



**Walter Reed Army Institute of Research
Standard Operating Procedure**



SOP Title	APPENDIX 1 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB	SOP No.	UWS-HP-603
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WRAIR Human Subjects Protection Branch (HSPB) Protocol Evaluation Form (PEF)

WRAIR #

Principal Investigator:

PI Qualification Summary Provided, as applicable:

Yes No N/A

WRAIR POC (if different from above):

Review Date: [Day/Month/Year]:

SUBJECT: “[Protocol Title],” Submitted by [PI Name, Institution, Department, Address].

1. Protocol Information.

Core Protocol Version/Date:

Site-Specific Addendum
(SSA) Version/Date:

SSA Principal Investigator:

ICF Version/Date:

International Study (Yes/No)

Study Design Single site Multicenter Sub-Study

Risk Level GTMR MR Exempt
 NHSR NR TBD



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Type of Study Drug Study Device Study Surveillance
 Participation Combination Product: IND or IDE
 Other: [describe] Regulated: _____

Research Team Roles Described? Yes No

Phase of Study Phase 1 Phase 2 Phase 3
 Phase 4 Other: [describe] N/A

Funding Source:

Research Sponsor or
Executing Authority:

WRAIR Scientific Approval or
Concurrence Date:

2. Background.

[Describe the program of research under which the protocol has been developed, if not fully captured above. 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 study duration will be less than or extend beyond 5 years, etc.]

3. Research Objectives.

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

4. 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/combination product, 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.]



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5. Scientific Review. [Provide who conducted the scientific review (e.g., WRAIR, outside institution, etc.), the date when the scientific review occurred and when it was approved. 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? 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 U. S. Army Medical Research and Development Command (USAMRDC), Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO).]

6. Collaborative Institutions Engaged in Research. *(Fill Table as appropriate)*

Name of Collaborating Institution	Name of Reviewing IRB	FWA # and Expiration Date	IRB Registration # and Expiration Date	Additional Details* [Has IRB Approval Occurred?, IRB Protocol Approval Period/ Expiration Date(s), IRB Continuing Review Date (if different from expiration date) IRB Risk Level Assignment (if available):

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

7. Additional Regulatory and Institutional Review Boards Special Considerations.

a. Waiver(s)?

- | | |
|---|--|
| <input type="checkbox"/> Informed Consent | <input type="checkbox"/> Documentation of I.C. |
| <input type="checkbox"/> Assent | <input type="checkbox"/> HIPAA |
| <input type="checkbox"/> Other (describe) | <input type="checkbox"/> N/A |

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



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submission of reports, etc.]

b. OHRO Review.

Yes No N/A

Reason for OHRO review:

c. Other (describe):

[Describe outcomes of additional required institutional reviews, e.g., Institutional Biosafety Committee, Radiation Safety Committee, Office of Biotechnology Activities/ Recombinant DNA Advisory Committee, Integrated Product Team, applicable local committees/regulatory bodies, and/ or Privacy Board.] Provide dates of approval and effective date for any approval periods.]

8. Study Population.

Gender:

Race:

Ethnic Distribution:

Population Age Range:

Age of Majority:

Study Sample Size (Screened & Enrolled):

Vulnerable Subjects *(Check all that apply)*

- | | |
|--|---|
| <input type="checkbox"/> Illiterate persons or persons for whom English is a second language | <input type="checkbox"/> WRAIR Employees |
| <input type="checkbox"/> Individuals with diminished mental capacity | <input type="checkbox"/> Active duty military personnel |
| <input type="checkbox"/> Pregnant women | <input type="checkbox"/> Veterans |
| <input type="checkbox"/> Children | <input type="checkbox"/> Prisoners |
| | <input type="checkbox"/> Other special considerations |
| | <input type="checkbox"/> N/A |



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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. Recruitment and Informed Consent (IC) Process.

