

POTENTIAL FINANCIAL CONFLICT OF INTEREST (COI) DISCLOSURE REPORT

For <u>SUBRECIPIENTS & OTHER AFFILIATES</u> under sponsored programs funded and administered by UCF

SUBRECIPIENT OR OTHER AFFILIATE name:	Reporting Period:	
If affiliated to a company/entity/institution, list name below:	Initial disclosures must be no less than 12 months prior to the subcontract/agreement start date: Subcontract Start Date: / /20	
Address:	Disclosure Period: From: / / 20	
or, Check here if not affiliated to a company/entity	To://20	
or institution	NOTE: A new COI disclosure form must be submitted annually	
Select type of disclosure:	during the period of performance covered by the Subcontract	
New annual disclosureAmendment to disclosure	Agreement.	

PURPOSE:

The Federal government established revised conflicts of interest (COI) regulatory standards effective August 24, 2012 for institutions applying for or that receive Federal research funding by means of a grant, cooperative agreement or contract. Recipients of Federal research funds must ensure their Subrecipients or Other Affiliates (herein called subrecipients) performing program work adhere to the Federal COI regulations. Subrecipients must declare whether their organization adheres to the Federal COI regulation. If a subrecipient does not adhere to the Federal COI regulations they must comply with the University of Central Florida's conflict of interest policies and procedures (http://www.coi.ucf.edu/policies.html).

Procedure

Federal COI regulations require recipient/subrecipient personnel responsible for the **design, conduct or reporting** of the research to disclose their significant financial interests no later than the time of application (see Notes). Changes to the conflict of interest disclosure must be posted (Amendment) by the employee within 30 days of discovering, acquiring, or committing to a new or changed financial conflict of interest. Changes shall be disclosed using <u>this form</u> by selecting the "**Amendment to Disclosure**" box under section "type of disclosure" located at top of Page 1.

Multiple activities for each question must be reported on a separate disclosure form. Answering "Yes" to any question requires the completion of all sub-questions. Use additional pages (if necessary) to complete your disclosure statement.

The subrecipient will be notified when a potential conflict of interest requires mitigation or elimination prior to the expenditure of Federal research funds.

NOTES:

- Refer to Pages 6 & 7 for a description of the most relevant definitions and criteria applicable to the content of this
 form.
- Questions relating to this COI disclosure form or submission process at UCF shall be addressed to the ORC's Office
 of Compliance/COI Office at coi@ucf.edu.
- http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf.



Sponsored and Non-Sponsored Research

UCF promotes objectivity in research by establishing policies and procedures that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from employees financial conflicts of interest.

Questions 1, 2 & 3 apply to an investigator/employee planning to participate (proposal application) in, or is responsible for the design, conduct and/or reporting of the research.

1. During the reporting period do you or your Immediate Family have a financial interest related to your company/institutional responsibilities, in a publicly or non-publicly traded entity in the form of remuneration and/or equity interest, that when aggregated, equals or exceeds \$5,000? [See Page 7 for reporting exclusions] (First time disclosures must include remuneration and/or equity interests received for the 12 months prior to the subcontract start date).
☐ Yes ☐ No
(If "No", proceed to question 2.)
If "Yes", provide the following information:
Entity name (Source of remuneration): Party receiving the remuneration: Self, or Immediate Family member Both Both
If "Immediate Family member", please identify family relationship:
Position type:
☐ President ☐ CEO ☐ CTO ☐ Board Member ☐ Director/Chief Research Officer
☐ Scientific Advisory Board Member ☐ Manager/Officer/Partner ☐ Other (provide details):
Type of remuneration: Salary Paid authorship Stock Options Consulting Fees Stock Stock Options Honoraria Other ownership interest (describe below):
Anticipated duration: Start date: to: End Date: Specify the anticipated time commitment to the activity: # hours: Hours are: □ Per Week □ Per Month □ Per Year
Describe how the activity interacts with your assigned duties:
 Has <u>or</u> will the Entity sponsor your research through the company/institution and/or execute a license agreement to use intellectual property authored or invented by you as a company/institution employee? Yes No
If "Yes", select Research sponsor License agreement
If "Research Sponsor", please provide details:
If "License agreement", please provide details:
Is the remuneration for services from the sponsor of a covered clinical study? ☐ Yes ☐ No
If "Yes", please describe:
If "Yes", is <u>or</u> will the amount of remuneration exceed \$25,000?



2. During the current reporting period have you been reimbursed, either directly or on your behalf, by an entity other than your employer for any extramural travel exceeding \$5,000 (per entity) that is related to your company/institutional responsibilities? [See Page 7 for
reporting exclusions] (First time disclosures must include reimbursed travel for the 12 months prior to the subcontract start date).
☐ Yes ☐ No (If "No", proceed to question 3.)
If "Yes", please provide the following information:
Entity name supporting travel:
Travel destination:;;
Travel Purpose:
3. Will the value of intellectual property rights (e.g. patents, copyrights, trademarks), upon receipt of income to you and/or your immediate family, during the reporting period, equal or exceed \$5,000 [See Page 7 for reporting exclusions] (First time disclosures must include the value of income received from intellectual property rights for the 12 months prior to the subcontract start date).
☐ Yes ☐ No
(If "No", proceed to the Certification section.)
If "Yes", please provide the following information:
Entity name:
Identify type of IP: Patents Royalties Royalty Options Option to receive Intellectual Property rights Copyrights Trademark
Party developing or who owns IP:
Short description of the property:
Describe in detail your role and responsibilities with the entity:

Certification:

I certify that the statements and disclosures provided herein are current, accurate, and complete, and understand that any false or misleading representation(s) may result in the removal of my services to UCF and/or termination of the subcontractual relationship with UCF.

