

**FINANCIAL CONFLICTS OF INTEREST AND OUTSIDE COMPENSATION FOR  
PERFORMANCE IN VA RESEARCH**

**1. SUMMARY OF CONTENT:** This is a new directive establishing policy and responsibilities for filing and reviewing the financial disclosure form (Alt-450) and outside compensation request related to Department of Veterans Affairs (VA) research for VA investigators.

**2. RELATED ISSUES:** VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019; VHA Directive 1200.05(3), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019; and VHA Directive 1200.07, VA Research with Animals, dated May 23, 2023.

**3. POLICY OWNER:** The Office of Research and Development (14RD) is responsible for the content of this directive. Questions may be addressed to [VHACOORDRegulatory@va.gov](mailto:VHACOORDRegulatory@va.gov).

**4. RESCISSIONS:** VHA Notice 2023-09(1), Outside Compensation for Performance of VA Research, dated November 28, 2023.

**5. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of May 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**6. IMPLEMENTATION SCHEDULE:** This directive must be implemented by VA medical facilities no later than 4 months after the date of publication.

**BY DIRECTION OF THE OFFICE OF  
THE UNDER SECRETARY FOR HEALTH:**

/s/ Carolyn M. Clancy, MD  
Assistant Under Secretary for Health  
for Discovery, Education and Affiliate  
Networks

**NOTE:** All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

**DISTRIBUTION:** Emailed to the VHA Publication Distribution List on May 6, 2024.

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## FINANCIAL CONFLICTS OF INTEREST AND OUTSIDE COMPENSATION FOR PERFORMANCE IN VA RESEARCH

### 1. POLICY

It is Veterans Health Administration (VHA) policy that all Department of Veterans Affairs (VA) investigators conducting VA research must file the financial disclosure form (Alt-450), and that each VA medical facility conducting research must review Alt-450s at their VA medical facility in conjunction with VA's Government Ethics program in order to identify and resolve financial conflicts of interest (FCOI) in research. It is also VHA policy that investigators who hold a VA compensated appointment and wish to receive outside compensation from an Affiliated University/Medical Center (Affiliate) or VA Nonprofit Research and Education Corporation (NPC) for performance of VA research must receive permission to accept the outside compensation. **NOTE:** *The provisions of this directive apply to all VA research regardless of funding source (i.e., funded by VA, Federal agencies, other entities or unfunded), type of research or location.*

**AUTHORITY:** 38 U.S.C. §§ 7301(b), 7382.

### 2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks.** The Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks is responsible for supporting the Office of Research and Development (ORD) with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **VA Designated Agency Ethics Official, Office of General Counsel.** The Designated Agency Ethics Official (DAEO) has responsibility for coordination and management of VA's Government Ethics program, including the following:

(1) Reviewing and certifying all financial disclosure reports submitted to VA under 5 C.F.R. part 2634.

(2) Delegating to the VA medical facility FCOI Administrator the authority to review and certify Alt-450s.

(3) Ensuring that an OGC Deputy Ethics Official reviews Alt-450s forwarded by the VA medical facility FCOI Administrator.

(4) Making legal determinations of FCOI (including outside compensation) and resolving identified conflicts under the ethics laws and regulations applicable to employees of the Federal Government.

**e. Chief Research and Development Officer, Office of Research and Development.** The Chief Research and Development Officer, ORD is responsible for:

(1) Providing oversight for VISN and VA medical facility implementation of this directive and ensuring corrective action is taken if implementation is not executed.

(2) Maintaining this directive in collaboration with the DAEO.

**f. Office of Research and Development Electronic System Administrator.** The ORD electronic System Administrator is responsible for updating the date of determination in the ORD electronic submission system when a decision is reached by the OGC Deputy Ethics Official.

**g. Veterans Integrated Services Network Director.** The VISN Director is responsible for ensuring that all research programs at VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

**h. VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring VA medical facility and VA investigator compliance with this directive.

(2) Ensuring the VA medical facility's research FCOI program is not a combined program with that of the VA medical facility's Affiliate or other entity.

(3) Ensuring dissemination of this directive.

