SOP Title	**APPENDIX 2 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB**	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	1 of 3

WRAIR Human Subjects Protection Branch (HSPB) Abbreviated Protocol Evaluation Form (PEF)

WRAIR #

PI Name:

PI Qualification Summary Provided: ☐ Yes ☐ No ☐ N/A

WRAIR POC (if different than 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:
ICF Version/Date:

SSA Principal Investigator:

International Study (Yes/No):

Study Design	☐ Single site	☐ Multicenter	☐ Sub-Study
Risk Level	☐ GTMR	☐ MR	☐ Exempt
	☐ NHSR	☐ NR	☐ TBD
Type of Study	☐ Drug Study	☐ Device Study	☐ Surveillance
	☐ Participation	☐ Other: [describe]	
	☐ Other: [describe]	☐ Combination Product: IND or IDE 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. Regulatory Section:

[Outline the regulations and regulatory requirements to be met by the study, please keep in mind that 45 CFR 46 applies as well as 32 CFR 219 if non-DoD personnel are engaged in human subjects research (e.g. other U.S. institutions or OCONUS sites). If minimal risk, does the study meet the requirements for expedited review? What are the categories? What other special considerations need to be followed? If a regulated product is being used what is the status of the IDE/IND/EMA/regulatory submission, as applicable? Does this need to be submitted to another country's equivalent to the U.S. FDA for approval? Does this require IBC review? Does this study meet the criteria for review under 10 USC 980? If so, does it provide for an individual benefit to each subject who cannot consent for themselves (i.e., children or mentally incapacitated persons)?]

3. Background. [Include the study objectives and a brief description of the study design, inclusion/exclusion criteria and study population. 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 study duration will be less than or extend beyond 5 years, etc.]

4. 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 parent/guardian form.

e. Revisions to be made to the assent form.

f. Revisions to be made to the future use donation form.

g. Revisions to be made to advertisements/recruitment posters.

h. Revisions to the International Form.

i. Revisions to Other Documents.

j. Minor Administrative Comments

5. 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
HSPB, WRAIR