SOP Title	APPENDIX 3 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	1 of 20

WRAIR HSPB Protocol Checklist (Preparatory to PEF)

WRAIR #:_____ PI: _____

Element	(✓) if required for research type				Notes
	NR	NHSR	MR	GTMR	
Cover memo signed thru Department Chief, Branch Director and/or OCONUS Director.	✓	✓	✓	✓	If NHSR: Then the Branch Director cannot sign for Scientific Review if they are on the protocol – Chief Science Officer (Peterson) or Deputy Commander must sign for them. If MR or GTMR: If submitting PI is the Branch Director, submission memo must be signed by the Chief Science Officer or Deputy Commander to attest to the study's military relevance and resources. The protocol will undergo an independent scientific review process.
Version Control of Submitted Documents- • Protocol title used consistently on all documents • Multi-center protocol proposal referenced appropriately (e.g., site specific addenda). • Each page of the protocol, consent forms, case report forms, subject diary, recruitment materials, tests of understanding, etc., must have version number and date. • 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.	✓	✓	✓	✓	**Note: Draft protocols are not accepted. However, we do accept draft copies of the CRFs and clinical monitoring plans as long as they are specific to the study and are not templates. We ask that these be finalized for Commander Approval Authorization.** Also, the protocol should be a sponsor approved version.

SOP Title	APPENDIX 3 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	2 of 20

Element	(✓) if required for research type				Notes
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International Research Study Information Form			✓	✓	Required for all international studies, including sites under WRAIR's HRPP (i.e., USAMRD-A, USAMRD-G, AFRIMS)
Data Security Form			✓	✓	Required for all MR and GTMR studies.
Submission Checklist	✓	✓	✓	✓	This must be completed and signed by the PI/ WRAIR POC. If not signed, it is considered incomplete. If items are missing, then the STUDY TEAM must obtain, fill and submit a SIGNED copy of the waiver. **HSPB staff – Do not proceed with the PEF until all items in checklist are addressed and present!**
PI Signature page	✓	✓	✓	✓	This is needed with both initial version and final versions of the protocol. Note: This can be a sponsor specific document or the WRAIR version. **If the sponsor version does not have all of the reporting elements as outlined in the WRAIR version, the WRAIR HSPB signature page must be provided as well.**
Sponsor/Executive Authority and specific funding information (i.e., core funding, extramural grant from MRDC, CRADA, contract #s) in the body of the proposal. Preferably on the front page.	✓	✓	✓	✓	

SOP Title	APPENDIX 3 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	3 of 20

Element	(✓) if required for research type				Notes
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List of all investigators involved in the study and a detailed description of their roles and responsibilities complete with contact information and affiliations. Personnel conducting the research are appropriate for their assigned roles and responsibilities. Please note that investigators cannot have dual affiliations; please list only one affiliation for each investigator. Please ensure that provisions are in place for AIs to serve in place of the PI in the event that the PI is deployed or away due to an emergency (AR 70-25, 3-1p., 3-1q.)	✓	✓	✓	✓	Be sure that all investigational tasks are covered- especially who is consenting potential subjects. Anyone with investigator in their title must provide their credentials (CV) and training (CITI).
Consultants • If assisting with technical advising/manuscript preparation and writing ONLY, then a determination from their institution is **NOT** needed. • If they are dealing with data/data** analysis, a determination from their institute **IS** needed.	✓	✓	✓	✓	** If working with aggregate data, then determination is not needed. However, a copy of his/her CV is still required. CITI/HSP Training Certificate and CV are only required if he/she is dealing with data/data analysis. If this is the case, we will need a determination/review from their institution.
Ombudsman- If military personnel are being recruited in formation or *en masse*. US troops only.			✓	✓	Refer to DODI 3216 to ensure the listed roles and responsibilities are accurate. The IRB will determine if an ombudsman is required for a MR study.
Collaborators	✓	✓	✓	✓	Refer to DODI 3216 to ensure the listed roles and responsibilities are accurate. OHRO must review for any Non-DoD Collaborators listed receiving DoD