(4) Appointing, in writing, a VA medical facility FCOI Administrator who is responsible for the VA medical facility's research FCOI program and reviewing and certifying Alt-450s. ***NOTE: Each VA medical facility FCOI Administrator must be a compensated VA employee who does not have an additional compensated appointment from the Affiliate or VA NPC. If it is determined that it is necessary to have more than one VA medical facility FCOI Administrator, the VA medical facility Director must designate one of the appointees as the principal VA medical facility FCOI Administrator responsible for the VA medical facility's research FCOI program.***

(5) Making final binding programmatic decisions in consultation with an OGC Deputy Ethics Official in situations in which an FCOI can be resolved. For further details, see paragraph 4.a.

(6) Terminating research or taking other appropriate actions upon receiving notification that a VA investigator is participating in VA research despite an FCOI that cannot be resolved (see paragraph 5).

(7) Serving as the Approving Official for requests for outside compensation from projects administered by the Affiliate or VA NPC and providing written approval as appropriate. **NOTE:** 38 U.S.C. § 7382(b)(1)(C) assigns authority to approve requests to the Secretary of VA. In February 2023, the Secretary of VA delegated this to the Under Secretary for Health who then re-delegated to VA medical facility Directors. The VA medical facility Director can delegate this to the VA medical facility Chief of Staff (CoS) only.

i. **VA Medical Facility Chief of Staff.** The VA medical facility CoS is responsible for:

(1) Approving, in writing, the compensation for the specified VA project following local Research and Development (R&D) Committee approval. **NOTE:** This can be done by the CoS by delegation from the VA medical facility Director only.

(2) Reviewing modifications to salary after final approval that require funder or sponsor approval or are considered substantial (>25% change to the approved effort or hours). A new Memorandum reflecting the modified outside compensation will be submitted thru the ACOS/R. **NOTE:** This is a limited situation circumstance where the ACOS/R&D is also the Principal Investigator (PI).

j. **VA Medical Facility Associate Chief of Staff for Research.** The VA medical facility Associate Chief of Staff for Research (ACOS/R) serves as the Executive Secretary to the VA medical facility R&D Committee and is responsible for:

(1) Ensuring that all VA investigators (compensated, without compensation (WOC) or appointed or detailed to VA under the Intergovernmental Personnel Act (IPA), 5 U.S.C. § 3371 et seq.) are assigned annual ethics training within VA Talent Management System (TMS). **NOTE:** For further information on training requirements, see paragraph 6.

(2) Tracking and verifying that VA investigators have completed the required ethics training within TMS on an annual basis. **NOTE:** For further information on training requirements, see paragraph 6.

(3) Overseeing VA medical facility FCOI Administrators in local research offices who perform their role as a collateral duty.

(4) Forwarding outside compensation requests to the Approving Official once the VA medical facility R&D Committee completes their review and provides a recommendation to approve or disapprove (see paragraph 4.c.).

(5) Reviewing modifications to salary after final approval that require funder or sponsor approval or are considered substantial (>25% change to the approved effort or hours) and ensuring the VA medical facility Administrative Officer for Research submits a new Memorandum reflecting the modified outside compensation. **NOTE:** *In limited situations where the VA medical facility ACOS/R is also the PI, this responsibility must be delegated to the VA medical facility CoS.*

(6) Providing the original approval to the VA employee upon receiving approval from the Approving Official. A copy of the letter must be placed in VA Innovation and Research Review System (VAIRRS) under the appropriate project.

(7) Notifying the VA Investigator if the Approving Official disapproves the outside compensation.

k. **VA Medical Facility Research and Development Committee.** The VA medical facility R&D Committee is responsible for:

(1) Reviewing outside compensation request recommendations by the VA medical facility FCOI Administrator and approving or disapproving the recommendation during the VA medical facility R&D Committee's initial review of the VA project. **NOTE:** *Once a decision is made by the VA medical facility R&D Committee, the VA medical facility ACOS/R forwards the outside compensation request to the Approving Official for final determination. See paragraphs 2.i.(4) and 2.h.(7).*

(2) Ensuring that each review assesses the request with regard to project budget appropriateness, the effort required to conduct the project and the rationale for outside compensation (i.e., why the work cannot be completed during the employee's VA tour of duty).

(3) Reviewing the memorandum submitted by the ACOS/R&D if the ACOS/R&D is the employee conducting the research.

(4) Ensuring written procedures for communicating its decisions on requests for outside compensation are provided to the VA medical facility research office.

(5) Suspending or terminating an approved VA project if a VA Investigator is participating in an approved VA project despite an FCOI that cannot be resolved.

