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

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| **1.** | Describe the international site(s), including the location and the population, if applicable: | |
| Response: | | |
| **2.** | Are there any cultural, political, religious, or other local influences that affect the research? How will these be addressed? | ☐ N/A |
| Response: | | |
| **3.** | Describe any local exceptions or additions to the normal consent process (i.e., permission of tribal council/elders, community consent, permission of male guardian, etc.).  \*If signing forms will not take place, fill out the Request for Waiver of Documentation of Consent. | ☐ N/A |
| Response: | | |
| **4.** | Will children be enrolled? | ☐ Yes  ☐ No |
| **If yes,** describe any local exceptions or additions to the normal consent process for children | |
| Response: | | |
| **5.** | Is a local ethics review required? | ☐ Yes  ☐ No |
| **If yes,** describe the local ethics review and provide their information. Documentation of local approval should be provided to the Montreat IRB. The principal investigator is responsible for confirming the permissions required to complete the exercise at the research site. | |
| Response: | | |
| **6.** | Describe the Principal Investigator’s experience/qualifications for working within the location and population used by this study. | |
| Response: | | |
| **7.** | List the language(s) in which the research will be conducted. Describe how communication in this language(s) will be completed. All consent forms and materials used by subjects must be in a language understandable to them. All translated documents must be submitted to the IRB. | |
| Response: | | |
| **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 investigator and describe the plans to be used between the PI and the local investigator. | |
| Response: | | |
| **9.** | Will the local community or population receive benefits by participating in this research? | ☐ Yes  ☐ No |
| **If yes,** describe: | |
| Response: | | |
| **10.** | Describe the data security at the locality and the transfer of data to Montreat College. | |
| Response: | | |
| **11.** | Will the research involve any medical procedures (including things like blood draws) or treatment? | ☐ Yes  ☐ No |
| **If yes,** how would adverse effects and emergencies be handled? | |
| Response: | | |