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| **PI NAME** |  |
| **STUDY TITLE** |  |

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| **1.** | Describe the international site(s), including the location and the particular community or population, if applicable: | | | |
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| **2.** | Describe any cultural, political, religious, or other local influences that may affect the conduct of the research and how these will be addressed (e.g., potential threats, different recruitment methods, local attitudes toward research, etc.). | | | N/A |
|  | | | | |
| **3.** | Describe any local exceptions to the normal required consent process and how these will be addressed (e.g., permission of tribal council/elders, community consent, permission of male guardian, etc.).  \*If signing forms is not the norm, fill out F-08 Request for Waiver of Documentation of Consent. | | | N/A |
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| **4.** | Will children be enrolled? | Yes  No | | |
| **If yes,** describe any local exceptions to the normal requirements for adult permission and child assent and how these will be addressed: | | | |
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| **5.** | Is local ethics review required? | Yes  No | | |
| **If yes,** provide information about the local ethics review. Documentation of local approval may be requested.  **\*\*The principal investigator is responsible for ascertaining if local permission is needed for conducting research at the proposed site(s).** | | | |
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| **6.** | Describe the Principal Investigator’s experience/qualifications for conducting research in this location/population. Include any relationship(s) with the community from which the subjects will be recruited: | | | |
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| **7.** | List the language(s) (other than English) in which the research will be conducted. State whether the Principal Investigator is fluent in the language(s). If not, identify who will be responsible for translating. If no language other than English will be used, explain why.  **NOTE:** All consent forms and other materials given to subjects must be in a language understandable to them. All translated documents must be submitted to the IRB along with an attestation or certificate of translation. | | | |
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| **8.** | Will the Principal Investigator travel to the research site(s) to conduct the study? | Yes  No | | |
| **If no,** provide the name and contact information of the local contact or investigator and describe the communication and oversight plans between the PI and the local contact/investigator. | | | |
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| **9.** | Will there be any benefits to the local community that will remain with the community once the research is complete? | Yes  No | | |
| **If yes,** describe: | | | |
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| **10.** | Describe the procedures for data storage and security in the local setting and for transfer of data to Baylor University. Please keep in mind any export/import controls. | | | |
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| **11.** | Will the research involve any medical procedures or treatment (e.g., blood draws, saliva collection, vaccines, etc.)? | | Yes  No | |
| **If yes,** indicate if any of the planned medical procedures are considered to be standard of care in the country/location: | | | |
| **If yes,** describe the provisions for emergency treatment that is available at the location. | | | |