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					funding. We need one for each institution: NHSR determinations IRB approvals. For MR and GTMR studies, IRB agreement relying on another institution for all US IRBs. **If there is non-DoD collaborator or if the study is funded by the HJF cooperative agreement - automatically submit for HRPO review** For NHSR studies where we are the lead, we can issue a limited NHSR memo. For NHSR studies where we are NOT the lead, we require the determination from the lead PI's site before issuing the NHSR memo. In such cases, the determinations from the other participating institutions should be provided once available. CV and CITI needed also, depending on their role.
Protocol Chair and Co-Chair			✓	✓	Depending on their role (i.e., acting more than just consultants), we will require CV and CITI/HSP Training Cert.
Curriculum Vitae(s) for Principal Investigator(s), Associate Investigator(s) and WRAIR POC (if applicable).	✓	✓	✓	✓	CVs must be dated, signed and current (within two years of initial submission). Bio sketches are acceptable.

SOP Title	**APPENDIX 3 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB**	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	5 of 20

Element	**(✓) if required for research type**				**Notes**
	NR	NHSR	MR	GTMR	
Human Subjects Protection Training Certificates for all investigators, Research Monitor (if applicable to the study), and ombudsman (if applicable). (Refer to WRAIR Policy #26, Initial and Continuing Human Subjects Protection Education and Training Requirements for details)	✓	✓	✓	✓	(NOTE: The PI must maintain the certificates for all site support staff in the study file). Must be current within the last three years- be aware of expiration dates within a year of the submission. We can accept outside institutional policies and training if they exist and they do not fall under our FWA. Must obtain a copy of their current training policy to have on file. However, if the institution falls under our FWA or they do not have a training policy, they must follow our training requirement.
Conflict of Interest Forms for investigators, Research Monitor (if applicable) and ombudsman (as applicable).			✓	✓	For device, drug, biologic, or combination product studies (US FDA regulated trials).
Recombinant DNA Advisory Committee (RAC) Approval for gene transfer research, if appropriate. (This may include Office of Biotechnology Activities (OBA) review.)		✓	✓	✓	IBC must review and approve all research projects involving hazardous biological materials including recombinant DNA and RNA as defined by the NIH guidelines. Dual use and select agents are also included for IBC review.
WRAIR/NMRC Biosafety review and approval	✓	✓	✓	✓	Will review all protocols for human subjects, Vet Med, BSL-3 and BSAT. Note: Public Health activities where infectious agents are being used may also require Biosafety review.

SOP Title	**APPENDIX 3 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB**	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	6 of 20

Element	(✓) if required for research type				Notes
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This protocol involves an investigational product (New drug, vaccine/biologic, device, combination product, or off-label use of an approved product). ___ Current Investigator's Brochure(s), package inserts, to include package inserts for placebos or standard of care if the investigational product is being compared to standard of care. ___Completed and signed U.S. FDA Form 1572 (if U.S. FDA Regulated and has an IND or IDE submission). ___ Data and Safety Monitoring Board (DSMB) or Safety Monitoring Committee (SMC) or Independent Data Monitoring Committee (IDMC) membership and charter.		✓	✓	✓	Required for all investigational product studies. If WRAIR's role is NHSR, and is providing lab support on a GTMR study, we must have these items, as well.
Description of Investigational Drugs/Biologics or Devices, Combination Product is adequate.		✓	✓	✓	Ensure regulatory status of the investigational drugs or biologics, devices, combination products is included in the protocol and ICF. For Device studies that are exempt from IDE regulations, they don't need to abide by the adverse device events reporting requirements.
For first-in-man studies, dose staggering is applied.				✓	**automatically submit to OHRO for HLAR review and approval**
Check all that are applicable: ___Use of an U.S. FDA Approved Product as the focus of the study (21 CFR Parts 50 and 56)		✓	✓	✓	If they will be abiding by U.S. FDA regs, the protocol should mention they will abide by the ICH guidelines.

