Appendix A

Investigator and Branch/Directorate Director Protocol/Amendment Submission Checklist

All required documents must be submitted before processing can occur. Scientific review, if needed, cannot occur prior to obtaining these documents (unless occurring at another institution or explicitly waived by the Chief Science Officer or Deputy Commander, WRAIR). For international research studies, please also complete and submit Appendix C, International Research Study Supplemental Information Form.

Check off each item as enclosed as part of the submission packet or indicate not applicable, as appropriate.

Forward the completed check list along with submission items to the Human Subjects Protection Branch (HSPB) electronic mailbox: usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil

Note: Please refer to WRAIR Commander's IRB Policy Memorandum #04, Use of Human Cadavers for Research, Development, Test and Evaluation (RDT&E), Education, or Training, for additional requirements to conduct or support activities involving the use of human cadavers.

General Submission Requirements:

___Cover memo signed through Department Chief, Branch and/or Directorate Director (Appendix B).
Note: If you are the Center/Branch/Directorate Director and the submitting study PI, the cover memo will require signature through the WRAIR Chief Science Officer.

___Version Control of Submitted Documents - each page of the protocol, consent forms, case report forms, subject diary, recruitment materials, tests of understanding, etc., must be identified by a protocol ID, version number and date. The submitted documents should be clean copies, free of typographical errors. Version control must be tracked on all documents throughout the course of the research project.
___Protocol - current version. In addition to version control requirements listed above, each page must be numbered in sequence from the cover page to the end (by hand if necessary). If a Table of Contents exists, be sure to match the pages appropriately.

___Sponsor/Executive Authority and preliminary funding information (i.e., core funding, extramural grant from USAMRDC, Cooperative Research and Development Agreement

(CRADA), contract numbers) in the body of the proposal (this is important as it determines the review pathway in some instances.)
Note: for NIH or HHS grants, a copy of the grant must be included in the submission packet.

___List of all investigators involved in the study and a detailed description of their roles and responsibilities.
Note: only a single PI should be named (refer to WRAIR Commander's IRB Policy Memorandum #06, Assignment of Principal Investigators to Human Subjects Research Conducted under the WRAIR HRPP for details).

___DoD Medical/Research Monitor is listed in the protocol (for Greater Than Minimal Risk studies).

___List of participating laboratories and their roles and responsibilities are included in the protocol.

___List of all Institutional Review Boards (and their DHHS IRB numbers) reviewing the study is included in the protocol.

___A military relevance section has been included in the protocol that states how the study is militarily relevant.

___Informed Consent Document – most current version. Each page must be numbered in sequence. Address in the body of the consent form or submit as a separate consent document (as applicable) for: HIV testing, Biological Specimen/Data Donation Consent (allows future use), and photographs, video, or audiotapes consent.

___Curriculum Vitae(s) for Principal Investigator(s), Associate Investigator(s), Research Support Personnel (consultants, laboratory investigators, etc.), Ombudsman, and DoD Medical/Research Monitor, as applicable. CVs must be dated, signed and current (within 2 years of initial submission).

___Conflicts of Interest (COIs)/Financial Disclosure Forms. Statement of COI (financial or otherwise) for all investigators listed in the protocol (required for studies involving commercial sponsors and/or studies with drugs, biologics, devices, or development of in vitro diagnostics).

___Human Subjects Protection Training Certificates for all Investigators, DoD Medical/Research Monitor, and Ombudsman (if applicable).

Note: The Principal Investigator is responsible for maintaining these certificates for all site support staff in the study file. Refer to WRAIR Commander's IRB Policy Memorandum #03, Initial and Ongoing Human Subjects Protection Education and Training Requirements for details.

Scientific Review (required prior to ethical review initiation)

Check One:

___Scientific Review approval documentation if obtained from a source other than WRAIR Scientific Review.

___Scientific Review has not been conducted (to date) for this proposal. Please submit to the WRAIR Scientific Review Committee or review for exemption.

Recruitment and Volunteer Contact Materials
Check One:

___Advertisements, recruitment scripts, recruiting material, briefing slides, emergency contact cards, etc., that will be used during the conduct of the study. This should include any items that will be given to, reviewed by, or seen/heard by volunteers.

___Not Applicable

Check One:

___ Letter(s) of Support (if using, contacting, recruiting, screening or enrolling subjects outside of WRAIR or WRAIR's databases). This might include University, Hospital, or Battalion/Command permission to recruit at a non-WRAIR site.

___Not Applicable

Comprehension Testing (not required)
Check One:
___Tests of Understanding (with answer key) that will be administered to the subjects. Include in the protocol a statement of how low test scores will be handled and how many times the test can be re-taken.

___Not Applicable

Case Report Forms/Source Documents
Check One:

___Case Report Forms or data collection documents (please print electronic versions). This would include questionnaires, surveys, SAE forms, etc.

___Not Applicable

Check One:

___Performance Tests that will be administered, including: memory tests and instructions to test givers, and examples/descriptions of performance tests.

___Not Applicable

List Collaborator/Partner or Other Involved Institutions

If applicable, please provide the following additional information:

Collaborator/ Partner Involved Institution	DHHS or DoD Federalwide Assurance # (Click here to search)	Name of Reviewing IRB or Ethics Committee	IRB Approval/ Determination Status* *(Indicate: Yes, No, Pending)*	IRB Determination**	IRB Approval Date
				Choose an item.	Click here to enter a date.
				Choose an item.	Click here to enter a date.

IRB Approval*: Indicate whether IRB approval has taken place or is pending. If there are any Institutional Agreements for IRB review planned, describe in the space provided.

IRB Determination**: Indicate the determination (exempt, not greater than minimal risk, greater than minimal risk) made by the IRB or the institution during the initial review of the protocol, to include "research not involving human subjects" determinations from participating institutions that do not have access to identifiable data or materials. Please contact the respective IRB office for assistance.

___Not Applicable

Collaborator/Partner or Other Involved Institutions - Documentation
Check One:

___Non-WRAIR IRB approval documents attached

___Non-WRAIR IRB approval documents will be submitted after WRAIR IRB Review

___Not Applicable

Important Reminder: Collaborations may require business agreements (CRADAs, Material Transfer Agreements, (MTAs), Memorandum of Understanding (MOU), contracts, etc.) This process should be initiated as early as possible.
Note: Contact the WRAIR Office of Research Technology and Applications (ORTA) for guidance.

Vulnerable Populations

___Pregnant Women, Human Fetuses and Neonates

___Prisoners

___Children (Not Greater Than Minimal Risk study)

___Children (Greater Thank Minimal Risk study). Please note: the study must provide a direct benefit for each and every individual subject that is participating.

___Other (e.g. active duty service members, impaired decision making, institutionalized)
Please list:_____

___Not Applicable

International Studies
Check One:

___International Research Study Supplemental Information Form (Required for all international studies)

___Not Applicable

Volunteer Registry Datasheets (greater than minimal risk protocols only, unless waived)
Check One:

___Volunteer Registry Database USAMRDC Form 60-R. These forms will be filled out when subjects are enrolled and will be submitted to USAMRDC.
Note: Only the study PI needs to be identified on the Volunteer Registry Database Form.

___Request for waiver of Volunteer Registry Datasheets. Please provide justification below:_____

___Not Applicable

Additional Approval for WRAIR Federal Personnel
Check One:

___Supervisor/Commander's approval form for Active Duty military volunteers. (Required for protocols involving significant time commitment, challenges, and/or investigational product use. Refer to WRAIR Commander's IRB Policy Memorandum #05, Compensation to Federal Personnel when They Participate in Research as Human Subjects, for details).

___Not Applicable

Additional Institutional Committee Reviews
Check One:

___Institutional Committee Reviews to include, if applicable:
- ___Radiation Control Committee
- ___Biosafety Committee
- ___Radioisotope/Radiation Control Committee
- ___Biomedical Engineering Committee
- ___Other (please list:_____)

___Not Applicable

Check One:

___Recombinant DNA Advisory Committee (RAC) Approval for gene transfer research, if appropriate. (This may include Office of Biotechnology Activities (OBA) review.)

___Not Applicable

Check as applicable (U.S. FDA or other Regulatory Bodies Reviewing):

___ This protocol involves an investigational product (new drug, vaccine/biologic, device, or off-label use of an approved product).

Please list Investigational New Drug/Vaccine/Biologic (IND) or Investigational Device Exemption (IDE) number or date of submission to the FDA:_____

___ Not Applicable

Check as applicable:
Required Documentation for IND protocols:

___Current & Official Investigator's Brochure(s).

___Completed and signed Conflict of Interest or Financial Disclosure statement (for all investigators listed on the protocol.)

___Completed and signed FDA Form 1572 (if U.S. FDA Regulated).

___Sponsor's name and contact information.

___ 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) (Please note that submission of the monitoring plan is required by the WRAIR IRB.)

___Not Applicable

Check as applicable:
Required Documentation for IDE protocols:

___A statement regarding safety of device from the manufacturer (Significant vs. Non-significant Risk)

___Manufacturer's device manual/guide/brochure.

___FDA 510(K) - Pre-Market Application (if U.S. FDA Regulated)

___DSMB, SMC, or IDMC membership and charter.

___Completed and signed Conflict of Interest or Financial Disclosure statement (for all investigators listed on the protocol.)

___Not Applicable

Check as applicable:

___Use of an U.S. FDA Approved Product (21 CFR Parts 50 and 56)

___Use of European Medicines Agency (EMA) Approved Product

___Local Approved Product (Country:_____)

___Current Package Insert(s).

___Completed and signed Conflict of Interest or Financial Disclosure statement (for all investigators listed on the protocol.)

___Sponsor's name and contact information.

___Statement from the manufacturer regarding the safety of the drug/vaccine/biologic/device.

___DSMB, SMC, or IDMC membership and charter.

By signing the below, the signatories are affirming that the above documents are in place for the submission of this study.

Signatures/Dates:

_____ _____
PI Date

_____ _____
Branch /Directorate Director Date

When Incomplete (Below Required)
WAIVER REQUEST GRANTED:

_____ _____
Deputy Commander Date

For HSPB Use Only

Received in HSPB by:_____Date:_____

Assigned WRAIR #_____

Initial Packet Review

____Complete, begin process Date:_____

____Incomplete: Notified PI on Date: _____

Preliminary Risk Assessment: _____ Date: _____

____Submitted to WRAIR Chief Science Officer or Scientific Review Committee Chair for Scientific Review

____ External scientific review; submitted to WRAIR Chief Science Officer for a determination of concurrence

____Scientific Review not required

Date Scientific Review Completed (if applicable): _____

Date Submitted for Ethical Review: _____