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 #24, Submission Requirements for Human Subjects, their Information or Biospecimens

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. §§ 50.1-50.56 and §§ 56.101-56.124 (2018).

d. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Biomedical and Behavioral Research),1979.

e. Department of Defense (DOD) 3216.02 (Protection of Human Subjects and Adherence to Ethical Standards in DOD-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 November 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 #25 (Determination that an Activity is Research Involving Human Subjects).

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

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*This supersedes WRAIR Policy #24, dated 27 January 2022.

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

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

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

p. WRAIR Policy #31 (Final Approval Authorization for Human Subjects Research Protocol Implementation).

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 incorporates a new submission checklist to be used by all USAMRDC laboratories to standardize protocol submissions. 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 criteria for submission of protocols involving human subjects, human specimens, and/or human data to the Human Subjects Protection Branch (HSPB). The Commander, WRAIR, has delegated authority to the HSPB to verify, via specific documentation, that these criteria have been met prior to protocol submission for scientific review, evaluation by HSPB, and/or ethical review, as appropriate.

4. Definitions.

a. Cadaver: A deceased person or portion thereof, and is synonymous with the terms "human cadaver" and "post-mortem human subject" (PMHS). The term includes organs, tissue, eyes, bones, arteries or other specimens obtained from an individual after death. The term "cadaver" does not include portions of an individual person, such as organs, tissue or blood, that were removed while the individual was alive (for example, if a living person donated tissue for use in future research protocols, that tissue is not considered a "cadaver" under this policy, regardless of whether the donor is living or deceased at the time of tissue use).

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

c. Human Research Protection Program (HRPP): An integrated institution-wide program coordinated by the Human Subjects Protection Branch (HSPB) with the main purpose of ensuring all of WRAIR's activities related to human subjects research are conducted in accordance with regulatory requirements and ethical principles as set forth in the Belmont Report. Major components of the HRPP include the Institutional Review Board (IRB), research review groups (the Research Programs Office (RPO), Scientific Review Committee (SRC), Institutional Biosafety Committee (IBC), WRAIR Safety Office, and USAMRDC Human Research Protections Office (HRPO)), assurances, regulations, policies, standard operating procedures (SOPs), investigators, sponsors, overseas Directors, USAMRDC headquarters, etc.

d. 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.

e. 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) FDA definition: Investigator means an individual who actually conducts a clinical investigation, such as, 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. See also Sub investigator.
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.

f. 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 biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

g. Research Support Personnel: (for example, consultants, laboratory investigators). Personnel who are engaged in conduct of the research, but who are participating in a limited or defined part of the protocol under the direct supervision or guidance of an investigator.

h. Site-Specific PI: For research studies conducted at multiple study sites, the individual who is responsible and accountable for conducting the research study at a specific study site.

i. Sub Investigator or Associate Investigator, Co-Investigator: An individual member of the research team delegated and supervised by the PI at a study site to perform critical study-related procedures and/or to make important study-related decisions.

j. 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. To ensure a timely review by the WRAIR Scientific Review Committee (SRC), the HSPB, and the WRAIR IRB, protocols should be submitted in final form (ready to start in the viewpoint of the research team, Branch Director, and Sponsor). This means the protocol is clearly written and concise, and the submission contains all required documentation for the review(s) to occur.

Note: Protocols should be submitted electronically to usarmy.detrick.medcom-wrair.mbx.hspb@health.mil. This includes protocols that may be determined to be human subjects research, research not involving human subjects, or not research (QA, public health, etc.).

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 also applies to contractors or partners who conduct

human subjects research under the WRAIR HRPP. WRAIR-associated research studies may include:

a. Research conducted at WRAIR, regardless of where the PI is located

b. Research conducted at or by WRAIR's Directorates

c. Research conducted using WRAIR funding, resources or support; and

d. Research conducted at or by other institutions where WRAIR personnel are investigators (PI, sub-investigators, co-investigators, or associate investigators), consultants or collaborators

Note: This policy also applies to studies in which WRAIR investigators are supporting in a peripheral capacity (such as, performing laboratory assays, data mining, serving as subject matter experts to collaborators etc.).

