



WALTER REED ARMY INSTITUTE OF RESEARCH  
Division of Human Subjects Protection  
Standard Operating Procedure



|                |   |         |           |
|----------------|---|---------|-----------|
| SOP Title      | <b>CONDUCTING INITIAL PROTOCOL REVIEW<br/>FOR HUMAN SUBJECTS RESEARCH</b> | SOP No. | UWZ-C-603 |
|                |   | Version | .01       |
| Effective Date |   | Page    | 1 of 11   |

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**Signatures and Dates:**

For Signatures, please see original at the DHSP Office.

Author:

QA Review:

Approving  
Authority:

**Review/Approval for unchanged documents**

|   | Author/Date | QA Review/Date | Approving Authority/Date |
|---|-------------|----------------|--------------------------|
| 1 |             |                |                          |
| 2 |             |                |                          |
| 3 |             |                |                          |
| 4 |             |                |                          |



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**1. Purpose/Applicability**

The following Standard Operating Procedure (SOP) outlines the process for conducting an initial review of human subjects research protocols submitted to the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB).

This SOP applies to the WRAIR Division of Human Subjects Protection (DHSP) staff, the WRAIR IRB, the WRAIR IRB Chair (or designee) and the Commander, WRAIR (Institutional Official; IO).

**2. Responsibilities**

- a. WRAIR DHSP Staff are responsible for reviewing human subjects research protocol submissions in accordance with applicable WRAIR and Federal policies, procedures, and guidance, after scientific review approval and receipt of a completed protocol packet.
- b. WRAIR DHSP Director, Deputy Director, or designee is responsible for:
  - 1) Designating a WRAIR DHSP reviewer for a new protocol submission (also referred to as the DHSP point of contact (POC) or Human Subjects Protection Scientist (HSPS))
  - 2) Reviewing all DHSP Protocol Evaluation Forms (PEF)
  - 3) Ensuring that the DHSP staff is trained on this SOP
- c. WRAIR IRB Chair and IRB members are responsible for the review and recommendation of approval, if appropriate, of protocol submissions, in accordance with this SOP.
- d. The WRAIR Commander is responsible for the review of the IRB recommendations of approval and makes a final determination for implementation within the scope of his/her authority.



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### 3. Investigator Guidance

The Principal Investigator (PI) is expected to:

- a. Consult early with the WRAIR DHSP in anticipation of the submission of a new protocol. (Note: collaborations may also require early consult with WRAIR Office of Research, Technology and Applications (ORTA) for the applicable agreements needed.)
- b. Prepare the protocol submission packet in accordance with the format and content specified in WRAIR SOP UWZ-C-623. Complete the International Research Study Information Form for all studies requiring review by USAMRMC ORP HRPO (Appendix 3). (Frequently used sites could have standing/overarching international forms (ie. Pre-populated with standard information, which would require only a short appendix for unique information.)
- c. Respond to and address all PEF comments within 30 days of receipt.
- d. Be available to discuss the protocol with the IRB Chair and/or IRB members.
- e. Address within 30 days any concerns/questions in the "Communication to the PI" from the WRAIR IRB meeting. Respond with the following information:
  - 1) An official memo signed through the PI's Detachment Commander, Division Director and Department Chief (as applicable)
  - 2) A point-by-point response integrating changes into the protocol and supporting documents.
  - 3) Two electronic versions of the revised protocol and supporting documents; one "clean" version and one "tracked changes" or equivalent (e.g., "Was-Is" document) while maintaining version control.
- f. Assure that no activities associated with the protocol begin until authorization to implement the research is received from the WRAIR Commander (IO).
- g. Follow the protocol as authorized and the processes outlined in this SOP.

### 4. Materials and Equipment

N/A



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## 5. Procedures

- a. Upon receipt of a new protocol submission, according to WRAIR SOP UWZ-C-623, the WRAIR DHSP administrative staff:
  - 1) Assigns a WRAIR number;
  - 2) Forwards the protocol to the WRAIR DHSP reviewer (also referred to as a the DHSP point of contact [POC] or Human Subjects Protection Scientist [HSPS]);
  - 3) Documents the protocol in the WRAIR DHSP logbook;
  - 4) Enters the protocol information into the database. *Note: The entering of information into the database is a continuous process.*
- b. The WRAIR DHSP reviewer (DHSP POC or HSPS):
  - 1) Reviews the submission packet for completeness as specified in the submission cover memo from the PI or e-mail correspondence. Incomplete packets will be returned to the investigator.
  - 2) Assesses the preliminary risk category to identify the appropriate scientific review pathway per WRAIR Office of the Science Director (WOSD) SOP.
  - 3) Reviews the protocol in accordance with applicable regulations and generate the PEF;
  - 4) Submits the draft PEF to the DHSP Director, Deputy Director, or designee for comment. Presents/consults the PEF/protocol with WRAIR IRB Chair (or designee), prior to issuance, as appropriate.
  - 5) Sends final PEF to WRAIR PI or WRAIR POC.
  - 6) Maintains regular communication with the WRAIR PI or the WRAIR POC until all PEF responses and supporting documents are received.
  - 7) Submits the protocol through the appropriate review process (e.g., expedited review, full board review). The WRAIR DHSP Director, Deputy Director (or designee) reviews all DHSP protocol PEFs and forwards the documentation to the WRAIR IRB Chair (or designee) for review and/or an ethical consultation, if applicable, prior to submitting the PEF to the PI. For studies requiring review by the fully convened WRAIR IRB, the DHSP Director or WRAIR IRB Chair (or designees) may determine that a protocol is suitable for IRB review prior to the PI responding to the PEF.



