Human Research Protection Program Departmental Policy and Procedure Manual

2.4 Department of Defense (DoD) Research

Effective Date: September 3, 2026

I. Procedures For Policy Implementation

a. When submitting an application for human subject research to the IRB, the principal investigator (PI) must identify the research as sponsored or funded by a DoD component (as defined in Department of Defense Directive 3216.02). The PI is responsible for identifying DoD component requirements specified in the grant application guidelines and for advising the HRPPD staff and IRB of the requirements.

b. If a DoD institution is collaborating with UTSW (a non-DoD institution) and relying on the UTSW IRB for review, the following conditions will be met:

   i. Each institution engaged in the non-exempt research must have a current federal assurance of compliance

   ii. The involvement of DoD personnel in the conduct of the research will be secondary to that of the UTSW personnel (non-DoD institution)

   iii. A written agreement defining the responsibilities and authorities of each organization will be executed (See 1.6 Reliance on a Non-UT Southwestern IRB or 2.8 Collaborative Research Involving External Investigators-Institutions Reviewed by UTSW IRB for detailed terms of what the agreement will describe). This agreement must be approved by the DoD component prior to the engagement of the DoD institution in research.

c. UTSW does not conduct classified research.

d. UTSW does not permit research involving chemical or biological agents, including research for prophylactic, protective, or other peaceful purposes involving chemical or biological agents.

e. The IRB and HRPPD staff will review protocols to ensure the following specific considerations and procedures for DoD sponsored research have been considered prior to approval.

i. Risk Assessment and Minimal Risk Determination

1. In evaluating the risks of DoD-supported research, the IRB will determine that risks to participants are minimized and are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge expected to result.

2. For research conducted under Department of Defense requirements, the definition of minimal risk in 32 CFR 219 does not include the inherent occupational risks that certain participants face in their everyday lives, such as those:

a. Encountered by Service members, law enforcement personnel, or first responders while on duty;

b. Resulting from or associated with high-risk behaviors or pursuits; or

c. Experienced by individuals whose medical conditions involve frequent tests or constant pain.

3. When determining whether research presents no more than minimal risk, the IRB will not consider these inherent occupational risks, high-risk activities, or medical-condition-related experiences as part of the minimal risk assessment.

ii. Educational Requirements

1. Initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human participants' research.

2. If there are specific DoD educational requirements or other certification requirements for study personnel, the Human Research Protection

Program Department (HRPPD) staff will ensure those requirements are met (See 5.2 RESEARCH EDUCATION AND TRAINING)

iii. Informed Consent

1. The informed consent must include (in addition to the basic and require consent disclosures):

   a. If the research involves DoD-affiliated personnel as participants, the informed consent document must, as applicable, include:

      i. A description of any risks to fitness for duty (e.g., health, availability to perform assigned duties, or consequences of a data breach) and a statement that participants should seek command or component guidance before participating if they have questions regarding such risks.

      ii. A statement regarding potential risks for revocation of a security clearance, credentials, or other privileged access or duty, when applicable.

      iii. A statement that the Department of Defense (DoD) or a DoD organization is funding the study, when applicable.

      iv. A statement that representatives of the DoD are authorized to review research records.

2. The IRB will determine that disclosures regarding research-related injury comply with the requirements of the applicable DoD component.

3. For greater than minimal risk research, the informed consent document must include a statement that participants may be eligible for health care services for research-related injuries at a military treatment facility for the duration of the study and, when applicable,

after study participation has ended in accordance with applicable DoD requirements.

4. The IRB will ensure that plans for the management of research-related injuries are documented, including injuries that are the direct result of activities performed by DoD-affiliated personnel in collaborative research conducted with non-DoD institutions.
5. A statement that the DoD or a DoD organization is funding the study, if applicable.
6. A statement that representatives of the DoD are authorized to review research records.

iv. The UTSW IRB will determine that the disclosure for research-related injuries follow the requirements of the DoD component.

v. Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless

1. the informed consent of the subject is obtained in advance; or
2. in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance.

vi. For research involving a human being as an experimental subject that is supported by DoD-appropriated funds, informed consent must be obtained from the participant in advance in accordance with 10 U.S.C. § 980. If a participant is unable to provide informed consent and consent will be obtained from the participant's legally authorized representative, the research must be intended to benefit the individual participant. The IRB will determine whether this requirement is satisfied.

vii. For non-exempt research supported by DoD-appropriated funds that involves a human being as an experimental subject, informed consent

must be obtained in advance in accordance with 10 U.S.C. § 980.

