ENCLOSURE C07

POLICY OR PRECEDENT

SUBJECT: USASOC Human Research Protection Program (HRPP) DATE: 17 JUL 2024

POLICY NUMBER:	ORIGINATING SECTION:	ORIGINATOR:	PHONE#:
24-14	AOHP (70-25k)	Dr. Hanson	910-432-4261

APPROVED BY: JOHN D. BISHOP, COLONEL, GS, Chief of Staff

SYNOPSIS:

1. Purpose: The USASOC HRPP establishes guidelines to ensure compliance with federal laws and regulations, uphold ethical standards, and protect the rights and welfare of participants, their data, and/or biospecimens involved in Human Subject Research (HSR).

2. Scope: The policy is applicable to all elements of the USASOC Headquarters, component subordinate commands, and component subordinate units.

3. General:

a. USASOC has been designated a HRPP through Army Human Research Protections Office. The USASOC Commanding General has delegated authority to the Deputy Commander – Support (DC-S). USASOC is authorized to conduct up to exempt HSR. USASOC may allow access to its facilities, equipment, information about DoD-affiliated personnel for recruitment, access to DoD affiliated personnel, data, and/or biospecimens.

b. Ensure that HSR receive both institutional and regulatory approval prior to commencement. The process must be clearly documented and followed to avoid any legal liabilities. Regulatory reviews are completed by the HRPP post institutional approval and are required even when units are added to an existing institutionally approved project.

PRESCRIBING DIRECTIVES: 32CFR219; 21CFR50; 21CFR56; 10 USC 980; 45CFR46, Subpart B, C, D, and E; 48CFR 252.235-7004; 48CFR252.235-7004; The Belmont Report: Ethical Principles and Guidelines for the Protection of HSR; Department of Defense (DoD) Directive 6000.4, Clinical Investigation Program; DoD Directive, Research Integrity and Misconduct; DoD Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted And - Supported Research; Army regulation (AR) 25-98, Information Management Control Requirements Program; AR 70-25, Use of Volunteers as Subjects of Research; United States Army HRPP Component Management Plan; Department of the Army (DA) 2023 Assistance Policy; DA Guidance, Command Approval for HSR.

DISTRIBUTION:	OTHER POLICIES AFFECTED:
This publication is available in electronic media and is intended for A5 distribution. Paper copies will be provided for those not having access to e-media.	Supersedes USASOC Policy 24-18, 19 Dec 2018

c. The authority of the USASOC exemption determination official is defined and documented in the regulations. Ensure that no individual self-determines what constitutes HSR to maintain compliance with regulations.

d. Post approval compliance monitoring (PACM) activities are thoroughly conducted and documented to ensure ongoing compliance with all applicable regulations. This includes risk assessments, educational training, random site assessments, for-cause audits, publication review and, monitoring maintenance of study records post-study closure and is a requirement for all HSR.

4. Responsibilities:

a. Institutional official –

(1) The DC-S serves as USASOC's senior person legally responsible to establish, implement, and maintain the HRPP.

(2) Senior USASOC official authorized to approve HSR.

b. Human protections director –

(1) Exercise operational authority for the HRPP (e.g., conduct reviews, record maintenance, and reporting requirements).

(2) Serve as the exemption determination official for USASOC to determine if an activity meets the regulatory definition of HSR.

(3) Conduct and document PACM activities.

(4) Conduct HRPP quality assurance activities to monitor institutional compliance and improve the HRPP, its policies, and procedures.

(5) Authority to suspend and conduct investigations into unauthorized HSR.

c. Human performance and wellness –

(1) Office of primary responsibility for obtaining institutional approval and HSR deliverables of study activities (e.g., results/ data).

(2) Implement support agreements (e.g., memorandum of agreement, memorandum of understanding), when needed.

d. Staff Judge Advocate –

(1) The Staff Judge Advocate must ensure that informed consents and other study related documents (conflict of interest management plans, individual investigator agreements, informed consents, and payments for participation in research) are in full compliance with lawful principles and ethical standards. This is crucial to protect the rights and welfare of participants.

(2) Conduct ethics review for applicability of DoD 5500.7R, when needed.

e. Public affairs office –

(1) Approve recruitment materials (e.g., flyers/emails/advertisements).

(2) Coordination with HRPP is essential to ensure that all HSR publications are consistent with approval and do not disclose sensitive or unauthorized information in IAW AR 360-1.

f. Component subordinate command/subordinate unit –

(1) Designate a point of contact responsible for maintaining command awareness of HSR activities.

(2) Identify a point of contact with direct oversight of each HSR activity.

(3) Comply with command responsibilities as outlined in DoD Instruction 3216.02 and Department of Army policies.

(4) Comply with HRPP PACM activities.

g. Primary investigators –

(1) Conduct HSR activities after receiving institutional and regulatory approvals.

(2) Execute protocol in accordance with approval, laws, and regulations.

(3) Responsible for maintaining study files and teams training.

(4) Comply with HRPP PACM activities.

5. Effective Date: This policy is effective immediately and remains in effect until rescinded.

(END)