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- 8) For studies requiring headquarters-level administrative review (HLAR) by the USAMRMC ORP HRPO (i.e., for greater than minimal risk research or contractually required extramural research or cooperative agreements), see the WRAIR Guidance on HLAR by USAMRMC HRPO. Some studies may require review by the USAMRMC Research Ethics Advisory Panel (REAP) review (e.g., investigational new drug studies that are first in man or with high toxicity profiles, gene transfer studies, non-lethal weapons studies, etc.) , see the WRAIR Guidance on HLAR by USAMRMC HRPO.
- 9) Contacts the PI for any missing elements and communicates any corrections/additions required for the review by sending the DHSP PEF.
- 10) For studies eligible for expedited review, please see WRAIR SOP UWZ-C-613).
- 11) For studies requiring a fully convened WRAIR IRB review:
  - a) Assists the WRAIR IRB Chair (or Acting Chair) in the identification of a primary and secondary reviewer for studies requiring full review by the WRAIR IRB. Contacts the primary and secondary reviewer selected by the WRAIR IRB Chair (or Acting Chair).
  - b) Notifies the PI and/or WRAIR POC of the study's inclusion on the IRB agenda.
  - c) Assists in ensuring the WRAIR IRB has all documents necessary for the full board review in accordance with WRAIR SOP UWZ-C-628.
- 12) Generates the recommendation of approval memorandum for the WRAIR IRB Chair (or designee). All memoranda are reviewed by the DHSP Director and/or DHSP Deputy Director (or designee) prior to obtaining the signatures from the WRAIR IRB Chair (or designee). For studies that required HLAR (i.e., either USAMRMC ORP HRPO or REAP) review and approval, the WRAIR IRB Recommendation of Approval memorandum is forwarded to the USAMRMC ORP HRPO POC prior to approval being issued from USAMRMC ORP HRPO.
- 13) Generates implementation approval memoranda for the Commander (or designee), who serves as the Institutional Official (IO), to review and sign (if approvable). All memoranda are reviewed by the DHSP Director and/or DHSP Deputy Director (or designee) prior to obtaining the signatures from the IO and the appropriate chain of command. For studies that required HLAR, the Commander's Implementation Approval memoranda are not issued until approval is received from the USAMRMC ORP HRPO.



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- 14) Forwards any approval documentation or correspondences to the PI.
  - 15) Maintains an IRB file on the protocol, with copies of all versions of the protocol and all accompanying documents, as well as documentation of any communication with those involved with the protocol, its submission, review(s) and approval.
- c. The WRAIR IRB Chair (or designee):
- 1) Reviews protocols submitted to the WRAIR DHSP, assigns/concurs with preliminary risk level, and whether or not the study is eligible for expedited review in accordance with the Federal Register (Refer to WRAIR SOP UWZ-C-613).
  - 2) Forwards any review questions and/or concerns to the WRAIR DHSP reviewer to include in the PEF, or these may be forwarded separately.
  - 3) Coordinates with the PI, as needed, to ensure the protocol meets appropriate regulations and guidelines.
  - 4) Provides approval recommendation for protocols approved via expedited review.
- d. The WRAIR IRB:
- 1) Reviews each protocol and supporting documents in accordance with applicable regulations, guidelines, and WRAIR SOP UWZ-C-616 & 628.
  - 2) Considers the protocol evaluations, recommendations of the Primary and Secondary reviewers, and recommendations from the PEF, if applicable. It is the responsibility of the Primary and Secondary reviewers, assigned to the protocol, to give a detailed overview of the protocol to the WRAIR IRB and state any concerns or issues to the committee for discussion (Refer to WRAIR SOP UWZ-C-628).
  - 3) Discusses any additional concerns about the protocol and any changes required to the protocol and the supporting documents.
  - 4) Establishes a review recommendation to approve, disapprove, table (defer) or approve with stipulations to, the protocol in accordance with regulations and WRAIR SOP UWZ-C-610, assign the risk level (per risk:benefit analysis), as well as, a continuing review period.



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**6. Explanation of Acronyms, Abbreviations, and Terms**

|                         |  |
|-------------------------|--|
| Best Practices          | Good Clinical Practice (GCP) and International Conference on Harmonisation (ICH) Guidelines  |
| CFR                     | Code of Federal Regulations  |
| DHSP                    | Division of Human Subjects Protection, WRAIR, is the administrative support for the WRAIR IRB  |
| DoD                     | Department of Defense  |
| Exempt                  | A protocol is exempt from certain reporting requirements when it meets the requirements set forth in 32 CFR 219.101 and/or 45 CFR 46.101   |
| Expedited Review        | A protocol is eligible for expedited review when it meets the requirements set forth in 21 CFR 56.110, 32 CFR 219.110, and/or 45 CFR 46.110.   |
| FDA                     | Food and Drug Administration   |
| GTMR                    | Greater than Minimal Risk  |
| HLAR                    | Headquarters level administrative review   |
| HSPS                    | Human Subjects Protection Scientist, Division of Human Subjects Protection   |
| Human Subjects Research | Research involving humans as research subjects, or involving biological specimens, data, specimens from repositories or anatomical substances of human origin. This includes the administration of questionnaires or surveys, as well as, research done in an educational setting. |
| IO                      | Institutional Official   |
| IRB                     | Institutional Review Board, a committee of individuals tasked with protecting the rights and welfare of human subjects and with supporting the institution's research mission.   |
| Minimal Risk            | A protocol constitutes minimal risk to subjects if the probability of harm or discomfort anticipated in the research is  |



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not greater than that encountered in daily life or during a routine physical or psychological examination.

- ORTA Office of Research, Technology, and Applications
- OTSG Office of The Surgeon General
- PI Principal Investigator
- POC Point of Contact
- REAP Research Ethics Advisory Panel
- Research A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- SSRC Standing Scientific Review Committee
- SOP Standard Operating Procedure
- USAMRMC ORP HRPO (United States Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office) The office responsible to The Surgeon General for headquarters-level oversight of all human subject research conducted or supported by the Army.
- WRAIR Walter Reed Army Institute of Research
- WRAIR IRB WRAIR Institutional Review Board (IRB), the ethical review committee or IRB for research involving human subjects at WRAIR, its Continental United States (CONUS) detachments or OCONUS Laboratories, or when WRAIR funding, support, facilities or personnel are involved in any way (investigator, consultant, collaborator, etc.). This includes protocols for which recruitment of subjects is being performed at WRAIR.



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**7. References**

| Reference Number or Authors              | Document Title  |
|--|---|
| 32 Code of Federal Regulations (CFR) 219 | Department of Defense, Protection of Human Subjects   |
| 45 CFR 46                                | Health and Human Services, Protection of Human Subjects   |
| 21 CFR 56                                | Food and Drug Administration, Institutional Review Board  |
| 21 CFR 50 Subpart B                      | General Requirements for Informed Consent   |
| AR 70-25                                 | <i>Use of Volunteers as Subjects of Research, 25 January 1990</i>   |
| 63 Federal Register (FR) 60364-60367     | <i>Categories That May be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure, 09 November 1998</i>  |
| DoD Directive 3216.02                    | <i>Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research</i>  |
| WRAIR Policy Letter #08-03               | Determination that an Activity is Research Involving Human Subjects   |
| Bankert, E. A. and Amdur, R. J.          | <i>Institutional Review Board Management and Function (2<sup>nd</sup> Edition), 2006, Boston: Jones and Bartlett Publishers.</i>  |
| OHRP                                     | <i>Guidance on Written IRB Procedures, 15 January 2007, <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/irbqgd107.htm">http://www.hhs.gov/ohrp/humansubjects/guidance/irbqgd107.htm</a></i> |
| WRAIR SOP UWZ-002                        | <i>Scientific Review of Human Subjects Protocols</i>  |
| WRAIR SOP UWZ-C-609                      | <i>Identification and Management of Conflicts of Interest</i>   |
| WRAIR SOP UWZ-C-610                      | <i>Institutional Review Board Voting Requirements</i>   |



