**DEPARTMENT OF THE ARMY**
**WALTER REED ARMY INSTITUTE OF RESEARCH**
**503 ROBERT GRANT AVENUE**
**SILVER SPRING, MD 20910-7500**

FCMR-UWZ (1200B) 10 April 2024

MEMORANDUM FOR All Personnel, Walter Reed Army Institute of Research (WRAIR)

SUBJECT: WRAIR Policy #31, Final Approval Authorization for Human Subjects Research Protocol Implementation

1. References.

a. Commerce and Trade, 15 United States Code (U.S.C.) §§ 3701-3724, (2017).

b. National Defense, 32 Code of Federal Regulations (C.F.R.) §§ 219.101-219.124, (2018).

c. Food and Drugs, 21 C.F.R. §§ 50.1-56.124, (2018).

d. Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research), 1979.

e. Department of Defense Instruction (DODI) 3216.02 (Protection of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and -Supported Research), 29 June 2022.

f. U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP) Guidance on Engagement of Institutions in Human Subjects Research, 16 October 2008.

g. Army Regulation (AR) 70-25, (Use of Volunteers as Subjects of Research).

h. AR 70-41, (International Cooperative Research, Development, and Acquisition).

i. AR 70-57, (Military–Civilian Technology Transfer).

j. U.S. Army Medical Research and Development Command (USAMRDC) Policy 12 (Requirements for Initial and Ongoing Education and Training in the Protection of Human Subjects in Research).

k. WRAIR Policy #24 (Submission Requirements for Human Subjects, their Information or Biospecimens).

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*This supersedes WRAIR Policy #30, dated 27 January 2022.

l. WRAIR Policy #25 (Determination that an Activity is Research Involving Human Subjects).

m. WRAIR Policy #26 (Initial and Continuing Human Subjects Research Protection Education Requirements

n. WRAIR Policy #27 (Submission and Review Requirements for WRAIR Human Cadaver Use

o. WRAIR Policy #28 (Compensation to Federal Personnel when They Participate in Research as Human Subjects).

p. WRAIR Policy #29 (Single Principal Investigator Requirement for Research).

2. History. This policy is being issued in accordance with WRAIR and USAMRDC requirements and is effective upon signature by the WRAIR Commander. This version of the policy includes minor editorial and administrative changes. This version of the policy is effective immediately and shall remain in effect until rescinded or superseded in writing, or when it exceeds its expiration on 10 April 2026.

3. Purpose. This policy establishes the minimum requirements prior to issuance of the WRAIR Commander's approval authorization of a human subjects research protocol or an amendment to a human subjects research protocol. The WRAIR Commander has delegated authority to the Human Subjects Protection Branch (HSPB), to verify, via specific documentation, that these requirements have been met.

4. Definitions.

a. Engaged in Human Subjects Research: An institution is engaged in research involving human subjects if its employee(s) (i) obtains information or bio-specimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or bio-specimens for research purposes; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio-specimens for research purposes.

b. Institutional Official (IO): Individual ultimately responsible for the implementation of the U.S. Department of Health and Human Services (DHHS) Federal wide Assurance and the DOD Assurance of Compliance for the Protection of Human Research Subjects and the associated HRPP at an institution engaged in research involving human subjects. Within the USAMRDC, the Commander of the institution/organization engaged in research is the IO.

c. Principal Investigator (PI): The individual who is responsible and accountable for conducting a research study. This individual will have the appropriate scientific and ethics training and experience to assume full responsibility and accountability for the scientific integrity of the research data and results. The PI is the individual responsible and

accountable for designing, conducting, and monitoring the research study, and has access to the data. For studies involving human research subjects, the PI, as the leader of the research study team, assumes full responsibility for the medical care and evaluation of subjects, either directly or indirectly (designee of a healthcare provider). The PI also is responsible for protecting the rights and welfare of human subjects and is responsible for carrying out sound ethical research consistent with research plans in a protocol approved by a properly-constituted IRB. The PI may formally delegate roles and responsibilities to other members of the research study team, as appropriate, but retains full responsibility for the conduct of all study activities.

(1) US Food and Drug Administration (FDA) definition: Investigator means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(2) ICH E6 Definition: Investigator means a person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

(3) Note: The above definition is not necessarily the same as that of a PI listed on a grant or research award, which may include other responsibilities not involving human subjects research.

d. Research Involving Human Subjects: Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research (i) obtains information or bio-specimens through intervention or interaction with the individual and uses, studies, or analyzes the information or bio-specimens, or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio-specimens.

e. WRAIR Point of Contact (POC): An individual, affiliated with WRAIR or its Directorates, who is responsible for submission of protocol documents to the HSPB over the lifecycle of the study as new protocol actions are processed, remains in continual communication regarding the study to regulatory authorities, and directs study execution wherein WRAIR is participating. This individual is generally the lead WRAIR Investigator on the protocol, but is not the overall study PI. The POC can be the site PI, a clinical coordinator, program manager, associate investigator, or other individual involved in the study in a scientific or administrative capacity.

