DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
503 ROBERT GRANT AVENUE
SILVER SPRING, MD 20910-7500

8 Feb 2021

FCMR-UWZ (1oo)

MEMORANDUM FOR All Personnel, Walter Reed Army Institute of Research (WRAIR)

SUBJECT: WRAIR Policy #24, Submission of Protocols Involving Human Subjects, Human Information or Biospecimens, for Scientific and Ethical Review

1. References.

a. Commerce and Trade, 15 United States Code (U.S.C.) §§ 3701-3724 (2017).

b. National Defense, 32 Code of Federal Regulations (C.F.R.) §§ 219.101-219.124 (2018).

c. Food and Drugs, 21 C.F.R. §§ 50.1-50.56 and §§ 56.101-56.124 (2018).

d. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Biomedical and Behavioral Research),1979.

e. Department of Defense (DODD) 3216.02 (Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research), 8 November 2011.

f. U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP) (Guidance on Engagement of Institutions in Human Subjects Research), 16 November 2008.

g. Army Regulation (AR) 70-25 (Use of Volunteers as Subjects of Research).

h. AR 70-41 (International Cooperative Research, Development, and Acquisition).

i. AR 70-57 (Military–Civilian Technology Transfer).

j. Message, ALARACT 031/2008 (Army Human Subjects Protection Requirements), 14 February 2008.

k. U.S. Army Medical Research and Development Command (USAMRDC) Policy #12 (Requirements for Initial and Ongoing Education and Training in the Protection of Human Subjects in Research), 16 March 2020.

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*This supersedes WRAIR Commander's IRB Policy #1, dtd 10 June 2019.

l. WRAIR Policy #25 (Determination that an Activity is Research Involving Human Subjects).

m. WRAIR Policy #26 (Initial and Ongoing Human Subjects Protection Education and Training Requirements).

n. WRAIR Policy #27 (Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training).

o. WRAIR Policy #28 (Compensation to Federal Personnel when They Participate in Research as Human Subjects).

p. WRAIR Policy #29 (Assignment of Principal Investigators to Human Subjects Research Conducted under the WRAIR HRPP).

q. WRAIR Policy #31 (Final Approval Authorization for Human Subjects Research Protocol Implementation).

2. History. This policy is being issued in accordance with WRAIR and USAMRDC requirements. This version of the policy includes revisions aligned with current Army and USAMRDC policies, and minor editorial changes. This version of the policy will remain in effect until amended or rescinded.

3. Purpose. This policy establishes the criteria for submission of protocols involving human subjects, human specimens, and/or human data to the Human Subjects Protection Branch (HSPB). The Commander, WRAIR, has delegated authority to the HSPB to verify, via specific documentation, that these criteria have been met prior to protocol submission for scientific review, evaluation by HSPB, and/or ethical review, as appropriate.

4. Definitions.

a. Cadaver: A deceased person or portion thereof, and is synonymous with the terms "human cadaver" and "post-mortem human subject" (PMHS). The term includes organs, tissue, eyes, bones, arteries or other specimens obtained from an individual after death. The term "cadaver" does not include portions of an individual person, such as organs, tissue or blood, that were removed while the individual was alive (for example, if a living person donated tissue for use in future research protocols, that tissue is not considered a "cadaver" under this policy, regardless of whether the donor is living or deceased at the time of tissue use).

b. Engaged in Human Subjects Research: An institution is engaged in research involving human subjects if its employee(s) (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens for research purposes; or (ii) obtains, uses, studies,

analyzes, or generates identifiable private information or identifiable biospecimens for research purposes.

c. Human Research Protection Program (HRPP): An integrated institution-wide program coordinated by the Human Subjects Protection Branch (HSPB) with the main purpose of ensuring all of WRAIR's activities related to human subjects research are conducted in accordance with regulatory requirements and ethical principles as set forth in the Belmont Report. Major components of the HRPP include the Institutional Review Board (IRB), research review groups (the Office of Research Technology and Applications (ORTA), Scientific Review Committee (SRC), Institutional Biosafety Committee (IBC), WRAIR Safety Office, USAMRDC Human Research Protections Office (HRPO), and Translational Medicine Branch), assurances, regulations, policies, standard operating procedures (SOPs), investigators, sponsors, overseas Directors, USAMRDC headquarters, etc.