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|---------------------|---|
| WRAIR SOP UWZ-C-613 | <i>Expedited Human Subjects Research Protocol Review</i>  |
| WRAIR SOP UWZ-C-616 | <i>Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Meetings</i> |
| WRAIR SOP UWZ-C-623 | <i>Submission of Human Subjects Research Protocols and Supporting Documents for Review</i>      |
| WRAIR SOP UWZ-C-628 | <i>Review of Human Subjects Research by the Fully Convened WRAIR Institutional Review Board</i> |
| WRAIR Guidance      | <i>HLAR by USAMRMC ORP HRPO</i>   |

**8. Forms and Appendices**

| Form or Appendix Number | Title   |
|-------------------------|---|
| UWZ-C-603-A1            | WRAIR DHSP PEF  |
| UWZ-C-603-A2            | Abbreviated WRAIR DHSP PEF                            |
| UWZ-C-603-A3            | WRAIR DHSP Protocol Worksheet<br>(Preparatory to PEF) |
| UWZ-C-603-A4            | WRAIR DHSP ICD Worksheet<br>(Preparatory to PEF)      |
| UWZ-C-603-A5            | Qualification Summary Sheet for PIs                   |

**9. Document Revision History**

| Version Number | Brief Description of Changes   | Effective Date |
|----------------|--|----------------|
| .00            | New SOP  | 9 May 2007     |
| .01            | Biennial review to include organization name updates and updates for consistencies with current policies and procedures. | SEP 08 2010    |

**WRAIR DHSP Protocol Evaluation Form (PEF)**

**WRAIR #**  
**PI Name:**  
**Day/Month/Year:**

Division of Human Subjects Protection (DHSP) Protocol Evaluation Form

SUBJECT: WRAIR # \_\_\_\_\_, Protocol Title“ \_\_\_\_\_,” Submitted by \_\_\_\_\_, Institution \_\_\_\_\_

**1. Protocol Information.**

Protocol Version/Date

ICF Version/Date

Study Design  Single site  Multicenter  Sub-Study

Site-Specific Addendum Version/Date NA

Risk Level  GTMR  MR  Exempt  NHSR  NR  TBD

Type of Study  Drug Study  Device Study  Surveillance

Participation  Other:

Research Team Roles Described?  Yes  No

Phase of Study  Phase 1  Phase 2  Phase 3  Phase 4

Other:

Funding Source

Sponsor of the Research or Executing Authority

WRAIR Scientific Approval/Concurrence Date

**2. Background.** [Describe the program of research under which the protocol has been developed, if not fully captured above. Describe the history of the protocol review or previous actions relevant to current review, if applicable. Include projected start date for protocol, if applicable. Describe any unique aspects of the proposal or protocol, e.g. single/multi-site, relationship of awardee to research site, relationship to other funded proposals, whether an extension will be filed, etc.]

**3. Scientific Review.** [Provide the date when the scientific review occurred. Describe the scientific review process. What type of scientific review occurred [e.g. institutional committee, external review board, American Institute of Biological Sciences (AIBS)]? Was the proposal and/or protocol reviewed? Were recommendations made? If so,

were the recommendations addressed by the PI and/or incorporated into the protocol? If reviewed by committee, did the committee approve the revised protocol? If a scientific review has not been conducted on a proposal or protocol, it must be stated in the recommendations that an appropriate scientific review and approval of the protocol must be completed before it is considered for approval by the WRAIR IRB or the HRPO, Research Ethics Advisory Panel (REAP).]

**4. Institutions Engaged in Research.** *(Copy and paste if more than one)*

Name:  
Assurance #  
Assurance Expiration Date:  
IRB Registration #  
IRB Registration Expiration Date:

[Provide any relevant comments for the engaged institutions involved here; including if there are Memorandum of Agreements (MOAs) or Memorandum of Understanding (MOUs) involved, multiple institutions involved, special considerations, describe Department of Defense Reciprocal Agreement for IRB Review (IAIR)/IRB Authorization Agreements (IAA) in place, Individual Investigator Agreements (IIA) in place, engaged personnel, etc.]

**5. Institutional Review Boards.**

**a. Review by IRBs.** *(Copy and paste if more than one)*

Name of IRB

Has IRB Approval Occurred? Yes No  In Process/Pending N/A

IRB Protocol Approval Period/Expiration Date(s)

IRB Continuing Review Date (if different than expiration date)

IRB Risk Level Assignment (if available)

Waiver(s)? Informed Consent Documentation of I.C.

Assent HIPAA Other N/A

[Provide any additional information here, e.g. explanation of waivers, specific stipulations such as submission of reports, etc.]

**b. Additional Regulatory/ Institutional Reviews.**

[Describe outcome of additional required institutional reviews, e.g., Institutional Biosafety Committee, Radiation Control Committee, Office of Biotechnology Activities/ Recombinant DNA Advisory Committee, Integrated Product Team, applicable local committees/regulatory bodies, and/ or Privacy Board.]

## 6. Research Objectives.

[Summarize the research objectives, questions, and/or hypotheses. Can include rationale for study, multi-site/single-site, military relevance, etc.]

## 7. Research Design.

[Briefly describe the research design. State the length of the study, if applicable. Can include a brief study summary, type of protocol: drug/device/biologic, social science, other; whether it involves survey/questionnaires/method of action, adequacy of procedures described, e.g. washout, length of study, randomized vs. open-label, use of placebo, etc.]

## 8. Study Population.

Gender and Racial/Ethnic Distribution

Population Age Range

Age of Majority

Study Sample Size (Screened & Enrolled)

Vulnerable Subjects (*Check all that apply*)

N/A

Individuals with diminished mental capacity

Children

Pregnant women

Prisoners

Veterans

Other/Special Considerations:

Active duty military personnel

Illiterate persons or persons or whom English is a second language

WRAIR Employees

Total Study Duration:

Duration of Each Subject's Participation:

[Provide information on whether the study includes a vulnerable population and the justification for the population selected; Is selection of subjects equitable? Is the sample size justified? Comment on whether the population is appropriate for the study objectives; special considerations; etc.]