Print Name:		
Signature: (Ma	anual signature required)	
Date:// <u>20</u>	_	
Contact information [REQUIRE	ED]:	
Telephone:		
E-mail:		



THIS SECTION IS TO BE USED BY UCF ONLY

Reviewer # 1: [Principal Investigator or delegated representative]

By means of an e-mail to be sent by me or my delegated representative to the ORC's COI Office (at coi@ucf.edu), which will become an attachment to this page of the form; and/ or via my signature below, as Principal Investigator or delegated representative for the proposal listed below, I affirm that my assessment of the information disclosed by the potential subrecipient who submitted this form to UCF is as follows:

□ No conflict □ Conflict identified: □ Monitoring Plan required □ Request for an Exemption/Disclosure required □ Monitoring Plan & Request for an Exemption/Disclosure required □ Unapproved conflict (Please provide details below)		
Comment(s):		
Print name:	Signature:	
Title:	Tel:	
Request fo	Plan required or an Exemption/Disclosure required Plan & Request for an Exemption/Disclosure required	
Comment(s): This disclosure pertains to:		
Proposal titled: "		
Proposal deadline:	Sponsor:	
UCF PI name:		
Notes:		
ORC reviewer:		
Print name:	 Signature:	
Title:	Tel:	
Date://20		

Definitions and criteria applicable to the content of this form

Covered Clinical Study

Covered clinical study means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase I tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols, and parallel track protocols. An applicant may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements.

Company/Institution

Business entity: means any for- profit and/or not-for profit corporation, partnership, limited partnership, proprietorship, firm, enterprise, franchise, association, self-employed individual, or trust.

Federal Conflict of Interest Criteria

A potential conflict of interest exists when a faculty member's Significant Financial Interest (anything of monetary value including salary, equity interests, and/or intellectual property rights) could directly and significantly affect the design, conduct or reporting of the research. (See National Institutes of Health Responsibility of Applicants for Promoting Objectivity in Research 42 CFR, Part 50.602, Part 50.603, and Part 50.604, National Science Foundation Proposal & Award Policies and Procedures Guide, Part II, Chapter IV. A., Grantee Standards, and U.S. Food and Drug Administration Financial Disclosure by Clinical Investigators 21 CFR, Part 54.1-3, and Part 54.4-6).

Under sponsored federal programs the potential conflict is between the investigator's personal financial interests and their ability to perform objective research.

Immediate Family

Immediate Family shall refer to the Subrecipient or Other Affiliate employee's spouse and dependent children.

Institutional Responsibilities

Institutional Responsibilities refers to an employee's professional responsibilities performed on behalf of the company/institution.

Manage

Taking action to address a financial conflict of interest, which can include reducing or eliminating the significant financial interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias or personal financial gain.

Remuneration

Means reward; recompense; salary; compensation.

Research

Research means a systematic experiment, study, demonstration, or survey designed to develop or contribute general knowledge (basic research) or specific knowledge (applied research) in all fields by establishing, discovering, developing, elucidating, or confirming engineering, science, medicine, education, mathematics, humanities, and research involving human subjects or animals. The term includes product development to include a diagnostic test or drug.

Significant Financial Interest (SFI)

The term significant financial interest consisting of one or more of the following interests of the employee (and those of the employee's spouse and dependent children) that reasonably appears to be related to the employee's company/institutional responsibilities:

- 1. with regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from an entity in the 12 months preceding the disclosure and the value of any equity interest or fixed asset value of an entity as of the date of disclosure, when aggregated, equals or exceeds \$5,000;
- 2. with regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from an entity in the 12 months preceding the disclosure, when aggregated, equals or exceeds \$5,000 or when the employee (or the employee's spouse and dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interest);
- 3. intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 4. the occurrence of any reimbursed or sponsored travel (i.e., that which is paid directly to and/or on behalf of the employee by an entity other than the subrecipient) exceeding \$5,000 (per entity for the stated disclosure period) related to the employees company/institutional responsibilities.

Exclusions relating to SFIs:

The term **Significant Financial Interest** does not include the following types of financial interests:



a. salary, royalties, or other remuneration paid by the subrecipient to the subrecipient's employee who is currently employed or otherwise appointed by the subrecipient, including intellectual property rights assigned to the subrecipient; agreements between subrecipient and its employees to share in royalties related to such rights; ownership interest in the subrecipient held by the subrecipient employee, if the subrecipient is a commercial or for profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the subrecipient employee does not directly control the investment decisions made in these vehicles;

b. income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Travel (required reporting and Exclusions):

Subrecipient employees must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid directly to or on behalf of the employee by an entity other than the subrecipient) exceeding \$5,000 (per entity for the stated disclosure period) related to the employees company/institutional responsibilities.

Exclusions relating to travel: Travel reporting requirements do not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Subrecipient or Other Affiliate

The term Subrecipient or Other Affiliate refers to a compensated or uncompensated subcontractor, sub-recipient, consultant, collaborator or other third-party entity performing research services for the University of Central Florida (UCF) under a written or verbal agreement. The term includes the subrecipient's project director (PD) or principal investigator (PI) and any other person, regardless of title or position who is responsible for the **design, conduct, or reporting** of sponsored and non-sponsored research.

----END OF DISCLOSURE FORM-----