SOP Title	**APPENDIX 3 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB**	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	7 of 20

Element	**(✓) if required for research type**				**Notes**
	NR	NHSR	MR	GTMR	
___Use of European Medicines Agency (EMA) Approved Product ___Local Approved Product (Country:_____) ___Statement from the manufacturer regarding the safety of the drug/vaccine/biologic/device.					
Sleep study? Are they using WRAIR actigraph?			✓	✓	If WRAIR is lending any equipment to someone else, they should detail the terms of that loan. Reporting of equipment failure or loss, as well as, replacement plan.
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*) * Best Practices refers to Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) Guidelines	✓	✓	✓	✓	Date of scientific review: The SRC reviews currently accepted by WRAIR are the following: AFRIMS PSRC (DAIDS) - Prevention Sciences Review Committee CSRC (DAIDS)- Clinical Science Review Committee For NR/NHSR/Exempt- Branch Director must sign off on scientific validity (submission memo), if there is a conflict of interest it must be signed off by Chief Science Officer, or Deputy Commander If WRAIR is relying upon another SRC, request proof of SRC review.

SOP Title	APPENDIX 3 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	8 of 20

Element	(✓) if required for research type				Notes
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Institutional Committee(s) Review. As appropriate, review by Radiation Safety Committee, Institutional Biosafety Committee, Biomedical Engineering Committee, other is completed. PI has responded appropriately to recommendations. (AR 70-25, 3-2c.(4))		✓	✓	✓	Date(s) of approval: Note: BSC approval/determination memo should be received for all AFRIMS studies regardless of risk determination.
OHRO Review: Include rationale for Headquarters Level Administrative Review (HLAR), HRPO, or CLAR review. (Per MRDC Policy, 21; e.g., study population, funding, etc.)	✓	✓	✓	✓	Date(s) of review: *Other notes indicate which triggers HLAR, HRPO or CLAR review Non DoD collaborators receiving DoD funds trigger review. WRAIR reliance on a non-DoD IRB DoD support where a non-DoD institution is conducting the work. Work being performed outside our HRPP. Depending on source of specimens, some secondary use of specimens will trigger review-reference OHRO Guidance (10 April 2017) for specific situations. Send to OHRO after IRB approval. When MRDC OHRO relies upon another for HRPO review,

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					OHRO should be contacting the other office and copying us, we will need to wait for documentation of that review before issuing Commander Authorization/start of study. For NHSR studies that meet certain criteria, you may use the 17 November 2022 Memorandum "Waiver of DoD-Unique Human Subjects Protection Requirements When USAMRDC Subordinate Commands Provide Assistance to Non-DoD Institutions
Study Locations. A list of all facilities and study locations are provided. (AR 70-25, App B-3)	✓	✓	✓	✓	Information regarding the study sites has to be included in the protocol. For example, for the hospitals out of the country the number of beds, personnel, general characteristics of the hospital and area of service should be included for better understanding if this site is qualify for conducting research. Information regarding the geographical location of the hospital/ research center, average distance between the site and the area where the potential participants live, how the participants will be able to reach the center for their enrollment/procedures/ follow ups.

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Collaborative Research. All collaborating institutions and corresponding assurances are listed. FWAs and IRB registrations are valid (use this website: https://ohrp.cit.nih.gov) If an Assurance must be negotiated (DoD Single Project Assurance, Multiple Project Assurance or OHRP Federal Wide Assurance) they need to have completed Assurance Documents			✓	✓	Reliance agreements between institutes or for individuals may be required for MR or GTMR studies. Reliance agreements do not apply to NR/NSHR studies. **If there is a non-DoD collaborator- check if it qualifies for MRDC waiver before submitting to OHRO for review and approval** Note: The agreement may require the approval of OHRO if we are relying on a non-DoD collaborator.
Non-WRAIR IRB approval documents attached or communication that they are pending.	✓	✓	✓	✓	
Protocol Timeline. Study Duration (AR 70-25, App B-4)	✓	✓	✓	✓	
Purpose(s) of the study, research objectives, questions, and/or hypotheses are provided. (AR 70-25, App B-5)	✓	✓	✓	✓	Provide historical background regarding previously conducted similar studies or studies that were investigated the same drug/device/combination product/hypothesis and their results
Military Relevance of the study is clearly stated.	✓	✓	✓	✓	Some studies without military relevance (e.g., sickle cell disease in newborns) will require a special approval from the Commander or CSO or Strategic Planning Committee. A separate memo can be submitted as proof of the approval from the IO. There should still be a military relevance section outlined in the protocol for those studies requiring

