



**Walter Reed Army Institute of Research  
Standard Operating Procedure**



SOP Title	<b>REVIEW OF HUMAN SUBJECTS RESEARCH BY THE FULLY CONVENED WRAIR INSTITUTIONAL REVIEW BOARD</b>	SOP No.	UWS-HP- 628.02 Appendix B
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**Appendix B**

**WRAIR IRB International Research Worksheet**

Protocol Title:

\_\_\_\_\_

Country in which study is to be conducted:

\_\_\_\_\_

A) Was a rationale provided for conducting research at this foreign site?

Yes  No

B) Foreign Study Site:

1. 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):

\_\_\_\_\_

2. Name of study site's ethics committee:

\_\_\_\_\_

Point of contact:

\_\_\_\_\_



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

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3. 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:

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4. Site PI name: \_\_\_\_\_

Contact information (telephone number/email):

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5. Research team roles adequately described?

Yes  No

6. Documentation of training in human subjects' protection provided?

Yes  No

7. Provide a brief description of performance site (hospital, clinic, Clinical Research Organization, etc.)

8. Are there sufficient/adequate staff and facilities to conduct the research?

Yes  No

C) Was a local Scientific Review conducted?

Yes  No

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

Yes  No

D) Was adequate information provided about the following items?

1. Description of the target population:



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- 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

2. 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

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

Yes  No

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

Yes  No

5. 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

6. 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

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

Yes  No



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8. 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.

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

Yes  No

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

Yes  No

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

Yes  No

Is this explicitly stated in the consent form?  Yes  No

12. 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

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

Yes  No

If Yes, describe:

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