Report of Non-University Activity (RNUA) Conflict Management Plan Terms and Conditions

Date: September 14, 2015

I. Introduction

Your Report of Non-University Activities (RNUA) indicated that you have a significant financial interest (SFI) or time commitment involving an entity external to the University of Illinois (Entity). This SFI or time commitment presents an apparent conflict of commitment or interest with your University responsibilities. Due to the nature of this relationship with the Entity, the University requires additional management of the apparent conflict of interest or commitment. Below is an outline of the University's expectations for managing the apparent conflict and any actual conflicts that may arise.

II. Conflict Management

A. Managing Conflicts of Commitment

- When your activities change, you must continue to disclose conflicts of commitment on your RNUA using the START myDisclosures application: https://myresearch.uillinois.edu/myDisclosures/
- Actual time commitment with the non-University activity must be reported retrospectively, and estimated time commitment prospectively.
- Even if you have discontinued activities, you still must report all past activities in the next RNUA reporting period.

B. Managing Your Role in Entity-related Research

- Neither you nor any other conflicted academic staff members may represent the University or the Entity in any contract negotiations between the Entity and the University, including but not limited to those relating to sponsored research and activities.
- You must disclose all significant financial interests (SFIs) on all protocol or proposal applications (e.g., Institutional Review Board (IRB) applications, Proposal Approval Forms/ PAF/ Proposal Transmittal Form, ICF, etc.) as required, and complete a project specific management plan for all transactional disclosures, as required by the campus Conflict of Interest (COI) office.
- *Impartial Review*: With department or college approval of a conflict management plan, you may serve as an investigator on a research project or other activity sponsored by the Entity, or conduct research related to the Entity's products or services, provided the research or activity includes an impartial review mechanism as part of a project specific management plan or a more general conflict management plan.
 - The impartial review management mechanism will be documented by the investigator, the department and the COI office, using the project specific management plan.
 - You must follow the University's guidelines on conducting the impartial review.

 The department must maintain the original report for the impartial review on file and submit a copy to the appropriate research office (OVCR for either UIUC or UIC and Provost for UIS).

See Resources below for campus-specific guidance and forms.

C. Managing Conflicts when Other University Employees or Students are Involved in the Outside Activity

- The campus COI office may contact University students or employees involved in the outside activity to provide guidance on their disclosure requirements or the conflict management process.
- The department must ensure that each student involved in sponsored research or other activities with the Entity has a non-conflicted point of contact at the University. You must record the name of the contact person on the RNUA using the START myDisclosures application.
- If you are aware of any other academic staff member from your unit who is involved in any activities with the Entity, you must inform your UEO, who will ask the University academic staff to update his or her RNUA form, or you must inform the UEO of the individual's home department, if different from your own. You are responsible for making sure that University academic staff disclose the proposed activities with the Entity on the RNUA form and obtain administrative review and approval before they may undertake the activities.
- Before involving any University students or employees with whom you work in research or other activities involving or related to the Entity, you must inform certain individuals of your interest or activity. Please follow your campus procedure, as indicated below.

For UIUC staff:

- You will notify your Unit Executive Officer and the Executive Associate Vice Chancellor for Research in writing of:
 - Each staff member or student name and address and
 - All related research projects in which the staff or student will be involved

For UIC staff:

- You will notify each student or employee in writing of:
 - Your relationship with the Entity
 - The University of Illinois Policy on Conflicts of Commitment and Interest
 - The conflict management mechanisms to protect them.
- You must upload the letter(s) in the START myDisclosures application when you submit your RNUA. After the RNUA has been finalized, if any new students or University employees with whom you work become involved in activities with the Entity, you must update to your RNUA in order to upload new letters.

For UIS staff:

• Contact your COI office.

See Resources below for templates that are available for your campus.

D. Managing Conflicts Involving the Use of Animal or Human Subjects

- Animal studies: For policies and guidelines related to animal studies, you must consult with the Office of Animal Care and Institutional Biosafety (OACIB)/ The Institutional Committee for the Care and Use of Animals (ICCUA)/Institutional Animal Care and Use Committee (IACUC).
- Human Subject studies: If your research qualifies as human subjects research, you must comply with all requirements of the campus institutional Review Board (IRB), including but not limited to disclose potential conflicts of interest to the IRB, provide information requested by the IRB, and comply with conflict management mechanisms required by the IRB.
- Typical management mechanisms include:
 - Disclosure of significant financial conflicts of interest on the protocol application (initial review, continuing review, or amendment)
 - Disclosure of significant financial interest requires that the Principal Investigator complete a project specific disclosure and management plan
 - Disclosure to subjects of all financial conflicts of interest as part of the informed consent process.