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					special approval.
Research design is described. (AR 70-25, App B-5, App B-6).	✓	✓	✓	✓	
Subject identification. Code system to be used to maintain subject identification is described. (AR 70-25, App B-5, App B-6)	✓	✓	✓	✓	NHSR studies need to identify that WRAIR Investigators will not receive any PII; the information will either need to be anonymized or coded and state that they will not have access to the key. Note: Avoid the term “de-identified” make sure the protocol utilizes one of the 3 defined terms: coded, anonymized and anonymous.
Subject assignment. Randomization process or other procedures used for subject group assignments is described. (AR 70-25, App B-5, App B-6)	✓	✓	✓	✓	
Target and all vulnerable populations are described. (AR 70-25, App B-5, App B-6). (e.g., children, pregnant women, prisoners; Screened vs. enrolled; Will there be replacements for withdrawals; what kinds of specimens used, be sure there is a cap on replacements) For protocols utilizing samples only, be sure there is a definitive number of samples being included in the study.	✓	✓	✓	✓	NHSR studies should describe what population the samples came from, if that information is known. AVOID the word “approximate” – pay attention to the data analysis section especially. Have them define specific numbers involved.

Element	(✓) if required for research type				Notes
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Sampling method is described.	✓	✓	✓	✓	
Inclusion and exclusion criteria are listed. (AR 70-25, App B-6)-		✓	✓	✓	Must also include if overarching protocol is GTMR but WRAIR involvement is NHSR.
Pregnancy exclusion procedures. If applicable, addresses pregnancy testing and contraceptive practices. (AR 70-25, App B-6) (Cultural sensitivities?)		✓	✓	✓	Must also include if overarching protocol is GTMR but WRAIR involvement is NHSR.
The recruitment process is described and recruitment and/ or advertisement materials provided. (21 CFR 312.7; AR 70-25, 3-1p.; Best Practices; U.S. FDA Information Sheet, "Recruiting Study Subjects")		✓	✓	✓	Must also include if overarching protocol is GTMR but WRAIR involvement is NHSR.
Screening procedures. Evaluations (lab, history, physical exam) to determine eligibility are clearly described. (AR 70-25, B-6, 7)		✓	✓	✓	Must also include if overarching protocol is GTMR but WRAIR involvement is NHSR.
Informed consent process takes place prior to the subject participating in the research. The possibility of coercion and undue influence is minimized. The consenting process described in the protocol? The consenting of illiterate subjects (reader) and assenting of minors/incapacitated (LAR) or recruitment of military personnel in formation (ombudsman) described. (32 CFR 219.116; AR 70-25, 3-1a.,f.,j.; Best Practices) U.S. Military personnel must also have a Supervisor/Commander approval to participate if they are to participate regardless of the timing of their participation (on or off duty hours) - WRAIR Policy 28.		✓	✓	✓	Consent of Legally Authorized Representative (LAR). If subjects cannot give their own consent to participate in the study, there is a plan for consent of the individual's LAR to be obtained prior to the subject's participation in the study. (AR 70-25, 3-1o.(3); Best Practices) ICFs should have a space to capture thumbprint or the mark of illiterate subjects and should have a space for an independent witness to sign. Consent for Medical or Surgical Procedures.

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If this is an international study, study team must submit the ICDs in the language of the population along with translation verification forms. Verification document must have the name of the translator.					Procedural consents for standard procedures performed as part of the research study and HIV consents are provided, where appropriate. (Best Practices) - This may be embedded in the main ICF and not as a separate document. If overall protocol is GTMR and WRAIRs involvement is NHSR – we still need to review. If the original protocol was not reviewed and approved at the WRAIR and the WRAIR is doing post-study analysis, we must review consent documents to prove that subjects agree to have samples/data stored for future use.
Benefits. Benefits of research to subjects are appropriately described. Note that if there are no benefits, this should be stated. Payment for research participation is not a benefit. (AR 70-25, App B-6)		✓	✓	✓	For GTMR studies involving children and/or mentally incapacitated persons, there should be intent to benefit each subject enrolled. The benefits should be described in the protocol. Must include if overarching protocol is GTMR but WRAIR involvement is NHSR.
Intent to Benefit. If subjects cannot give their own consent to participate in the study, there is intent to benefit each such subject enrolled in the study, if the subject is an experimental subject. (10 USC 980; AR 70-25, 3-1o.; Best Practices)		✓	✓	✓	Must also include if overarching protocol is GTMR but WRAIR involvement is NHSR.
Is risk/benefit ratio described in relation to current standard of care?		✓	✓	✓	Must also include if overarching protocol is GTMR but WRAIR involvement is NHSR.

