



Defense Health Agency

ADMINISTRATIVE INSTRUCTION

NUMBER 3200.01

April 28, 2022

DAD R&E

SUBJECT: Research Subject Compensation

References: See Enclosure 1

1. PURPOSE. This Defense Health Agency-Administrative Instruction (DHA-AI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (i), establishes the Defense Health Agency's (DHA) responsibilities, procedures, and guidance for the compensation of study subjects for their participation in human subject research within the DHA's research programs (referred to collectively in this DHA-AI as the "DHA Research Enterprise").

2. APPLICABILITY. This DHA-AI applies to the DHA, DHA Activities (under the authority, direction, and control of DHA), Military Health System (MHS) Military Medical Treatment Facility directors or designees, Principal (Key) Investigators (PIs) and their research staff, and all other organizational entities and activities (referred to collectively in this DHA-AI as the "DHA Activities").

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to References (d) through (g), that the DHA Research Enterprise:

a. Contributes to the DHA's research mission by implementing the provisions of References (d) through (i) to ensure that research activities within the DHA are equitable in their availability and scope to the potential study subjects drawn from the MHS beneficiary population (Active Duty personnel, Federal Civilian Employees, and other MHS beneficiaries who agree to participate in research) to realize the fullest potential of the DHA's medical discoveries.

b. Provides for the fair and equitable treatment of the individuals who agree to participate as research subjects with regard to the administration of their involvement in support of the DHA research enterprise.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3.

6. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director (DAD), Research and Engineering (R&E). When Activities are unable to comply with this publication the activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to the DAD, R&E to determine if the waiver may be granted by the Director, DHA or their designee.

7. RELEASABILITY. **Cleared for public release.** This DHA-AI is available on the Internet from the Health.mil site at: <https://health.mil/Reference-Center/Policies> and is also available to authorized users from the DHA SharePoint site at: <https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx>.

8. EFFECTIVE DATE. This DHA-AI:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or canceled before this date in accordance with Reference (c).

/S/
RONALD J. PLACE
LTG, MC, USA
Director

Enclosures

1. References
2. Responsibilities
3. Procedures

Glossary

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD(HA)),” September 30, 2013, as amended
- (b) DoD Directive 5136.13, “Defense Health Agency (DHA),” September 30, 2013
- (c) DHA-Procedural Instruction 5025.01, “Publication System,” August 24, 2018
- (d) United States Code, Title 5, Section 5533
- (e) United States Code, Title 24, Section 30
- (f) Code of Federal Regulations, Title 5, Section 550.112
- (g) Code of Federal Regulations, Title 32, Part 219
- (h) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research," April 15, 2020
- (i) DHA Office of Research Protections, Component Management Plan, December 31, 2020¹

¹ This reference can be found at: <https://www.milsuite.mil/book/docs/DOC-949202>.

ENCLOSURE 2
RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA, or designee (herein after referred to as "Director, DHA") will have overarching responsibility and control for research conducted within DHA and designate DHA laboratories.

2. DAD, R&E. The DAD, R&E will:

a. Perform the duties of the Senior Designated Official set out in Reference (h).

b. Develop and implement a Component Management Plan (CMP) for the DHA Human Subject Protection strategy to align with DHA objectives and priorities.

c. Maintain oversight of the activities performed by or at the direction of the Director, DHA Office of Research Protections (ORP) in accord with the DHA Human Subject Protection strategy.

3. DIRECTOR, DHA ORP. The Director, DHA ORP, will:

a. Formulate, direct, and execute the overall DHA Human Subject Protection strategy to align with DHA objectives and priorities.

b. Establish and lead the DHA ORP office to:

(1) Develop the DHA Human Research Protections Program (HRPP), the HRPP policies, standard operating procedures, and templates to achieve efficient, effective, and protective research practices.

(2) Develop a system to, among other things, track HRPP activities, generate HRPP reports, and serve as a DHA point of contact for the best Human Subject Protection practices.

(3) Develop a CMP to operationalize the DHA HRPP.

(4) Develop and oversee a DHA ORP website for posting the latest versions of HRPP templates.

(5) Foster communication and harmonization among DHA and non-DHA DoD research activities.

(6) Coordinate between DHA and industry, academia, other government entities, and non-profit organizations in alignment with strategic partnerships.

c. Establish inter-agency and intra-agency working group(s), drawing from subject matter experts (e.g., scientists, medical doctors, researchers, policy experts, regulatory affairs experts, research and technology application managers, lawyers, business managers, information technology experts) to advise the DHA HRPP.

d. Serve as the DHA Director's primary point of contact, represent DHA at HRPP-related activities, and advise DHA senior leadership on HRPP-related matters.

