**Summary of Requirements for Department of Defense (DoD)**
**Supported Human Research**

In addition to the Common Rule, Human Research supported by the DoD is subject to requirements and ethical standards outlined in the Department of Defense Instruction 3216.02. The University of Kentucky DoD/IRB/ORI Coordination SOP describes policies and procedures for review, conduct and oversight of human research supported by the DoD.

Support of a study generally means the provision of funding, military or civilian personnel (study personnel or participants), facilities, and any other resource. For survey research, if subjects may be recruited without using any DoD assistance (e.g., no DoD equipment, facilities, personnel, e-mail addresses, or property used or accessed), then it is not technically DoD supported.

Office of Research Integrity (ORI) Staff may:

☑ Discuss with Principal Investigator (PI) to Confirm the proposed research is DoD supported.

☑ Request PI contact DoD Component (i.e., Air Force, Army, Navy) supporting the research to confirm additional human subject research requirements. The Human Research Protection Official (HRPO) for specific Components provides administrative review and approval to confirm protocol is compliant with federal and DoD requirements.

**General DoD Requirements**

☑Use the IRB DoD Checklist for DoD supported research to facilitate IRB review.

**1. Scientific Merit**

The IRB must consider the review by the investigator's department relative to **scientific merit** of the research.

☑ Ensure scientific review discussions are documented in IRB review materials or minutes.

**2. Classified Research**

Research involving classified information must be reviewed by the full convened IRB; requires descriptions and clarifications be included in the informed consent process (waiver is prohibited); and must be approved by the Secretary of Defense, prior to initiation.

**3. Survey Research**

If DoD supported study involves survey research or surveys in DoD personnel, additional level of DoD review is typically required.

**Summary of Requirements for Department of Defense (DoD)
Supported Human Research**

## 4. Compensation

Dual compensation rules limit subject payment. Options vary depending on participation on or off active duty and source of funds for payment.

- Ensure that investigator is aware of compensation policies as applied to proposed research if subject payment is involved.

For DoD supported research involving more than minimal risk, subjects are provided with an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Additional requirements may apply to collaborative research where the DoD component is engaged in the conduct of the research. Additional injury payment rules apply to research conducted by DoD; not research supported by DoD.

## 5. International citizen populations

Research involving international citizen populations should adhere to any local applicable laws, regulations, customs, and required local ethics review. Consult the current edition of the International Compilation of Human Research Standards for reference.

- Ensure researcher has permission to conduct research in the country by certification or local ethics review.
- Ensure knowledge of local context is met by standing or ad hoc IRB member or cultural consultant.

## 6. Armed Services personnel, Military or Civilian DoD Employees

If study is a clinical investigation including Armed Services personnel, women and minorities must be included as subjects.

Research with DoD personnel (military or civilian DoD employees) must include a recruitment plan that incorporates safeguards to ensure no undue influence from superiors in the chain of command (i.e., superiors may not be present at time of recruitment and must be provided a separate opportunity to consider participation themselves).

If research includes military personnel, the HRPO may require PIs to obtain permission from local command to allow subject's participation during or off duty particularly if research could impact the Service members' ability to perform his/her military duties.

If recruitment for a greater than minimal risks study occurs in a group setting (e.g., involved a percentage of a unit), an IRB-appointed ombudsperson must observe the recruitment and informed consent process to ensure voluntariness and be available to address concerns about participation. The ombudsperson cannot have a conflict of interest with the research or be part of the research team. This

is required for military, (not civilian), DoD personnel, but the IRB may require use of this safeguard for civilian DoD employees when appropriate.

### 7. Humans as Experimental Subjects

The following additional requirements apply **only** to the sub-category of human research entitled, ***Research involving Humans as Experimental Subjects*.** This is a category of research conducted for the purpose of obtaining data regarding the effect of an intervention or interaction.

- For Research involving Humans as Experimental Subjects, ensure that:
    - informed consent is obtained;
    - waiver of informed consent is never granted (unless prohibition waived by Secretary of Defense based on specific criteria); and
    - the research intends and has potential to benefit the subjects in studies where consent could be obtained from a subject's legally authorized representative.

### 8. Planned emergency research

As planned emergency research meets the above definition of research involving humans as experimental subjects, a waiver of informed consent is prohibited unless DoD has issued a waiver.

### 9. Vulnerable Subject Subparts

The DoD has adopted 45 CFR 46 Subpart B (pregnant women, fetuses, and neonates), C (prisoners), and D (children) with **limitations and modifications**.