(a) The VA medical facility R&D Committee Chair can suspend the VA project but cannot terminate the VA project. Any suspension of VA research by the VA medical facility R&D Committee Chair must be reported at the next convened meeting.

(b) Termination of a project can only be done by the VA medical facility R&D Committee during a convened meeting.

(c) In addition to termination of a VA project, the VA medical facility R&D Committee may take other corrective actions it determines to be appropriate to resolve the FCOI.

l. **VA Medical Facility Administrative Officer for Research.** The Administrative Officer for Research is responsible for:

(1) Preparing the Request for Outside Compensation for VA Approved Research memorandum upon receiving approval from the VA medical facility R&D Committee.

(2) If the outside compensation request is not approved by the VA medical facility R&D Committee, ensuring the appropriate follow up actions are taken before research is initiated. For more information see paragraph 4.c.(4).

m. **VA Medical Facility Financial Conflicts of Interest Administrator.** *NOTE: If this position is in a VA medical facility research office and performed as a collateral duty, the VA medical facility FCOI Administrator reports to the VA medical facility ACOS/R or equivalent. Due to the nature of the review process, a Research Compliance Officer may not serve in the capacity of the VA medical facility FCOI Administrator.* The VA medical facility FCOI Administrator is responsible for:

(1) Reviewing Alt-450s upon receipt from VA investigators and, based upon guidance provided by OGC Ethics, certifying the report or forwarding the report to OGC Ethics for review (see paragraph 4.a.).

(2) Notifying the VA investigator if the Alt-450 is incomplete (see paragraph 4.a.).

(3) Documenting the review of the Alt-450 and accompanying documents of the project submissions and filing the signed Alt-450 within the ORD electronic submission system.

(4) Notifying both the OGC Deputy Ethics Official and the VA medical facility Director within 3 business days upon becoming aware that a VA investigator is participating in VA research despite an FCOI that cannot be resolved. *NOTE: For more information on failure to comply with an FCOI determination, see paragraph 5.*

(5) Reviewing requests for outside compensation and providing a recommendation to the VA medical facility R&D Committee as part of the project approval process. *NOTE: For more information on the VA medical facility R&D Committee, see VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019.*

n. **VA Investigator.** The VA investigator (also referred to as filer in paragraphs 4 and 5 in this directive) is responsible for:

(1) Filing an initial and annual Alt-450 in the ORD electronic submission system. *NOTE: For more information, see paragraph 3.*

(2) Complying with all requests by the VA medical facility FCOI Administrator or OGC Deputy Ethics Official for additional information.

(3) Completing the required annual ethics training (see paragraph 6).

(4) Not participating in or withdrawing from a research study if an identified FCOI cannot be resolved.

(5) Submitting outside compensation requests to the VA medical facility FCOI Administrator for review in accordance with paragraph 3.c.

(6) Submitting, in writing, modifications to the impacted VA employee's salary after final approval that require funder or sponsor approval or are considered substantial (>25% change to the approved effort or hours) to the VA medical facility ACOS/R for review. **NOTE:** *In limited situations where the VA medical facility ACOS/R is also the principal investigator (PI), modifications must be submitted to the VA medical facility CoS instead.*

o. **VA Medical Facility Study Team Member.** Each member of the VA medical facility study team is responsible for submitting outside compensation requests to the VA medical facility FCOI Administrator for review in accordance with paragraph 3.c. **NOTE:** *While study team members are not required to submit the Alt-450, study team members must avoid participating in VA research studies where they have a conflict of interest. Study team members are encouraged to consult with an OGC Deputy Ethics Official if they have conflict of interest concerns.*

### **3. REQUIREMENT TO FILE A FINANCIAL DISCLOSURE FORM (ALT-450)/OUTSIDE COMPENSATION REQUEST**

a. All VA investigators (compensated, WOC or IPA), who meet either of the following criteria are considered to hold a position that requires them to complete and submit an Alt-450 form as required by this directive:

(1) Hold the position of VA investigator (i.e., principal investigator, co-principal investigator, investigator, co-investigator, sub-investigator or VA medical facility site investigator). **NOTE:** *A VA medical facility site investigator in a multiple-site study can be a VA site principal investigator, co-principal investigator or sub-investigator.*

(2) Are being proposed for the position of VA investigator.