d. Institutional Official (IO): Individual ultimately responsible for the implementation of the U.S. Department of Health and Human Services (DHHS) Federal wide Assurance and the DOD Assurance of Compliance for the Protection of Human Research Subjects and the associated HRPP at an institution engaged in research involving human subjects. Within the USAMRDC, the Commander of the institution/organization engaged in research is the IO.

e. Principal Investigator (PI): The individual who is responsible and accountable for conducting a research study. This individual will have the appropriate scientific and ethics training and experience to assume full responsibility and accountability for the scientific integrity of the research data and results. The PI is the individual responsible and accountable for designing, conducting, and monitoring the research study, and has access to the data. For studies involving human research subjects, the PI, as the leader of the research study team, assumes full responsibility for the medical care and evaluation of subjects, either directly or indirectly (designee of a healthcare provider). The PI also is responsible for protecting the rights and welfare of human subjects and is responsible for carrying out sound ethical research consistent with research plans in a protocol approved by a properly-constituted IRB. The PI may formally delegate roles and responsibilities to other members of the research study team, as appropriate, but retains full responsibility for the conduct of all study activities.

(1) FDA definition: Investigator means an individual who actually conducts a clinical investigation, such as, under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(2) ICH E6 Definition: Investigator means a person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial

site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Sub investigator.

Note: The above definition is not necessarily the same as that of a PI listed on a grant or research award, which may include other responsibilities not involving human subjects research.

f. Research Involving Human Subjects: Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research (i) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

g. Research Support Personnel: (for example, consultants, laboratory investigators). Personnel who are engaged in conduct of the research, but who are participating in a limited or defined part of the protocol under the direct supervision or guidance of an investigator.

h. Site-Specific PI: For research studies conducted at multiple study sites, the individual who is responsible and accountable for conducting the research study at a specific study site.

i. Sub Investigator or Associate Investigator, Co-Investigator: An individual member of the research team delegated and supervised by the PI at a study site to perform critical study-related procedures and/or to make important study-related decisions.

j. WRAIR Point of Contact (POC): An individual, affiliated with WRAIR or its Directorates, who is responsible for submission of protocol documents to the HSPB over the lifecycle of the study as new protocol actions are processed, remains in continual communication regarding the study to regulatory authorities, and directs study execution wherein WRAIR is participating. This individual is generally the lead WRAIR investigator on the protocol, but is not the overall study PI. The POC can be the site PI, a clinical coordinator, program manager, associate investigator, or other individual involved in the study in a scientific or administrative capacity.

5. Background. In order to ensure a timely review by the WRAIR Scientific Review Committee (SRC), the HSPB, and the WRAIR IRB, protocols should be submitted in final form (ready to start in the viewpoint of the research team, Branch Director, and Sponsor). This means the protocol is clearly written and concise, and the submission contains all required documentation for the review(s) to occur.

Note: Protocols should be submitted electronically to usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil. This includes protocols that may be determined to be human subjects research, research not involving human subjects or not research.

6. Applicability and Scope. This policy applies to all personnel employed by or affiliated with the WRAIR who conduct, review, approve, support, manage, or oversee research under the WRAIR HRPP. This also applies to contractors or partners who conduct human subjects research under the WRAIR HRPP. WRAIR-associated research studies may include:

a. research conducted at WRAIR, regardless of where the PI is located

b. research conducted at or by WRAIR's Directorates

c. research conducted using WRAIR funding, resources or support; and

d. research conducted at or by other institutions where WRAIR personnel are investigators (PI, co-investigator, or associate investigators), consultants or collaborators

Note: This policy also applies to studies in which WRAIR investigators are supporting in a peripheral capacity (such as, performing laboratory assays, data mining, serving as subject matter experts, etc.)

