



## **FINANCIAL CONFLICT OF INTEREST POLICY**

for U.S. Department of Health & Human Services (HHS) - U.S. Public Health Service (PHS)<sup>1</sup> Funded Projects only

### **I. INTRODUCTION**

This policy governing financial conflict of interest applies to all PHS-sponsored Investigators of the London

**Significant Financial Interest** means a Financial Interest that reasonably appears to be related to the Investigator's School Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds USD5,000<sup>2</sup>; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds USD5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding USD5,000 related to intellectual property rights and interests not reimbursed through the School, or
- e)

## **1) DISCLOSURE OF FINANCIAL INTERESTS**

All Investigators are required to disclose their outside fi

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

In the event of non-compliance with reporting and/or management of a financial conflict of interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the Investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

#### **4) REPORTING TO PHS**

The School Official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfil their reporting obligations to the PHS.

#### **5) INVESTIGATOR NON-COMPLIANCE**

##### **a) Disciplinary Action**

In the event of an Investigator's failure to comply with this Policy, the School Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the School Official is implemented.

A School Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the School Official, will be described in a written explanation of the decision to the Investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The School will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

##### **b) Retrospective Review**

In addition, if the School Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a retrospective review of the Investigator's activities and the PHS-sponsored research project will be undertaken to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the Investigator's response to the research project and the PHS Awarding Component's response to the research project.

The NIH online FCOI tutorial is available here:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

A copy of the Certificate of Completion, issued upon having successfully completed the NIH FCOI online