## 9. Inclusion/Exclusion Criteria.

[Briefly describe the planned inclusion/exclusion criteria. If extensive, summarize and cite protocol pages.]

**10. Recruitment & Informed Consent Process.**

Recruitment Method Described  Yes  No  N/A

Recruitment Material Used  Yes  No  N/A

Type(s):

Adequate Recruitment and Screening Processes  Yes  No  N/A

Informed Consent Process is Adequately Described in Protocol  Yes  No  N/A

Separate Consent Provided for Testing for Communicable Diseases  Yes  No  N/A

Separate Consent Provided for Genetic Testing  Yes  No  N/A

Use of Samples in Future Research Adequately Addressed  Yes  No  N/A

Assent Form Included for Minors:  Yes  No  N/A

Provisions for Legal Authorized Representative (LAR)  Yes  No  N/A

Provisions for Illiterate Subjects  Yes  No  N/A

Compensation Listed  Yes  No  N/A

Translation(s) Included:  Yes  No  N/A

Type(s):

Verification of Translation included:  Yes  No  N/A

[Brief summary of recruitment plan/process, screening [e.g. if before consent] and the consent process. This section can also address the following: setting, subject autonomy concerns, language difficulties, document storage, compensation amounts are described and appropriate, compensation for injured research subjects, comments about adequacy of documents or procedures, risks, HRPO language, plan to protect the privacy of subjects, including the Health Insurance Portability and Accountability Act (HIPAA) authorization to use/disclose Private Health Information (PHI), identification of missing elements of the Informed Consent Form (ICF), any extra costs to subjects for their participation in the study, etc. Indicate plans for use of Legally Authorized Representatives in the consent process.]

**11. Data Collection & Analysis Plan.**

[Briefly summarize the data collection methods described in the protocol. List all data collection instruments to be used. Note if plans are adequate and if plans to protect data confidentiality are adequately described. Summarize the investigator's plan for data analysis (or if extensive, cite page of protocol).]

**12. Risks to Subjects.**

Are all reasonably foreseeable risks identified in documents?  Yes  No

[Can include Human Subjects Protection Scientist (HSPS) risk assessment, to include procedural risks and risks not listed in the protocol, ICF, or IB (or in one but not the other), PI provided and HSPS suggested measures to minimize risks, etc. Distinguish risks identified in the protocol and consent form from potential risks identified by the HSPS by *italicizing* HSPS comments.]

| Procedure | Risks | Measures to Minimize Risks |
|-----------|-------|----------------------------|
|           |       |                            |

**13. Benefits to Subjects.**

Potential benefits identified in documents?  Yes  No  N/A

Preliminary assessment: Risk/Benefit Ratio Reasonable  Yes  No  N/A

[Identify benefits stated in the protocol and/or consent form. Comment if benefits appear to be overstated in ICF. If 10 USC 980 is applicable, intent to benefit subjects must be documented.]

**14. FDA Regulatory Elements. (Delete section if not necessary)**

**a. IND/Drugs/Biologics.**

Name of Test Article(s)

Name of Comparator(s)

Source of Drug

Experimental Indication:

**Describe the current "Established Effective Treatment" (EET) for this medical indication:**

Drug Storage and Accountability Addressed  Yes  No

Plan for Disposition of Unused Drug Addressed  Yes  No

IND Exempt  Yes  No Reason:  
IND Status  Pending  Clinical Hold  N/A  
 Active, #  Other  
Date IND Filed with FDA  N/A  
Version/Date of Investigator's/Manufacturer Brochure(s)  
Version/Date of Package Insert(s)  
1572 Completed?  Yes  No  N/A  
Financial Disclosure Forms Completed?  Yes  No  N/A  
Sponsor's Clinical Monitoring Plan Provided  Yes  No  N/A  
 Other

[Provide a brief description of the test article, dosage, administration or mode of use, etc. Comment on any other relevant information, e.g. Form 1571 or other like information.]

**b. Investigational Device Exemption (IDE)/Devices.**

Source of Device  
Sponsor's Risk Assessment  Significant Risk (SR)  Non-SR  N/A  
Sponsor/PI Provided  
SR/NSR Statement/Letter  Yes  No  N/A  
IDE Exempt  Yes  No Reason:  N/A  
IDE Status  Pending  Clinical Hold  N/A  
 Active, #  Other  
Date IDE Filed with FDA  N/A  
FDA-Required Monitoring  
Plan Provided [812.43(d)]  Yes  No  N/A  
 Other  
Device/Manual Brochure  
or information is Provided  Yes  No  N/A  
Version/Date of Product Information

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[Provide a brief description of the test article, device, administration or mode of use, person providing maintenance, etc. Comment on any other relevant information, e.g. Pre-market Approvals (PMAs), 510k (e.g. dates, approval – see 21 CFR 807), device class, etc. (IDEs - see 21 CFR 812, IVDs – see 21 CFR 862, 864, 866)]

**15. Safety.**

- Monitoring Plan Provided  Yes  No  N/A  
Charter Provided  Yes  No  N/A  
DoD Medical Monitor Role Described  Yes  No  N/A

[Identify the safety board and the DOD-required Medical Monitor designated for this study. May include any other relevant comments regarding the adequacy of the monitoring plan, etc. Financial Conflict of Interest certification/disclosure addressed as appropriate to minimize harm to participants.]

**16. DOD/USAMRMC Unique Requirements Adequately Addressed in Protocol.**

- Current Curricula Vitae for all Investigators Listed on the Protocol  Yes  No  
Current Human Subjects Training Certificates for All listed Study Staff  Yes  No  
Reporting of Adverse Events  Yes  No  N/A  
Protocol Modifications/ Amendments  Yes  No  N/A  
Protocol Deviations  Yes  No  N/A  
Unanticipated Problems  Yes  No  N/A  
Review of Research Records by DoD Representatives in Protocol and ICF  Yes  No  N/A  
Medical Care for Research Related Injury  Yes  No  N/A  
Continuing Review & Closeout Study Reports  Yes  No  N/A  
Recruitment Issues/Ombudsman  Yes  No  N/A  
10 USC 980  Yes  No  N/A  
Recruitment of Military Subjects/Confidentiality Issues  Yes  No  N/A  
Supervisor Approval Form for Military Subjects  Yes  No  N/A  
Payment to Military Personnel  Yes  No  N/A  
Volunteer Registry Data Base Requirement:  Yes  No  N/A

SEP 08 2010

[Can include further comments here - or include deficiencies in the recommendations below. If study enrollees cannot provide their own consent, address whether or not 10 USC 980 is applicable to the protocol. If there are military subjects, are potential undue influence and confidentiality issues addressed?]

**17. Required Items for WRAIR Commander Implementation Approval:**

- |  |                              |                             |                              |
|--|------------------------------|-----------------------------|------------------------------|
| Letters of Support:                              | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Business Agreements                              | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Command Briefing/Ex Summary                      | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Registration with clinicaltrials.gov             | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Import/Export Permits                            | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Sponsor's Implementation Authorization Volunteer | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Collaborating IRB Approvals/Determinations       | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Other:   | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |

**18. Recommendations for Approval.**

[List required protocol/consent form revisions as well as documents or information that must be obtained for protocol approval. List each recommendation separately. Be as specific as possible. Address the following, as appropriate.]

- a. Required documents/information.
- b. Revisions to be made to the protocol.
- c. Revisions to be made to the consent form.
- d. Revisions to be made to the sample donation form.
- e. Revisions to be made to advertisements/recruitment posters.

NOTE: Formats for each section

- (1) Narrative starts two spaces after punctuation.
- (2) To have a section (1) must have a section (2).
  - (a) Narrative starts two spaces after punctuation.
  - (b) to have an (a) must have a (b).

**19. Points to Consider.**

[Include this section to highlight any points that the Board or other approval authority should consider regarding the protocol.]

NAME, credentials  
Human Subjects Protection Scientist  
DHSP, WRAIR

**WRAIR DHSP Abbreviated Protocol Evaluation Form (PEF)**

**WRAIR #**  
**PI Name:**  
**Day/Month/Year:**

Division of Human Subjects Protection (DHSP) Protocol Evaluation Form

SUBJECT: WRAIR # \_\_\_\_\_, Protocol Title“ \_\_\_\_\_,” Submitted by \_\_\_\_\_, Institution \_\_\_\_\_

**1. Protocol Information.**

Protocol Version/Date

ICF Version/Date

Study Design  Single site  Multicenter  Sub-Study

Site-Specific Addendum Version/Date NA

Risk Level  GTMR  MR  Exempt  NHSR  NR  TBD

Type of Study  Drug Study  Device Study  Surveillance  
 Participation  Other:

→ Research Team Roles Described?  Yes  No

Phase of Study  Phase 1  Phase 2  Phase 3  Phase 4  
 Other:

Funding Source

Sponsor of the Research or Executing Authority

WRAIR Scientific Approval/Concurrence Date

**2. Background.** [Describe the program of research under which the protocol has been developed, if not fully captured above. Describe the history of the protocol review or previous actions relevant to current review, if applicable. Include projected start date for protocol, if applicable. Describe any unique aspects of the proposal or protocol, e.g. single/multi-site, relationship of awardee to research site, relationship to other funded proposals, whether an extension will be filed, etc.]

### 3. Recommendations for Approval.

[List required protocol/consent form revisions as well as documents or information that must be obtained for protocol approval. List each recommendation separately. Be as specific as possible. Address the following, as appropriate.]

- a. Required documents/information.
- b. Revisions to be made to the protocol.
- c. Revisions to be made to the consent form.
- d. Revisions to be made to the sample donation form.
- e. Revisions to be made to advertisements/recruitment posters.

NOTE: Formats for each section

- (1) Narrative starts two spaces after punctuation.
- (2) To have a section (1) must have a section (2).
  - (a) Narrative starts two spaces after punctuation.
  - (b) to have an (a) must have a (b).

### 4. Points to Consider.

[Include this section to highlight any points that the Board or other approval authority should consider regarding the protocol.]

NAME, credentials  
Human Subjects Protection Scientist  
DHSP, WRAIR

### WRAIR DHSP Protocol Worksheet (Preparatory to PEF)

WRAIR #: \_\_\_\_\_

PI: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewer: \_\_\_\_\_

Initial: \_\_\_\_\_ Update: \_\_\_\_\_

| Element   | Is Element Addressed? |    |     | Comments                   |
|---|-----------------------|----|-----|----------------------------|
|   | Yes                   | No | N/A |                            |
| A. Protocol Title. Protocol title used consistently on all documents and multi-center protocol proposal referenced appropriately (e.g site specific addenda). Version is consistent. (AR 70-25, App B-1)  |                       |    |     |                            |
| B. Scientific Review. PI has responded appropriately to recommendations of the Scientific Review Committee. (32 CFR § 219.115(a)(1); AR 70-25, 2-9c.(6), 3-2c.(3), App. B-17; Best Practices*)  |                       |    |     | Date of scientific review: |
| C. Institutional Committee(s) Review. As appropriate, review by Radiation Control Committee, Biosafety Committee, BioMedical Engineering Committee, other is completed. PI has responded appropriately to recommendations. (AR 70-25, 3-2c.(4)) |                       |    |     | Date(s) of approval:       |
| D. HRPO Pre-Review  |                       |    |     | Date(s) of review          |
| E. Study Locations. A list of all facilities and study locations are provided. (AR 70-25, App B-3)  |                       |    |     |                            |
| F. Collaborative Research. All collaborating institutions and assurances are listed. Other reviewing IRBs are identified.   |                       |    |     |                            |
| G. Protocol Timeline. Study Duration. (AR 70-25, App B-4)   |                       |    |     |                            |
| H. Description of Investigational Drugs/Biologics or Devices is adequate. (AR 70-25, App B-5)   |                       |    |     |                            |
| I. Purpose. Purpose of the study and/or research objectives, questions, and/or hypotheses are provided. (AR 70-25, App B-5)   |                       |    |     |                            |