See Resources below for your campus IRB policies and template language for consent disclosure.

E. Managing Conflicts Concerning Use of University Resources, Including Intellectual Property

- Unless otherwise agreed by the University, you must disclose all intellectual property created as a result of your research, including Entity sponsored research, In compliance with the General Rules.
- You may not use University employees, intellectual property or resources (e.g., labs, equipment, reagents, computers, data) for the benefit of the Entity without prior written approval by the appropriate University official.
- All agreements with the Entity for the use of University intellectual property must comply in all respects with the University's Intellectual Property Policy and be approved by the Director of the OTM.
- You will not provide the Entity access to non-publicly available information unless agreed to by the University. Relevant agreements include, but are not limited to, sponsored research agreements or external data use agreements.

F. Managing Publication Rights Pertaining to Entity Sponsored Research

- Unless otherwise agreed by the University, the Entity may have no more than 90 days to review manuscripts or presentation materials.
- You must disclose your relationship with the Entity in all of your presentations and publications, taking into account any requirements of the journal or venue, when your Entity-related research is included in the publication or presentation.

G. Managing Conflicts Related to Procurement

• Conflicts of interest in procurement may arise from your non-University activity that will require management. You should be aware that your situation may implicate other state

UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN · CHICAGO · SPRINGFIELD laws or University policies. You are advised to consult with the Office for Business and Financial Services as well as the University Ethics Office.

OBFS: https://www.obfs.uillinois.edu/

Ethics Office: https://www.ethics.uillinois.edu/

III. Institutional Obligations to Report Financial Conflicts of Interest

A. Federal Reporting Requirements

- The National Institutes for Health (NIH)/Public Health Service (PHS) requires notification of all financial conflicts of interest (FCOI). When you receive a notification of award of any NIH/PHS funds for any project that presents a potential conflict of interest, you must notify the campus COI office immediately and complete the appropriate sponsor-specific disclosure. If a FCOI is found to exist, you must cooperate in the development of a management plan to manage the FCOI or eliminate the conflict. When the conflict is deemed managed, the COI office will report the conflict to the proper funding agency.
- The University has an obligation to make certain information publicly available. For example, a report of an FCOI to PHS must include the name of the investigator with the FCOI, the entity with which the Investigator has an FCOI, the nature and value of the financial interest, a description of how the financial interest relates to the PHS-funded research and a description of the key elements of the Institution's conflict management plan. See http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3212.
- If a conflict of interest was not disclosed, reviewed or managed in a timely manner, or if you failed to comply with a conflict management plan, the University will complete a retrospective review, a mitigation report or other procedures required by law.

IV. Sanctions

 The University Policy on Conflict of Commitment and Interest states that sanctions are warranted for failure to report potential conflicts and/or failure to abide by a management plan. The University may impose sanctions consistent with the rights of academic staff members under the University Statutes and other applicable policies and practices. Severity of sanctions depends on the extent of the violations.

V. Resources

University Policy on Conflict of Commitment and Interest: <u>http://research.uillinois.edu/coci/cocipolicy</u>

Campus Resources – Use resources specific to your campus.

Urbana-Champaign (UIUC)

Office for the Protection of Research Subjects policy on investigator conflict of interest: http://oprs.research.illinois.edu/?q=investigator-handbook/index.html. Model Language for disclosing financial conflict of interest to potential research participants. Examples are available to fit a variety of situations. http://research.uic.edu/sites/default/files/forms/files/Model%20Language.doc

Guidelines for Start-up Companies: http://www.cam.illinois.edu/iii/iii-20.htm

Chicago (UIC)

Impartial Review campus guidelines are available at: http://research.uic.edu/sites/default/files/form/files/Guidelines_Impartial.pdf

Template letters for disclosure to faculty, staff, or students: http://research.uic.edu/compliance/coi/forms

Human Subjects Protections Program policy on investigator conflict of interest: <u>http://research.uic.edu/node/1721</u>

Model Language for disclosing financial conflict of interest to potential research participants. Examples are available to fit a variety of situations. http://research.uic.edu/sites/default/files/forms/files/Model%20Language.doc

Guidelines for Start-up Companies: http://research.uic.edu/coi/managing-conflicts/faqs_sbir%26sttr

Springfield (UIS)

The UIS Human Subjects in Research policy on investigator conflict of interest: http://www.uis.edu/grants/irb/policy/