SOP Title	**APPENDIX 4a CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB**	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	1 of 7

WRAIR HSPB Informed Consent Document (ICD) Checklist (Preparatory to PEF)

WRAIR #: _____ PI: _____

Date: _____ Reviewer: _____

Elements	Is Element Addressed? Yes	No	N/A	Comments
A. Research Description.				
1. Title and location of study consistent with protocol. (AR 70-25, App E-1; Best Practices*) Version is consistent.				
The Sponsor and funding information are on the first page of the ICF.				
The consent begins with concise and focused presentation of the "key information" that includes reasons why one might want to or not participate in research (32 CFR 219.116(a)(5)(i)):				
a) A statement that the project is research and that participation is voluntary				
b) A summary of the research including i. Purpose ii. Duration iii. List of Procedures				
c) Reasonable, foreseeable risks or discomforts (include likely and/or serious risks)				
d) Reasonable, expected benefits				
e) Alternative Procedures or course of treatment, if any				
2. A statement that the study involves research and an explanation of the purpose and objectives of the research. (32 CFR 219.116(b)(1); AR 70-25, App E-3; Best Practices) (May be answered in the key information section)				
3. Include a statement that the Department of Defense is either supporting, funding, and/or conducting the research, as appropriate; this statement should be included in the beginning of the consent form.				

Elements	Is Element Addressed? Yes	No	N/A	Comments
4. The expected duration of the subject's participation. (Best Practices) (May be answered in the key information section)				
5. The number of subjects in the entire study, as well as, the number of subjects at the site, if a multicenter trial. Need to also outline the number of subjects to be screened at the site. (32 CFR 219.116(c)(6); AR 70-25, App E-11f.;, App B-2f. ; Best Practices)				
6. A description of the procedures followed, and identification of any procedure that is experimental. (Best Practices) (May be answered in the key information section)				
7. Inclusion and exclusion criteria (summarized in layman's terms. (Best Practices)				
8. Pregnancy. Address pregnancy testing and contraception, if applicable. Include what will happen in the event of pregnancy. Follow-up only or will pregnant subjects continue with experimental procedures? Pregnancy of partners of male participants addressed? (Best Practices)				
9. Information about prior, similar, or related studies. (AR 70-25, App E-3)				
10. Description of any genetic testing to be conducted, associated risks, and inclusion of GINA language, as applicable. Additionally, subjects are informed if they will receive genetic test results, and if not, why. (Genetic Information Nondiscrimination Act of 2008 for U.S. sites only)				
11. HIPAA addressed for those studies conducted in the U.S. with U.S. citizens?				
12. For research involving biospecimens, participants are informed of whether the research will (if known) or might include whole genome sequencing (WGS) (32 CFR 219.116(c)(9)).				
B. Risks.				
1. Description of reasonably foreseeable risks and discomforts, to include breach of confidentiality and social harms, and methods for minimizing them. These should be identified in the beginning of the consent form (32 CFR 219.116(b)(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(c)(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.)				

Elements	Is Element Addressed?			Comments
	Yes	No	N/A	
4. Investigational New Drugs, Investigational devices, and/or Combination Products, and placebos, as applicable, are described. (Best Practices)				
C. Benefits.				
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)				
1. Description of benefits to the subject or others. If this study is GTMR to which 10 USC 980 applies, ensure that there are direct benefits for each participant in the study that cannot consent for themselves, and that these benefits are clearly explained. (32 CFR 219.116(b)(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.)				
3. Clinically Relevant Results: a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (32 CFR 219.116(c)(8)).				
D. Alternatives to Participation (if applicable). Disclosure of appropriate alternative procedures or courses of treatment, if any, which may be advantageous to the subject. (32 CFR 219.116(b)(4); AR 70-25, App E-6; Best Practices) (May be answered in the key information section)				
E. Payment/Costs.				
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(c)(3); AR 70-25, App E-11c.; Best Practices)				
F. Possible Sample Donation/Commercial Products. (AR 70-25, 3-1c., 3-1d.) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit (32 CFR 219.116(c)(7));				

Elements	Is Element Addressed?			Comments
	Yes	No	N/A	
G. Medical Care for Research Related Injury. For research involving more than minimal risk and conducted in a USAMRDC facility or by a USAMRDC PI, the suggested consent form language for medical care for research related injury is in the USAMRDC Policy 26. For all other research also refer to this Command Policy Memo for determination of medical care for research related injury. (32 CFR 219.116(b)(6); AR 70-25, 3-1k.; Best Practices; Command Policy Memorandum 2013-10, Medical Care for Research Related Injury)				
H. Confidentiality.				
1. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. (32 CFR 219.116(b)(5); AR 70-25, App E-7; Best Practices)				
2. For investigational drug, biologic, device, or combination product studies, a statement that WRAIR, U.S. FDA and MRDC representatives may review the records. As well as the Sponsor or Sponsor's Representative (CRO) may review the study records, if applicable. For contractor studies, a statement that U.S. 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 or voice recordings 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.)				
5. If the study is U.S. FDA-regulated, ensure the following statement is included: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time."				

Elements	Is Element Addressed?			Comments
	Yes	No	N/A	
6. FOR CLINICAL TRIALS: The Revised Common Rule (45 CFR 46), as codified by 32 CFR 219, requires clinical trials to post one IRB-approved consent form that has been used to enroll subjects on a public federal website. The WRAIR is requiring that clinical trials' informed consent documents be uploaded to www.ClinicalTrials.gov. Directions to post the informed consent documents can be found here: https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html. The consent form must be posted after enrollment closes, and no later than 60 days after the last study visit. Status of this posting will be requested in the next progress report/continuing review report.				
I. Participation and Withdrawal.				
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(b)(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. Also, parent/guardian/LAR consent will be needed for those who provide assent and those who cannot assent for themselves. (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(c)(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(c)(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(c)(5); AR 70-25, App E-11e.; Best Practices)				
J. Future Research				
A statement that participants' information or biospecimens collected as part of the research will or will not be used or distributed for future research, even if identifiers are removed 32 CFR 219.116(b)(9)(ii),				
Brief discussion of data/specimen disposition plan.				
K. Contact Information Provided.				

Elements	Is Element Addressed?			Comments
	Yes	No	N/A	
1. Whom to contact with questions about the research, including name or office and telephone numbers. (32 CFR 219.116(b)(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(b)(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(b)(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)				
5. Name of Sponsor.				
6. Name of funder(s).				
L. Documentation.				
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 non-U.S. citizens or 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; 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)				
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. If applicable, explain whether samples will be sent out of country. (AR 70-25, 3-1c., 3-1d.)				
7. Justification to have subject ID/SSN on ICD.				
8. 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. Also, Hep B and Hep C testing may also be required and may be reportable (positives are reportable in Maryland).				

Elements	Is Element Addressed?			Comments
	Yes	No	N/A	
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(a)(6))				
2. The document avoids used 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. (U.S. 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. (U.S. FDA Guide to Informed Consent)				
e. Presents information in a way to facilitate subject understanding and decision making. Concise and focused. 32 CFR 219.116(a)(5)(ii)				
f. Appropriate translation and certificate of translation provided, as applicable.				
N. Supportive Materials – Any additional information used in the consent process has been reviewed (e.g., information sheets, videos, visit schematic).				