\* Best Practices refers to Good Clinical Practice (GCP) and International Conference on Harmonisation (ICH) Guidelines

| Element   | Is Element Addressed? |    |     | Comments |
|---|-----------------------|----|-----|----------|
|   | Yes                   | No | N/A |          |
| J. Research Design.   |                       |    |     |          |
| 1. Research design is described. (AR 70-25, App B-5, App B-6).  |                       |    |     |          |
| 2. Subject identification. Code system to be used to maintain subject identification is described. (AR 70-25, App B-5, App B-6)   |                       |    |     |          |
| 3. Subject assignment. Randomization process or other procedures used for subject group assignments is described. (AR 70-25, App B-5, App B-6)  |                       |    |     |          |
| K. Study Population and Sample.   |                       |    |     |          |
| 1. Target population is described. (AR 70-25, App B-5, App B-6). All vulnerable are populations described. (Screened vs. enrolled; replacements for withdrawals are addressed)  |                       |    |     |          |
| 2. Description of the sample size justifies that the proposed number of subjects is reasonable and is the minimum required to achieve the research objectives. (AR 70-25, 3-1h)   |                       |    |     |          |
| 3. Sampling Method. Sampling method is described.   |                       |    |     |          |
| 4. Inclusion and exclusion criteria are listed. (AR 70-25, App B-6)   |                       |    |     |          |
| 5. Pregnancy exclusion procedures. If applicable, addresses pregnancy testing and contraceptive practices. (AR 70-25, App B-6) (Cultural sensitivities?)  |                       |    |     |          |
| 6. Biomedical and behavioral research involving prisoners as subjects. If applicable, must comply with Federal, DOD, State, and local law. (Subpart C, 45 CFR § 46.306; 32 CFR § 219.111(b); AR 70-25, App C-4c.; Best Practices) |                       |    |     |          |

| Element  | Is Element Addressed? |    |     | Comments |
|--|-----------------------|----|-----|----------|
|  | Yes                   | No | N/A |          |
| <b>L. Recruitment and Informed Consent Process.</b>  |                       |    |     |          |
| 1. The recruitment process is described and recruitment and/ or advertisement materials provided. (21 CFR § 312.7; AR 70-25, 3-1p.; Best Practices; FDA Information Sheet, "Recruiting Study Subjects")  |                       |    |     |          |
| 2. An appropriate informed consent process that takes place prior to the subject participating in the research is described. Individuals are given adequate time to review and understand all information before agreeing to take part in the study. The possibility of coercion and undue influence is minimized. (32 CFR § 219.116; AR 70-25, 3-1a.,f.,j.; Best Practices) |                       |    |     |          |
| 3. Intent to Benefit. If subjects cannot give their own consent to participate in the study, there is an intent to benefit each such subject enrolled in the study. (10 USC 980; AR 70-25, 3-1o.; Best Practices)  |                       |    |     |          |
| 4. Consent of Legally Authorized Representative. If subjects cannot give their own consent to participate in the study, there is a plan for consent of the individual's legally authorized representative to be obtained prior to the subject's participation in the study. (AR 70-25, 3-1o.(3); Best Practices)   |                       |    |     |          |
| 5. Consent for Medical or Surgical Procedures. Procedural consents for standard procedures performed as part of the research study and HIV consents are provided, where appropriate. (Best Practices)  |                       |    |     |          |
| <b>M. Data Collection.</b>   |                       |    |     |          |
| 1. Screening procedures. Evaluations (lab, history, physical exam) to determine eligibility are described. (AR 70-25, B-6, 7)  |                       |    |     |          |
| 2. Laboratory Evaluations. Data collection procedures are described (e.g. lab evaluations, specimens, special precautions, labeling and storage) (AR 70-25, B-7)   |                       |    |     |          |
| 3. Clinical Assessments. Clinical assessments, for example schedule of clinical evaluations and follow-up procedures, are described. (AR 70-25, B-7, B-11)   |                       |    |     |          |
| 4. Research instruments. Research instruments, such as case report forms, data collection forms, questionnaires, rating scales, and interview guides, are described. (AR 70-25, Apps B-6, B-7, B-9, B-11; Best Practices)  |                       |    |     |          |

| Element  | Is Element Addressed? |    |     | Comments |
|--|-----------------------|----|-----|----------|
|  | Yes                   | No | N/A |          |
| <b>N. Data Management.</b>   |                       |    |     |          |
| 1. Data analysis plan is outlined. (AR 70-25, App B-6, App B-7)  |                       |    |     |          |
| 2. Disposition of Data. Where, how and by whom data will be stored and the length of time data will be stored are described. (AR 70-25, Apps B-6, B-7; Best Practices)   |                       |    |     |          |
| 3. Confidentiality. Where appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. (AR 70-25, Apps B-6, B-7, E-7; Best Practices)   |                       |    |     |          |
| 4. For extramural studies, there should be a statement that representatives of the DOD may inspect the records. (AR 70-25 App E-7; Best Practices)   |                       |    |     |          |
| <b>O. Risks/Benefits and Safety Assessment.</b>  |                       |    |     |          |
| 1. Risks. Risks to subjects and study personnel are adequately described. (AR 70-25, App B-6; Best Practices)  |                       |    |     |          |
| 2. Precautions. Measures to be taken to minimize or manage risks to subjects and study personnel are described. (AR 70-25, App B-6)  |                       |    |     |          |
| 3. Special care needs. Special medical/nursing care and equipment that will be needed for subjects are described. (AR 70-25, App B-6)  |                       |    |     |          |
| 4. Benefits. Benefits of research to subjects are appropriately described. Note that if there are no benefits, this should be stated. Also, payment for research participation is not a benefit. (AR 70-25, App B-6)   |                       |    |     |          |
| <b>P. Study Personnel.</b>   |                       |    |     |          |
| 1. CV/Qualifications Summary of Principal Investigators indicates qualified for position. (AR 70-25, App B-17d.)   |                       |    |     |          |
| 2. A description of roles and responsibilities of study personnel is provided. Personnel conducting the research are appropriate for their assigned roles and responsibilities. (AR 70-25, 3-1p., 3-1q.)   |                       |    |     |          |
| 3. If an interventional trial, PI has not disclosed any conflict of interest. If appropriate, Conflict of Interests declared in written statement by investigator(s); includes description of measures to eliminate, manage or reduce COIs. (WRAIR SOP UWZ-C-609, HSRRB Policy Memo) |                       |    |     |          |
| 4. If GTMR, DoD Medical Monitor is assigned to protocol, role and responsibilities are described, & biosketch indicates qualified for position. (AR 70-25, 2-9e., 3-1r., 3-2e. (2)(c), App B-14)   |                       |    |     |          |