7. Policy. WRAIR Investigators or WRAIR POCs shall officially submit protocols involving human subjects, human data, and/or human biological materials (human biospecimens) to include all applicable documents per Appendix A. All WRAIR-associated projects utilizing or potentially utilizing human subjects are required to be submitted through the HSPB to begin the review process.

a. This policy applies to categories of research to include: studies which may be determined to be "research not involving human subjects"/"not research", exempt, minimal risk, and greater than minimal risk studies. The category of research will be determined per WRAIR Policy #31(08), not by the submitting party.

b. This policy also applies to protocol/study amendments or modifications.

c. Studies which may be determined by the HSPB or the IRB Chair, to be "research not involving human subjects"/"not research" may also require the elements in Appendix A. Investigators are encouraged to seek guidance from the HSPB for this category of research project. Additionally, consultations by the HSPB of unofficial submissions will only be permitted as time and resources allow.

Note: There is a separate policy addressing the requirements to gain the WRAIR Commander's authorization to implement a protocol (see WRAIR Policy #31, Final Approval Authorization for Human Subjects Research Protocol Implementation.)

8. Execution.

a. Responsibility.

(1) PIs (and/or WRAIR POCs) and Center/Branch/Directorate Directors are responsible for ensuring the required items, per Appendix A, are in place prior to submitting a protocol for scientific review, protocol evaluation by HSPB, and/or ethical review. Failure to do so will delay processing of the submission. Repeated failure to do so could have a negative impact on performance review and/or may lead to further disciplinary action.

(2) HSPB is responsible for reviewing submissions and informing PIs (and/or WRAIR POCs) if submissions are considered incomplete/complete.

(3) The IO (or designees) and Deputy Commander, WRAIR, are responsible for enforcing this policy as well as intervening with PIs/Center/Branch/Directorate Directors, as appropriate, if incomplete submissions are received.

b. Documentation (See Appendix A). All required protocol documents must be submitted to the WRAIR HSPB before processing can occur. Scientific review, if needed, cannot occur prior to obtaining these documents (unless waived by the Chief Science Officer or Deputy Commander, WRAIR, with strong justification).

9. Point of contact for this memorandum is [redacted], Director, Human Subjects Protection Branch (FCMR-UWS-HP) at [redacted] or [redacted].

SIGNATURE ON FILE

CLINTON K. MURRAY
COL, MC
Commanding

3 Encls
1. Appendix A: Submission Checklist
2. Appendix B: Cover Memo
3. Appendix C: Information Form

Appendix A

Investigator and Branch/Directorate Director Protocol/Amendment Submission Checklist

All required documents must be submitted before processing can occur. Scientific review, if needed, cannot occur prior to obtaining these documents (unless occurring at another institution or explicitly waived by the Chief Science Officer or Deputy Commander, WRAIR). For international research studies, please also complete and submit Appendix C, International Research Study Supplemental Information Form.

Check off each item as enclosed as part of the submission packet or indicate not applicable, as appropriate.

Forward the completed check list along with submission items to the Human Subjects Protection Branch (HSPB) electronic mailbox: usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil

Note: Please refer to WRAIR Policy #27, Use of Human Cadavers for Research, Development, Test and Evaluation (RDT&E), Education, or Training, for additional requirements to conduct or support activities involving the use of human cadavers.

General Submission Requirements:

___Cover memo signed through Department Chief, Branch and/or Directorate Director (Appendix B).

Note: If you are the Center/Branch/Directorate Director and the submitting study PI, the cover memo will require signature through the WRAIR Chief Science Officer .

___Version Control of Submitted Documents - each page of the protocol, consent forms, case report forms, subject diary, recruitment materials, tests of understanding, etc., must be identified by a protocol ID, version number and date. The submitted documents should be clean copies, free of typographical errors. Version control must be tracked on all documents throughout the course of the research project.

___Protocol - current version. In addition to version control requirements listed above each page must be numbered in sequence from the cover page to the end Enclosure 1 necessary). If a Table of Contents exists, be sure to match the pages appropriately.

___Sponsor/Executive Authority and preliminary funding information (such as,, core funding, extramural grant from USAMRDC, Cooperative Research and Development Agreement (CRADA), contract numbers) in the body of the proposal (this is important as it determines the review pathway in some instances.)

Note: for NIH or HHS grants, a copy of the grant must be included in the submission packet.

___List of all investigators involved in the study and a detailed description of their roles and responsibilities.

Note: Only a single PI should be named (refer to WRAIR Policy #29, Assignment of Principal Investigators to Human Subjects Research Conducted under the WRAIR HRPP for details).

