DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
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SILVER SPRING, MD 20910-7500

FCMR-UWZ (1200B) 10 April 2024

MEMORANDUM FOR All Personnel, Walter Reed Army Institute of Research (WRAIR)

SUBJECT: WRAIR Policy #28, Compensation to Federal Personnel when They Participate in Research as Human Subjects

1. References.

a. Department of Defense Instruction (DODI) 3216.02 (Protection of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and -Supported Research), 29 June 2022.

b. 5 United States Code (U.S.C.), Government Organization and Employees, §§ 5536.

c. 24 U.S.C. §§ 30, Payments to donors of blood for persons undergoing treatment at Government expense.

2. History. This policy is being issued in accordance with WRAIR and United States Army Medical Research and Development (USAMRDC) requirements and is effective upon signature by the WRAIR Commander. This version of the policy includes minor editorial and administrative changes. This version of the policy is effective immediately and shall remain in effect until rescinded or superseded in writing, or when it exceeds its expiration on 10 April 2026.

3. Purpose. This policy establishes the criteria for compensation of federal personnel participating as human subjects in research conducted or supported by WRAIR or its Directorates.

4. Definitions.

a. Clinical Investigation: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA) under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of 21 C.F.R. § 58, regarding nonclinical laboratory studies.

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*This supersedes WRAIR Policy #28, dated 02 November 2022.

b. Human Subjects Protection Branch (HSPB): The administrative support team for the WRAIR IRB and the WRAIR HRPP (i.e., IRB Support Staff, Human Subjects Protection Scientists, IRB Administrators, Human Protection Administrators, Exemption Determination Officials).

c. Institutional Official (IO): Individual ultimately responsible for the implementation of the U.S. Department of Health and Human Services (DHHS) Federal wide Assurance and the DOD Assurance of Compliance for the Protection of Human Research Subjects and the associated HRPP at an institution engaged in research involving human subjects. Within the USAMRDC, the Commander of the institution/organization engaged in research is the IO.

d. Principal Investigator (PI): The individual who is responsible and accountable for conducting a research study. This individual will have the appropriate scientific and ethics training and experience to assume full responsibility and accountability for the scientific integrity of the research data and results. The PI is the individual responsible and accountable for designing, conducting, and monitoring the research study, and has access to the data. For studies involving human research subjects, the PI, as the leader of the research study team, assumes full responsibility for the medical care and evaluation of subjects, either directly or indirectly (designee of a healthcare provider). The PI also is responsible for protecting the rights and welfare of human subjects and is responsible for carrying out sound ethical research consistent with research plans in a protocol approved by a properly-constituted IRB. The PI may formally delegate roles and responsibilities to other members of the research study team, as appropriate, but retains full responsibility for the conduct of all study activities.

(1) FDA Definition: Investigator means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(2) ICH E6 Definition: Investigator means a person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Note: The above definition is not necessarily the same as that of a PI listed on a grant or research award, which may include other responsibilities not involving human subjects research.

e. Research: A systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge (32 C.F.R. § 219.102d).

f. Research Involving Human Subjects: Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research (i) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

g. Sponsor: An individual, company, institution or organization that takes responsibility for the initiation, management, and/or financing of clinical research (ICH E6). The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators. The USAMRDC Office of Regulated Activities (ORA) serves as the Sponsor's Representative when programs within USAMRDC initiate the development of a new experimental product and conduct clinical investigations with the new experimental product. There are no sponsor-investigators in the USAMRDC.

h. WRAIR IRB: The committee that has been formally designated to review, approve, and monitor biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects at WRAIR, its Directorates, or when WRAIR funding, facilities or personnel are involved in any way (investigator, consultant, collaborator, etc.) This includes protocols for which recruitment of subjects is being performed at WRAIR. Selection for the board is in accordance with Federal guidelines outlined in 21 C.F.R. § 56.107 and 32 C.F.R. § 219.

i. WRAIR Point of Contact (POC): An individual, affiliated with WRAIR or its Directorates, who is responsible for submission of protocol documents to the HSPB over the lifecycle of the study as new protocol actions are processed, remains in continual communication regarding the study to regulatory authorities, and directs study execution wherein WRAIR is participating. This individual is generally the lead WRAIR investigator on the protocol, but is not the overall study PI. The POC can be the site PI, a clinical coordinator, program manager, associate investigator, or other individual involved in the study in a scientific or administrative capacity.

