Department of Veterans Affairs Veterans Health Administration Washington, DC 20420

November 28, 2023

OUTSIDE COMPENSATION FOR PERFORMANCE OF VA RESEARCH

Amendment dated December 5, 2023, updates the date in paragraph 4 from December 31, 2023 to February 29, 2024.

1. This Veterans Health Administration (VHA) notice establishes interim policy implementing 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). This statute allows, under limited circumstances, a VA employee who has a compensated appointment within the Department to be directly paid (outside compensation) from an affiliated university/medical center (Affiliate) or the Department of Veterans Affairs (VA) Non-Profit Corporation (NPC) for performance of VA research. **2. DEFINITIONS**

a. **Investigator.** An Investigator is any individual who conducts research including, but not limited to, the Principal Investigator (PI), Co-Principal Investigator (co-PI), sub-investigator, and Local Site Investigator (LSI). All investigators on a VA research study or program must hold a VA appointment.

(1) **<u>Co-Principal Investigator</u>**. A Co-principal Investigator (co-PI) is one of two or more PIs who share equally in the accountability for a study.

(2) <u>Principal Investigator.</u> The Principal Investigator (PI) is a qualified person who directs a research study or program. The PI oversees scientific, technical, and day-to-day management of the research. If a study is conducted by a team of individuals, the PI is the responsible leader of that team.

(3) <u>Site Investigator or Local Site Investigator.</u> A Site Investigator or Local Site Investigator (LSI) is the investigator at one of the participating sites in a VA multi-site study who is responsible for the conduct of the study at the local site. The LSI serves as the PI at that local site.

b. <u>VA Investigator.</u> A VA investigator is an individual who conducts research approved by the R&D Committee while acting under a VA appointment on VA time, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970 (5 U.S.C. § 3371 et seq.). As a VA investigator, that individual represents the interests of the VA in conducting the study. *NOTE: 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. Not all members of a VA medical facility study team are considered VA investigators. For example, research study coordinators are not usually considered VA investigators. Health professional trainees, who are* appointed either as WOC employees or full- or part-time employees, may also be investigators.

c. <u>VA Research.</u> 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, by other sponsors, or be unfunded. The research must be approved by the R&D Committee before it is considered VA research and before it can be initiated. All research activities approved by the R&D Committee are considered VA Research.

3. AFFILIATE OR VA NPC COMPENSATION APPROVAL PROCESS.

VA employees with VA compensated appointments may also receive compensation directly from VA NPCs or Affiliates separate from their VA compensated duties to conduct VA research activities. For the VA employee to accept the outside compensation to perform VA research, the following criteria must be met:

a. The terms of compensation must be in writing addressing the following conditions:

(1) 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 Research and Development (R&D) Committee.

(2) 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_inst itutions_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.

b. The employee conducting the research must be supervised by a VA employee.

c. The VA medical facility Director or VA medical facility Chief of Staff (CoS), following proper delegation, must approve in writing the compensation for the specified VA project following R&D Committee approval. For this guidance, the Director and CoS will be referred to as the Approving Official. A template Request for Outside Compensation Affiliate or VA NPC memorandum is in Appendix A.

4. PROCEDURES FOR EXISTING RESEARCH PROJECTS

For research projects existing as of the date of this notice administered by the VA NPC or Affiliates not covered under the State Treasury exception, the VA medical facility's research office must complete all of the following by February 29, 2024. **NOTE:** The State Treasury exception permits employees to be compensated for VA work despite the general outside compensation prohibition of 18 U.S.C. § 209(a). Existing research projects, where the

outside compensation paid to the employee is from a State university that appears on the list of entities approved for the State Treasury exception, are not required to obtain approval as discussed in paragraph 3. Research projects that are approved after the date of this notice, where a State university seeks to compensate a VA compensated employee for performance of VA research, must obtain approval as discussed in paragraph 3. The list of entities approved for the State Treasury exception is found here: <u>https://dvagov.sharepoint.com/sites/OGC-</u>

<u>Client/law/ethics/SitePages/PaymentstoVAResearchers_FAQs.aspx</u>. This is an internal VA website that is not available to the public.

a. Identify all VA existing research projects where outside compensation is paid directly to any individual who also holds a paid VA appointment (VA employee) to perform the VA research. Ensure that the VA Innovation and Research Review System (VAIRRS) Project Cover Sheets has been completed.

b. For each project and each VA employee for whom outside compensation is paid directly to the individual, determine the amount of compensation, effort, and source of funding as identified in the VAIRRS Cover Sheet.