4. HUMAN PROTECTION ADMINISTRATORS/DIRECTORS. The Human Protection Administrators/Directors will:

a. Oversee their DHA institution's HRPP office and activities in compliance with the DHA ORP CMP.

b. Perform HRPP functions, consult with, and obtain guidance from the DHA ORP.

c. Ensure sponsors of research be made aware of this DHA-AI to the maximum extent possible.

5. STUDY SPONSORS AND PIs. Study Sponsors and PIs will:

a. Conduct research in accordance with References (d) through (i) and any local regulations that may apply to their institution.

b. Ensure that if compensation is provided to study subjects, it is administered fairly and equitably in accordance with this DHA-AI.

c. Ensure that DoD study participants are offered the same level of compensation to all participating populations to the extent permissible and consistent with law, regulation, and this DHA-AI.

d. Ensure that the study documents used for the enrollment of study participants within the DoD include the protocol, any investigator brochures, and any consent documents contain the DoD language required under References (d) through (i) and a statement that compensation (other than payments for blood draws as set out in Reference (e)) can only be received by active duty members and Federal civilian members of the workforce enrolled in the study, if the activities necessary to meet those requirements occur during their off-duty hours and not while they are on duty.

ENCLOSURE 3

PROCEDURES

1. BACKGROUND

a. Historically, when research studies, to include clinical trials, have been conducted within DoD that have enrolled active duty members, these personnel have been required to obtain approval from their command to participate. The rationale for this requirement has been to ensure that the command knows about the activities that may affect the fitness for duty of the personnel due to their participation.

b. DoD has historically limited the participation of both active duty members and members of the Federal civilian workforce. It has permitted their on-duty participation with command/supervisor permission if participating does not adversely impact their ability to perform assigned duties. However, the language in References (d) and (e) has limited the ability for Federal employees to receive compensation while on-duty to \$50 for a blood draw required by a research study. In terms of payment for research participation other than for blood draws, Federal law limits what they may receive. Reference (d) reflects that, except in certain limited circumstances, a Federal employee (which includes active duty members) is not entitled to receive basic pay from more than one position while on duty working for the Federal Government. It should be noted that these restrictions do not apply to other beneficiaries of the MHS. For some research and for some researchers, these payment limitations for Federal employees can result in challenges for their projects. However, many within the DoD have construed the requirement for command/supervisor approval and the Dual Compensation Act language as prohibiting the compensation of DoD personnel who participate in research when off-duty. These limitations have resulted in the imposition of significant restrictions on the ability of the DoD and the DHA to enroll study subjects in meaningful research.

c. It is also now the case that DoD and non-DoD Study Sponsors and PIs (both within the Federal Government and from industry) have access to and utilize advanced record-keeping methods to track the effect of their study interventions on study subjects and provide compensation to their study subjects for the time and effort expended by those subjects in furtherance of their research.

d. The intent of this DHA-AI is to ameliorate those restrictions by revising the standards that have heretofore been construed by some commanders and supervisors to limit the ability of DoD personnel, both military and civilian, to enroll in these research activities.

2. PROCEDURES TO BE FOLLOWED

a. As of the effective date of this DHA-AI, DHA PIs and their research staff must implement the policies set forth in this DHA-AI for study subjects enrolled from the active duty ranks or from the Federal civilian workforce of the DoD. This can and will include

compensation for active duty members/Federal employees completing daily eDiary and/or other diaries of health symptoms and collection of specimens (e.g., nasal swabs) as long as such study-related activities are conducted while they are off-duty.

b. For the purposes of implementation of this DHA-AI, the following definitions of on-duty and off-duty status apply to active duty members and Federal civilian members of the workforce study participants:

(1) An individual is on-duty when they are expected or required to perform the duties of their assigned job or position.

(2) An individual is off-duty if the individual is not scheduled to perform any work that may arise during the period.

c. Study Sponsors and/or PIs enrolling study participants within the DoD concurrently with their enrollment of study participants in the private sector should offer the same level of compensation to all study participants. The study documents utilized at the DoD study sites, including the protocol, any investigator brochures, and any consent documents, in addition to the DoD language required under References (d) through (h), must describe any requirements for the completion of daily eDiary and/or other diaries of health symptoms and collection of specimens (e.g., nasal swabs) required by the study. The documents must also contain a statement that the compensation can only be received if the activities necessary to meet those requirements occur during the DoD study subject's off-duty hours and not while they are on duty.

GLOSSARY

ABBREVIATIONS AND ACRONYMS

CMP	Component Management Plan
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHA-AI	Defense Health Agency-Administrative Instruction
HRPP	Human Research Protections Program
MHS	Military Health System
ORP	Office of Research Protections
PI	Principal Investigator
R&E	Research and Engineering