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Is compensation listed? Is it consistent between sites? Do they address between scheduled and unscheduled study visits? Compensation of federal or military personnel- only on off hours etc. (Refer to DoDI for specifics)		✓	✓	✓	Compensation can NEVER be listed as a benefit. Ensure the U.S. dollar equivalent and the local currency is described in the protocol for international studies. Be sure for international studies, average annual income is included in the international research form so relative value of compensation can be evaluated.
Laboratory Evaluations. Data collection procedures are described (e.g. lab evaluations, specimens, special precautions, labeling and storage) (AR 70-25, B-7)	✓	✓	✓	✓	Clarify in the protocol that if the test results are received from the not-approved or investigational testing assays/ devices, the results will not be used for diagnostic purpose, only for research.
Clinical Assessments. Clinical assessments, for example schedule of clinical evaluations and follow-up procedures, are described. (AR 70-25, B-7, B-11)		✓	✓	✓	
Is there explicit consent for testing of communicable diseases, genetic testing, whole genome sequencing, or future use of samples? HIV counseling if the participant is tested positive.	✓	✓	✓	✓	If genetic testing is to be conducted, a description of the tests is provided, associated risks, and it is explained whether or not the results will be relayed to the subject(s) (GINA Non-Discrimination Act of 2008). GINA language is only applicable to US studies. Clarify in the protocol if the samples/images/device readings would be sent to another country for additional testing at the collaborating labs/institutions and the new findings, that have a clinical impact, will be reported/not reported back to the participants. Need to explicitly state whether or not whole genome sequencing will be conducted.

SOP Title	**APPENDIX 3 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB**	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	15 of 20

Element	(✓) if required for research type				Notes
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					IF no genetic testing will be done on samples, that should also be explicitly stated.
Consent for future research purposes	✓	✓	✓	✓	For NHSR studies, the studies that provide the samples/data must indicate proof that participants agreed to their samples/data being used for future use and for the purposes outlined in the study. This may have been a separate document or embedded in the main ICF.
Research instruments (Research instruments, such as case report forms, data collection forms, questionnaires, rating scales, and interview guides) are described and included in submission. (AR 70-25, Apps B-6, B-7, B-9, B-11; Best Practices)		✓	✓	✓	
Data analysis plan is outlined. (AR 70-25, App B-6, App B-7)	✓	✓	✓	✓	
Disposition of samples. Identify who is performing analysis, if they will be sent out of the country, where will they be stored, the duration of storage, and whether samples will be destroyed or retained for future use, and if there is any commercial applicability.	✓	✓	✓	✓	When, how and who will destroy the samples?
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)	✓	✓	✓	✓	When, how and who will destroy the data?
Confidentiality. Where appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. Those with access to study documents are identified (e.g.,		✓	✓	✓	

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U.S. FDA, USAMRDC, Sponsor, etc.). (AR 70-25, Apps B-6, B-7, E-7; Best Practices)					
For extramural studies, there should be a statement that representatives of the US DOD may inspect the records. (AR 70-25 App E-7; Best Practices)	✓	✓	✓	✓	
Risks. Risks to subjects and study personnel are adequately described, to include breach of confidentiality and social harms, as applicable. (AR 70-25, App B-6; Best Practices)		✓	✓	✓	Blood Draw Note- be sure that protocol and ICF specify total volume of blood being collected, not just the volume needed for testing. Blood volumes should include the amounts in tablespoons as well. Subjects should avoid participating in consecutive multiple blood draw studies that require excessive amounts of blood until a certain period of time has passed to ensure blood amounts remain within the acceptable limits as stated within the Code of Federal Regulations.
Precautions. Measures to be taken to minimize or manage risks to subjects and study personnel are described. (AR 70-25, App B-6)		✓	✓	✓	
Special care needs. Special medical/nursing care and equipment that will be needed for subjects are described. (AR 70-25, App B-6)	-	✓	✓	✓	
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)	✓	✓	✓	✓	Use Special NHSR language – See HSPB Template Team