| Element  | Is Element Addressed? |    |     | Comments |
|--|-----------------------|----|-----|----------|
|  | Yes                   | No | N/A |          |
| 5. Medical Monitor's role is appropriately described, and the Medical Monitor has no apparent conflict of interest. Medical Monitor not under supervision of PI or other investigators or research staff. (AR 70-25, 2-9e., 3-1q., App B-14)   |                       |    |     |          |
| Q. Protocol Amendments. The procedure to be followed if the protocol is modified, terminated, or extended is described. (AR 70-25, 2-9c.(6), App B-10)   |                       |    |     |          |
| R. Protocol Deviation. The procedure to be followed if departure from the protocol should occur (including who will be notified) is described. (AR 70-25, App B-8)   |                       |    |     |          |
| S. Withdrawal from Protocol.   |                       |    |     |          |
| 1. The consequences of a subject's decision to withdraw and procedures for orderly end of subject's participation are described, if appropriate. (32 CFR § 219.116(b)(4); AR-70-25, App E-9, App E-11)   |                       |    |     |          |
| 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator are described, if appropriate. (32 CFR § 219.116(b)(2); AR 70-25 App E-11)  |                       |    |     |          |
| T. Adverse Event Reporting. Plan for reporting AEs to subject included in protocol. [AR 70-25, 2-9c.(4), App B-9; Best Practices]  |                       |    |     |          |
| U. Unanticipated problems involving risks to subjects or others (UPIRTSO). Plan for reporting UPIRTSOs included in protocol. [AR 70-25, 2-9c.(4), App B-9; Best Practices]   |                       |    |     |          |
| V. Medical Care for Research Related Injury. For research involving more than minimal risk and conducted in a USAMRMC facility or by a USAMRMC PI, suggests the consent form language for medical care for research related injuries (see Command Policy Memorandum 2010-10, Medical Care for Research Related Injury). For all other research refer to this policy for determination of medical care for research related injury. |                       |    |     |          |
| W. Volunteer Registry Database. If a GTMR intramural study, a plan for collection of Volunteer Registry Data Sheets is included in protocol. (AR 70-25, App H)   |                       |    |     |          |
| X. Continuing Review Language  |                       |    |     |          |
| Y. Closeout Report Language  |                       |    |     |          |
| Z. <i>intentionally left blank</i>   |                       |    |     |          |

**WRAIR DHSP Informed Consent Document (ICD) Worksheet  
(Preparatory to PEF)**

WRAIR #: \_\_\_\_\_

PI: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewer: \_\_\_\_\_

| Elements   | Is Element Addressed? |    |     | Comments |
|--|-----------------------|----|-----|----------|
|  | Yes                   | No | N/A |          |
| <b>A. Research Description.</b>  |                       |    |     |          |
| 1. Title and location of study consistent with protocol. (AR 70-25, App E-1; Best Practices*) Version is consistent.   |                       |    |     |          |
| 2. A statement that the study involves research and an explanation of the purpose and objectives of the research. (32 CFR § 219.116(a)(1); AR 70-25, App E-3; Best Practices)  |                       |    |     |          |
| 3. The expected duration of the subject's participation. (Best Practices)  |                       |    |     |          |
| 4. The number of subjects in the study. (32 CFR § 219.116(b)(6); AR 70-25, App E-11f.; App B-2f. ; Best Practices)   |                       |    |     |          |
| 5. A description of the procedures followed, and identification of any procedure that is experimental. (Best Practices)  |                       |    |     |          |
| 6. Inclusion and exclusion criteria. Pregnancy testing and contraception, if applicable (Best Practices)   |                       |    |     |          |
| 7. Information about prior, similar, or related studies. (AR 70-25, App E-3)   |                       |    |     |          |
| <b>B. Risks.</b>   |                       |    |     |          |
| 1. Description of reasonably foreseeable risks and discomforts and methods for minimizing them. (32 CFR § 219.116(a)(2); AR-70-25, App E-4; Best Practices)  |                       |    |     |          |
| 2. A statement that the treatment or procedure may cause risks to the subject (or embryo or fetus) which are currently unforeseeable. (Subpart B, 45 CFR § 46.205; 32 CFR § 219.116(b)(1); AR 70-25, App E-11a.; Best Practices) |                       |    |     |          |
| 3. Description of possible genetic effects to the offspring of males (AR 70-25, App E-11a.)  |                       |    |     |          |
| 4. Investigational New Drugs described. (Best Practices)   |                       |    |     |          |
| 5. The precautions to be observed by the subject before or after the study to minimize risk are stated (AR 70-25, App E-11g.; Best Practices)  |                       |    |     |          |

\* Best Practices refers to Good Clinical Practice (GCP) and International Conference on Harmonisation (ICH) Guidelines

| Elements   | Is Element Addressed? |    |     | Comments |
|--|-----------------------|----|-----|----------|
|  | Yes                   | No | N/A |          |
| <b>C. Benefits.</b>  |                       |    |     |          |
| 1. Description of benefits to the subject or others. (32 CFR § 219.116(a)(3); AR-70-25, App E-5; Best Practices)   |                       |    |     |          |
| 2. Explanation of whether the results of the research will be made available to the subject (AR 70-25, App E-11i.)   |                       |    |     |          |
| <b>D. Alternatives to Participation.</b> Disclosure of appropriate alternative procedures or courses of treatment, if any, which may be advantageous to the subject. (32 CFR § 219.116(a)(4); AR 70-25, App E-6; Best Practices)   |                       |    |     |          |
| <b>E. Payment/Costs.</b>   |                       |    |     |          |
| 1. Where private citizens are enrolled, "Other than medical care that may be provided and any other payment specifically stated in the consent form, there is no other compensation available for your participation in this research." (Best Practices)   |                       |    |     |          |
| 2. Additional costs to the subject that may result from participation in the research. (32 CFR § 219.116(b)(3); AR 70-25, App E-11c.; Best Practices)  |                       |    |     |          |
| <b>F. Possible Sample Donation/Commercial Products.</b> (AR 70-25, 3-1c., 3-1d.)   |                       |    |     |          |
| <b>G. Medical Care for Research Related Injury.</b> For research involving more than minimal risk and conducted in a USAMRMC facility or by a USAMRMC PI, the suggested consent form language for medical care for research related injury is in the Command Policy 2010-10. For all other research also refer to this Command Policy Memo for determination of medical care for research related injury. (32 CFR § 219.116(a)(6); AR 70-25, 3-1k.; Best Practices; Command Policy Memorandum 2010-10, Medical Care for Research Related Injury) |                       |    |     |          |
| <b>H. Confidentiality.</b>   |                       |    |     |          |
| 1. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. (32 CFR § 219.116(a)(5); AR 70-25, App E-7; Best Practices)   |                       |    |     |          |
| 2. For investigational drug or device studies, a statement that WRAIR, FDA and MRMC representatives may review the records. For contractor studies, a statement that DOD may inspect the records. (AR 70-25, App E-7)  |                       |    |     |          |
| 3. Alternative statement about confidentiality of information for studies using military personnel as subjects. (Best Practices)   |                       |    |     |          |
| 4. If photographs are taken, the degree to which actions will be taken to protect the identity of the subject is described. (AR 70-25, App E-11h.)   |                       |    |     |          |