___DoD Medical/Research Monitor is listed in the protocol (for Greater Than Minimal Risk studies).

___List of participating laboratories and their roles and responsibilities are included in the protocol.

___List of all Institutional Review Boards (and their DHHS IRB numbers) reviewing the study is included in the protocol.

___A military relevance section has been included in the protocol that states how the study is militarily relevant.

___Informed Consent Document – most current version. Each page must be numbered in sequence. Address in the body of the consent form or submit as a separate consent document (as applicable) for: HIV testing, Biological Specimen/Data Donation Consent (allows future use), and photographs, video, or audiotapes consent.

___Curriculum Vitae(s) for Principal Investigator(s), Associate Investigator(s), Research Support Personnel (consultants, laboratory investigators, etc.), Ombudsman, and DoD Medical/Research Monitor, as applicable. CVs must be dated, signed and current (within 2 years of initial submission).

___Conflicts of Interest (COIs)/Financial Disclosure Forms. Statement of COI (financial or otherwise) for all investigators listed in the protocol (required for studies involving commercial sponsors and/or studies with drugs, biologics, devices, or development of in vitro diagnostics).

___Human Subjects Protection Training Certificates for all Investigators, DoD Medical/Research Monitor, and Ombudsman (if applicable).

Note: The Principal Investigator is responsible for maintaining these certificates for all site support staff in the study file. Refer to WRAIR Policy #26, Initial and Ongoing Human Subjects Protection Education and Training Requirements for details.

Scientific Review (required prior to ethical review initiation)
Check One:

___Scientific Review approval documentation if obtained from a source other than WRAIR Scientific Review.

___Scientific Review has not been conducted (to date) for this proposal. Please submit to the WRAIR Scientific Review Committee or review for exemption.

Recruitment and Volunteer Contact Materials
Check One:

___Advertisements, recruitment scripts, recruiting material, briefing slides, emergency contact cards, etc., that will be used during the conduct of the study. This should include any items that will be given to, reviewed by, or seen/heard by volunteers.

___Not Applicable

Check One:

___ Letter(s) of Support (if using, contacting, recruiting, screening or enrolling subjects outside of WRAIR or WRAIR's databases). This might include University, Hospital, or Battalion/Command permission to recruit at a non-WRAIR site.

___Not Applicable

Comprehension Testing (not required)
Check One:

___Tests of Understanding (with answer key) that will be administered to the subjects. Include in the protocol a statement of how low test scores will be handled and how many times the test can be re-taken.

___Not Applicable

Case Report Forms/Source Documents
Check One:

___Case Report Forms or data collection documents (please print electronic versions). This would include questionnaires, surveys, SAE forms, etc.

___Not Applicable

Check One:

___Performance Tests that will be administered, including: memory tests and instructions to test givers, and examples/descriptions of performance tests.

___Not Applicable

List Collaborator/Partner or Other Involved Institutions

If applicable, please provide the following additional information:

Collaborator/ Partner Involved Institution	DHHS or DoD Federalwide Assurance # (Click here to search)	Name of Reviewing IRB or Ethics Committee	IRB Approval/ Determination Status* *(Indicate: Yes, No, Pending)*	IRB Determination**	IRB Approval Date
				Choose an item.	Click here to enter a date.
				Choose an item.	Click here to enter a date.

IRB Approval*: Indicate whether IRB approval has taken place or is pending. If there are any Institutional Agreements for IRB review planned, describe in the space provided.

IRB Determination**: Indicate the determination (exempt, not greater than minimal risk, greater than minimal risk) made by the IRB or the institution during the initial review of the protocol, to include "research not involving human subjects" determinations from participating institutions that do not have access to identifiable data or materials. Please contact the respective IRB office for assistance.

___Not Applicable

Collaborator/Partner or Other Involved Institutions - Documentation
Check One:

___Non-WRAIR IRB approval documents attached

___Non-WRAIR IRB approval documents will be submitted after WRAIR IRB Review

___Not Applicable

Important Reminder: Collaborations may require business agreements (CRADAs, Material Transfer Agreements, (MTAs), Memorandum of Understanding (MOU), contracts, etc.) This process should be initiated as early as possible.
Note: Contact the WRAIR Office of Research Technology and Applications (ORTA) for guidance.

Vulnerable Populations

___Pregnant Women, Human Fetuses and Neonates

___Prisoners

___Children (Not Greater Than Minimal Risk study)

___Children (Greater Thank Minimal Risk study). Please note: the study must provide a direct benefit for each and every individual subject that is participating.

___Other (for example, active duty service members, impaired decision making, institutionalized)
Please list:_____

___Not Applicable

International Studies
Check One:

___International Research Study Supplemental Information Form (Required for all international studies)

___Not Applicable

Volunteer Registry Datasheets (greater than minimal risk protocols only, unless waived)

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Check One:

___Volunteer Registry Database USAMRDC Form 60-R. These forms will be filled out when subjects are enrolled and will be submitted to USAMRDC.
Note: Only the study PI needs to be identified on the Volunteer Registry Database Form.

___Request for waiver of Volunteer Registry Datasheets. Please provide justification below:_____

___Not Applicable

Additional Approval for WRAIR Federal Personnel
Check One:

___Supervisor/Commander's approval form for Active Duty military volunteers. (Required for protocols involving significant time commitment, challenges, and/or investigational product use. Refer to WRAIR Policy #28, Compensation to Federal Personnel when They Participate in Research as Human Subjects, for details).

___Not Applicable

Additional Institutional Committee Reviews
Check One:

___Institutional Committee Reviews to include, if applicable:
- ___Radiation Control Committee
- ___Biosafety Committee
- ___Radioisotope/Radiation Control Committee
- ___Biomedical Engineering Committee
- ___Other (please list:_____)

___Not Applicable

Check One:

___Recombinant DNA Advisory Committee (RAC) Approval for gene transfer research, if appropriate. (This may include Office of Biotechnology Activities (OBA) review.)

___Not Applicable

Check as applicable (U.S. FDA or other Regulatory Bodies Reviewing):

___ This protocol involves an investigational product (new drug, vaccine/biologic, device, or off-label use of an approved product).

Please list Investigational New Drug/Vaccine/Biologic (IND) or Investigational Device Exemption (IDE) number or date of submission to the FDA:_____

___ Not Applicable

Check as applicable:
Required Documentation for IND protocols:

___Current & Official Investigator's Brochure(s).

___Completed and signed Conflict of Interest or Financial Disclosure statement (for all investigators listed on the protocol.)

___Completed and signed FDA Form 1572 (if U.S. FDA Regulated).

___Sponsor's name and contact information.

___ Data and Safety Monitoring Board (DSMB) or Safety Monitoring Committee (SMC) or Independent Data Monitoring Committee (IDMC) membership and charter.

___ Monitoring plan (draft or final version) (Please note that submission of the monitoring plan is required by the WRAIR IRB.)

___Not Applicable

Check as applicable:
Required Documentation for IDE protocols:

___A statement regarding safety of device from the manufacturer (Significant vs. Non-significant Risk)

___Manufacturer's device manual/guide/brochure.

___FDA 510(K) - Pre-Market Application (if U.S. FDA Regulated)

___DSMB, SMC, or IDMC membership and charter.

___Completed and signed Conflict of Interest or Financial Disclosure statement (for all investigators listed on the protocol.)

___Not Applicable

Check as applicable:

___Use of an U.S. FDA Approved Product (21 CFR Parts 50 and 56)

___Use of European Medicines Agency (EMA) Approved Product

___Local Approved Product (Country: _____)

___Current Package Insert(s).

___Completed and signed Conflict of Interest or Financial Disclosure statement (for all investigators listed on the protocol.)

___Sponsor's name and contact information.

___Statement from the manufacturer regarding the safety of the drug/vaccine/biologic/device.

___DSMB, SMC, or IDMC membership and charter.

By signing the below, the signatories are affirming that the above documents are in place for the submission of this study.

Signatures/Dates:

_____ _____
PI Date

_____ _____
Branch /Directorate Director Date

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When Incomplete (Below Required)
WAIVER REQUEST GRANTED:

_____ _____
Deputy Commander Date

For HSPB Use Only

Received in HSPB by: _____ Date: _____
Assigned WRAIR #_____

Initial Packet Review

____Complete, begin process Date: _____

____Incomplete: Notified PI on Date: _____

Preliminary Risk Assessment: _____ Date: _____

____Submitted to WRAIR Chief Science Officer or Scientific Review Committee Chair for Scientific Review

____ External scientific review; submitted to WRAIR Chief Science Officer for a determination of concurrence

____Scientific Review not required

Date Scientific Review Completed (if applicable): _____

Date Submitted for Ethical Review: _____

Appendix B: Cover Memo

THE Highlighted Areas on this memo are to be tailored to your submission** REMOVE THIS SENTENCE.

FCMR-UWZ-X Date

MEMORANDUM THRU

Chief X
Center/Branch/Directorate Director

FOR Commander, Walter Reed Army Institute of Research (ATTN: Human Subjects Protection Branch), 503 Robert Grant Avenue, Silver Spring, MD 20910

SUBJECT: Request for Submission of a Protocol/Amendment to a Protocol Involving Human Subjects, Human Biological Materials, and/or Human Data for Scientific and Ethical Review

1. Request submission for review of new/amended human subjects research protocol entitled "X" (version, date), PI, institution affiliation.

2. The submission checklist has been verified by the Principal Investigator (PI) and Center/Branch/Directorate Director. Please process for scientific and ethical review, as appropriate.

3. The primary objectives/the key changes to the protocol are:

4. The following documents are attached:

   a. Completed Submission Checklist
   b. Protocol (version X, dated X)
   c. Informed Consent Document (version X, dated X)
   d. Case Report Forms (version x, dated X)
   e. CVs for:
   f. HSP Training certificates for:
   g. ETC

5. As the PI/WRAIR POC, I will carry out the study as outlined in the attached proposal.

Enclosure 2

FCMR-UWZ (1oo)
SUBJECT: WRAIR Policy #24, Submission of Protocols Involving Human Subjects, Human Information or Biospecimens, for Scientific and Ethical Review

6. The point of contact for this action is undersigned at telephone number XXXX, Email XXXX.

SIGNATORY
RANK
ROLE

Center/Branch/Directorate Director Approval

This study is:

- Scientifically feasible and valid,
- Militarily relevant, and
- Appropriately resourced (funding, personnel, equipment, etc.)

SIGNATORY
RANK
Center/Branch/Directorate Director

Appendix C

WRAIR Human Subjects Protection Branch International Research Study Supplemental Information Form

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The following information is required by the WRAIR Human Subjects Protection Branch in addition to the Protocol Submission Checklist, in order to obtain information about the host nation's research site and the local context within which it will be conducted. The form should be completed by the Principal Investigator/WRAIR POC in conjunction with the investigator(s) in the host nation.

If information requested in this form is described within the protocol, the corresponding protocol section/page number(s) where the information is located in the protocol may be entered instead.

Country and city in which study is to be conducted: _____

A. Explain the rationale for conducting research in this host country.

B. Explain how this research relates to the current health care needs of the community. For example evaluation of malaria treatments/vaccines in a malaria endemic area and not in an area where malaria is not commonly present.

C. Provide the name and contact information for the investigator who will conduct the research in the host country.

Host country site investigator name: _____
Address: _____
_____
Phone number: _____
E-mail address: _____

D. Regulatory Information

1. List the regulations governing human subjects research in this host country: (*for example, ICH, CIOMS*):

_____

_____

2. Name of study site's ethical review committee (ERC):

_____

_____

ERC Point of Contact: _____

ERC Contact Information (address, phone number, email address, etc.): _____
_____
_____

3. Does the protocol require review by other Host Nation institutions, offices, departments, Scientific Committees (*for example, Ministry of Public Health*) or by a Host Country Drug and/or Device oversight agency? ___ Yes ___ No

If 'Yes', provide the following information:

Name of Committee	Date of Review	Point of Contact	Phone Number	Email

E. Site Information

1. Describe in detail the study site, to include but not limited to, the location in the host nation, geographical characteristics, distance volunteers will have to travel to get to the site, and whether transportation will be available/offered.

2. Describe in detail the facilities where the study will be conducted, to include but not limited to, buildings and equipment available for the conduct of the study, number of study staff and their availability at the study site, etc.