- Subpart B:
    - For the purposes of applying Subpart B risk-benefit analysis, DoD replaces the phrase "biomedical knowledge" with "generalizable knowledge".
    - The DoD limits the applicability of Subpart B 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*
        - fetuses or neonates as participants.
    - Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.

**Summary of Requirements for Department of Defense (DoD)
Supported Human Research**

- Subpart C:
    - For research intended to enroll prisoners, the DoD does not allow review by expedited mechanism. When the IRB reviews research involving prisoners, at least one prisoner representative is present.

    - Epidemiological research is also allowable when: the research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease; the research presents no more than minimal risk; and the research presents no more than an inconvenience to the participant.

    - If a PI attests that it is in the best interest of a subject who becomes a prisoner to continue participation in the research, the DoD allows the IRB chair to make a preliminary determination until the convened IRB (and DoD Component if applicable) can review the request. Otherwise, the IRB may require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB with consultation from the prisoner representative, can review this request to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy.

      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.

- Subpart D:
    - The DoD does not apply subpart D to active duty personnel under the age of 18 as it considers all active duty military to be adults with legal capacity to participate in DoD supported research.

Should the DoD protocol include or have potential to enroll any vulnerable population protected under the Common Rule subparts, refer to the DoD Instruction 3216.02 and/or the supporting Component for specific determinations required on the part of the IRB.

Determinations authorizing or requiring any action by an official of HHS about any requirements of subparts B-D would be submitted to and authorized by the Assistant Secretary of Defense for Research and Engineering ASD(R&E).

**10. Detainees**

☑ Research with detainees is prohibited (or prisoners of war). Prohibition of detainee participation may not apply to specific research involving investigational drugs and devices

when the same products would be offered to US military personnel in the same location for the same condition.

**11. Multi-site or Collaborative Research**

Standard requirements apply to multi-site or collaborative research supported by the DoD.

- Ensure investigators conducting DoD-sponsored multi-site research have provided the IRB with information on the federal assurance(s) held by collaborating institutions, including the existence of any DoD Addendum or other direct DoD assurance.

| **DoD Components** (Air Force, Army, Navy, etc.) |
|---|

1. DoD Components may have additional requirements beyond those outlined in the OHRP FWA. The Component will communicate the unique requirements by providing the investigator with an early communication applicable to the proposed research, (common Army practice) **or** by requiring an FWA Addendum which conveys the unique requirements (common Navy and Air Force practice). Once a DoD Addendum is in place it covers all DoD research sponsored or initiated by that Component.

   ☑ Ensure investigator has provided the IRB with any specific unique requirements outlined in DoD Component communication or FWA addendum.

   Potential additional Component requirements may include:

   - Requirement for an FWA Addendum
   - Specific educational or certification requirements
   - Documentation submission (e.g., meeting minutes for all meetings in which research is reviewed; continuation review approval or materials)
   - Reporting or record retention requirements
   - Additional levels of review

2. The investigator submits documentation of IRB review and approval to the DoD Component. The HRPO provides an administrative review to confirm the protocol is compliant with Federal and DoD requirements and to concur with UK IRB's determinations (i.e., activity not HSP research; research is exempt; level of risk; protocol approval).

   ☑ Investigator should not initiate the study until approved by HRPO or relevant Component designee.

3. Standard reporting and recordkeeping procedures apply unless additional requirements are made by the supporting DoD Component. Any determinations of serious or continuing non-compliance of DoD supported research must be promptly (no longer than within 30 days) reported to the DoD HRPO.

**Summary of Requirements for Department of Defense (DoD)**
**Supported Human Research**

## 12. Points of Contact

DoD Office for Human Research Protections: jill.r.conover.ctr@mail.mil

Army Human Research Protections Office (AHRPO)- https://ahrpo.amedd.army.mil/
includes National Guard and Army Reserve and will assist with determining the applicability of DoD requirements.
Phone: 703-681-5702 or Email: usarmy.ncr.hqda-otsg.mbx.otsg-ahrpo@health.mil

Compliance Office of the Vice President for Research Uniformed Services University of the Health Sciences: compliance@usu.edu

Department of the Air Force Component Office of Human Research Protections: https://www.airforcemedicine.af.mil/Organizations/AF-Research-Oversight-Compliance/Human-Research-Protection-Programs/

Source: Department of Defense Instruction 3216.02, Protection of Human subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research, April 15, 2020: https://rt.cto.mil/wp-content/uploads/2020/06/15APR2020DoDI321602DoDHumanSubjectResearchOversight.pdf

J:\Master Outreach Documents\Survival Handbook\D - Guidance-Policy-Educational\D107-Summary-of-DoD-Requirements.doc

1/21/25 update links 6/6/2025