HOWARD UNIVERSITY (HU)
OFFICE OF REGULATORY RESEARCH COMPLIANCE (ORRC)
INSTITUTIONAL REVIEW BOARD (IRB)

ADDENDUM TO IRB STANDARD OPERATING PROCEDURE (SOP)
SUPPLEMENT-3: IRB REVIEW OF DOD-SUPPORTED HUMAN SUBJECTS RESEARCH

3. IRB Review of DoD-Supported Human Subjects Research
Informed Consent Compliance under 32 CFR §219.116 and DoDI 3216.02

3.1 PURPOSE

This SOP establishes procedures for Institutional Review Board (IRB) review of human subject research conducted or supported by the U.S. Department of Defense (DoD), with a specific focus on **informed consent requirements under 32 CFR §219.116** and additional protections required by **DoD Instruction 3216.02**.

Before initiating any DoD-supported research at Howard University and its Affiliated Centers, the ORRC will file its OHRP Federal-Wide Assurance (FWA) with the DoD. Also, the Investigator will notify the DoD of the HU IRB approval and await the DoD notification that it accepts the HU IRB approval before initiating the research.

3.2 SCOPE

This SOP applies to:

- All DoD-supported or DoD-conducted human subjects research reviewed by the Howard University IRB(s)
- Research involving:
  - Active-duty Service Members
  - Reserve/National Guard personnel
  - DoD Civilians and Contractors
  - Other Populations in DoD Contexts (e.g., deployed environments, operational settings)

3.3 REGULATORY FRAMEWORK

IRB review shall comply with:

- 32 CFR Part 219 (DoD implementation of the Common Rule)

- 32 CFR §219.116 (General Requirements for Informed Consent)
- DoD Instruction 3216.02
- 45 CFR 46 (Common Rule), as applicable

Where differences exist, **DoD requirements take precedence**.

The review of such protocols will be performed by two of the following IRB members: the Chair, or Co-Chair, or another additional designated IRB member (when the Chair and Co-Chair are unavailable) of the applicable IRB (Biomedical or Socio-behavioral), and or Community/nonaffiliated member. All the reviewers shall be U.S. Citizens.

The ORRC will ensure appropriate DoD-related research training before approval and the start of research implementation. The study team shall recertify their training every three years.

Because the use of chemical or biological agents is prohibited in DoD-funded research, pursuant to Section 1520a of Title 50 United States Code (U.S.C.), the Investigator must obtain approval from the Department of Defense Human Research Protection before the HU IRB can even review any such research.

3.4 RESPONSIBILITIES

3.4.1 IRB/ORRC Compliance Officer

- Assess the protocol for completeness in accordance with pre-review administrative requirements.
- Assigns the protocol to the Chair, or Co-Chair, and a Community Member
- In the absence of the Chair and Co-Chair, the protocol can be assigned to a member experienced/with an understanding of DoD review requirements
- The Compliance Officer marks the protocol “DoD” during the assignment and notes the funding source on the meeting agenda to ensure proper context review

3.4.2 IRB Chair / Designee

- Ensure DoD-specific expertise is available during review
- Confirm compliance with DoD regulatory and ethical requirements
- Announces that the protocol is DoD-supported research

3.4.3 IRB Reviewers

- Apply this SOP and checklist during protocol review
- Evaluate both **regulatory compliance** and **military-specific ethical risks**

3.4.4 Human Research Protection Program (HRPP)

- Coordinate with DoD Component Human Research Protection Office (HRPO)
- Ensure documentation and communication of approvals

3.5 PROCEDURES

3.5.1 Determination of DoD Applicability

- The IRB shall determine whether the research:
  - Is funded by a DoD component
  - Involves DoD personnel or facilities
  - Is subject to DoD regulatory oversight
- **If YES**, then apply this SOP in full.

3.5.2 Pre-Review Administrative Requirements

- Confirm inclusion of:
  - Protocol
  - Consent documents
  - Recruitment materials and other participant-facing documents as necessary
- Verify:
  - DoD Component identified
  - HRPO review requirements understood
  - Assurance approvals, if applicable (e.g., an assurance of compliance with Export Control regulations and applicable Research Security requirements)

3.5.3 Informed Consent Review (Core Requirement)

The IRB shall evaluate consent materials using the following **combined regulatory (as noted below and details outlined in the IRB SOP predicated on the Common Rule) and DoD-specific criteria**:

3.5.3.1 General Consent Requirements

- Consent obtained prospectively
- Circumstances minimize coercion and undue influence
- Language understandable to subjects
- No exculpatory language

