**Appendix B**

 **WRAIR IRB International Research Worksheet**

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country in which study is to be conducted: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Was a rationale provided for conducting research at this foreign site?

\_\_\_ Yes \_\_\_No

1. Foreign Study Site:
2. Is there an Assurance of compliance with human subjects protection regulations:

\_\_\_ Yes \_\_\_No

 Type of Assurance: \_\_\_ DOD \_\_\_ HHS/OHRP \_\_\_ Other

 Assurance No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Assurance Expiration Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Regulations the institution is required to follow, as per the Assurance: (*e.g. ICH, CIOMS*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Name of study site’s ethics committee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Point of contact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact information (phone number, email address, etc): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Review required by other institutions, offices, departments (*e.g. Ministry of Public Health, Drug/Device oversight agencies*):

\_\_\_ Yes \_\_\_ No

If Yes, provide name(s)/contact information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Site PI name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact information (telephone number/email): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Research team roles adequately described?

\_\_\_ Yes \_\_\_ No

1. Documentation of training in human subjects’ protection provided?

\_\_\_ Yes \_\_\_ No

1. Provide a brief description of performance site (hospital, clinic, Clinical Research Organization, etc.)
2. Are there sufficient/adequate staff and facilities to conduct the research?

\_\_\_ Yes \_\_\_ No

1. Was a local Scientific Review conducted?

\_\_\_ Yes \_\_\_ No

If Yes, name of local committee/body who conducted scientific review provided?

\_\_\_ Yes \_\_\_ No

1. Was adequate information provided about the following items?
2. Description of the target population:
* Legal age for individual to provide own consent to participate in research
* Ethnic composition
* Literacy and level of education
* Language/dialects spoken
* Economic issues (typical occupation(s), living conditions, wages/average income, cost of living, income factors, etc.)
* Structure of community and family

\_\_\_ Yes \_\_\_ No

1. Description of the local standards of health care for condition/disease under study, and the established effective therapy. Usual access to care and availability of health insurance was addressed.

\_\_\_ Yes \_\_\_ No

1. Description of this research in relation to the health care needs of the local site.

\_\_\_ Yes \_\_\_ No

1. Description of the post study plan for care/referral/medications/other.

\_\_\_ Yes \_\_\_ No

1. Description of medical care that will be available in the event of a research-related injury was provided. \_\_\_ Yes \_\_\_ No

Is this consistent with the current USAMRDC Policy? \_\_\_Yes \_\_\_No

1. The risk/benefit ratio was described in the social context and cultural norms of the local community. The PI considered the individual, family, community benefits, and any additional benefits for subjects at this site.

\_\_\_ Yes \_\_\_ No

1. Unique recruitment strategies/processes for this site were identified.

\_\_\_ Yes \_\_\_ No

1. Describe the consent process, including the standard methods of consent (community consent, tribal elder consent, husband, use of information sheet, etc. as applicable). Explain how the research team will ensure informed consent is obtained.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. If minors are the targeted study population, a description of assent/parental permission processes was provided.

\_\_\_ Yes \_\_\_ No

1. If compensation is being offered, a justification was provided and explained in terms of average wage.

\_\_\_ Yes \_\_\_ No

1. Will samples be taken out of the country for analysis, etc?

 \_\_\_ Yes \_\_\_ No

Is this explicitly stated in the consent form? \_\_\_ Yes \_\_\_ No

1. Are there unique data and/or specimen management issues for this foreign site?

\_\_\_ Yes \_\_\_ No

If there are unique issues, the PI described them adequately and provided a plan for dealing with them. \_\_\_ Yes \_\_\_ No

1. Is there potential for the outcomes of the research negatively or positively impact the host community?

 \_\_\_ Yes \_\_\_ No

If Yes, describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_