

## **CONFLICTS OF INTEREST NEWS:**

New regulations governing Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94) ( hereinafter referred to collectively as the “Public Health Service Regulations”), will impact the manner in which Thomas Jefferson University identifies and manages financial conflicts of interest. The Public Health Service Regulations require Thomas Jefferson University, an institution applying for and receiving NIH funding from grants and cooperative agreements, to comply with all of the revised regulatory requirements on or before August 24, 2012.

The University’s Conflicts of Interest Policies will reflect the regulatory changes outlined by the Public Health Service Regulations. Some of the notable changes mandated by the new regulations include:

- A lower dollar threshold (\$5,000) for financial interests that the University will review for potential conflicts of interest;
- Public disclosure by Thomas Jefferson University of investigators’ Financial Conflict of Interest Information including the name of the investigator, the conflicted company, and the amount of the financial interest provided in response to written inquiry from received from individuals who have satisfied the requirements for requesting the information;
- Enhanced Investigator training efforts related to conflicts of interest in research, including but not limited to mandatory investigator training at least every four years; and
- Retrospective review of grants and financial relationships when financial interests are not disclosed or reviewed in a timely manner, or management plans are not followed.

## **HELPFUL RESOURCES:**

Current Public Health Service (PHS) Regulations (effective August 24, 2012):

- Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (*provide access via link to* [\(42 C.F.R. Part 50, Subpart F\)](#))
- Responsible Prospective Contractors (*provide access via link to*) [\(45 C.F.R. Part 94\)](#) (PDF - 22 KB)
- NIH Frequently Asked Questions regarding the new regulations may be found (*provide link to FAQs on NIH site*) [FAQs to 2011 Revised Regulation](#))
- Thomas Jefferson University Policy on Conflicts of Interest ( *need link*)
- Form and Procedures Governing Requests for Financial Conflict of Interest Information (*need link*)

## Public Accessibility to Financial Conflict of Interest Information

Persons seeking information concerning any Significant Financial Interest related to NIH-funded research at Thomas Jefferson University may submit an electronic or mailed request directed to the Coordinator for University Conflicts of Interest using the official information request form posted at *(insert web address where form will be located)*. If a properly submitted written request for information is received by the Coordinator for the University's Conflicts of Interest Committee, and the following three criteria are met:

- A. The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
- B. The University's Conflicts of Interest Committee has determined that the Significant Financial Interest is related to NIH-funded research; and
- C. The University's Conflicts of Interest Committee has determined that the Significant Financial Interest is a Financial Conflict of Interest under the University's Conflicts of Interest Policy''

The University's Conflicts of Interest Committee will, within five (5) business days of receipt of the written request, issue to the requestor(s) a written Financial Conflict of Interest Information Disclosure letter, which contains the following information:

- i. Investigator's name;
- ii. Investigator's title and role with respect to the research project;
- iii. Name of the entity in which the Significant Financial Interest is held;
- iv. Nature of the Significant Financial Interest; and
- v. Approximate dollar range of the Significant Financial Interest (dollar ranges will be reported using the following format:

Dollar Range	Increments
\$0-\$4,999	
\$5,000-\$9,999	
\$10,000 - \$19,999	
\$20,000-\$100,000	by increments of \$20,000
amounts above \$100,000	by increments of \$50,000

The Conflicts of Interest Committee will not assign a dollar range value to a Significant Financial Interest if it cannot readily determine the value of the Significant Financial Interest through reference to public prices or other reasonable measures of fair market value.