#### **b. When and How to File an Alt-450.**

(1) The initial Alt-450 must be completed and submitted by each VA investigator into the ORD electronic submission system in accordance with timelines established by ORD.

(2) If a new VA investigator is added to the study after initial VA medical facility R&D Committee review, an Alt-450 must be submitted through the ORD electronic submission system for the VA medical facility FCOI Administrator to document the review before the added VA investigator can begin work on the project.

(3) Each VA investigator must complete and update the Alt-450 form annually for each active research protocol and submit it to the VA medical facility FCOI



Administrator through the ORD electronic submission system. **NOTE:** *The annual update is required as of the calendar date of the subsequent year. For example, if a VA investigator completed the Alt-450 on October 1, 2023, the next annual update is required to be completed no later than October 1, 2024.*

(4) At any time, if a VA investigator has a change in a financial interest that requires disclosure, such as when a new financial interest may result in a potential conflict, a new Alt-450 must be submitted to the VA medical facility FCOI Administrator within 45 calendar days of the time the change occurred.

**c. When and How to Submit an Outside Compensation Request.**

(1) When a VA investigator or VA medical facility study team member who is a compensated VA employee receives outside compensation in addition to VA compensation for conducting VA research sponsored by a non-VA entity, an outside compensation request must be submitted to the VA medical facility FCOI Administrator for review and approval either prior to the initiation of the project or when the outside compensation directly related to the VA research project is initiated.

(2) The following information must be provided along with the outside compensation request when the VA NPC or Affiliate is providing compensation to individuals who hold a VA-compensated appointment to perform the proposed VA research outside their paid tour of duty:

(a) Name of the VA employee receiving outside compensation.

(b) Full-time or part-time status (if part-time, number of hours per week).

(c) Name of the study sponsor or external funder.

(d) Designation whether the VA NPC or Affiliate will be providing the direct payment to the VA employee(s).

(e) Percent of effort (or hours per week) in support of the VA research project.

(f) Amount of the VA employee's annual salary derived from the project.

(g) Justification as to why the project requires salary support to VA-compensated employees.

(3) At any time after initial approval, if a VA investigator or VA medical facility study team member has a substantial modification that requires sponsor/funder approval (>25% change to effort or hours), the impacted employee must submit a request in writing to the VA medical facility FCOI Administrator for review, which is then forwarded to the Approving Official for approval.

#### 4. REVIEW OF DOCUMENTS AND COMMUNICATION OF FINDINGS

a. **Initial Review of Alt-450.** The initial review of the Alt-450 ensures that the VA investigator is compliant with the reporting requirements.

(1) If the submission package associated with the Alt-450 is incomplete, the VA medical facility FCOI Administrator or OGC Deputy Ethics Official communicates with the filer by email or via the ORD electronic submission system and requests that the submission be updated and completed. Review and certification of the Alt-450 cannot occur without receipt of all requested information.

(2) If all questions on the initial Alt-450 are answered “No,” the VA medical facility FCOI Administrator can determine there is no FCOI and certify the Alt-450. The filer receives a notification in the ORD electronic submission system when the VA medical facility FCOI Administrator marks the review as complete. The ORD electronic submission system records that the Alt-450 was completed and reviewed, and there are no disclosures.

(3) If any question is answered with a “Yes,” or there are other concerns giving rise to a potential FCOI, the VA medical facility FCOI Administrator reviews the Alt-450 in accordance with guidance provided by OGC. If the OGC guidance permits the FCOI Administrator to determine that no FCOI exists, and if the FCOI Administrator determines that no FCOI exists, the FCOI Administrator certifies the Alt-450. If the FCOI Administrator cannot determine that no FCOI exists, the FCOI Administrator forwards the Alt-450 to an OGC Deputy Ethics Official utilizing the ORD electronic submission system. The OGC Deputy Ethics Official reviews the Alt-450 and communicates the determination to the filer, VA medical facility FCOI Administrator and the ORD electronic System Administrator via email. The ORD electronic System Administrator then updates the date of the determination in the ORD electronic submission system. Review of the project submission is recorded and the signed Alt-450 is filed within the ORD electronic submission system. Unauthorized users can only see that a disclosure was made by the filer, but not the nature of the disclosure.

(4) If a disclosure is made and OGC Ethics review is necessary, the VA medical facility FCOI Administrator forwards the Alt-450 using the ORD electronic submission system to the appropriate OGC Ethics region or other OGC representative(s), as appropriate.