7. Policy. WRAIR Investigators or WRAIR POCs shall officially submit protocols involving human subjects, human data, and/or human biological materials (human biospecimens) to include all applicable documents per Appendix B. All WRAIR-associated projects utilizing or potentially utilizing human subjects are required to be submitted through the HSPB to begin the review process.

a. This policy applies to categories of research to include: studies which may be determined to be "research not involving human subjects, "not research", exempt, minimal risk, and greater than minimal risk studies. The category of research will be determined per WRAIR Policy #25 not by the submitting party.

b. This policy also applies to protocol/study amendments or modifications.

c. Studies which may be determined by the HSPB or the IRB Chair, to be "research not involving human subjects" or "not research" may also require the elements in Appendix B. Investigators are encouraged to seek guidance from the HSPB prior to submission for this category of project. Additionally, consultations by the HSPB of unofficial submissions will only be permitted as time and resources allow.

Note: There is a separate policy addressing the requirements to gain the WRAIR Commander's authorization to implement a protocol (see WRAIR Policy #31, Final Approval Authorization for Human Subjects Research Protocol Implementation.)

8. Execution.

a. Responsibility.

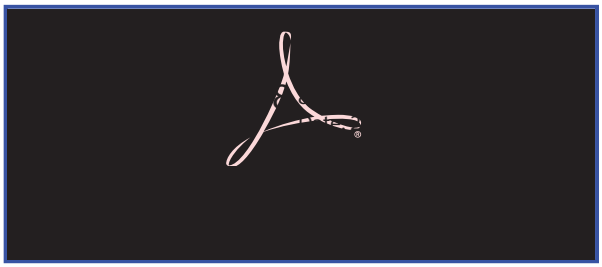
(1) PIs (and/or WRAIR POCs) and Center/Branch/Directorate Directors are responsible for ensuring the required items, per Appendix B, are in place prior to submitting a protocol for scientific review, protocol evaluation by HSPB, and/or ethical review. Failure to do so will delay processing of the submission. Repeated failure to do so could have a negative impact on performance review and/or may lead to further disciplinary action.

(2) HSPB is responsible for reviewing submissions and informing PIs (and/or WRAIR POCs) if submissions are considered incomplete/complete.

(3) The IO (or designees) and Deputy Commander, WRAIR, are responsible for enforcing this policy as well as intervening with PIs/Center/Branch/Directorate Directors, as appropriate, if incomplete submissions are received. Please Note: Only under limited and justified conditions should draft versions of submission requirements be included for review.

b. Documentation (See Appendix B). All required protocol documents must be submitted to the WRAIR HSPB before processing can occur. Scientific review, if needed, cannot occur prior to obtaining these documents (unless waived by the Chief Science Officer or Deputy Commander, WRAIR, with strong justification).

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.



3 Encls
1. Appendix A: Cover Memo
2. Appendix B: Submission Checklist

Appendix A: Cover Memo

THE Highlighted Areas on this memo are to be tailored to your submission** REMOVE THIS SENTENCE.

FCMR-UWZ-X Date

MEMORANDUM THRU

Chief X
Center/Branch/Directorate Director

FOR Commander, Walter Reed Army Institute of Research (ATTN: Human Subjects Protection Branch), 503 Robert Grant Avenue, Silver Spring, MD 20910

SUBJECT: Request for Submission of a Protocol/Amendment to a Protocol Involving Human Subjects, Samples, and/or Data for Scientific and Ethical Review

1. Request submission for review of new/amended human subjects research protocol entitled "X" (version, date), PI, institution affiliation.

2. The submission checklist has been verified by the Principal Investigator (PI) and Center/Branch/Directorate Director. Please process for scientific and ethical review, as appropriate.

3. The primary objectives of this protocol are to/the key changes to the protocol are…(fill in as appropriate)

4. These activities will be/are funded through: fill in as appropriate

5. The following documents are attached:

   a. Completed Submission Checklist
   b. Protocol (Version X, dated X)
   c. Informed Consent Document (Version X, dated X)
   d. Subject/Data Collection Forms (Version x, dated X)
   e. CVs for: (list individuals, and their affiliations)
   f. HSP Training certificates for: (list individuals, and their affiliations)
   g. etcetera

6. As the PI/WRAIR POC, I will carry out the study as outlined in the attached proposal.

7. The point of contact for this action is undersigned at telephone number XXXX, Email XXXX.

SIGNATORY
RANK
ROLE

Center/Branch/Directorate Director Approval

This study is:

- Scientifically feasible and valid,
- Militarily relevant, and
- Appropriately resourced (funding, personnel, equipment, etc.)

