PENNSTATE

Form A

Documentation of Subrecipient Financial Conflict of Interest Policy
The Pennsylvania State University – Office of Sponsored Programs
(use for PHS funded projects only)

Dear Potential Subrecipient:

You are receiving this letter and the attached forms because you are a proposed subrecipient on a proposal that The Pennsylvania State University intends to submit for funding from one of the PHS agencies listed below. The PHS regulations require us to collect Conflict of Interest information from you at time of proposal, and during the life of the award. **If your Institution is not listed in the FDP Clearinghouse, which tracks institutions with PHS compliant FCOI policies, Step 1 is required.** Step 2 is required *only if Box C.2. of Form A is checked*. Step 3 is required *only if Box C.1. of Form A is checked.*

PHS Agencies:	
National Institutes of Health	(NIH)
Food and Drug Administration	(FDA)
Centers for Disease Control	(CDC)
Agency for Healthcare Research and Quality	(AHRQ)
Agency for Toxic Substances and Disease Registry	(ATSDR)
Health Resources and Services Administration	(HRSA)
Indian Health Services	(IHS)
Substance Abuse and Mental Health Services Admin	(SAMHSA)

Step 1. Subrecipient Authorized Organizational Official: Please complete, sign and return the attached Form A along with the approved proposal to The Pennsylvania State University. This form must be on file before The Pennsylvania State University can submit a proposal containing your proposed subaward. ***Please return the completed Form A to the email address located on Form A, Section A: Proposal Information.***

Step 2. If (and only if) the authorized organizational official has checked **Box C.2.** of Form A indicating The Pennsylvania State University's conflict of interest policy will be followed (because your organization does not have its own FCOI policy), then EACH subrecipient Investigator (defined as a person responsible for the design, conduct or reporting of the research proposed under the subaward) must also complete, sign, and return a Form B to The Pennsylvania State University. As part of Form B, each Investigator must certify that they have read and understood the attached SFI Training. Training must be repeated every four years. ***Please return the completed Form B to: coistaff@psu.edu.***

Step 3: If the Authorized Organizational Official has checked **Box C.1.** of Form A indicating that your institution's COI policy will be followed, *and* if the COI Official at your institution determines that one or more Investigators on this project have an FCOI related to the project, then your institution must **submit all information required for an FCOI report.**

- For new awards, information on identified FCOI must be submitted prior to execution of the subagreement;
- For disclosures of SFI made during the course of an award, information on identified FCOI must be submitted within 45 days of your institution receiving the pertinent Investigator disclosure.

Please email the following FCOI report information to The Pennsylvania State University via *coistaff@psu.edu*:

- Name of the Investigator with an FCOI;
- Name of the Entity with which the Investigator has an FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the PHS-funded research and the basis for your Institution's determination that the financial interest conflicts with such research; and
- A description of the key elements of your institution's management plan, including:
    - Role and principal duties of the conflicted Investigator in the research project;
    - Conditions of the management plan;
    - How the management plan is designed to safeguard objectivity in the research project;
    - Confirmation of the Investigator's agreement to the management plan;
    - How the management plan will be monitored to ensure Investigator compliance; and
    - Other information as necessary.

Further information regarding the PHS regulations may be found at:
http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf

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Form A

Documentation of PHS Subrecipient Financial Conflict of Interest (FCOI) Policy
The Pennsylvania State University – Office of Sponsored Programs

The information on this form is required when a proposed PHS Award subrecipient institution is not registered on the FDP Clearinghouse.

A. PROPOSAL INFORMATION (To be completed by Penn State Research Coordinator)

Penn State PI:	OSP #:
Prime Sponsor:	Proposal/Project Title:
Proposed Subaward Period of Performance:	Proposed Subaward Total:

*Return Form to (email): _____

B. SUBRECIPIENT INFORMATION (To be completed by Subrecipient)

Subrecipient Organization legal name:

Organization's address (include zip/postal code):

DUNS #:

C. SUBRECIPIENT FCOI POLICY STATEMENT (To be completed by Subrecipient)

1. ☐ My institution has a PHS-compliant Conflict of Interest policy and I will follow it. My institution will provide information related to any identified FCOI to The Pennsylvania State University prior to execution of the subagreement, or in cases where disclosure is made during the course of the subaward, within 45 days of receiving the pertinent Investigator disclosure. (Skip to Section D)
2. ☐ My institution does not have a PHS-compliant Conflict of Interest Policy, and I will follow the Conflict of Interest policy established and enforced by The Pennsylvania State University. Names of individuals working on this project who are responsible for design, conduct, or reporting of the research are shown below. (Attach Form B for each)

Investigators	Form B attached?	Date of Form B
Subrecipient PI:	☐ Yes ☐ No	
Investigator/Key Personnel:	☐ Yes ☐ No	
Investigator/Key Personnel:	☐ Yes ☐ No	
Investigator/Key Personnel:	☐ Yes ☐ No	

D. APPROVAL

To be completed by Subrecipient Authorized Organizational Official:

I certify that the information listed above is true, complete and accurate to the best of my knowledge, and that I am an Authorized Organizational Official for my institution. The appropriate programmatic and administrative personnel involved in this disclosure are aware of agency policy in regard to subawards and are prepared to establish the necessary inter-institutional agreements and/or FCOI management plans consistent with those policies.

Signature:_____ Date:_____

Printed Name:_____ Title:_____