(5) An OGC Ethics review may include a decision on whether and to what extent an authorization should be granted to allow the filer to engage in activities normally prohibited by 5 C.F.R. § 2635.502, which do not rise to the level of a criminal FCOI. An authorization is issued by an “agency designee” (such as the VA medical facility Director, Associate Director or Chief of Staff) after appropriate OGC review. OGC Ethics review may also include a decision on a filer’s request that a criminal FCOI be waived pursuant to 18 U.S.C. § 208(b)(1). A waiver of a criminal FCOI requires approval by the VA medical facility Director after OGC consultation with the Office of Government Ethics (OGE). ***NOTE: The DAEO or OGC Deputy Ethics Official must concur with the VA***

*medical facility Director's authorization or waiver decision, and that will be the final authority on the legal issues involved.*

b. **Annual Review of Alt-450.** The VA medical facility FCOI Administrator reviews an annual Alt-450 which is submitted for each active project. The annual Alt-450 is also compared to the initial Alt-450, as relevant, to identify any changes.

(1) If all questions on the annual Alt-450 are answered "No," the VA medical facility FCOI Administrator can determine there is no FCOI and certify the annual Alt-450.

(2) If any of the questions on the Alt-450 are answered "Yes," the annual form must be compared to the initial form to determine if the "Yes" answers represent new or previously resolved FCOI.

(3) If any question is answered "Yes," but there is no change from the initial Alt-450, and review of the initial Alt-450 resulted in a determination that there is no conflict or the conflict was resolved, then the VA medical facility FCOI Administrator may certify the Alt-450.

(4) If any question is answered "Yes," and there is a change from the initial reported conflict, including a change in financial position, the VA medical facility FCOI Administrator reviews the annual Alt-450 in accordance with paragraphs 4.a.(3)-(5).

**NOTE:** *The VA medical facility FCOI Administrator may request additional information from the VA investigator as needed.*

c. **Initial Review of Outside Compensation Request.** The initial review of a request for outside compensation must be approved by the Approving Official prior to the receipt of outside compensation tied to the VA approved research.

(1) The VA investigator submits the request for outside compensation to the VA medical facility FCOI Administrator, who then provide a recommendation to VA medical facility R&D Committee for review. The terms of the outside compensation must address the following conditions in writing:

(a) The amount of compensation paid by the VA NPC or Affiliate in support of the project must be delineated in the project budget submitted with the project when reviewed and approved by the local VA medical facility R&D Committee.

(b) If compensation is derived from an award to the VA NPC or Affiliate by a third-party funder or sponsor, the compensation must comply with the funder or sponsor policies, with specific attention paid to the funding policies of other Federal agencies (e.g., [https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_17/17\\_grants\\_to\\_federal\\_institutions\\_and\\_payments\\_to\\_federal\\_employees\\_under\\_grants.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_17/17_grants_to_federal_institutions_and_payments_to_federal_employees_under_grants.htm)). The compensation must be paid to the VA employee by the VA NPC or Affiliate, not from the third-party funder/sponsor.

(c) The employee conducting the research must be supervised by a VA employee.

(2) If approved by VA medical facility R&D Committee, the research office prepares a Memorandum for Request for Outside Compensation for VA Approved Research) and routes to the Approving Official for final determination. See Appendix A for memorandum template.

(3) If approved, the Approving Official returns the decision to the research office for action. A copy must be provided to the VA investigator and to the entity providing the outside compensation (i.e., the VA NPC or Affiliate).

(4) If the outside compensation request is not approved, the VA medical facility Administrative Officer for Research must ensure at least one of the following is completed before research is initiated:

(a) The VA investigator or VA employee declines the additional salary support and restructure the budget.

(b) The VA investigator or VA employee performs the research during their VA tour of duty by offloading other responsibilities.

(c) VA increases the number of paid hours of the VA investigator or VA employee (e.g., from 20 to 30 hours). If the VA NPC or Affiliate is receiving funding from a third party to cover the additional effort of the investigator or VA employee, the VA NPC or affiliate must develop a MOU to reimburse VA for the Investigator and staff effort.

(d) The award must be assigned to another VA investigator who does not have a conflict to interest to serve as the new VA investigator. The primary investigator can no longer act as a VHA investigator on the VA portion of the study; or

(e) The award must not be considered as VA research and cannot be initiated at VA.

