

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

SOP# HRP 01.17

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Approved	Thomas J. Hornyak, ACOS/R&D Date:		
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CONFLICT OF INTEREST (COI)

OBJECTIVES:

- To establish the process to identify, evaluate and manage any perceived or actual conflicts of interest involving the research projects brought before the VAMHCS R&D Committee (RDC).
- To preserve and enhance integrity of research activity that could be subject to intentional or unintentional bias as a result of real or perceived institutional conflict of interest (ICOI)

SCOPE & POLICY:

This SOP applies to all human research projects submitted to the VAMHCS R&D Committee (RDC).

All VAMHCS investigators and research team members must comply with VA and University of Maryland Baltimore (UMB) (as applicable) requirements relating to conflict of interest. This includes disclosure of any perceived or actual conflicts of interest.

Federal employees are prohibited from participating personally and substantially in official VA matters affecting their own financial interest or those imputed to them. In addition, in research a real or perceived conflict of interest 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. Completion of OGE Form 459 Alternative-VA (Nov 2013) is designed to assist employees to avoid a conflict between their official duties and private financial interests or affiliations.

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DEFINITIONS

Conflict of Interest (COI). Any situation in which financial or personal obligations or interests may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing, or reporting research. An appearance of COI is when the circumstances would cause a reasonable person with knowledge of the relevant facts to question an employee's impartiality in the review and conduct of human research protocols.

Institutional Conflict of Interest (ICOI). A significant financial interest or significant relationship which may compromise the institution's research activity. ICOI may be present or be perceived to be present when the VAMHCS, its senior leadership, or its investigators and scientists involved in specific VAMHCS research activity have a significant financial interest or when the VAMHCS has a significant relationship with persons who are identified with entities (1) that are sponsors of research activity or (2) that have an interest in the outcome of research activity. The threshold amount of >\$1 million/year from a single sponsor could represent institutional COI (VA and NIH sponsorship excluded).

Financial Interest. Financial interests are limited to those owned by the employee or by the employee's spouse or minor children. It includes any current or contingent ownership, equity, or security interest in real or personal property or a business and may include an indebtedness or compensated employment relationship. It includes interests in the nature of stocks, bonds, partnership interests, fee and leasehold interests, mineral and other property rights, deeds of trust, and liens. It extends to any right to purchase or acquire any such interests, such as a stock option or commodity future. It does not include a future interest created by someone other than the employee, the employee's spouse, or dependent child or any right as a beneficiary of an estate that has not been settled. It does include service, with or without compensation, as an officer, director, trustee, general partner, or employee of any person, including a nonprofit entity, whose financial interests are imputed to the employee (5 CFR 2635.403(c)).

RESPONSIBILITIES:

1. The ACOS/R&D is responsible for notifying the VAMHCS R&D Committee of technology transfer agreements, large contracts or any other cases of potential institutional conflict of interest (COI).
2. The Executive Director, Baltimore Research & Education Foundation (BREF) is responsible for notifying the ACOS/R&D of technology transfer agreements, large contracts or any other cases of potential institutional conflict of interest (COI).
3. The VAMHCS Research COI Officer (RCOIO) is responsible for:
 - Evaluating potential RCOI based on information submitted by VAMHCS investigators on OGE Form 459 Alternative-VA (Nov 2013);
 - Contacting OGC Specialty Team Advising Research (STAR) for consultation on potential RCOI and RCOI management plans;

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- Notifying the RDC of any cases of and management plans;
 - Notifying the UMB IRB or the VA CIRB of the RDC's discussion and any determinations or recommendations.
4. VA R&D Committee is responsible for:
- Reviewing the findings of the IRB's COI evaluation and management plan and making any other appropriate recommendations;
 - Communicating these recommendations to the investigator and the IRB.
5. The Principal Investigator and Research Team Members are responsible for:
- Completing OGE Form 459 Alternative-VA (Nov 2013) accurately and honestly; .
 - Complying approved management plans for COI (if applicable).

PROCEDURE:

1. VA investigators including Principal Investigators (PI), Co-PIs, Site Investigators, co-investigators, etc. must complete OGE Form 459 Alternative-VA (Nov 2013) (a) at the time of initial submission of a new protocol to the R&D Committee (R&DC), (b) at the time of continuing review (CR), (c) when added to a protocol as an Investigator, or (d) when an investigator has a change in relevant information that requires the investigator to change an answer on Section I of the Statement to "yes" or that changes the reason for a "yes" answer.
2. This applies to VA investigators whether they are compensated, WOC, or IPAs.
3. Investigators must submit a completed OGE Form 459 Alternative-VA (Nov 2013) for each protocol in which they are an investigator.
4. The VAMHCS RCOIO reviews the investigator's Statement to determine whether there are any actual or perceived conflicts of interest. The Statement may be reviewed by other VA personnel only on an "as needed" basis when required by the responsibilities of their positions. The information provided in OGE Form 459 Alternative-VA (Nov 2013) will not be otherwise disclosed unless authorized.
 - 4.1. VAMHCS RCOIO consults with the ACOS/R&D, the Deputy ACOS/R&D and/or OGC STAR as necessary.
 - 4.2. If an actual RCOI is determined to exist, the RCOIO, in consultation with the ACOS/R&D, the Deputy ACOS/R&D, the Investigator, and/or OGC STAR (as necessary), will develop a COI management plan.
 - 4.3. The VAMHCS R&DC and the UMB IRB are notified that a COI has been detected and that a management plan has been developed.
5. Institutional COI:
 - 5.1. The Deputy ACOS/R&D notifies the ACOS/R&D at the time that a VAMHCS technology transfer agreement is initiated.
 - 5.2. The Executive Director of the VAMHCS nonprofit (BREF) notifies the ACOS/R&D at the time that a large contract for research services is initiated.

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- 5.3. Other individuals may also notify the ACOS/R&D when the institution, or any of its senior management, has an external relationship or financial interest in a company or organization that itself has a financial interest in a VA investigator's research project.
- 5.4. The ACOS/R&D in consultation with VAMHCS RCOIO and OGC STAR (when necessary), will develop a COI management plan.
- 5.5. The VAMHCS Research COIO will notify the UMB IRB or the VA Central IRB (whichever is applicable) of the RDC's discussion and any determinations or recommendations.

REFERENCES:

VA ORD	12/9/2013 Guidance from VA ORD via VA ORO
VA CIRB SOP 103	Managing Conflict of Interest