SIGNATORY
RANK
Center/Branch/Directorate Director

Appendix B: New Protocol IRB Submission Checklist

Directions: The Principal Investigator (PI) or a designated study team member completes Part 1 through 3, as applicable. The Institution's Human Protections Office [Human Protections Director (HPD) or designated Human Subjects Protection Scientist (HSPS)], completes Part 4.

For questions about the completion of this form related to submissions to the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) contact the WRAIR Human Subjects Protection Branch (HSPB) at : usarmy.detrick.medcom-wrair.mbx.hspb@health.mil.

For questions about the completion of this form related to submissions to the Headquarters, US Army Medical Research and Development Command's Institutional Review Board (HQ USAMRDC IRB) contact your institution's Human Research Protections office or the HQ USAMRDC Office of Animal and Human Research Oversight (OHARO) Institutional Review Board Office (IRBO) at usarmy.detrick.medcom-usamrmc.other.irb-office@health.mil.

Note: The IRB may require additional documents/information be submitted, on a case-by-case basis.

Part 1: General Information (*Completed by PI or designated Study Team Member*)

Review and complete for documents requiring submission to the IRB, as applicable. Ensure all pertinent applicable information and required documents are included in the submission. Incomplete information or an incomplete submission packet will delay the IRB's consideration of the study.

1. Protocol Title: _____

2. Principal Investigator Name and Contact Information:

Note: Only a single PI should be named (refer to WRAIR Policy #29, Single Principal Investigator Requirement for Research, for details).

Name: _____
Telephone number: Commercial _____ DSN _____
Email address: _____

3. Other Point of Contact for study-related questions (e.g., study coordinator):

Name: _____
Study Role: _____
Telephone number: Commercial _____ DSN _____
Email address: _____

4. Funding Source(s): (Check all that apply)

☐ Internal (core) funding
☐ MRDC (e.g., Congressionally Directed Medical Research Programs (CDMRP), Telemedicine & Advanced Technology Research Center's (TATRC), Joint Warfighter, etc.) _____
☐ DOD agency (e.g., Defense Health Program (DHP), Defense Advanced Research Projects Agency

(DARPA), Navy, Air Force) _____
☐ Other Federal agency (e.g., National Institutes of Health (NIH), National Science Foundation (NSF), National Institute for Occupational Safety and Health (NIOSH), etc.) _____
☐ Other: _____

Grantee: _____

Grant/contract number: _____

Grant/Contract or Project Title: _____

5. The research study involves: (*Please check all that apply. Mark all applicable documents and requests in Appendix B being submitted for IRB approval and consideration.*)

☐ Service Members as the target study population
☐ Foreign military members as the target study population
☐ Other DoD-affiliated personnel as the target study population
☐ Veterans
☐ Employees of the research institution
☐ Minors
☐ Emancipated minors
☐ Pregnant Women, Human Fetuses and/or Neonates
☐ Prisoners
☐ Individuals with Impaired Decision-Making Ability
☐ Individuals who are illiterate
☐ Drugs, dietary supplements, and/or biologics
☐ Medical devices and/or Mobile Medical Applications
☐ Combination products

6. FDA Regulatory Status (for drugs, biologics, medical apps, devices, or dietary supplements that require FDA review):

☐ Investigational product(s) not approved/cleared by the FDA
☐ FDA-approved/cleared and used in a manner **not** in accordance with its approved labeling
☐ FDA-approved/cleared and used in accordance with the approved labeling
☐ Other (e.g., use of non-FDA regulated devices. Include description in Appendix B below; if applicable, include/provide significant/non-significant risk determination from Sponsor/Manufacturer).

7. Other regulatory considerations/requirements:

☐ European Medicines Agency (EMA)
☐ Other international authority (e.g., WHO)
☐ Local/host nation regulatory authority(ies) (Country:)
☐ Other Regulatory Agency(ies) oversight (please list all):

8. The research study involves collaboration with researchers from other institutions? ☐ No ☐ Yes

If Yes, complete table, adding rows as needed.

Collaborating Institution (CI)	CI Personnel Name	Role of Personnel at Collaborating Institution (e.g. receipt and analysis of coded data)**	Engaged in Human Subjects Research***
			☐ No ☐ Yes

			☐ No ☐ Yes
			☐ No ☐ Yes

** - Role of Personnel at Collaborating Institution must be clearly indicated in the protocol

***- CI Personnel interact with subjects or their identifiable data or biospecimens

9. The research study is a multi-site study: ☐ No ☐ Yes

If Yes, this submission represents: (check all that apply)

☐ the Lead/Core Site
☐ a Research Site
☐ a Collaborating Site
☐ the Coordinating Center
☐ Other: _____

10. The research study involves research at an international research site:

☐ No ☐ Yes

If Yes, please complete Appendix B, International Research Study Supplemental Information Form.

