

Sheppard Pratt Announcement to Researchers Regarding Changes to the U.S. Public Health Service Financial Conflict of Interest Requirements

The U.S. Public Health Service (PHS) amended its Financial Conflict of Interest (FCOI) Regulations, with the changes becoming effective on **August 24, 2012**. As a consequence, Sheppard Pratt has adopted a new **Conflict of Interest Policy for Public Health Service-Funded Research** (the "Policy"), effective immediately to incorporate the changes made by the PHS. If you, as a direct grantee, contractor or subrecipient, currently receive funding from, plan to apply for funding from, or have your salary funded by a grant from any PHS agency, you must comply with the new **Conflict of Interest Policy for Public Health Service-Funded Research**.

Important changes which may affect you:

Who must report? Any person who is an Investigator must report significant financial interests on a **Sheppard Pratt Public Health Service Funded Research Financial Disclosure Form which is available at www.sheppardpratt.org (click on Research/IRB)**. The Policy defines "Investigator" to mean the project director or principal investigator and any other person, regardless of title or position, who is responsible for any part of the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, senior/key personnel, collaborators or consultants, post-doctoral associates or residents.

When must the Disclosure Form be filed? The initial Disclosure Form must be filed by **September 15, 2012**, by all researchers engaged in PHS-funded research whether or not a significant financial interest exists. Thereafter, the Disclosure Form must be updated (i) annually each April 1; (ii) at any time that a new grant, award, or subrecipient relationship is to be applied for or undertaken; and (iii) within 30 days of any change with regard to a significant financial interest which might create a conflict of interest, including within 30 days of the occurrence of travel expense provided or reimbursed by third parties for which disclosure is required.

What must be disclosed? The PHS regulations and the Policy have broadened the disclosures which must be made. The disclosure thresholds for financial interests have been lowered from \$10,000 to \$5,000 and the requirements regarding the disclosure of travel expense provided or reimbursed by third parties have been revised to create greater transparency. The changes regarding disclosure of travel expense provided or reimburse by third parties may require more frequent updates of the Disclosure Form.

Other changes that may affect you:

1. There are new training requirements with respect to the regulations and the Policy which are applicable to all persons who qualify as Investigators or who directly or as subrecipients are applying to or receiving funding from a PHS agency with respect to a research project. **All persons who currently qualify as Investigators on PHS funded projects must complete training in the Regulations and the Policy by September 15, 2012.** A link is provided to the training website at www.sheppardpratt.org (click on Research/IRB).
2. Conflicts of interest which are identified must be disclosed by Sheppard Pratt on a publicly accessible web-site.

What If I Have a Conflict of Interest?

The Sheppard Pratt Conflict of Interest Officer and the Sheppard Pratt Institutional Review Board (IRB) will work with you to eliminate, reduce, or manage the conflict.