c. For each VA employee, enter the information into the attached Memorandum: Request for Outside Compensation from the Affiliate or VA NPC delineating each project, effort, and proposed amount of outside compensation. A sample memorandum is provided in Appendix A.

d. The Associate Chief of Staff of Research and Development (ACOS/R&D) reviews the memorandum for accuracy taking into consideration the funding source, type of research, and amount of compensation from the project. If the ACOS/R&D is the employee receiving compensation, the review must be completed by the VA medical facility CoS.

e. Following the review and confirmation of the details for VA employees who receive outside compensation, the ACOS/R&D forwards the memorandum to the Approving Official for approval or disapproval.

(1) The R&D Committee is not required to review and approve the salary compensation for existing projects.

(2) If the ACOS/R&D is the employee, the memorandum is forwarded by the VA medical facility CoS to the VA medical facility Director.

f. If the Approving Official approves the Memorandum, skip to step h.

g. If the Approving Official disapproves the Memorandum, one of the following must occur before the research continues:

(1) The VA employee, such as the VA investigator or VA research staff employee, must decline the additional salary support and restructure the budget.

(2) The VA NPC or Affiliate must develop a Memorandum of Understanding (MOU) to reimburse VA for the investigator and staff effort.

(3) The award must be assigned to another VA investigator without a financial conflict of interest to serve as the VA investigator. The primary investigator can no longer act as a VA investigator on the VHA portion of the study.

(4) The award must be closed at VA and fully moved to the Affiliate. If this is the option pursued, consideration must be given to all administrative, regulatory and data management issues associated with the proper conduct of the study.

h. Following the VA medical facility Director's decision, each Memorandum must be filed in VAIRRS and easily accessible for review or audit with a copy provided to the VA employee. A copy must also be provided to the entity providing the outside compensation. For example, if the VA NPC is providing the outside compensation for a Department of Defense award, a copy of the signed Memorandum will be provided to the VA NPC.

5. RESPONSIBILITIES

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

(1) Approving, in writing, the compensation for the specified VA project following local R&D Committee approval. See Appendix B for the template Request for Outside Compensation for VA Approved Research.

b. **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 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&D. **NOTE:** This is a limited situation circumstance where the ACOS/R&D is also the *PI*.

c. <u>Associate Chief of Staff of Research and Development.</u> The ACOS/R&D is responsible for:

(1) Forwarding the memorandum (see appendix A for example) to the Approving Official for final approval or disapproval. If the ACOS/R&D is the employee, the letter would be forwarded by the Chair, R&D Committee.

(2) Providing the original approval to the VA employee upon receiving approval from the Approving Official. A copy of the letter must be placed in VAIRRS under the appropriate project.

(3) Notifying the PI if the Approving Official disapproves the outside compensation.

(4) 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&D.

d. <u>Chair, Research and Development Committee.</u> The Chair, R&D Committee is responsible for:

(1) 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).

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

e. <u>Administrative Officer for Research.</u> 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 R&D Committee.

(2) Ensuring that one of the following is completed before research is initiated if the R&D Committee does not approve the compensation:

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

(b) The 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 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.

f. Principal Investigator. The PI is responsible for:

(1) Submitting the project, including the project budget, through VAIRRS to the R&D Committee for review by the Financial Conflict of Interest Administrator (FCOIA) and the R&D Committee.

(2) Ensuring that the following information is provided 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 employee.

(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 employee's annual salary derived from the project.

(g) Justification as to why the project requires salary support to VA-compensated employees (this could be the Affiliate-VA MOU outlining the effort and hours for all projects).

(3) Submitting, in writing, modifications to the 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 ACOS/R&D for review (or to the CoS if the ACOS/R&D is the PI).

6. A sample memorandum is provided in Appendix A.

7. All inquiries concerning this action should be addressed to the Office of Research and Development (14RD) at <u>VHA14RDaction@va.gov</u>.

8. This VHA notice will expire and be archived on November 30, 2024.

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

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

DISTRIBUTION: Emailed to the VHA Publications Distribution List on November 29,

2023. Amendment dated December 5, 2023 emailed to the VHA Publications Distribution on December 8, 2023.

SAMPLE MEMORANDUM

	Department of N Veterans Affairs	lemorandum
Date:	, 202#	
From:	ACOS for Research and Development or R&D Chair (151)	Committee
Subj: To:	Outside Compensation from the Affiliate or VA Corporation (NPC) Approving Official (VA Medical Facility Director	

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.

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