DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
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FCMR-UWZ (1200B) 2 November 2022

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

SUBJECT: WRAIR Policy #28, Compensation and Permission for Participation of Federal Personnel in WRAIR Research Studies

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), 15 April 2020.

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.

d. WRAIR Policy #34 (Personnel and Family Participation in WRAIR Research Studies).

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 major editorial changes and minor administrative changes. This version of the policy will remain in effect until amended or rescinded.

3. Purpose. This policy establishes the criteria for compensation of all federal personnel from any U.S. government agency participating as human subjects in research conducted or supported by WRAIR or its Directorates, regardless of whether those federal personnel are employed at WRAIR or its Directorates.

4. Definitions.

a. 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, Exempt Determination Officials).

****This supersedes WRAIR Policy #28, dated 05 February 2021.**

b. Principal Investigator (PI): The individual who is responsible and accountable for conducting a research study. For the purposes of this policy, the PI is the individual designated as such on the human subjects research protocol submitted to the WRAIR HSPB.

c. 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).

d. 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.

e. 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.

5. Background: WRAIR's investigators conduct or support much research involving human subjects; a number of the subjects for the studies are federal employees, military or civilian. It is standard practice in these studies to compensate subjects for general participation in research; however, 5 U.S.C. 5536 prohibits 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. Federal employees therefore may not receive compensation for their participation in federal research that takes place during their duty hours, with one exception: 24 U.S.C. 30 makes an exception to 5 U.S.C. 5536 and allows compensation for blood draws, regardless of whether the subjects are employed by the U.S. government, whether they are on or off duty, or whether the funds are from federal or non-federal sources, but limits 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.

a. 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).

b. Note that independent of this policy, additional requirements apply to WRAIR personnel and some family members regarding participation in certain categories of research, per WRAIR Policy #34, Personnel and Family Participation in WRAIR Research Studies.

7. Policy.

a. Federal personnel, whether civil servants or Active Duty service members, who participate as human subjects in research studies conducted at or supported by WRAIR:

(1) May be compensated up to $50 for each blood draw, as defined in the IRB-approved protocol, regardless of whether the funds come from a federal or non-federal source.

(2) May be compensated for aspects of research participation other than blood draws only if the federal personnel participant is off duty when the activity for which they are being compensated occurs.

b. Active Duty service members, whether assigned to WRAIR or another DOD institution, who wish to participate as human subjects in research studies conducted at or supported by WRAIR:

(1) Must receive informed approvals for their participation in the study from their immediate duty supervisor and their Company Commander/Department Chief/Service Chief.

(2) Must provide clear documentation of approvals to participate to the WRAIR study team before being engaged in any aspects of the research other than screening for enrollment.

(3) May be compensated for aspects of research participation other than blood draws only directly from a non-federal source (for example, from a federal contractor).

c. Active Duty service members who are assigned to WRAIR and wish to participate as human subjects in research studies conducted at or supported by WRAIR or another institution:

(1) Must meet the requirements in section 7(b) in order to participate in research conducted or supported by any non-WRAIR institution.

(2) Must not participate in research that could render them unfit for duty or travel for an excessive period of time, as determined by their immediate duty supervisor or their Company Commander/Department Chief/Service Chief. This provision is especially pertinent to studies that include challenges with pathogens for which there is no immediately effective treatment, such as dengue virus.

8. Procedures.

a. Each protocol submitted to the WRAIR Human Subjects Protection Branch (HSPB) involving blood draws must include a definition of what is considered a blood draw so that all subjects will receive the proper compensation.

b. Each protocol submitted to the WRAIR Human Subjects Protection Branch (HSPB) where there is an intention to exclude federal personnel from participation will so state in its description of the study population.

c. For protocols in which federal personnel are not explicitly excluded from participation, the WRAIR study team must provide all participants, either separately or as part of the primary informed consent document, with:

(1) An information sheet (Appendix A or equivalent document) that explains the compensation allowed for federal personnel as outlined above; and

(2) An appropriate statement explaining the allowable compensation, depending on the federal personnel status of the participant and the source of funding for the study.

d. Principal Investigators (PIs) and study teams will provide Active Duty service members who are considering enrolling as a participant in WRAIR human subjects research with 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. This form will be kept with the study records.

e. Active Duty service members who are assigned to WRAIR and wish to participate as human subjects in a research study conducted by another institution can use Appendix B or a form approved at the institution for obtaining supervisory permission for research participation.

9. Point of contact for this memorandum is [redacted] ection Branch (FCMR-UWS-H [redacted] or [redacted].

SIGNATURE ON FILE

Encls
1. Appendix A
2. Appendix B

COL, SP
Commanding

APPENDIX A

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

WRAIR Protocol #_____, 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 receive payment for your participation in research supported by the Department of Defense (DOD) only 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 if they are on-duty federal employees.

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 their requirements for your participation as a research subject. Active Duty service members who want to participate as research subjects must have their immediate supervisor and Company Commander (or equivalent) sign the "Statement of Supervisors' Approval," Appendix B.

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 at usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil.

Check your work designation below:

☐ I am a federal employee *(check one)*:
- ☐ Civilian
- ☐ Active Duty military

☐ I am NOT a federal employee, but will inform the staff if that changes during the study.

Participant Signature: _____ Date: _____

APPENDIX B

STATEMENT OF SUPERVISORS' APPROVAL FOR ACTIVE DUTY SERVICE MEMBERS TO PARTICIPATE IN RESEARCH AS HUMAN SUBJECTS

I am requesting permission to participate in the study, _____

_____.

- 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.

In the judgment of the Principal Investigator (PI), my participation in this study has a reasonable likelihood of rendering me unfit for duty or travel for a maximum period of

_____ days.

_____	_____	_____
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