



DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
503 ROBERT GRANT AVENUE
SILVER SPRING, MD 20910-7500

REPLY TO
ATTENTION OF

MCMR-UWZ

30 August 2012

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: WRAIR Policy Letter 12-28, 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-Supported Research", 8 November 2011.

b. Section 5536 of Title 5, United States Code (5 USC 5536)

c. Section 30 of Title 24, United States Code (24 USC 30)

2. HISTORY: This policy supersedes WRAIR Policy Letter 11-45, "Participation of Active-Duty Soldiers in Clinical Trials". This policy is effective for studies approved for implementation after the date of this letter. *This version of the policy will remain in effect until amended or rescinded.*

3. PURPOSE: This policy establishes the criteria for compensation of federal personnel participating as human subjects in research conducted or supported by Walter Reed Army Institute of Research (WRAIR) or its Special Foreign Activities.

4. BACKGROUND:

a. The WRAIR's investigators conduct or support much research involving human subjects; a number of the subjects for the studies are federal employees of the Institute, military or civilian. It is standard practice in these studies to compensate subjects for general participation in research; however, 5 USC 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.*, not on leave and participating during their duty hours). 24 USC 30 and DoDI 3216.02 make an exception to 5 USC 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 withdrawal. What constitutes a "blood draw" is defined by the protocol.

b. Additionally, federal personnel while off duty may be compensated for general research participation other than blood draws in the same way as participants who are not federal personnel. 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).

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5. **APPLICABILITY:** This policy applies to all WRAIR centers, overseas labs, and branches, and to all WRAIR military, civilians, contractors, and affiliates who conduct Human Subjects' research supported by the DoD.

6. **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. 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. 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) On or after the effective date of this policy, each protocol submitted 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 should include a definition of what is considered a single blood draw so that all subjects will receive the proper compensation under this policy.

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

(a) When an Active Duty service member is screened for a research study, he or she will be given a Supervisors' Approval form (Appendix B), 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. 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, Branch Director, 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. They can use the form in Appendix B, if appropriate. 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, which 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 will make the final determination whether a study subject is restricted by this provision.

7. POINT OF CONTACT: The point of contact for this action is the Deputy Commander, WRAIR, at (301) 319-9956.

Signature on File

ENCLS
Appendix A
Appendix B
DISTRIBUTION:
A&B

✓ RALPH L. ERICKSON
COL, MC
Commanding

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APPENDIX A

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

WRAIR Protocol #XXXXX "*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 can receive up to \$50 per blood draw even while on duty.

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, Branch Director 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. 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 federal policy, please do not hesitate to contact the the WRAIR Human Subjects Branch (HSPB) by phone at 301-319-9940 or by email: wrairhspb@amedd.army.mil.

Check your work designation below:

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

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

If you have any questions or concerns about this federal policy, please do not hesitate to contact the WRAIR Human Subjects Branch (HSPB) by phone at 301-319-9940 or by email: wrairhspb@amedd.army.mil.

Participant signature: _____ Date: _____

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APPENDIX B

FOR WRAIR ACTIVE DUTY SERVICE MEMBERS: STATEMENT OF SUPERVISORS' 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 another human research study.
- 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 federal employee'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 _____

Branch Director (*Print*) _____ (*Sign*) _____ Date _____
or Equivalent

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

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