11. Please provide below a brief explanation and relevant dates of a/any condition(s) that impact the IRB review timeline and proposed study start dates (e.g., funding timeline, subject population deployment/availability, resource availability, documents needed for IRB review that are still pending, etc.).

_____

_____
Signature of PI or Study Team Member Completing the Checklist

_____ _____
Name of PI or Study Team Member Completing the Checklist **Date**

Part 2: Submission Checklist (*Completed by PI or designated Study Team Member*)

Directions: Check applicable boxes to reflect all documents and requests submitted **for IRB review**.

Note: Please ensure version control of submitted documents. Each page of the protocol, consent forms, study instruments, data collection forms, recruitment materials, etc., must be identified by a version number and/or date. Version control must be tracked on all documents throughout the course of the research project. The submitted documents should be clean copies, free of typographical errors.

☐ Research protocol

☐ A military relevance section has been included in the protocol that states how the study aligns with WRAIR's mission and is militarily relevant.

☐ Sponsor's protocol/Core protocol (e.g., if multi-site study)

☐ Site-specific Addendum (e.g., if multi-site study)

☐ Study-specific procedures (SSPs) for procedures that may pose increased risks to subjects (e.g., procedures that deviate from standard data collection or well-known clinical procedures and may involve increased risks to subjects above and beyond these standard procedures)

☐ Scientific Review

- ☐ Scientific Review completed (provide review(s), Principal Investigator's response, and approval)
- ☐ Scientific Review in-progress
- ☐ Scientific Review is requested

☐ **All Study** Consent form(s)

- ☐ Indicate here if the protocol includes a request for waiver or alteration of informed consent
- ☐ Indicate here if the protocol includes a request for waiver of documentation of informed consent
- ☐ Indicate here if the protocol includes a request for HIV testing consent

☐ Audio/Photo/Video Release Form (if applicable)

☐ HIPAA Authorization

- ☐ Request for Partial HIPAA Waiver
- ☐ Request for Full HIPAA Waiver
- ☐ Not applicable (e.g., not a covered entity)

☐ Signed and dated Investigator Agreement

☐ Curricula vitae/résumé for Principal Investigator - dated, signed and current (within 2 years of initial submission

☐ Curricula vitae/résumés for all study investigators/research personnel listed on the protocol - dated, signed and current (within 2 years of initial submission

☐ Curricula vitae/résumés for study Ombudsperson listed on the protocol - dated, signed and current (within 2 years of initial submission

☐ Curricula vitae/résumés for all study DoD Medical/Research Monitor listed on the protocol - dated, signed and current (within 2 years of initial submission

☐ PI Qualifications Summary (for first-time PIs conducting clinical trials)

☐ Documentation of human subjects protection training for study investigators listed on the protocol having direct interaction with subjects or their identifiable information

☐ Completed conflict of interest and Financial Disclosure forms for all study investigators listed on the protocol (required for studies involving commercial sponsors and/or studies with drugs, biologics, devices, or development of in vitro diagnostics). For FDA-regulated studies, all investigators listed on the FDA Form 1572. Any other investigators or key personnel who have a COI should document this in the submission. (For example, significant share in the Pharma company, a pending patent, or royalties being earned from a component of the product.)

All recruiting material, including but not limited to:

☐ Flyers/posters

☐ Phone Scripts

☐ Briefing Materials

☐ Recruitment Letters/Emails

☐ Announcements

☐ Advertisements

☐ Pre-Screening Questionnaires

☐ Tests of Understanding and Answer Key (Include in the protocol a statement of how low test scores will be handled and how many times the test can be re-taken)

All research instruments/tools utilized for collecting data directly from subjects, including but not limited to:

☐ Screening Form(s)

☐ Questionnaires/Surveys

☐ Interview Guides

☐ Study Instruments/Subject Questionnaires

☐ Case Report Forms

Note: the above are required to be provided for IRB review if these are investigator-generated (not validated/standardized) instruments; the IRB may also ask that validated/standardized instruments be provided for information only

