [ ]  If yes, please provide details and attach copy of signed form for each individual.

 If so, name each person, indicate employment status and engagement on the project involving the Entity:

 Name EmplID/Student ID Involvement with Entity Activity

10) Are the students/laboratory staff aware of/have been notified of the Principal Investigators relationship with the entity that resulted in the need for a management plan? Yes [ ]  No [ ]

10A) Schedule one-on-one meeting(s) with students/laboratory staff (if applicable) involved in the research project. Re-confirm whether Principal Investigator has disclosed his/her relationship with the Entity.

11) What UNTHSC equipment and/or facilities are utilized for this research project? Please provide a list of equipment/purpose and location of facilities.

12) Does the Principal Investigator have any additional information to add to their current management plan that has not previously been disclosed? Yes [ ]  No [ ]  If yes, please provide details.

13) Does the Principal Investigator identify anything else that they would like to disclose that has not been previously disclosed? Yes [ ]  No [ ]  If yes, please provide details.

14) The Principal Investigator has provided the following documents indicating compliance with their management plan. (Please check all that apply.)

[ ]  Copies of any manuscripts related to the project which is being managed

[ ]  Copies of any disclosures submitted with any journal article submissions

[ ]  List of all students/laboratory staff involved in the project.

[ ]  List of students’ degree program and thesis/dissertation committee, if applicable.

[ ]  Signed copies of students/laboratory staff involvement forms

[ ]  Progress/data reports related to the Entity

[ ]  Additional documents requested.

**Information Provided by Research Monitor:**

1) Description of Entity and Principal Investigator’s relationship that resulted in a need for a management plan. (This will provide the background for why the management plan was necessary.)

2) Was the Principal Investigator involved in the formation of the start-up Entity?

Yes [ ]  No [ ]  If yes, please provide details.

3) Is there intellectual property involved? Yes [ ]  No [ ]  If yes, please provide details.

4) What was the Principal Investigator’s time commitment to the Entity?      %

5) What steps has the Principal Investigator been taking to manage this potential research conflict of interest?

6) Has the Principal Investigator forwarded progress reports or data related to the Entity to the research monitor for review? Yes [ ]  No [ ]  If yes, please provide copies of the reports. If No, explain:

6A) Please provide a brief description of the Principal Investigator’s Research and how it is related to the Entity.

7) Has the Principal Investigator conducted presentations paid for or on behalf of the Entity?

Yes [ ]  No [ ]  If yes, please provide details.

8) Has the Principal Investigator submitted publications paid for or on behalf of the Entity?

Yes [ ]  No [ ]  If yes, please provide a copy of the publication and disclosure.

9) Do any of the students/laboratory staff have a relationship with the Entity? Yes [ ]  No [ ]  If yes, please provide details and attach copy of signed form for each individual.

 If so, name each person, indicate employment status and engagement on the project involving the Entity:

 Name EmplID/Student ID Involvement with Entity Activity

10) Are the students/laboratory staff aware of/have been notified of the Principal Investigators relationship with the entity that resulted in the need for a management plan? Yes [ ]  No [ ]

11) What UNTHSC equipment and/or facilities are utilized for this research project? Please provide a list of equipment/purpose and location of facilities.

12) The Principal Investigator has provided the following documents indicating compliance with their management plan. (Please check all that apply.)

[ ]  Copies of any manuscripts related to the project which is being managed

[ ]  Copies of any disclosures submitted with any journal article submissions

[ ]  List of all students/laboratory staff involved in the project.

[ ]  List of students’ degree program and thesis/dissertation committee, if applicable.

[ ]  Signed students/laboratory staff involvement forms

[ ]  Progress/data reports related to the Entity

[ ]  Additional documents requested.

**Supervisor Information:**

1) Description of Entity and Principal Investigator’s relationship that resulted in a need for a management plan. (This will provide the background for why the management plan was necessary.)

2) Was the Principal Investigator involved in the formation of the start-up Entity?

Yes [ ]  No [ ]  If yes, please provide details.

3) Is there intellectual property involved? Yes [ ]  No [ ]  If yes, please provide details.

4) What was the Principal Investigator’s time commitment to the Entity?      %

5) What steps has the Principal Investigator been taking to manage this potential research conflict of interest?

6) Has the Principal Investigator forwarded progress reports or data related to the Entity to the research monitor for review? Yes [ ]  No [ ]  If yes, please provide copies of the reports. If No, explain:

7) Has the Principal Investigator conducted presentations paid for or on behalf of the Entity?

Yes [ ]  No [ ]  If yes, please provide details.

8) Has the Principal Investigator submitted publications paid for or on behalf of the Entity?

Yes [ ]  No [ ]  If yes, please provide a copy of the publication and disclosure.

9) Do any of the students/laboratory staff have a relationship with the Entity? Yes [ ]  No [ ]  If yes, please provide details and attach copy of signed form for each individual.

 If so, name each person, indicate employment status and engagement on the project involving the Entity:

 Name EmplID/Student ID Involvement with Entity activity

10) Are the students/laboratory staff aware of/have been notified of the Principal Investigators relationship with the entity that resulted in the need for a management plan? Yes [ ]  No [ ]

11) What UNTHSC equipment and/or facilities are utilized for this research project? Please provide a list of equipment/purpose and location of facilities.

12) The Principal Investigator has provided the following documents indicating compliance with their management plan. (Please check all that apply.)

[ ]  Copies of any manuscripts related to the project which is being managed

[ ]  Copies of any disclosures submitted with any journal article submissions

[ ]  List of all students/laboratory staff involved in the project.

[ ]  List of students’ degree program and thesis/dissertation committee, if applicable.

[ ]  Signed students/laboratory staff involvement forms

[ ]  Progress/data reports related to the Entity

[ ]  Additional documents requested.

**Signatures**

To the best of my knowledge and with information available to me, the information provided in this audit report checklist is accurate.

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Compliance Auditor/Reviewer Date

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Principal Investigator Date

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

Research Monitor Date

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Principal Investigator’s Supervisor Date

**RCOI**

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UNTHSC RCOI Committee Chairperson or Designee Date

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UNTHSC VP for Research & Innovation Date