3.5.3.2 Key Information (Enhanced DoD Review)

- Clearly states:
  - Research vs. mission/training distinction
  - Participation is not a required duty
- Includes:
  - Purpose
  - Risks (including operational risks)
  - Benefits (not overstated)
  - Alternatives
- Avoids:
  - Command Endorsement

- Therapeutic misconception
- Concomitant commander/supervisor's presence during recruitment

3.5.3.3 Voluntariness in Military Context

The IRB must explicitly assess:

- Safeguards against:
  - Chain-of-command influence
  - Rank-based/supervisory coercion (prohibited) and must not be present at any human participants' recruitment and consenting session.
- Consent states no impact on:
  - Promotion
  - Duty assignments
  - Evaluations
  - Benefits
- Recruitment methods are appropriate:
  - Neutral setting
  - Independent recruiter if needed
- A greater-than-minimal-risk study recruiting DoD personnel in a group setting requires the presence of an Ombudsman without conflict of interest to monitor recruitment, consenting, and monitoring

3.5.3.4 Required Consent Elements (Expanded)

- Study purpose, duration, procedures described
- Experimental procedures identified
- Risks include:
  - Physical and psychological
  - Career/fitness-for-duty implications
  - Confidentiality risks affecting command
  - Operational/deployment risks
- Benefits:
  - Reasonable and not overstated
  - Not framed as mission enhancement without evidence
- Alternatives disclosed
- Confidentiality:
  - Data access clearly defined (including DoD entities)
  - Limits of confidentiality disclosed
- Injury/compensation:
  - Accurate per DoD policy
  - No implied guarantees
- Contacts provided
- Voluntary participation clearly stated

3.5.3.5 Additional Elements (When Applicable)

- Unforeseeable risks
- Investigator termination conditions

- Additional costs
- Withdrawal procedures
- Significant new findings
- Number of subjects
- DoD-specific:
  - Mission interruptions
  - Deployment contingencies

3.5.3.6 Privacy and Confidentiality (DoD-Specific)

- Separation between research and personnel records
- Disclosure of command access (if applicable)
- Compliance with DoD data security standards
- Adequate plans for:
  - Data storage
  - Transmission
  - Access control
- Research involving large-scale genomic data, including secondary use or sharing of deidentified data, describes commensurate
  - Administrative, technical, and physical safeguards
  - Certificate of Confidentiality for DoD-affiliated personnel
  - Obtain DoD component security review and approval

3.5.3.7 Compensation and Undue Influence

- Compensation appropriate relative to rank/pay
- Does not create undue influence
- No compensation for study participation during work hours
- Consent clarifies:
  - Duty status during participation
  - Compensation vs. pay

3.5.3.8 Waiver or Alteration of Consent

- If requested, IRB must verify:
  - Minimal risk
  - No adverse effect on rights/welfare
  - Impracticability
- Additional DoD constraints:
  - Not prohibited due to classified/sensitive research
  - Appropriate for the service member population
  - Debriefing plan adequate

3.5.3.9 Documentation of Consent

- Written consent obtained OR
- Waiver justified with:
  - Operational constraints
  - Acceptable alternative documentation

3.5.3.10 Special Populations

- Service members: protections adequate
- DoD civilians/contractors: no employment coercion
- Legally Authorized Representative (LAR) use:
  - Legally appropriate
  - Re-consent plan included

3.5.3.11 Ongoing Consent and Monitoring

- Plan for re-consent when conditions change
- Communication of new findings
- Additional monitoring if:
  - High-risk
  - Vulnerable population
  - Operational instability

3.5.3.12 Dual-Use and Secondary Use

- Consent discloses:
  - Future use of data/specimens
  - Potential military applications
- Broad consent compliant (if applicable)

3.5.4 IRB Determination and Review Outcome

- The IRB shall document:
  - Compliance with 32 CFR §219.116
  - Adequacy of DoD-specific protections
  - Required modifications
- **Determination Options: As outlined in the overall IRB SOP**
  - Approved or accepted as submitted
  - Revision
    - Revision requested (return to the board)
    - Additional information requested with administrative review
  - Disapprove as submitted
  - Approve with Modifications
  - Tabled
  - Suspension
  - Temporary hold
  - Termination

3.5.5 Post-Review Requirements

- Submit the IRB outcome/determination/approval to DoD HRPO (per DoD requirements)
- Ensure final HRPO approval before study initiation

- Maintain documentation of:
  - IRB review
  - Consent materials
  - Correspondence
- Within 30 days, the Researcher must report to the DoD HRPO:
  - All IRB-approved changes
  - Addition of vulnerable populations or DoD-affiliated personnel
  - Change of study oversight to a different IRB
  - Notice that HU or DoD-supported Human Subject Research is under investigation
  - Notice of serious continuous non-compliance, study suspension, or termination of IRB approval
  - Outcome of annual continuing renewal as necessary or study closure
  - When an enrolled human subject becomes pregnant with or without protocol amendment, IRB review and approval are required
  - When a previously enrolled human subject becomes a prisoner, and applicable protocol was not reviewed and approved by the IRB, consistent with Subpart C, 45 CFR 46.

