FCMR-UWZ (1200B)
SUBJECT: WRAIR Policy #24, Submission Requirements for Human Subjects, their Information or Biospecimens

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**