1. The IRB may waive or alter certain elements of informed consent for research involving a human being as an experimental subject when permitted by applicable law and DoD requirements, provided the informed consent process preserves the participant's voluntary agreement to participate and the participant or the participant's legally authorized representative is informed of the research risks.

viii. The Secretary of Defense may waive the prohibition with respect to a specific research project to advance the development of a medical product necessary to the armed forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws.

ix. Exception from Informed Consent (EFIC)

1. DoD regulations prohibit an exception from informed consent in planned emergency medicine research unless the PI obtains a waiver from the Secretary of Defense.

x. Inclusion of Vulnerable Populations

1. US Military Personnel

a. Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.

b. The IRB will confirm the following additional protections are in place to minimize undue influence (as applicable):

i. For greater than minimal risk research involving DoD-affiliated personnel, when recruitment or informed consent occurs in a group setting, the IRB will appoint an ombudsperson. The ombudsperson:

ii. Must not have a conflict of interest with the research

or be a member of the research team.

iii. Must be present during research recruitment and informed consent activities.

iv. Must be independent of the research.

v. Must monitor the recruitment and consent process to ensure participation is voluntary and that information provided to prospective participants is consistent with IRB-approved materials, including electronic or digitally delivered materials.

vi. Should be available to address concerns of DoD-affiliated personnel regarding participation in the research.

vii. Serves as an additional safeguard to help ensure that participation is voluntary and free from undue influence or coercion.

viii. Officers are not permitted to influence the decision of their subordinates.

ix. Officers and senior non-commissioned officers may not be present at the time of recruitment.

x. Officers and senior non-commissioned officers have a separate opportunity to participate.

xi. When recruitment involves a percentage of a unit, an independent ombudsman is present.

c. The IRB will confirm that there are limitations on dual compensation:

i. Which prohibit an individual from receiving pay of compensation for research during duty hours.

ii. US military personnel may be compensated for research if the participant is involved in the research when not on duty

iii. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw.

iv. Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

d. Survey Research

i. Survey or questionnaire research involving DoD personnel must receive IRB approval and may require additional review and approval by the applicable DoD Component prior to initiation. Such research is not eligible for expedited review when DoD Component-level review is required. The PI must submit surveys and all required documentation to the appropriate DoD Component in accordance with applicable DoD directives (SECNAVINST 3900.39D, para. 6e; OPNAVINST 5300.8B)

e. Pregnant Women and Fetuses

i. DoD research involving pregnant women is subject to the DHHS 45 CFR 46 Subpart B.

ii. For purposes of applying Subpart B to DoD research, the phrase “biomedical knowledge” shall

be interpreted as “generalizable knowledge.”

iii. The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus; or involves fetuses or neonates as participants.

iv. Fetal DoD research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.

f. Children

i. DoD research involving children is subject to the DHHS 45 CFR 46 Subpart D.

ii. DoD research involving children cannot be exempt

g. Prisoners

i. DoD research involving prisoners is subject to the DHHS 45 CFR 46 Subpart C.

ii. DoD research involving prisoners cannot be reviewed by the expedited procedure.

iii. When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.

iv. In addition to allowable categories of research on prisoners in Subpart C, the following two additional categories are allowable:

1. Epidemiological research is also allowable when:
    a. The research describes the prevalence or incidence of a disease

by identifying all cases or studies potential risk factor association for a disease.

b. The research presents no more than minimal risk.

c. The research presents no more than an inconvenience to the participant.

v. Prisoners are not the focus of the research. Research involving human subjects that would meet the criteria described in 32 CFR 219.101(b) can be conducted, but must be approved by a convened IRB and meet the requirements of subpart C, DODI 3216.02, and other applicable requirements.

vi. When a previously enrolled human subject becomes a prisoner and the relevant research protocol was not reviewed and approved by the IRB to include prisoners, the PI should promptly notify the IRB.

vii. The prisoner participant may continue only if:

viii. the researcher asserts to the IRB that it is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, and

ix. the IRB chair determines that the prisoner-participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB's approval to change the research

protocol.

x. Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol.

xi. The convened IRB shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy.

xii. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative.

xiii. If the prisoner participant can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner participant's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner participant to continue to participate in the research. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants.

xiv. This type of request for change in the research

protocol cannot be reviewed and approved by the IRB using expedited review procedure.

xv. The research involving human subjects does not have to meet one of the six allowable categories of research involving prisoners (described in subparagraph 7.b.(2) of the DODI 3216.02).

xvi. For all DoD research involving human subjects, the applicable DoD Component office conducting the reviews must concur with the IRB before the human subject can continue to participate while a prisoner.

xvii. If the research involving human subjects is conducted by a non-DoD institution, the non-DoD institution shall promptly report all decisions in this matter to the HRPO.