F. Study Population

1. What is the legal age at which individuals can provide their own consent to participate in research? _____

_____

2. What is the study population's ethnic composition? _____

_____

3. What is the literacy level and general level of education?

_____

4. What language and/or dialects are spoken? _____

_____

5. Are all languages/dialects written? If not, please explain. _____

_____

6. Are there any additional benefits to the individual, family and community at this site over those described in the protocol (for example cross-over vaccinations for volunteers in the placebo arm of the study, better health care monitoring for the volunteers and their families, building local medical or research capacity and expertise)? ___ Yes ___ No

If 'Yes', describe:

G. Local Community

1. Describe the healthcare system available to the community/study population.

2. If vulnerable individuals will be involved in the research (children, active duty military, prisoners), describe the safeguards in place to protect their rights and welfare.

3. If vulnerable individuals will be involved in the research (children, active duty military, prisoners), describe the safeguards in place to protect their rights and welfare.

4. If compensation is being offered, how does it compare to the average host nation daily wage?

_____
_____

a. Explain its equivalence to US currency. _____
_____

b. If the study requires multiple visits, describe the plan to pro-rate payments in the event of volunteer withdrawal.

5. Describe how the research will impact the community.

If 'Yes', describe:

6. Are there any relevant political issues that could impact the study (for example, war, civil unrest)? ___ Yes ___ No

If 'Yes', describe:

H. Medical Care

1. What are the local standards of health care for condition/disease under study?

2. How does treatment of participants on study compare to the local standard of care for this condition/disease?

3. What is the usual access to care and availability of health care in the region/nation? Include the ease of access and availability of medical care (average distance to medical treatment facilities, hours of operation, availability of transportation to and from the medical treatment facility), and availability of private or host country-funded health insurance.

4. Does the study require a plan for continued health care, medications, and/or referral to the local health care providers after the completion of the study?
___ Yes ___ No ___ NA

If 'Yes', describe the plan:

5. Do you plan to offer the study drug treatment to placebo-arm subjects after the study is completed? ___ Yes ___ No ___ NA

If 'Yes', describe the plan:

6. Describe the medical care that will be available to volunteers in the event of a research-related injury, to include who will provide the care, the duration of the care the cost of this care to the subject.

I. Unique Recruitment/Consent Processes

1. Will recruitment materials to be used be translated in the language of the volunteer?

___ Yes ___ No ___ NA

If 'Yes' please provide copies of all the recruitment materials that will be used and translated copies along with Certification of Translation Accuracy declaration (this should include, on the English version, the statement "I certify that this is an accurate and true translation" as well as the signature, name, address, phone number and, if available, FAX number of the translator).

2. *If not already provided in the protocol*, describe local cultural and legal considerations in obtaining informed consent of research volunteers, for example, individual meetings with host national and local government officials; proxy consent by tribe elder, community, or husband consent; assent in children, thumb print in lieu of signature, use of information sheet.

3. Does the informed consent document contain a local emergency contact phone numbers for volunteers? ___ Yes ___ No ___ N/A

If not, this information must be incorporated into the document.

4. Are there any unique issues/regulations regarding use of private health information?

If 'Yes', describe:

J. Specimen/Data Management

1. Will samples be taken out of the country for analysis, etc.? ___ Yes ___ No

If Yes, is this explicitly stated in the consent form? ___ Yes ___ No

2. Are there unique data and/or specimen management issues for this country, for example any restrictions (cultural, regulatory, etc.) to moving data and/or samples out of country? ___ Yes ___ No

If 'Yes', describe:

NOTE: Before the WRAIR Commander issues an approval authorization for the implementation of the research at this site, the local Ethics Review Committee's final approved version of all recruitment material, information sheets and consent forms, that are *in the language(s)of study participants,* must be submitted for review.

A certification of the translated documents' accuracy by the individual who translated the documents must accompany the approved documents along with the English version of the documents used for the translation(s) (this should include, on the English version, the statement "I certify that this is an accurate and true translation" as well as the signature, name, address, phone number and, if available, FAX number of the translator).

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(Principal Investigator/WRAIR POC Signature) **Date**

_____

(Principal Investigator/WRAIR POC Printed Name)