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| HRPP | Title: International Research Submission | |
| Form #: FM 404 | Version Date: 18 July 2019 |

Combat Capabilities Development Command (CCDC) Army Research Laboratory (ARL)

Human Research Protection Official (HRPO)

**INSTRUCTIONS:** The following information is required by the Human Research Protection Official in order to obtain information about the host nation’s research site and the local context which it will be conducted. The form should be completed by the Principal Investigator in conjunction with the investigator(s) in the host nation*. Fill out one form for each country engaged in research.* Submit this completed form and the project documents to the electronic mailbox [usarmy.apg.ccdc.mbx.arl-irb-office@mail.mil](mailto:usarmy.apg.ccdc.mbx.arl-irb-office@mail.mil). For questions regarding CCDC ARL HRPO review requirements or assistance in completing this form, email [usarmy.apg.ccdc.mbx.arl-](mailto:usarmy.apg.ccdc.mbx.arl-)[irb-office@mail.mil](mailto:usarmy.apg.rdecom.mbx.arl-irb-office@mail.mil) a staff member will contact you.

**1.**

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| **Study Information** | |
| Principal Investigator (PI) Name |  |
| Title of Study |  |
| PI Phone # |  |
| PI Email |  |
| PI Address |  |
| **Country Study Information** | |
| Country in which study is to be conducted |  |
| City(ies) in which study is to be conducted |  |

**2.**

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| **Rationale** |
| Explain below the rationale for conducting research in this host country. (e.g. What is the benefit to the U.S. Army?) |
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| **Relation of Need to Community** | | | |
| Explain how this research relates to the current needs of the community and its impact. | | | |
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| Are there any additional benefits to the individual, family and community at this site over those described in the protocol (better health care monitoring for the volunteers and their families, building local medical or research capacity and  expertise)? | | * Yes**\*** | * No |
| **\***If yes, describe below: | | | |
| **Investigator in Host Country Information** | | | |
| Host Country Site Investigator |  | | |
| Address |  | | |
| Phone Number |  | | |
| E-mail Address |  | | |
| Provide current **CV** for the **local investigator** who will **conduct** the **research** in the host  country. | | | |

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| **Regulatory Required Review** | | | | | | |
| 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, list the regulations governing human subjects research in this host country: (*e.g. ICH, CIOMS*) *Add additional lines to table below as needed.* | | | | | | |
| **Name of Committee** | **Date of Review** | **Point of Contact** | **Phone Number** | | **Email** | |
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| **Reliance Agreement with U.S. Institution** | | | |
| List all reliance agreements between the host country and any U.S. institution below: | | | |
| Name of U.S. Institution | Approval Date | Expiration Date | |
|  |  |  | * NA |
|  |  |  | * NA |
|  |  |  | * NA |
|  |  |  | * NA |

**4.**

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| **Site Information** |
| A. Describe in detail the study site and facilities where study will be conducted, to include but not limited to, the location in the host nation, buildings, equipment available, number of study staff, availability of staff at study site, geographical characteristics, distance subjects will have to travel  to get to the site, and whether transportation will be available/offered |
|  |
| **Local Community** |
| Describe the healthcare system available to the community/study population. |
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| 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. |
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| 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. | | * NA | |
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| If compensation is being offered, how does it compare to the average host nation daily wage? Explain its equivalence to US currency. | | | |
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| If the study requires multiple visits, describe the plan to pro-rate payments in the event of subject’s withdrawal. | | | |
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| Are there any relevant political issues that could impact the study (e.g. war, civil unrest)? | * Yes**\*** | | * No |
| **\***If yes, describe below: | | | |
| Are there any religious/cultural customs that must be considered in implementing the research in the host country? | * Yes**\*** | | * No |
| **\***If yes, describe below: | | | |

**5.**

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| **Study Population** | | | |
| What is the legal age at which individuals can provide their own consent to participate in research? |  | | |
| What is the study population’s ethnic composition? |  | | |
| What is the literacy level and general level of education? |  | | |
| What language and/or dialects are spoken? |  | | |
| Are all languages/dialects written? | | * Yes | * No**\*** |
| **\***If no, please explain below: | | | |

**6.**

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| **Unique Recruitment/Consent Processes** | | |
| Will recruitment materials to be used be translated in the language of the subject? | * Yes**\*** | * No^ |
| **\***If ‘**Yes**’ 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 and contact information. | | |
| ^If ‘**No**’, explain: | | |
|  | | |
| Describe local cultural and legal considerations in obtaining informed consent of research subjects, 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. | | |
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| The informed consent document contains a local emergency contact phone number(s) for volunteers. | | | |
| * Yes | * **No -** If no, *this information must be incorporated into the document.* | | |
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| Are there any unique issues/regulations regarding use of private health information? | | * Yes**\*** | * No |
| **\***If yes, describe below: | | | |

**7.**

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| **Data Management** | | | |
| Will data be taken out of the country for analysis, etc.? | | * Yes**\*** | * No |
|  | **\***If yes, is this explicitly stated in the consent form? | * Yes | * No |
| Are there unique data management issues for this country, for example any restrictions (cultural, regulatory, etc.) to moving data? | | * Yes\* | * No |
| \*If yes, describe below: | | | |

**8.**

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| **Medical Care – ☐ NA –** If study does **not** involve medical research. (Skip section 8) |
| What are the local standards of health care for condition/disease under study? |
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| How does treatment of subjects on study compare to the local standard of care for this condition/disease? | | | |
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| 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. | | | |
|  | | | |
| 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 below: | | | |
| 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 below: | | | |
| Describe the medical care that will be available to subjects 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. | | | |
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NOTE: before the CCDC ARL HRPO issues an approval for the implementation of the research at this site, the local Ethics Committee’s final approved version of all recruitment material, information sheets and consent forms, that are *in the language(s) of study subjects,* 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 and contact information.

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(Principal Investigator’s Signature) Date