Any change in participant status to prisoner that was not previously approved under Subpart C must also be reported in accordance with DoDI 3216.02 reporting requirements.

h. Adult subjects unable to provide informed consent

i. Adult subjects will be enrolled after a legally authorized representative provides consent

ii. If consent is to be obtained from the experimental subjects' legal representative, the research must intend to benefit the individual participants.

iii. The determination that research is intended to be beneficial to the individual experimental subjects must be made by an IRB.

i. Prisoners of War

i. Research involving prisoners of war is prohibited unless:

ii. The activities are covered by investigational new drug or investigational device provisions for the purpose of diagnosis or treatment of a medical condition in a patient, and

iii. Such treatment (e.g., an investigational new drug) may be offered to detainees with the detainees' informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and

iv. Only when the same product would be offered to members of the

v. U.S. Military Services in the same location for the same medical condition and only when consistent with established medical practice involving investigational drugs and devices.

j. Compensation for Research Related Injury a. All non-exempt research involving human subjects shall, at a minimum, meet the requirement of section 219.116(a)(6). The Common Rule does not require payment or reimbursement of medical expenses, provision of medical care, or compensation for research-related injuries. However, components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.

k. Research Monitor

i. A research monitor is not required for DoD-supported research. The IRB may require a research monitor or other additional safety oversight measures when appropriate based on the nature, risks, complexity, or participant population of the research. Researchers may remove a previously imposed research monitor requirement from existing open studies through a modification reviewed and approved by the IRB.

ii. For studies requiring a research monitor, the following are considered by the IRB:

iii. The research monitor is appointed by name and shall be independent of the team conducting the research.

iv. There may be more than one research monitor (e.g., if different skills or experience are needed.

v. The monitor may be an ombudsman or a member of the data safety monitoring board. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.

vi. The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.

vii. The duties of the research monitor are determined on the basis of specific risks or concerns about the research, such as:

viii. Perform oversight functions (e.g., observe recruitment, enrollment procedures, and the

consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis)

ix. Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.

x. Report observations and findings to the IRB or a designated official.

xi. The research monitor has the authority to:

xii. Stop a research study in progress.

xiii. Remove individuals from study.

xiv. Take any steps to protect the safety and well-being of participants until the IRB can assess.

l. Scientific Merit

i. For non-exempt research, the IRB considers the scientific merit of the research.

ii. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

m. Reporting

i. The following shall be promptly (within 30 days) reported to the DoD Human Research Protection Officer (HRPO) and when applicable, the Component Office for Human Research protections (COHRP)through the PI:

ii. The following approvals must be sent to the HRPO for an administrative review of the research before human subject research activities may begin:

iii. Initial IRB approval of the research including risk level

iv. IRB approval of significant changes to the research protocol

v. IRB continuing review approval.

vi. When there is a change of reviewing IRB

vii. Any IRB determinations of unanticipated problems involving risks to participants or others for any DoD research

viii. Any suspension or termination of DoD research

ix. Notifications by any Federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DoD research protocol.

x. Reports of audits of DoD-conducted or DoD-supported human participant research by another federal or state agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government.

xi. Allegations of serious or continuing noncompliance related to research involving human participants that are substantiated by investigation, and subsequent actions taken based on the findings.

xii. When serving as the reviewing IRB/EC for DoD-

supported research, the following must be promptly reported to the Component Office for Human Research Protections (COHRP) in accordance with DoDI 3216.02 §3.6:

xiii. Protocol Changes

xiv. Approval of significant changes to the research protocol, including:

xv. Changes to key investigators or participating institutions

xvi. Changes that increase risk or decrease anticipated benefit in greater than minimal risk research

xvii. Addition of vulnerable populations as participants

xviii. Addition of DoD-affiliated personnel as participants

xix. Change of the reviewing IRB/EC

xx. Oversight / Compliance

xxi. Notification that any part of the HRPP is under investigation for cause involving a DoD-supported research protocol by:

xxii. A federal or state agency

xxiii. A tribal authority

xxiv. A foreign government

xxv. Any other oversight entity

xxvi. Any of the following related to DoD-supported research:

xxvii. Unanticipated problems involving risks to

participants or others

xxviii. Suspension or termination of IRB/EC approval

xxix. Serious or continuing noncompliance

xxx. Continuing Review and Participant Status Changes

xxxi. Results of continuing review, when required

xxxii. When a previously enrolled participant:

