

**POLICY NUMBER: 010**

**TITLE: Financial Conflict of Interest (FCOI)**

**1.0 PURPOSE**

The VAPHS Research Office recognizes the importance of conducting research-related business with integrity. Therefore, it is critical that any conflicts of interest (real or perceived) be managed appropriately. Within VAPHS, conflicts of interest (real or perceived) may be financial or non-financial in nature. This policy outlines the various types of financial conflicts of interest that may exist related to the review of research proposals, compliance issues, and other research-related issues.

**2.0 REVISION HISTORY**

R&D Committee Approval Date	Revision #	Change	Reference Section(s)	Effective Date
February 10, 2015	1.3	Change regarding the time points at which the FCOI Statement is required and the process related to submission and preliminary review of the Statements.	6.1	March 12, 2015
April 22, 2014	1.2	Change regarding which Research Staff are required to submit FCOI Statements. Update to procedures related to the collection and review of FCOI Statements	5.1 6.1	April 23, 2014
February 8, 2011	1.1	Clarification of applicability of evaluation criteria	5.1	February 9, 2011
December 7, 2010	1.0	New policy/procedure		December 8, 2010

**3.0 SCOPE**

This policy applies to all Research conducted at or under the auspices of VA Pittsburgh Healthcare System (VAPHS). All members of the VAPHS Research Community, including but not limited to, investigators, research staff, research administration, and committee members, are expected to familiarize themselves with the contents of this policy and to ensure appropriate disclosure should a conflict exist.

**4.0 POLICY**

A Financial Conflict of Interest (FCOI), real or perceived, occurs when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct,

results, or reporting of research activities or findings. In cases of FCOI, an independent determination has to be made regarding the potential impact of the FCOI on the integrity of the study as well as the potential influence that the FCOI may have on study participants and the facility.

## **5.0 TYPES OF CONFLICT**

5.1 Research Staff FCOI. Any Principal Investigator, co-Principal Investigator, Investigator (including a collaborator who has a VA appointment), study chair or site Principal Investigator must disclose all possible financial conflicts of interest held by themselves, their spouse, dependent child or general partner, as applicable, by filing a Research Financial Conflict of Interest Statement. The disclosure criteria do not vary by funding or regulatory oversight.

Examples of FCOI are outlined on the Research Financial Conflict of Interest Statement.

5.2 Institutional Financial Conflict of Interest. Within VA, Institutional FCOI might occur when research involves patents or royalties as the VA retains a portion of the earned income from patents and royalties (see Appendix I).

## **6.0 PROCEDURES**

### **6.1 Research Team Member Conflict of Interest:**

All Principal Investigators, co-Principal Investigators, Investigators (including a collaborator who has a VA appointment), study chairs, or site Principal Investigators regardless of effort on a particular study must submit a Research Financial Conflict of Interest (COI) Statement to the Research Office. The Research Financial Conflict of Interest Statements must be submitted to the appropriate subcommittee (IRB, IACUC, or RSEC) at the following time points:

- Initial review
- Continuing review
- At the time that any individual in one of the roles listed above is added to a study
- When there is a change in relevant information that requires a change in an answer on Section I of the Statement to “yes” or that changes the reason for a “yes” answer.

The designated subcommittee staff member will review the Research COI Statements to ensure completeness and to assess whether there are any reported potential conflicts or not:

- a. If a potential conflict is identified the committee staff will alert a FCOI administrator who will complete a review and then sign off on the FCOI statement. Any statement that warrants escalation will be forwarded to the FCOI working group.
- b. If no conflict is identified the committee staff will complete an attestation that no conflict was identified and the COI statement will remain in the study file.

If, upon review, the FCOI Administrator determines that a real or perceived FCOI does exist a FCOI working group will be convened to discuss appropriate management of the FCOI. The FCOI working

group must meet and a management plan developed prior to the protocol being forwarded to the subcommittee for review and approval. Any management plan(s) recommended by the FCOI Working Group will be sent to the appropriate review unit and will be discussed at the time the protocol is reviewed by the review unit.

## 6.2 Institutional Conflict of Interest

The VAPHS, through the ACOS/R&D, must insure that patent and royalty applications are reviewed and approved by ORD's Technology Transfer Office before they are initiated. After ORD notifies the ACOS/R&D of approval of patents and royalties, the ACOS/R&D will notify the R&D Committee and the appropriate research review unit, through the Administrative Officer (AO/ACOS/R&D) of a VA protocol with a potential institutional financial interest. Issues will also be referred to the Office of Regional Counsel who will evaluate whether an institutional financial conflict of interest exists. If an institutional financial conflict of interest is identified, the Office of General Counsel (OGC) Deputy Ethics Official will consult on management strategies with the Financial Conflict of Interest Working Group. Any management plan(s) recommended by the FCOI Committee will be forwarded to the appropriate review unit and will be discussed at the time the protocol is reviewed by the review unit.

6.3 Confidentiality: All materials associated with the review of research-related issues, as well as the discussions that take place regarding such issues are strictly confidential and must not be disclosed or discussed with anyone who has not been officially designated to participate in the review process.

## 7.0 Appendices

### [Research Financial Conflict of Interest Statement](#)

/signature on file in Research Office/  
Gretchen Haas, PhD  
Research and Development Committee Chair

/signature on file in Research Office/  
Steven H. Graham, MD, PhD  
Associate Chief of Staff for Research and Development

## Appendix I: VHA Technology Transfer Program Royalty Distribution

Institutional compensation is according to the Royalty Distribution Policy as outlined by the VHA Office of Research and Development. Please refer to the Office of Research and Development Technology Transfer Program website

[http://www.research.va.gov/programs/tech\\_transfer/policies/default.cfm](http://www.research.va.gov/programs/tech_transfer/policies/default.cfm) for current information.