## 5. FAILURE TO COMPLY WITH CONFLICTS OF INTEREST DETERMINATION

a. If the VA medical facility FCOI Administrator or any VA medical facility R&D Committee member becomes aware that a VA investigator is participating in VA research despite an FCOI that cannot be resolved, they must notify an OGC Deputy Ethics Official and the VA medical facility Director within 3 business days of being notified. **NOTE:** *VA medical facility R&D Committee responsibilities are described further in VHA Directive 1200.01(1).*

b. The VA investigator must comply with the decisions of an OGC Deputy Ethics Official, the VA medical facility Director or an agency designee (as defined in paragraph 4.a.(5)) involved in resolving the identified actual or perceived FCOI. If the VA investigator does not agree with the decisions, they may contact the VA medical facility FCOI Administrator or an OGC Deputy Ethics Official to express such disagreement and provide the basis for the disagreement.

c. Such failure to comply may result in the imposition by the VA medical facility Director of other conditions or restrictions consistent with applicable laws and policies. These conditions or restrictions include but are not limited to:

(1) Removal of the VA investigator from the study or VA medical facility study team.

(2) Revocation of the VA investigator's ability to conduct the research. This sanction may include a prohibition on submitting proposals to the Institutional Review Board, Institutional Animal Care and Use Committee and the VA medical facility R&D Committee and suspension of the VA investigator's ability to conduct VA research.

d. Violation of the Standards of Ethical Conduct for Employees of the Executive Branch in 5 C.F.R. part 2635 may result in corrective or disciplinary actions. Violation of criminal conflict of interest statutes may result in prosecution. Punishment may include civil and criminal penalties.

## 6. TRAINING

The following training is **required** for all VA investigators unless live training is provided by a qualified OGC instructor prior to first project submission and annually thereafter: Government Ethics – The Essentials (TMS #3812493). For health professions trainees, completing VHA Mandatory Training for Trainees (TMS #3185966) and VHA Mandatory Training for Trainees – Refresher (TMS #3192008) meets this requirement.

## 7. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

## 8. BACKGROUND

a. As a public agency, VHA has an obligation to preserve public trust in the integrity and quality of research carried out by its investigators, among its patients and in VA medical facilities and to exercise prudent stewardship of public resources, including public funds that support research programs. Appropriate mechanisms must be in place to ensure that actual or perceived FCOI do not undermine that trust.

b. In 2022, the Joseph Maxwell Cleland and Robert Joseph Dole Memorial Veterans Benefits and Health Care Improvement Act of 2022 (Cleland-Dole Act) § 182, codified at 38 U.S. C. § 7382(b), was passed. This statute allows, under limited circumstances, a VA employee who has a compensated appointment within VA to be directly paid (outside compensation) by an Affiliate or VA NPC for performance of VA research.

c. **Financial Conflict of Interest in Research.** An FCOI in research, or the appearance of an FCOI, exists 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. Concerns related to FCOI have increased as the relationships of investigators with third parties such as pharmaceutical companies and outside institutions have become more complex. These concerns are based on the potential effects the conflicts may have on the actual or perceived quality of the research and the treatment of research subjects. VA research must be free of financial influence, including any on outside financial interests that may compromise, or have the appearance of compromising, the professional judgment of a VA researcher when designing, conducting or reporting research. The impact of the conflicts may occur in any phase of the research including the development of the study design, obtaining consent from research subjects, obtaining funding or the management and conclusions of the study. The conflicts may also bias review of proposals, analysis of data and dissemination of research results through publications and presentations.

d. **Conflict of Interest Reporting.** All Federal employees are subject to the criminal Conflict of Interest statutes codified at 18 U.S.C. §§ 205, 208, 209 and the Standards of Ethical Conduct for Employees of the Executive Branch (Standards of Conduct) codified at 5 C.F.R. part 2635. The Research FCOI Statement, United States OGE Alt-450 is the alternative financial disclosure form for VA investigators, approved by OGE, that allows VA to identify and resolve FCOI in VA research. The Alt-450 is used by VA investigators in accordance with this directive and pursuant to regulations promulgated by OGE to create uniform procedures and requirements for financial disclosure by employees across the Executive Branch of the Federal Government. See 5 C.F.R. part 2634, subpart I. **NOTE:** *The Alt-450 form is available at (see Conflict of Interest under Forms): [https://www.research.va.gov/resources/policies/general\\_admin.cfm](https://www.research.va.gov/resources/policies/general_admin.cfm).*