1. Becomes pregnant, and the protocol was not previously approved under 45 CFR 46 Subpart B
2. Becomes a prisoner, and the protocol was not previously approved under 32 CFR 219 Subpart C

xxxiii. Study Completion

xxxiv. Closure of a DoD-supported study

xxxv. DoD Component-Level Administrative Review (CLAR) must be conducted when any of the following apply:

xxxvi. Human participant research is conducted in a foreign country, unless:

xxxvii. The research is conducted by a DoD overseas institution; or

xxxviii. The research involves only DoD-affiliated personnel who are United States citizens.

xxxix. The research requires a waiver of informed consent

pursuant to 10 U.S.C. § 980(b).

xl. The research is fetal research as described in 42 U.S.C. §§ 289g–289g-2.

xli. The research involves collection of Large-Scale Genomic Data (LSGD) from DoD-affiliated personnel, including data derived from:

xlii. Genome-wide association studies;

xliii. Single nucleotide polymorphism (SNP) arrays;

xliv. Genome or exome sequencing;

xlv. Transcriptomic, metagenomic, epigenomic, or gene expression analyses; as defined in DoDI 3216.02, Glossary (G.2).

xlvi. The research constitutes classified research involving human participants in accordance with DoDI 3216.02, Section 3.13.

xlvii. The research requires approval by the DoD Human Research Protections Official (DOHRP) in addition to the Component Office for Human Research Protections (COHRP), as required by DoDI 3216.02.

xlviii. When a DoD institution collaborates with UT Southwestern and relies on a non-DoD IRB for review, DoD Component-Level Administrative Review includes review and approval of the reliance agreement, as applicable. Reliance agreements must be approved by the appropriate DoD Component prior to the DoD institution's

engagement in the research.

xlix. Human participant research activities involving DoD oversight, support, or approval may not begin until all required DoD Component approvals have been obtained, verified by HRPPD staff, and documented in the study record.

l. Studies requiring DoD Component-Level Administrative Review (CLAR) may not be reviewed or approved using expedited procedures when such review would bypass required DoD oversight.

li. Expedited Review of DoD-Supported Research

lii. DoD-supported research reviewed by the expedited procedure must comply with HRPP Policy [Expedited Review Policy #], including all criteria for expedited review under 45 CFR 46.110 and 21 CFR 56.110.

liii. The IRB/EC will ensure that any DoD-specific limitations on expedited review are applied, including:

liv. Research involving prisoners may not be reviewed using the expedited procedure.

lv. Research requiring DoD Component-Level Administrative Review (CLAR) or additional DoD review may not proceed under expedited procedures until all applicable DoD requirements are satisfied.

lvi. Survey or questionnaire research involving DoD

personnel must comply with DoD component-specific review requirements and is not eligible for expedited review when additional DoD-level review is required

lvii. Expedited review may be used, when appropriate, for:

lviii. Initial review of research meeting minimal risk criteria and eligible categories

lix. Continuing review, when permitted under applicable regulations

lx. Review of minor changes to previously approved research

lxi. Recordkeeping

lxii. Records will be maintained such that document compliance or non-compliance with DoD requirements shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

II. Definitions

a. See Glossary of Human Research Terms

b. Research involving an Experimental subject: An activity, for research purposes, where there is an intervention or interaction with a human subject for the primary purpose of obtaining the effect of the intervention of interaction (32 CFR 219.102(f)).

c. Prisoner of war: any person captured, detained, held or otherwise under the control of Department of Defense personnel (military or civilian, or contractor employee). Such persons include: enemy prisoners, civilian internees, retained persons, and lawful and unlawful enemy combatants. Such persons do not include Department of Defense personnel being held for law enforcement purposes.

III. References

a. 21 CFR 50 – Protection Of Human Subjects

b. 45 CFR 46 – Protection Of Human Subjects

c. 45 CFR 164 – Security And Privacy (HIPAA Privacy Rule)

d. 21 CFR 56 – Institutional Review Boards

e. DoDI 3216.02 - Department Of Defense (DOD) Instruction

f. 32 CFR 219 – Protection Of Human Subjects (DOD)

g. US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g - Fetal Research

IV. Revision History and Review History

a. June 2026; HRPP; Updates regarding DoD components and minor clarifications

b. November 2021; HRPP; Defined requirements when DoD component relies on UTSW, defined how UTSW IRBs will review classified research, and defined additional requirements for informed consent

c. June 2021; HRPP; Separated policy from P&P manual. Updated references to AVPHRA and IRB Director and Minor administrative edits.

a. August 2017; HRPP; New Policy Development

d. March 2012; IRB Office; IRB Written Procedures