RESEARCH INVOLVING MINORS ☐ NA

☐ Parental permission form ☐ Assent form

RESEARCH INVOLVING INDIVIDUALS WITH IMPAIRED DECISION-MAKING ABILITY ☐ NA

☐ LAR Consent form ☐ Assent form ☐ Process for participant consent upon regaining capacity

RESEARCH INVOLVING NON-ENGLISH-SPEAKING PARTICIPANTS ☐ NA

☐ Translated Consent Form ☐ Short Form ☐ Translation Verification Certificates

RESEARCH INVOLVING ACTIVE DUTY MILITARY ☐ NA

☐ Supervisor/Commander Approval form for Active Duty Military Personnel (Please refer to WRAIR Policy #28)

RESEARCH INVOLVING DRUGS, VACCINES, BIOLOGICS, AND/OR DIETARY SUPPLEMENTS ☐ NA

☐ Product/package insert
☐ Certificate(s) of Analysis
☐ Documentation that no IND is required
☐ Documentation specifying IND number, OR date of submission to the FDA: _____
☐ Current Investigator's Brochure
☐ US FDA Form 1572
☐ FDA correspondence

RESEARCH INVOLVING DEVICES ☐ NA

☐ Documentation specifying IDE Number, OR documentation that no IDE is required
☐ Manufacturer's Device Manual/supplemental device information
☐ Document from manufacturer/sponsor with declaration of level of risk for device (NSR or SR)
☐ FDA Correspondence

Part 3: International Research Study Supplemental Information Checklist
(*Completed by PI or designated Study Team Member*)

Directions: The following information is required by the WRAIR and HQ USAMRDC IRB in addition to the Protocol Submission Checklist, in order to obtain information about the host nation's research site and the local context within which it will be conducted.
Note: The information requested does NOT need to be entered on this form. Please ensure the information listed below is addressed ***in the protocol or site-specific addendum (SSA),*** as applicable.

☐ NA (no international research site)

Element	Yes	No	N/A	Comments
1. Country and city in which study is to be conducted	☐	☐	☐	
2. The name and contact information (address, phone number and email) for the investigator who will conduct the research in the host country	☐	☐	☐	
3. The name of study site's ethical review committee (ERC), the name and contact information of the ERC POC	☐	☐	☐	
4. The regulations/guidance governing human subjects research that will be followed when implementing the study in this host country or countries (e.g., CIOMS, ICH, etc.)	☐	☐	☐	
5. Does the protocol require review by other Host Nation institutions, offices, departments, Scientific Committees (*e.g. Ministry of Public Health*) or by a Host Country Drug and/or Device oversight agency?	☐	☐	☐	
6. Explain the rationale for conducting research in this host country • If relevant consider explaining how it relates to current healthcare needs.	☐	☐	☐	
7. Study Site Information: • Detailed description of the study site and any factors or procedures relating to risks or burdens to volunteers or feasibility of conducting the study.	☐	☐	☐	

Element	Yes	No	N/A	Comments
8. Risks and Benefits to the Study Population: • Include a description of any unique factors that affect risks and benefits to the study population in this setting of the research. • For certain studies involving individuals who cannot consent, such as children or adults lacking decisional capacity, address in the protocol and the consent document how the study will provide direct benefit to each subject. o Direct benefit may include enhanced clinical care or health monitoring and/or benefits of research interventions.	☐	☐	☐	
9. Local Community: • Include a description of any characteristics of the setting, the population, or the current social, economic, or political situation that could affect risk/benefits of the research, scientific integrity, or feasibility of conducting the study. • Include any mechanisms to mitigate or manage potential challenges. Considerations include local customs, religious practices, civil society and economic factors.	☐	☐	☐	
10. Medical Care: • If relevant, include a description of locally available medical care, the relationship of the study procedures to local care, and plans for addressing health care needs of research volunteers. • Discuss any plans for post-trial access, if known • If applicable, discuss medical care that will be available to volunteers in the event of a research-related injury and how that will be provided	☐	☐	☐	
11. Recruitment/Consent Processes: • If relevant, include a description of any requirements specific to the local setting regarding recruitment and informed consent procedures, for example: o The legal age at which individuals can provide their own consent to participate in research and/or status for emancipated minors o Plan to consent illiterate individuals, if applicable o Language and/or dialects used to obtain informed consent o Plan to use oral communication if no written language/dialect o Any local cultural practices that affect the informed consent process	☐	☐	☐	