5. Background.

a. This policy is in place to comply with Federal, DOD, Army, and USAMRDC regulatory requirements. The DODI 3216.02, Protection of Human Subjects, requires that awareness

of human subjects protection requirements be established for all DOD personnel involved in the conduct, review, approval or oversight of research involving human subjects. A DOD-unique human subjects protection requirement is the Commander approval authorization to implement a human subjects research study. The Commander is provided with documentation of the WRAIR Institutional Review Board (IRB) approval of the protocol or protocol amendment and makes a final determination to grant authority to implement the human subjects research study or to not concur with the IRB's approval. In circumstances where the WRAIR defers IRB review to another organization, the WRAIR Commander does NOT defer his/her responsibility and authority for approval. A signed Commander approval authorization memorandum is still required to implement human subjects research conducted by, or in collaboration with WRAIR.

b. The WRAIR Commander will not issue an approval authorization until ethical review(s) have been conducted at collaborating institutions, approval/determinations are in hand, and funding has been identified. In addition, while WRAIR IRB approval and WRAIR Commander approval authorization records may be in place, initiation cannot occur until all of the requirements found in Appendix A (Commander Authorization Checklist) have been addressed and met (when applicable and appropriate).

*Note: Appendix A is not an all-inclusive list and it is the responsibility of the PI or WRAIR POC to ensure these and all other requirements are in place prior to initiating work.*

6. Applicability and Scope. This policy applies to all personnel employed by or affiliated with the WRAIR who conduct, review, approve, support, manage, or oversee research under the WRAIR HRPP. This policy also applies to contractors or partners who conduct human subjects research under the WRAIR HRPP and to studies in which WRAIR investigators are supporting in a peripheral capacity (i.e., performing laboratory assays, data mining, serving as consultant, etc.).

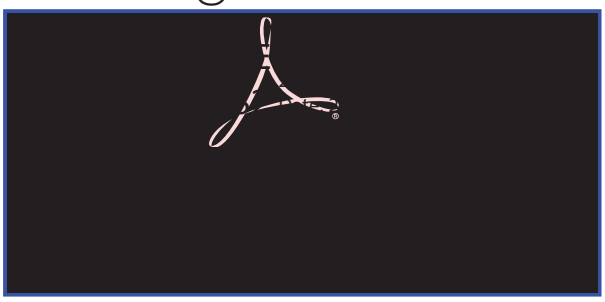
7. Policy. No WRAIR investigators shall commence with any human subjects research activity on a research protocol, until an approval authorization memorandum is signed by the WRAIR Commander or his/her alternate approving authorities. This includes contacting, advertising to, recruiting, screening and/or enrolling subjects. This policy applies to categories of research to include minimal risk and greater than minimal risk studies, as per WRAIR Policy #25.

a. Studies determined to be "exempt", "not research" and "research not involving human subjects" by the HSPB or the WRAIR IRB Chair may also require certain elements to be in place prior to initiation. Investigators are encouraged to seek guidance from the HSPB for these categories of research and the Technology Transfer Office (TTO), as needed.

b. This policy also applies to amendments to a human subjects research protocol. Please note: a protocol change intended to eliminate an apparent immediate hazard to subjects may be implemented immediately provided the WRAIR IRB is subsequently notified in accordance with applicable regulations, policies and procedures.

8. Execution. PIs (and/or WRAIR POCs) and Center/Branch/Directorate Directors are responsible for ensuring required items are in place prior to implementation of a human subjects research protocol or an amendment to a human subjects research protocol. Failure to do so will result in involvement of the Deputy Commander or Chief Science Officer to rectify the deficiencies through the Center/Branch/Directorate Directors. The Deputy Commander or Chief Science Officer could intervene via multiple avenues including, but not limited to, poor performance review and/or disciplinary action.

9. Point of contact for this memorandum is Ms. Jody Ference, Director, Human Subjects Protection Branch (FCMR-UWS-HP), at Jody.L.Ference.civ@health.mil. or 301-319-9940.



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1. Appendix A: Commander Authorization Checklist

## Appendix A: Commander Authorization Checklist

***Based off the Commander Authorization Checklist found in Policy 31***

☐ Cover memo signed through the submitting PI's department/division leadership

☐ Commander Letter of Support for military units that will be recruited (if different than PI's institution)

☐ Supervisor/Commander's Approval Form for participation in research (for Active-Duty Personnel)

☐ Translation verifications/certificates

☐ Sponsor's Implementation Authorization

☐ Host Country Ethics Committee Approval (for international research)

☐ Host Country Other Regulatory Approvals (for international research)

☐ Registration with clinicaltrials.gov

☐ HRPO Approval by USAMRDC OHARO or delegate

☐ Component-level Administrative Review (CLAR) approval by USAMRDC OHARO

☐ Headquarters-level Administrative Review (HLAR) approval by the HQ USAMRDC OHARO

☐ Scientific Review

**For FDA Regulated Studies (drugs, biologics, devices, apps, combination products, dietary supplements that require FDA review), as applicable:**

☐ Documentation of all investigators' most recent GCP training

☐ Data and Safety Monitoring Board (DSMB) or Safety Monitoring Committee (SMC) or Independent Data Monitoring Committee (IDMC) membership and charter

☐ Monitoring plan (draft or final version)

**For Collaborative research**

☐ Collaborating Institution's internal protocol number (if applicable)

☐ Federal Wide Assurance Number and expiration of collaborating institutions that are engaged in human subjects research.

☐ Documentation that all study team members, including contractors working at the collaborating Institution, are covered by the Institution's Assurance

☐ IRB review Plan (reliance agreements) for each institution engaged in human subjects research

☐ Other Institutional Approvals (Institutional Biosafety Committee, Radiation Safety Committee, Recombinant DNA Advisory Committee (RAC) etc.)

**Other additional approvals/reviews that may be required:**

☐ Radiation/Safety Committee

☐ Institutional Biosafety Committee

☐ Biomedical Engineering Committee

☐ NIH Recombinant DNA Advisory Committee (RAC)