SOP Title	**APPENDIX 3 CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB**	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	17 of 20

Element	**(✓) if required for research type**				**Notes**
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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)	✓	✓	✓	✓	Use Special NHSR language – See HSPB Template Team
The consequences of a subject's decision to withdraw and procedures for orderly end of subject's participation are described, if appropriate. A description of what happens to data/samples for withdrawn subjects is provided. (32 CFR 219.116(c)(4); AR-70-25, App E-9, App E-11)		✓	✓	✓	Must also include if overarching protocol is GTMR but WRAIR involvement is NHSR.
Anticipated circumstances under which the subject's participation may be terminated by the investigator are described, if appropriate. (32 CFR 219.116(c)(2); AR 70-25 App E-11)		✓	✓	✓	Must also include if overarching protocol is GTMR but WRAIR involvement is NHSR.
Adverse Event Reporting. Plan for reporting AEs to subject included in protocol. [AR 70-25, 2-9c.(4), App B-9; Best Practices]		✓	✓	✓	NHSR/MR protocols may or may not have adverse events depending on whether they are evaluating an investigational product. If no product - include the UAP language ONLY. Must also include if overarching protocol is GTMR but WRAIR involvement is NHSR.
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]		✓	✓	✓	See note above.
Local Reporting requirements adequately addressed and incorporated		✓	✓	✓	For International studies- these cannot just be referenced, they should be specified. (This includes regulatory requirements)
Medical Care for Research Related Injury. For research involving more than minimal risk and conducted in a USAMRDC facility or by a USAMRDC PI, suggests the consent form language for medical care for research related injuries (see USAMRDC Policy 26,			✓	✓	This is not required for minimal risk studies that do not involve investigational products/devices/combination products or do not involve the study of approved regulated products.

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Medical Care for Research Related Injury in Human Research conducted by the USAMRDC, dated 07 December 2020). For all other research refer to this policy for determination of medical care for research related injury. Also, follow-up with JAG, as needed.					
Continuing Review/ Progress Report Language			✓	✓	
Closeout Report Language	✓	✓	✓	✓	We will default to the five year plan unless the protocol and/or the study team explicitly states the timeframe that will be needed. The study team must submit a close out report (MR/GTMR) or closeout notification (NR/NHSR) to WRAIR or ask for an extension (if applicable).
Student project?		✓	✓		Items/Information the WRAIR HSPB will need for student project proposals: 1) Identify whether the project is a stand-alone project or if the work will fall under another existing protocol; 2) If the work will fall under another protocol, we require the delegation log to confirm the student is authorized to work with samples/data from the 'parent' protocol; 3) CITI training (HSP training expires every 3 years); 4) CV of the student - updated within the last 2 years - must demonstrate that the student has been working at the location of the study during the timeframe outlined in the study's delegation log ,

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					and affiliation of the student on the CV must match that of the delegation log, 5) the protocol must have a section describing how it is relevant to the military and its mission; and 6) funding must come from the DoD, at least in part.
Human Bait/Lure Study		✓	✓	✓	Consult with HSPB leadership. If a protocol is collecting only mosquitoes and does not use repellents of any kind, to include spatial, treated clothing, topical, spray, etc. then the study is not human subjects research. If using repellents (topical and/or spatial), this would need to be reviewed by the IRB, as there is the potential for the human participants to be exposed to the repellents and the safety factors must be taken into consideration.
Involvement of Emancipated Minors			✓	✓	Emancipated minors are considered adults and therefore the regulations pertaining to children will not apply for this population. The protocol and consent form should specify if this population is being recruited.
Clarification of Investigators' Affiliations	✓	✓	✓	✓	Affiliations need to be clear to determine the path of money and funding, as well as the appropriate business agreements. Investigators cannot have more than one affiliation.

SOP Title	**APPENDIX 3** **CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB**	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	20 of 20

Additional Comments: