

**SUBJECT: Managing Potential Conflicts of Interest (COIs) for Investigators engaging in VA Research**

**1. PURPOSE:**

Although the current version of VA Directive 1200.01 (dated 01/24/2019, amended 01/08/2021) does not include any reference to the RDC's role in reporting or evaluating potential COIs for investigators participating in VA research, MVAHCS Research and Development Committee has established the following procedures to ensure compliance with 18 U.S.C. § 208 which requires that *"federal employees refrain from participating personally and substantially in an official capacity in any particular matter that will have a direct and predictable effect on the financial interests of any organization in which the individual serves as an officer, director, trustee, or employee."*

**2. DEFINITIONS:**

ACOS/R: Associate Chief of Staff for Research

fCOI: Financial Conflict of Interest

HRPP: Human Subjects Protection Program

IACUC: Institutional Animal Care and Use Committee

IPA: Intergovernmental Personnel Act

IRB: Institutional Review Board

OGC: Office of the General Counsel

R&D: Research and Development

RDC: Research & Development Committee

SRS: Subcommittee on Research Safety

WOC: Without Compensation Employee

VA Research is research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded.

Financial Conflict of Interest (fCOI) Statement means OGE form 450 alternative-VA.

Financial Conflict of Interest (fCOI) Panel is chaired by the Technology Transfer Specialist, who serves as the COI Administrator. The panel includes the ACOS/R, the deputy ACOS/R, the research privacy officer, the research compliance officer, the RDC chair, and the HRPP director.

**3. OVERVIEW:**

The following procedures apply to all VA research studies overseen by the RDC or any of its subcommittees (IRB, IACUC, SRS, IBC). The purpose of the fCOI panel is to guide investigators as they navigate the process of reporting and mitigating potential COIs.

**4. PROCEDURES:**

- a) All investigators (e.g., principal investigator, co-principal investigator, co-investigator) must complete an fCOI statement at the following times for each active study:
  - i) at initial study review;
  - ii) when added to an ongoing study as a new investigator;
  - iii) annually thereafter if Continuing Reviews are required; and

- iv) when there is a change in a personal or financial situation that potentially puts the investigator in conflict with that study
- b) fCOI statements are to be completed and submitted via the VAIRRS (IRBNet) platform, where the COI Administrator will review the statement for completeness and to determine whether a potential COI is indicated.
- c) The COI Administrator, in consult with the fCOI Panel, will review and seek clarification from the investigator regarding statements on which the investigator has marked “yes” to any of the questions in Section I as necessary.
- d) The COI Administrator will forward unresolved fCOI statements to OGC-Ethics via the IRBNet system as necessary.
- e) The COI Administrator will work with the OGC attorneys and the involved PI(s) to develop and implement a mitigation plan, if needed.

**5. REFERENCES:**

VHA Directive 1200.01 “Research and Development Committee” (8 January 2021)  
18 U.S. Code § 208 – Acts affecting a personal financial interest

**6. R&D COMMITTEE APPROVAL:** 07 March 2023

**7. RECISSIONS:** Minneapolis Research Service SOP R&D-021 “Managing Potential Conflicts of Interest (COIs) for Investigators engaging in VA Research” (02 November 2021)

**8. EXPIRATION DATE:** N/A

**9. FOLLOW-UP RESPONSIBILITY:** Research and Development (R&D) Committee