

University of Tennessee, Knoxville
Research Conflicts of Interest (RCOI) Management Plan

Researcher: _____

Effective Date: _____

This RCOI Management Plan is to assist in managing or reducing real or potential financial conflicts of interest in research that may develop related to the named researcher's outside interests. This plan is developed to meet requirements of [COI Policy GE0002](#).

Outside Interest(s)

1. Company
 - a. Description of interest in the company.

Scenarios Necessitating Management Plan

1. _____ sponsors funded projects which _____ also works on.
 - a. Cayuse Project # _____ – Title
 - b. Cayuse Project # _____ – Title
2. Licensing agreement _____ (UTRF Number)

Plan Action Items

Item #1 – Notification of Changes in Outside Interests	
Performed by: _____	Oversight by: Supervisor
Performance Frequency: Ongoing; Notification provided within 30 days of a change in status.	
Action Points:	
<ol style="list-style-type: none"> 1. An updated Outside Interest Disclosure (OID) form is to be submitted within 30 days of a change in the status of any outside interest in accordance with COI Policy GE0002. 2. You must notify the Assistant Vice Chancellor for the Responsible Conduct of Research, their designee, and/or the Committee at the time of submission of the updated OID form. A response to the notification will be provided within 48 hours after the next scheduled RCOI Committee meeting. 	

Item #2 – Data Review	
Performed by: _____	Oversight by: RCOI Committee
Performance Frequency: Annually; Prior to submission for publication or delivery of report	
*Data monitor selected by _____ & approved by the RCOI Committee	
Action Points:	
<ol style="list-style-type: none"> 1. A data analysis of the study must be verified by a third party who has no financial ties to _____, or to the research. 2. Prior to submission to academic journals, the Researcher will provide the paper with sufficient details of the data analysis to the Monitor (_____). In some cases, the Researcher may be asked (by Monitor) to present his/her work including a Q&A session. 3. If the Monitor becomes unable to verify work, the Researcher will notify the Assistant Vice Chancellor for the Responsible Conduct of Research (Dr. Pruett), her designee, and/or the Committee within 10 days. A response to the notification will be provided within 48 hours after the next scheduled RCOI Committee meeting. 4. The Monitor's role will be to determine if there are any systematic/abnormal biases (positive or negative) in the analysis. If there are issues that appear to abnormally bias the results or the analysis can't be defended to the satisfaction of the Monitor, he/she will raise the issue with the Assistant Vice Chancellor for the Responsible Conduct of Research (Dr. Pruett) for further review. The Monitor is simply providing an informed opinion about the validity of the research and in no way is accepting liability for any issue arising from this situation. 	

Item #3 – Disclosure of Financial Interest	
Performed by: _____	Oversight by: Conflict of Interest Officer
Performance Frequency: Ongoing; At time of publication and upon initial engagement with collaborators/trainees	
Documentation: Written confirmation of publications, presentations, and discussions to be retained by _____	
Action Points:	
1. Public Disclosures	

- You must disclose your related significant financial interests in future publications and presentations that involve research supported by ___ as well as any research which may appear to affect or be affected by your financial interest. The disclosure should be obvious in nature (i.e. in the title footnotes). Recommended language is, “_____ has research-related financial interests in [the sponsor].”
2. Disclosure to Collaborators & Trainees
- Collaborators must be informed in writing that you have significant financial interests if they participate in research supported by _____ and/or research that might appear to affect or be affected by your significant financial interests.
 - Trainees must be informed in writing of your significant financial interests (including but not limited to, pre- and post-doctoral students, collectively referred to as trainees) if they participate in research supported by _____ and/or research that might appear to affect or be affected by your significant financial interests, since your interests may potentially impact the trainees’ research if the trainees are pursuing University of Tennessee, Knoxville degrees where research is required (e.g., confidentiality issues, risks of publications delays, direction of research).

Item #4 – Annual Review of Management Plan Performance	
Performed by: _____ & COI Officer	Oversight by: RCOI Committee
Performance Frequency: Completed on annual basis from date of plan approval	
Action Points:	
<p>1. A written report will be provided to the RCOI Committee on an annual basis which covers, at a minimum:</p> <ul style="list-style-type: none"> Review of documents related to above action items. Review of each action item indicated above and steps taken towards their fulfillment. Updating any transactions or activities with _____ that have occurred since the effective date of the management plan or last annual review. 	

Add sections as needed for human subjects, etc.

Ongoing Responsibilities & Policy

- You must provide additional information and/or reports as requested by the RCOI compliance officer or RCOI committee within fifteen business days of a request (unless otherwise noted).
- University of Tennessee, Knoxville resources must not be inappropriately utilized for the benefit of any company in which you have a significant financial interest, or any other personal financial interest.
- No materials or proprietary information regarding your current or future inventions may be transferred to licensees or other entities without an appropriately executed Material Transfer Agreement or other necessary agreement executed by University of Tennessee, Knoxville as applicable.
- If intellectual property invented by the Researcher is licensed to ____, an independent oversight committee will annually assess/monitor for potential financial conflicts of interest in research and will review interim disclosures and research grants/contracts on an ongoing basis.
- The RCOI Committee has a responsibility to inform the IRB of all management plans being implemented which involve human subjects or animal subjects. Should research involve human or animal subjects, the IRB or IACUC may enact additional measures if necessary to manage an identified potential conflict of interest.
- Faculty, staff, or students under the direction of the Researcher as part of their university role are not to be employed for _____ sponsored research not associated with the University, nor employed by _____, unless reviewed and approved by the RCOI committee (typically prohibited).
- A completed Invention Disclosure Form must be completed for current or future inventions as required by the University of Tennessee policy BT0024 - Statement of Policy on Patents, Copyrights, and Other Intellectual Property.
- In addition to this RCOI management plan, these outside interests may be subject to review and implementation of a plan which provides mitigation in another area (Export Control, Technology Control, etc.).

AGREEMENT

By signing below, you are certifying to University of Tennessee, Knoxville the following:

I have read, understand, and agree to comply with the requirements for managing potential financial conflicts of interest in research as set forth in this RCOI Management Plan.

I understand and agree that failure to comply with applicable federal regulations, state laws, University of Tennessee, Knoxville policies, and the terms of this RCOI Management Plan shall result in the total withdrawal of or limitations to University of Tennessee, Knoxville's approval for me to hold a financial interest and/or participate in the research.

I have read the Policy and other information available on the University of Tennessee, Knoxville Office of Research web site and have completed the University of Tennessee, Knoxville training module on financial conflicts of interest in research.

Name (Date)
Title

Monitor Name (Date)
Title

Supervisor
Title

Scott Canner (Date)
Research Conflict of Interest Officer

Dr. Sarah Pruett (Date)
Assistant Vice Chancellor for the Responsible Conduct of Research
Research Integrity Officer