12. Specimen/Data Management: • If relevant, describe any host country approvals or permissions needed for storage of specimens or shipping outside the country.	☐	☐	☐	
13. Informed Consent Form Considerations: • The informed consent form contains a local emergency contact phone numbers for volunteers • If required by the host country, the informed consent form explicitly states that samples will be taken out of the host country	☐	☐	☐	

Part 4: Commander Authorization Checklist
(*Completed by the Institution's Human Protections Office [Human Protections Director (HPD) or designated Human Subjects Protection Scientist (HSPS)]*)

Directions: These documents are not required for IRB review; however, applicable documents must be received to obtain Commander Authorization to start the research study. Check applicable boxes to reflect applicable additional documents required for Commander Authorization.

☐ 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 (Active-Duty Personnel)

☐ Translation verifications/certificates

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

☐ Sponsor's Implementation Authorization

☐ Host Country Ethics Committee Approval (for international research)

☐ Host Country Other Regulatory Approvals (for international research)

☐ Registration with clinicaltrials.gov

☐ OHRO Approval

☐ Other applicable Institutional Forms/approvals

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

☐ 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)

1. Institution's internal protocol number (if applicable)**:** _____
2. All study team members, including contractors working at your Institution, are covered by the Institution's Assurance.

   ☐ Yes
   ☐ No - EXPLAIN: _____

3. The research study involves collaboration with researchers from other institutions. ☐ No ☐ Yes

Based on Question #8 from Appendix B, Part 1, complete the table below (add rows as needed):

Collaborating Institution (CI)	CI POC and Contact Information for IRB Reliance discussions	Role of Personnel at CI*	IRB Review Plan** (*make one selection*)
☐ Mark FWA is current (if engaged in human subjects research)		☐ Mark if CI is **not** engaged in human subjects research	☐ Request WRAIR/HQ MRDC to be the IRB of Record ☐ CI's IRB will review the research. Single IRB Review Exception is requested. Review is expected on or about
☐ Mark FWA is current (if engaged in human subjects research)		☐ Mark if CI is **not** engaged in human subjects research	☐ Request WRAIR/HQ MRDC to be the IRB of Record ☐ CI's IRB will review the research. Single IRB Review Exception is requested. Review is expected on or about
☐ Mark FWA is current (if engaged in human subjects research)		☐ Mark if CI is **not** engaged in human subjects research	☐ Request WRAIR/HQ MRDC to be the IRB of Record ☐ CI's IRB will review the research. Single IRB Review Exception is requested. Review is expected on or about

* - Please refer to the OHRP guidance on Engagement of Institutions in Human Subjects Research
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

** - Please contact the Director or Deputy Director of the WRAIR HSPB/HQ USAMRDC IRB Office (IRBO) to discuss presence of reliance agreement(s)

The research involves:

☐ International Research Study Site
☐ International collaborator engaged in human subjects research
☐ International collaborator not engaged in human
☐ Other: ______
☐ N/A

4. Does the protocol require a Human Research Protection Official (HRPO) review (i.e., for the involvement of a non-DoD collaborator)?

☐No ☐Yes If Yes, explain why:

5. Does the protocol require a Component-level Administrative Review (CLAR) review IAW DoDI 3216.02 3.5(b)?

☐No ☐Yes If Yes, explain why:

6. Does the protocol require Headquarters-level Administrative Review (HLAR) by the HQ USAMRDC OHARO (i.e., first in human IND/IDE studies, other research determined to need HLAR)?

☐No ☐Yes If yes, explain why:

7. Scientific Review:

Performed by: _____

Date of final approval (or concurrence): _____

Date submitted to the Scientific Review Committee: _____

The Principal Investigator adequately addressed all deficiencies identified by the scientific review process:

☐ Yes ☐ No - EXPLAIN: _____

8. Additional approvals/reviews required by the institution: (C*heck all that apply; please state if any are pending*)

☐ Cover memo signed thru PI's department/division leadership – memo date: _____
☐ Radiation/Safety Committee - date completed: _____
☐ Institutional Biosafety Committee - date completed: _____
☐ Biomedical Engineering Committee - date completed: _____
☐ NIH Recombinant DNA Advisory Committee (RAC) - date completed: _____
☐ Other: _____

Comments: _____

I have verified the information above reflects the documents and requests submitted for IRB approval and consideration.

_____
Human Protections Office Representative's Name

_____ _____
Signature **Date**