

## COI Committee Management Plan Letter Template

Date

Name

Department Name

Re: **Name of Outside Entity/Entities** (“Conflicted Entity” and/or “Conflicted Entities”)

Dear \_\_\_\_\_,

On Date of COI Committee meeting, the Conflict of Interest Committee (COI Committee) reviewed your COI/COC Disclosure Form (the “COI/COC Disclosure”) dated Date of Disclosure Form in which you disclose a financial interest in Name of Conflicted Entity, either through ownership, remuneration, or some other provision of value. The COI Committee has determined that your interest in the Conflicted Entity constitutes a conflict of interest that could be reasonably construed as relating to your institutional responsibilities and/or your sponsored research, and therefore creates a potential, perceived, or actual conflict of interest that must be managed, reduced, and/or eliminated through the use of a Management Plan. Therefore, beginning on page 3, please find the COI Committee’s proposed Management Plan. **Please review, sign, and return the Management Plan to Research Compliance Services (RCS) within fourteen (14) days of receipt. Electronic delivery of the signed Management Plan through DocuSign, email, or other similar methods will satisfy this requirement.**

As a reminder, you are responsible for submitting an updated annual COI/COC Disclosure Form (or Change Request Form as applicable) within thirty (30) days of any changes to the financial interest(s) identified above and/or when you acquire any new financial interests and/or relationships that may constitute a significant financial interest under the University of Nebraska-Lincoln’s Conflict of Interest Policy. If appropriate, the COI Committee will review your updated COI/COC Disclosure Form to determine whether your changed and/or new activities create potential, perceived, or actual conflict(s) of interest and whether a revised Management Plan is required to manage, reduce, and/or eliminate the changed and/or new potential, perceived, or actual conflict(s) of interest.

Be advised that the COI Committee will also review your current, active COI/COC Disclosure any time you are added to new or existing research, sponsored program, or educational project, to determine if your interest(s) in the Conflicted Entity/Conflicted Entities creates potential, perceived, or actual conflict(s) of interest requiring updates to this Management Plan. Should the COI Committee update your Management Plan, you will be notified and required to implement the revised Management Plan to participate in the new or continuing project(s).

Additionally, please make sure to complete and maintain conflict of interest training to ensure you remain current with the University’s conflicts of interest and conflicts of commitment policies. The University-approved training module is currently included as part of the annual completion of the COI/COC Disclosure form. Your COI training is up to date and complete.

Prior to one year from the effective date of this Management Plan, RCS will send you a compliance checklist that you will need to complete and return prior to the applicable COI Committee meeting

wherein your management will be discussed. More information on this meeting and the timeline for the checklist's return will be provided at the time the checklist is sent.

As an Institution, the University of Nebraska-Lincoln is committed to encouraging its employees to pursue endeavors outside the University as a means of contributing to the economic growth and development of the state. The COI Committee would like to thank you for your important efforts in pursuing such endeavors and assisting in the disclosure and management of potential, perceived or actual conflicts.

As a reminder, the Board of Regents (BOR) maintains a policy on Conflicts of Commitment and limits outside activities to no more than two (2) days per month and not exceeding two (2) years, without Board approval. The UNL Conflict of Interest (COI) website provides links to the BOR policy, UNL COI policy, and other helpful documents and information:  
<http://research.unl.edu/researchresponsibility/conflict-of-interest/>.

Please feel free to contact UNL COI staff within RCS at 402-472-6965 or unlcoi@unl.edu if you have any questions regarding the COI Committee's review or your future disclosure responsibilities.

Sincerely,

Chair, Conflict of Interest Committee

## Conflict of Interest Committee Management Plan

Investigator/Support Personnel: **Name**

Research/Projects Affected: Any UNL project involving or funded by **Name of Conflicted Entity/Entities** (“Conflicted Entity” and/or “Conflicted Entities”)

### A. Summary of COI Committee’s Determination

You, Name, disclosed a significant financial interest in the Conflicted Entity. The COI Committee reviewed your relevant documentation, including your COI/COC Disclosure and determined that this significant financial interest creates a potential, perceived, or actual conflict of interest that must be managed.

### B. COI Committee’s Management Plan

\*Add clauses from management plan template language (page 4) as appropriate.

### C. COI Committee Chair

\_\_\_\_\_

Chair, Conflict of Interest Committee

### D. Investigator/Conflict Individual

If you accept this Management Plan, sign below. If you want to appeal the COI Committee’s Management Plan, you must submit a written request for reconsideration to the COI Committee along with any supporting materials. **Please return this form signed or your written request for reconsideration by the COI Committee within fourteen (14) days of receipt.**

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

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

**Return to Research Compliance Services within fourteen (14) days of receipt.**

Cc: Name of Dept. Chair, Title, Department

File

## Management Plan Template Language

### General Provisions

- 1) Any publications, lectures, presentations, and/or dissemination of knowledge that could be reasonably construed as relating to any conflicting outside activities must be accompanied with a full disclosure statement. The disclosure statement should be included in relevant publications, lectures, presentations, and dissemination of knowledge as necessary. At your option, you may make a general reference to the conflict, and refer or link to a full disclosure on your professional website. All disclosure statements must include the nature of the conflict and the name of the entity. Dissemination of knowledge is interpreted broadly and would include, but is not limited to, press releases, question and answer sessions, advisory opinions, email/electronic communication, the online dissemination of information, interviews, and/or community engagements when such items could be reasonably construed as relating to any conflicting outside activity or conflicted entity.