- | | | | |
|---|------------------------------|-----------------------------|------------------------------|
| Recruitment Method Used | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Describe recruitment materials here: | | | |
| Adequate Recruitment and Screening Process | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| IC Process is Adequately Described in Protocol | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Key Information presented up front in the ICF | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| ICF states DoD Conducted/Supported Upfront in the ICF | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Separate Consent Provided for Testing for Communicable Diseases | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Separate Consent Provided for Genetic Testing | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Separate Consent for Use of Samples in Future Research (if appropriate) | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Assent Form Included for Minors | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |



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- | | | | |
|---|------------------------------|-----------------------------|------------------------------|
| Legally Authorized Representative (LAR) signature solicited | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Provision for Illiterate Subjects | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Compensation Listed | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Translation(s) Included | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Verification of Translation(s) Included | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Confidentiality Section, included that USAMRDC or DoD representatives will review for regulatory purposes | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |

[Briefly summarize the recruitment plan/process, timing of screening (e.g. if before consent) and description of the consent process. This section can also address the following: setting, subject autonomy concerns, language difficulties, document storage, adequate description of compensation, compensation for injured research subjects, comments about adequacy of documents or procedures, risks, OHRO 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), as applicable, identification of missing elements of the Informed Consent Form (ICF), any extra costs to subjects for their participation in the study, etc. Describe the role of Legally Authorized Representatives in the consent process. For OCONUS studies, please describe the consenting process for emancipated minors, as applicable.]

10. 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).]

11. 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, data risks (refer to Data Risk form), etc. Distinguish risks identified in the protocol and consent form from potential risks identified by the HSPS by *italicizing* HSPS comments.]



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Procedure	Risks	Measures to Minimize Risks

12. 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 if the subjects cannot consent for themselves.]

13. U.S. FDA Regulatory Elements. Yes No N/A

a. IND/Drugs/Biologics/Combination Product.

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

Drug Storage and Accountability Addressed Yes No

Plan for Disposition of Unused Drug Addressed Yes No

IND Exempt Yes No Reason:

Sponsor’s Clinical Monitoring Plan Provided Yes No N/A

Financial Disclosure Forms Completed Yes No N/A

Form 1572 Completed Yes No N/A



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Other

Device/Combination Product

Manual Brochure or information is Provided: Yes No N/A

Version/Date of Product Information

[Provide a brief description of the test article, device, combination product, 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

Identify the safety board 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/USAMRDC Unique Requirements Adequately Addressed in Protocol.

- | | | | |
|---|------------------------------|-----------------------------|------------------------------|
| Current Curricula Vitae for all investigators and Consultants listed on the protocol | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Current Human Subjects Training Certificates for all investigators listed on the protocol | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Current Signed COI Forms | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Reporting of Adverse Events | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Protocol Modifications / Amendments | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Protocol Deviations | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Unanticipated Problems | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Review of Research Records by DoD Representatives in Protocol and ICF | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Medical Care for Research Related Injury | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |



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Continuing Review/Progress Report and Closeout Study Reports	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Recruitment Issues / Ombudsman	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
10 USC 980	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Recruitment of Military Subjects / Confidentiality Issues – Use of Ombudsman	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Supervisor Approval Form for Military Subjects	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Payment to Military Personnel	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Genetic Information Nondiscrimination Act Language	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

[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 the Study Team must meet/receive prior to Study Initiation:

Letters of Support:	<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	<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
OHRO Approval	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Data Security (Approval?)	<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.]



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- 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 parent/guardian form.
- e. Revisions to be made to the assent form.
- f. Revisions to be made to the sample donation form.
- g. Revisions to be made to advertisements/recruitment posters.
- h. Revisions to be made to the Briefing Slides.
- i. Revisions to the International Form.
- j. Revision to Other Documentation
- k. Minor Administrative Revisions

19. Points to Consider.

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

NAME, credentials
Human Subjects Protection Scientist
HSPB, WRAIR