| Elements  | Is Element Addressed? |    |     | Comments |
|---|-----------------------|----|-----|----------|
|   | Yes                   | No | N/A |          |
| <b>I. Participation and Withdrawal.</b>   |                       |    |     |          |
| 1. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, the subject may withdraw at any time without penalty or loss of benefits. (32 CFR § 219.116(a)(8); AR 70-25, App E-9; Best Practices) |                       |    |     |          |
| 2. Assent is obtained from minors, if applicable (consider age, maturity, psychological state) or conditions for waiver of assent are met. Assent form should be provided when applicable. (AR 70-25, 3-1o.)  |                       |    |     |          |
| 3. The consequences of a subject's decision to withdraw and procedures for orderly end of subject's participation. (32 CFR § 219.116(b)(4); AR-70-25, App E-11d.; Best Practices)   |                       |    |     |          |
| 4. Anticipated circumstances under which the subject's participation may be terminated by the investigator. (32 CFR § 219.116(b)(2); AR 70-25, App E-11b.; Best Practices)  |                       |    |     |          |
| 5. A statement that significant new findings developed during the course of research which may relate to the subject's willingness to continue participation will be provided. (32 CFR § 219.116(b)(5); AR 70-25, App E-11e.; Best Practices)             |                       |    |     |          |
| <b>J. Contact Information Provided.</b>   |                       |    |     |          |
| 1. Whom to contact with questions about the research, including name or office and telephone numbers. (32 CFR § 219.116(a)(7); AR 70-25, App E-8)   |                       |    |     |          |
| 2. Whom to contact with questions about subjects rights including name or office and telephone numbers. (32 CFR § 219.116(a)(7); AR 70-25, App E-8; Best Practices)   |                       |    |     |          |
| 3. Whom to contact in the event of a research-related injury including name or office and telephone numbers. (32 CFR § 219.116(a)(7); AR 70-25, App E-8; Best Practices)  |                       |    |     |          |
| 4. Name and contact information for the principal investigator and degree/type of healthcare provider (M.D. )(AR 70-25, App E-2; Best Practices)  |                       |    |     |          |
| <b>K. Volunteer Registry.</b> For GTMR studies, see Volunteer Registry Data Sheets are required. (AR-70-25, App H)  |                       |    |     |          |
| <b>L. Documentation.</b>  |                       |    |     |          |
| 1. Printed or typed name and signature of the subject or legally authorized representative (21 CFR § 50.27; AR 70-25, DA 5303-R; Best Practices)  |                       |    |     |          |
| 2. Permanent address of subject, unless waived. (AR 70-25, DA 5303-R; Best Practices)   |                       |    |     |          |
| 3. Printed or typed name and signature of witness, if illiterate or following ICH GCP. (32 CFR § 219.117(b)(2); AR 70-25, DA 5303-R; Best Practices)  |                       |    |     |          |
| Note: if ICH GCP, person conducting consent should sign as well.  |                       |    |     |          |
| 4. Copy to be provided to subject and legal representative. (Best Practices) (Signed copy if following ICH GCP)   |                       |    |     |          |

| Elements   | Is Element Addressed? |    |     | Comments |
|--|-----------------------|----|-----|----------|
|  | Yes                   | No | N/A |          |
| 5. Consent for photos or audiotapes. (AR 70-25, App E-11h.)  |                       |    |     |          |
| 6. Documentation of the consent if donated samples may be used in future research studies and/or have some commercial applicability. (AR 70-25, 3-1c., 3-1d.)  |                       |    |     |          |
| 7. Justification to have subject ID/SSN on ICD.  |                       |    |     |          |
| 7. Documentation of consent for HIV antibody testing, if scheduled, may be addressed in the body of the consent form or as separate HIV test consent form.   |                       |    |     |          |
| M. Presentation and Language.  |                       |    |     |          |
| 1. The document is free from any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. (32 CFR § 219.116)                |                       |    |     |          |
| 2. The document avoids use of the term "I understand" and does not require subjects to certify completeness of disclosure, make claims of effectiveness that may unduly influence subjects, or include explicit statements that an IRB has approved solicitation of subjects to participate in research. (FDA Guide to Informed Consent) |                       |    |     |          |
| 3. The document presented meets the following requirements: (32 CFR § 219.116, AR 70-25, 3-2d.; Best Practices)  |                       |    |     |          |
| a. Legible   |                       |    |     |          |
| b. Adequate font size (10 or greater)  |                       |    |     |          |
| c. At a reading level appropriate for the subjects   |                       |    |     |          |
| d. Written in the second person. (FDA Guide to Informed Consent)   |                       |    |     |          |
| e. Appropriate translation and certificate of translation provided if necessary.   |                       |    |     |          |
| N. Supportive Materials – Any additional information used in the consent process has been reviewed (e.g., information sheets, videos, visit schematic).  |                       |    |     |          |

Additional Comments

# Investigator Qualifications Summary

(a CV that contains this information may be substituted)

Investigator: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

WRAIR Protocols #: \_\_\_\_\_

## Training

**Human Subjects Protection:** Course and Date: \_\_\_\_\_

**HIPAA:** Date initial: \_\_\_\_/\_\_\_\_/\_\_\_\_ Refresher: \_\_\_\_/\_\_\_\_/\_\_\_\_

**Good Clinical Practices:** Date initial: \_\_\_\_/\_\_\_\_/\_\_\_\_ Refresher: \_\_\_\_/\_\_\_\_/\_\_\_\_

## Experience

|   |                                 |                                       |                               |                              |  |
|---|---------------------------------|---------------------------------------|-------------------------------|------------------------------|--|
| <b>Principal Investigator:</b>  |                                 |                                       |                               |                              |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| <b>Associate Investigator:</b>  |                                 |                                       |                               |                              |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| WRAIR Protocol #: _____   | <input type="checkbox"/> Exempt | <input type="checkbox"/> Minimal Risk | <input type="checkbox"/> GTMR | <input type="checkbox"/> IND |  |
| <b>Medical Monitor:</b>   |                                 |                                       |                               |                              |  |
| WRAIR Protocol #: _____   |                                 | <input type="checkbox"/> GTMR         | <input type="checkbox"/> IND  |                              |  |
| WRAIR Protocol #: _____   |                                 | <input type="checkbox"/> GTMR         | <input type="checkbox"/> IND  |                              |  |
| <b>Other Qualifications (such as protocols conducted elsewhere):</b> attach on a separate page or the back of the sheet |                                 |                                       |                               |                              |  |