*The following is an example of a full-disclosure statement that could be used:*

(Name), author(s) of this [publication, lecture, presentation or poster, or similar dissemination of knowledge] has disclosed a significant financial interest in [Entity/Relationship]. In accordance with its Conflict of Interest policy, the University of Nebraska-Lincoln's Conflict of Interest Committee has determined that this must be disclosed.

- 2) Any administrators with a financial interest in a company sponsoring research or perceived to be involved at the University must recuse themselves from decision making processes involving these companies or projects.
- 3) If you are involved in a project with a Conflicted Entity, you may serve as PI for *either* the University of Nebraska-Lincoln or the Conflicted Entity but may not serve as PI at both.
- 4) You must step down from the position of Principal Investigator on IRB/OSP/Other Project #XX. You may/may not remain involved in the project as a (list allowable role).
- 5) In your capacity as an UNL employee, you shall not process, sign-off, or authorize payments to/from the Conflicted Entity or any Conflicted Entities.

### Provisions regarding student/employee protections

- 6) You shall inform any students or team members involved in work associated with the Conflicted Entity / one or more Conflicted Entities about your conflict of interest ("Student Notification"). Student Notifications must be in writing with signed copies uploaded to your current Disclosure Form in NuRamp. See Appendix A for the Student Notification template as well as instructions for uploading the notification to your Disclosure Form in NuRamp.
- 7) You shall abstain from voting when any affected student is being graded, their thesis/dissertation is reaching a formal state of approval, and during any formal discussion by the Committee. You shall also recuse yourself from any vote by the Committee on all official grading decisions.

## **IRB Specific Provisions**

- 8) To manage the conflict of interest and significant financial interest identified above, you shall disclose your financial interest to all future subjects enrolled in the below research project as part of the Informed Consent process. Current subjects that have already consented do not need to be re-consented. This clause and modified informed consent language applies to the following IRB projects:

Example:

- Applicable IRB projects

The current approved consent form language for IRB Project PROJECT # is:

“The investigator, Dr. NAME, owns stock in NAME OF COMPANY. This ownership has been deemed a potential conflict of interest in regard to the conduct of this research project sponsored by SPONSOR NAME. The University of Nebraska-Lincoln’s Conflict of Interest Committee (COI Committee) and Institutional Review Board (IRB) have reviewed Dr. NAME’s stock ownership and the possible financial benefit to Dr. NAME resulting from the research project. The COI Committee and the IRB believe that Dr. NAME’s stock ownership is not likely to affect your safety and/or the scientific quality of this research project. Additional information is available upon request from the investigator, or if you would like to speak to someone unaffiliated with this research project, please contact Research Compliance Services at (402) 472-6965.”

- 9) To manage the conflict of interest and significant financial interest identified above, you shall disclose your financial interest to all future and current subjects enrolled in the below research project, as part of the informed consent process. Current subjects that have already consented must be re-consented with the updated consent document. This clause and modified informed consent language applies to the following IRB projects: (See Example in clause #8).
- 10) The disclosure statement in the consent must be updated to the University of Nebraska-Lincoln’s template language. Subjects already consented do not need to be re-consented; however future subjects will have to sign the updated consent. (See Example in clause #8).
- 11) Informed consent for the study will be obtained by a non-conflicted co-investigator or study coordinator, and you may/may not be involved in the explanation of the protocol and its risks and benefits, answering participant questions, and in assuring that participants meet the study entry criteria.
- 12) If you are involved in data collection and/or detection of adverse events for this study, the objectivity of the data will be confirmed by a non-conflicted co-investigator.
- 13) The statistical methods for data analysis in this study will be, or have been, designed in conjunction with a non-conflicted statistician and your work in data analysis and interpretation will be in conjunction with a non-conflicted co-investigator.
- 14) You will not be involved in the primary data analysis for this study but can maintain involvement in the data interpretation for this study, as required for authorship.

15) You must not be solely responsible for determining the severity, causality, and/or reporting requirements of reportable items, including adverse events (AE), noncompliance, and/or unanticipated problems, that are reportable to the IRB, the sponsor, or external entities. You may assist with reportable items attributions only if a non-conflicted member of the study team conducts an independent review and documents the reportable item reporting determination.

UNL RCS TEMPLATE