3.6. SPECIAL CONSIDERATIONS

3.6.1 Operational/Field Research

- Ensure the feasibility of consent in austere environments
- Evaluate risks tied to mission conditions

3.6.2 International Research

- Verify host nation approvals – The researcher is responsible for obtaining the appropriate DoD component approval before the human subject research begins, regardless of whether it involves only DoD-affiliated personnel who are U.S. citizens.
- Ensure cultural appropriateness without compromising voluntariness

3.6.3 Classified Research

Whereas HU does not conduct classified research at the moment, the following should be noted:

- Apply additional DoD restrictions as applicable
- Limit use of consent waivers unless explicitly justified and authorized

3.6.4 Definition of Minimal Risk

Under 32 CFR 219, minimal risk shall not be construed to include everyday risks associated with certain work environments (e.g., service members, law enforcement, or first responders while on duty) or with certain medical conditions.

3.6.4 DoD Directive 3216.02 – Modified Common Rule Applicability of Subpart B (Pregnant Women/Fetuses)

- In DoD-funded research, the applicability of subpart B is limited to the participation of pregnant women in research that is greater than minimal risk and:
  - Includes an intervention or invasive procedure to the woman or fetus
  - Involves fetuses and neonates as participants
- Fetal research must comply with section 289g(b) of Title 42, U.S.C. and Subpart B of 46 CFR 45. Under these codes, research or experimentation may not be performed on a nonviable living human fetus (ex utero) or living human fetus (ex utero) without ascertainment of viability. However, the following are excluded from this tenet when research or experimentation:
  - May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability.
  - Will pose no additional risk of suffering, injury, or death to the fetus, and the purpose of the research or experimentation is to develop important biomedical knowledge that cannot be obtained otherwise.
- The risk standard must remain the same as for fetuses intended to be aborted or carried to term.
- For human participants' research that is unprovable under this code(s), but has the potential to increase understanding, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, the Investigator must obtain the Directorate of Human Subject Protection's (DOHRP) approval through the Commission for Protection of Human Subjects of Biomedical and Behavioral Research (COHRP).

3.6.5 DoD Directive 3216.02 – Modified Common Rule Applicability of Subpart C (Prisoners).

- When a previously enrolled human participant becomes a prisoner, and the protocol has not been reviewed and approved by the IRB in accordance with Subpart C, the investigator must promptly notify the IRB and the DoD HRPO (and other federal agencies where required).
- Research involving detainees or prisoners of war is prohibited, except where:
  - It is conducted under FDA investigational new drug or investigational device regulations when the purpose is for diagnosis or treatment of a medical condition in a patient:
  - The informed consent of the detainees or prisoners of war is obtained; and,
    - Only when the same product may be available to DoD-affiliated personnel, consistent with established medical practices.
- In addition to the research on prisoners permissible under Subpart C, two more permissible categories include:
  - Epidemiological research is permitted when:
    - The main purpose of the research is to describe the prevalence or incidence of a disease by identifying all cases or studying potential risk factor associations for a disease.
    - The research presents no more than minimal risk.

        - The research involves no more than inconvenience to the prisoner-participants.
        - Prisoners are not a particular focus of the research.
    - Nonetheless, the IRB must approve the research documenting that the above conditions are met.
- Human participant research involving prisoners that would otherwise meet exemption criteria may be conducted when approved by an IRB**.**

3.7. NON-COMPLIANCE REPORTING REQUIREMENTS APPLICABLE TO NON-DOD INSTITUTIONS PER DOD INSTRUCTION 3216.02:

For allegations involving a non-DoD institution, such as HU, HU shall conduct an investigation in accordance with the applicable support agreement and furnish the supporting DoD organization via the HRPO. The DoD institution supporting the HSR must ensure that, in its agreements with the non-DoD institution, allegations are promptly and properly investigated. The DoD institution will then promptly report substantiated serious and/or continuing non-compliance findings to the COHRP.

3.8. QUALITY ASSURANCE

- Periodic audits of DoD protocols
- Reviewer training on DoD-specific requirements
- Continuous alignment with updates to DoD regulations

3.9. REFERENCES

- 32 CFR Part 219
- 32 CFR §219.116
- DoD Instruction 3216.02
- 45 CFR 46