

Appendix C

WRAIR Human Subjects Protection Branch International Research Study Supplemental Information Form

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: (e.g. 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 (e.g. 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. Describe the socio-economic environment, to include but not limited to, structure of community and family, typical occupation(s), living conditions, average daily wage/average income, cost of living, and other income factors.

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.

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

If 'Yes', describe:

7. Are there any religious/cultural customs that must be considered in implementing the research in the host country? ___ 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).

(Principal Investigator/WRAIR POC Signature)

Date

(Principal Investigator/WRAIR POC Printed Name)