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| 1. **Protocol Information** | | |
| SPUP REC Protocol Code | | Submission Date |
| Protocol Title | | Study Site |
| Name of Principal Investigator | Sponsor/Contract Research Organization/Institution | |

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| 1. **Protocol Assessment** | | |
| **Questions** |  | **Comments** |
| 1. Does this research involve human participants? | Yes  No |  |
| 1. Does this research involve use of non-identifiable human tissue/biological samples? | Yes  No |  |
| 1. Does this research involve use of non-identifiable publicly available data? | Yes  No |  |
| *Note: Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGHHR 2017).* | | |
| 1. Does this research involve interaction with human participants? | Yes  No |  |
| 1. Type of Research |  |  |
| * 1. Institutional quality assurance | Yes  No |  |
| * 1. Evaluation of public service program | Yes  No |  |
| * 1. Public health surveillance | Yes  No |  |
| * 1. Educational evaluation activities | Yes  No |  |
| * 1. Consumer acceptability test | Yes  No |  |
| *Note: These 5 have been identified in the NEGHHR as exemptible, as long as it does not involve more than minimal risk.* | | |
| 1. What is/are the method/s of data collection? |  |  |
| * 1. Surveys and /or questionnaire | Yes  No |  |
| * 1. Interviews or focus group discussion | Yes  No |  |
| * 1. Public observations | Yes  No |  |
| * 1. Research which only uses existing data | Yes  No |  |
| * 1. Audio/video recordings | Yes  No |  |
| *Note: These 5 have been identified in the NEGHHR as exemptible, as long as anonymity and/or confidentiality is maintained.* | | |
| 1. Will the collected data be anonymized or identifiable? | Anonymized  Identifiable  De-identified |  |
| 1. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHRR 2017)   *Note: Please refer to section III. Risk Assessment, prior to answering this item.* | Yes  No  *Note: If Yes, then this protocol does not qualify for exemption.* |  |

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| 1. **Risk Assessment** | | |
| **Questions** |  | **Comments** |
| 1. Does this research involve the following: |  |  |
| * 1. Any vulnerable group/s | Yes  No |  |
| * 1. Sensitive topics that may make participants feel uncomfortable (i.e. sexual behavior, illegal activities, racial biases, etc.) | Yes  No |  |
| * 1. Use of Drugs | Yes  No |  |
| * 1. Invasive procedure (e.g. blood sampling) | Yes  No |  |
| * 1. Physical stress/distress, discomfort | Yes  No |  |
| * 1. Psychological/mental stress/distress | Yes  No |  |
| * 1. Deception of/or withholding information from subjects | Yes  No |  |
| * 1. Access to data by individuals or organizations other than the investigators. | Yes  No |  |
| * 1. Conflict of interest issues | Yes  No |  |
| * 1. Or any other ethical dilemmas | Yes  No |  |
| * 1. Is there any blood sampling involved in the study | Yes  No |  |

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| **Decision** | Qualified for Exemption  Unqualified for Exemption | ***Justification for the Decision:*** |

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