5. Background: WRAIR's investigators conduct or support much research involving human subjects; a number of the subjects for the studies may be federal employees of the Institute or other institutions, military or civilian. It is standard practice in these studies to compensate subjects for general participation in research; however, 5 U.S.C. 5536 and DODI 3216.02 prohibit federal personnel whose pay or allowance is fixed by

statute or regulation from receiving additional pay or allowance for any other service he or she might perform while on duty (i.e. participating during their duty hours while not on leave). 24 U.S.C. 30 and DODI 3216.02 make an exception to 5 U.S.C. 5536 and allow compensation for blood draws, whether or not the subjects are in the employ of the U.S. Government, whether they are on or off duty, and whether the funds are from federal or non-federal sources, but limit the amount paid to $50 for each blood draw. What constitutes a “blood draw” is defined by the Institutional Review Board (IRB)-approved protocol.

6. Applicability and Scope. This policy applies to all WRAIR Centers, Branches, and Directorates, and to all WRAIR Military, Civilians, Contractors, and affiliates who conduct human subjects research supported by the Department of Defense (DOD).

7. Policy.

a. Compensation to Human Subjects for Participation in DOD-Conducted Research:

(1) When the Human Subjects are On-Duty Federal Personnel:

(a) Federal personnel, whether civil servants or Active Duty service members, participating as human subjects in DOD-conducted research while on duty may be compensated up to $50 for each blood draw, as defined in the IRB-approved protocol. Payment for blood draws may come directly from a federal or non-federal source.

(b) Federal personnel participating as human subjects in DOD-conducted research while on duty may only be compensated for blood draws and may not be compensated for general research participation.

(2) When the Human Subjects are Off-Duty Federal Personnel:

(a) Federal personnel participating as human subjects in DOD-conducted research while off duty may be compensated up to $50 for each blood draw, as defined in the IRB-approved protocol. Payment for blood draws may come directly from a federal or non-federal source.

(b) Additionally, federal personnel while off duty may be compensated for research participation other than blood draws in the same way as human subjects who are not federal personnel (i.e. compensated for participation in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research). However, payment to off-duty federal personnel for research participation other than blood draws must not be directly from a federal source (payment from a federal contractor or other non-federal source is permissible).

b. Procedures for Implementation:

(1) Each protocol submitted to the WRAIR Human Subjects Protection Branch (HSPB) where there is an intention to exclude federal personnel will so state in its description of the study population. Unless federal personnel are to be excluded, an information sheet (Appendix A or equivalent statement) that will explain the compensation allowed for federal personnel as outlined above will be provided to all participants, either separately, or as part of the primary informed consent document. In addition, each study not excluding federal personnel will include the appropriate statement explaining the allowable compensation, depending on the status of the subject and the source of funding for the study, either separately, or as part of the primary informed consent document. For all participants, including non-federal employees, the protocol must include a definition of what is considered a blood draw so that all subjects will receive the proper compensation under this policy.

(2) When the Human Subjects Are Active Duty Service Members:

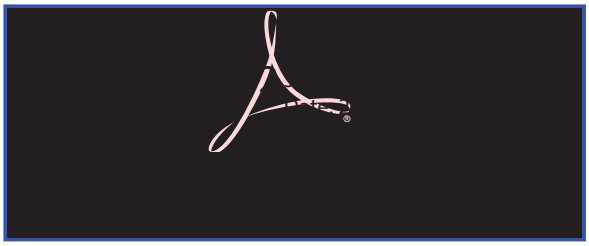
(a) When an Active Duty service member is screened for a research study, he/she/they will be given a Supervisors' Approval form (Appendix B or equivalent), as well as a copy of the study Time and Event Table or other statement of the time needed for participation, to clearly show supervisors the commitment required for research participation. WRAIR Active Duty service members cannot participate in the study, beyond the screening process, until they return the completed form to the study team, noting approval by their immediate supervisor and Company Commander. Active Duty service members from units other than the WRAIR who wish to participate as human subjects in research covered by this policy cannot participate in these studies, beyond the screening process, until they return a completed document to the study team, noting approval by their duty supervisor and their Department Chief or Service Chief. If appropriate, the form in Appendix B may be used to document approval by their duty supervisor and their Department Chief or Service Chief. The approved form (or other evidence of permission) will be used by the study team to calculate proper compensation. The approved form (or other evidence of permission) will be kept with the study records.