e. **VHA and the Government Ethics Program.** Use of the Alt-450 falls within VA's Government Ethics program. VA's DAEO within the OGC manages and coordinates VA's Government Ethics program through OGC Deputy Ethics Officials, including the attorneys on the OGC Ethics Specialty Team. VHA, through this directive, implements this alternative financial disclosure process for VA investigators in coordination with VA's Government Ethics Program. **NOTE:** *An OGC Deputy Ethics Official is an attorney in OGC who has been delegated ethics responsibilities by the DAEO.*

## 9. DEFINITIONS

a. **VA Investigator.** For purposes of this directive, a VA investigator is an individual who is responsible for the conduct of research approved by the VA medical facility R&D Committee while acting under a VA appointment on VA time, including full- and part-time employees, WOC employees and individuals appointed or detailed to VA under the IPA, 5 U.S.C. § 3371 et seq. **NOTE:** *Not all members of VA medical facility study team are considered VA investigators. For example, research study coordinators are not usually considered VA investigators. Individuals working under a contract with VA cannot be given a WOC appointment to conduct research on their contract time. Contractors can provide clinical services or other activities in support of VA research in*

*accordance with their contract. Health professions trainees, who are appointed either as WOC employees or full- or part-time employees, may also be VA investigators.*

b. **VA Research.** VA research is research 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, other sponsors or be unfunded. The research must be approved by the VA medical facility R&D Committee before it is considered VA research and before it can be initiated. All research activities approved by the VA medical facility R&D Committee are considered VA research.

c. **Outside Compensation.** For purposes of this directive, outside compensation is compensation from an Affiliate or VA NPC that is paid directly to a VA employee with an existing paid VA appointment who is performing VHA-approved research under the supervision of VA personnel. See 38 U.S.C. § 7382(b). Outside compensation for these VA employees must be reviewed by the VA medical facility as specified in paragraph 4. **NOTE:** *IPA staff are not considered compensated VA employees.*

## 10. REFERENCES

- a. 5 U.S.C. § 3371 et seq.
- b. 18 U.S.C. §§ 205, 208, 209.
- c. 38 U.S.C. §§ 7301(b), 7382.
- d. 5 C.F.R. part 2634, subpart I; part 2635.
- e. VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019.
- f. ORD. General Administrative Page.  
[https://www.research.va.gov/resources/policies/general\\_admin.cfm](https://www.research.va.gov/resources/policies/general_admin.cfm).
- g. Research FCOI Statement, OGE Form 450 Alternative- VA (“Conflict of Interest” under Forms): [https://www.research.va.gov/resources/policies/general\\_admin.cfm](https://www.research.va.gov/resources/policies/general_admin.cfm).

**SAMPLE MEMORANDUM**

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** ....., 202#

**From:** ACOS for Research or R&D Committee Chair (151)

**Subj:** Outside Compensation from the Affiliate or VA NPC

**To:** Approving Official (VA Medical Facility Director or COS)

1. This memorandum concerns approval for the VA employees listed below to receive outside compensation from [ENTER AFFILIATE OR NPC NAME] to perform the VA-approved research project titled [ENTER TITLE]. The project is funded/sponsored by (XXX) and administered through the Affiliate or VA NPC.

VA Employee Name	VA Title	Payor: Affiliate or NPC Name	Yearly Amount

2. This direct compensation from the Affiliate/NPC is consistent with the intent of 38 U.S.C. § 7382(b).

3. All future changes that impact the approved compensation by greater than 25% of the approved amount will require: 1) an updated Agreement between the institutions and 2) an updated Request for Outside Compensation memorandum.

4. The R&D Committee considers this research beneficial to VA and Veterans' Health Care. The proposed outside compensation for the specified VA employee(s) has been reviewed by (enter R&D Committee for initial review or ACOS/R&D for modifications following initial approval) and approval has been recommended.



**May 2, 2024**

**VHA DIRECTIVE 1200.13  
APPENDIX A**

5. Approval will be considered for the life of the project unless future changes as designated in #2 occur.

Approve   Not Approve

VA Medical Facility Approving Official