(b) If a WRAIR Active Duty service member wants to participate in a study outside of WRAIR, they must still receive approval. They can use Appendix B or a form approved at the institution performing the research.

(c) Active Duty service members assigned to the WRAIR may not be permitted to participate in any human research study, whether or not it is conducted at the WRAIR, that could render them irreversibly unfit for duty or travel for more than 48 hours. This provision is especially pertinent for those studies that include challenges with pathogens for which there is no immediately effective treatment, such as dengue

virus. The study's principal investigator in coordination with the Research Ethics Consultation Service, will make the determination on whether a study subject is restricted by this provision.

8. Point of contact for this memorandum is Ms. Jody Ference, Director, Human Subjects Protection Branch (FCMR-UWS-HP) at Jody.L.Ference.civ@health.mil or 301-319-9940.



Encls
1. Appendix A
2. Appendix B

APPENDIX A

INFORMATION SHEET REGARDING COMPENSATION TO FEDERAL PERSONNEL WHEN THEY PARTICIPATE IN RESEARCH AS HUMAN SUBJECTS

WRAIR Protocol #XXXX "*Insert study title"*

If you are currently a federal employee (military or civilian) or become a federal employee while you are a research subject in this study, you need to be aware of certain payment restrictions due to U.S. laws. If you are a federal employee or become one during this study, please inform the study team right away.

As a federal employee, you can only receive payment for your participation in research supported by the Department of Defense (DoD) if you are on leave or off-duty. The laws requiring this are in place to ensure that federal employees are not paid twice for the same time period ("double-dipping"). There is one exception to this requirement: all research participants are allowed to receive up to $50 per blood draw even while on duty (what constitutes a blood draw is defined in the research protocol).

Please indicate below whether or not you are a federal employee, then sign and date this form. A copy of the signed form will be kept with the study records.

For Active Duty service members, the definitions of "on leave" and "off duty" are determined by your supervisor. Please talk with your supervisor about his/her requirements for your participation as a research subject. In order for any Active Duty service members to participate in research as human subjects, you must have your immediate supervisor and Company Commander sign the "Statement of Supervisors' Approval", Appendix B. You should utilize the provided study "Schedule of Events", which details the planned dates and duration of study visits, to discuss the study with your chain of command and/or immediate supervisor. You must submit Appendix B, signed and dated, to the study team before you can participate in the study. A copy of Appendix B will be placed in the study file.

If you have any questions or concerns about this policy, please do not hesitate to contact the WRAIR Human Subjects Branch (HSPB) by phone at 301-319-9940 or by email: usarmy.detrick.medcom-wrair.mbx.hspb@health.mil.

Check your work designation below:

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□ I am a federal employee *(check one)*:
    □ Civilian
    □ Active Duty military
□ I am NOT a federal employee, but will inform the study staff if that changes during the study.

Participant signature: _____ Date: _____

APPENDIX B

FOR WRAIR ACTIVE DUTY SERVICE MEMBERS: STATEMENT OF SUPERVISOR'S APPROVAL

I would like to participate in the study "*Insert study title"*

- I have reviewed the schedule of events for the study and do not believe that my participation will interfere with my normal duties.
- Compensation may vary depending on whether study events are done during normal duty hours or off-duty. If scheduled visits are to be done during duty hours, my supervisor will note by initialing on the study's 'schedule of events'.
- I will review the study and schedule with my chain-of command (listed below). I understand I need their approval to participate.
- I will inform my supervisor and the study team if I am a subject in any other human research study (whether at WRAIR or at other locations).
- Copies of the form(s) will be placed in my study file.

_____	_____	_____
Subject *(Print)*	*(Sign)*	Date

Supervisory Chain-of-Command:

- I understand that participation in this study will require the Service member's time and there may be side effects that might compromise their performance.
- I approve the Service member's participation in this study.

_____	_____	_____
Supervisor *(Print)*	*(Sign)*	Date

_____	_____	_____
Company Commander *(Print)* or Equivalent	*(Sign)*	Date