**Agency of Human Services Institutional Review Board**

**Request for Continuing Review**

|  |  |  |
| --- | --- | --- |
| ***AHS-IRB-#:*** | Review Period Beginning: | Date Form Completed: |
| ***Protocol Title:*** |  | |
| Principal Investigator: |  | |
| Address: |  | |
| Email: |  | |
| Telephone: |  | |
| Co-Principal Investigator: |  | |
| Address: |  | |
| Email: |  | |
| Telephone: |  | |
| Primary Contact: |  | |
| Address: |  | |
| Email: |  | |
| Telephone: |  | |

***Protocol Status*** (Check One):

|  |  |
| --- | --- |
|  | Work Not Yet Started |
|  | Active; Work in Progress |
|  | Follow-Up Only (enrollment closed, all interventions complete) |
|  | Data Analysis Only (no additional subject contact) |
|  | Work Completed – Close Protocol |
|  | Work Will Not Be Done – Close Protocol |
|  | Check here if this is your final report: |

***Recruitment/Enrollment***

|  |  |
| --- | --- |
| Are you still enrolling subjects? | Yes  No |
| *If yes, attach copy of current consent form* |  |
| Number of subjects who signed a consent form |  |
| Number of subjects who actually started the study |  |
| Number of subjects who remain in the study |  |
| Number of subjects who withdrew, discontinued, or died  during the study after being enrolled |  |
| Number of subjects who completed the study |  |
| The currently approved number of subjects for this research |  |
| *Remain+Withdrew+Completed* | 0 |
| *Discrepancy* | 0 |

|  |  |
| --- | --- |
| If Discrepancy above, please explain: |  |
| Summarize any withdrawals, discontinuations or deaths reported above: |  |

***Demographics of Enrolled Subjects***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Gender** |  | **Ethnicity** |  | **Race** |  |
| Male |  | Hispanic  Or Latino |  | American Indian or  Alaskan Native |  |
| Female |  | Not Hispanic  Or Latino |  | Asian |  |
| Unknown |  | Unknown |  | Black or African  American |  |
|  |  |  |  | Native Hawiian or  Other Pacifc Islander |  |
|  |  |  |  | White |  |
|  |  |  |  | Unknown |  |
|  | 69 |  | 0 |  | 0 |

*Were there any subject complaints during this review period?*  Yes  No *(If yes, explain)*

***Summary of Activities***

Provide a brief summary of the research activities and preliminary observations and findings obtained since the last review*.*

Are you aware of any recent literature, findings or other relevant information affecting the risk/benefit ratio of this study?  Yes  No (*If yes, summarize)*

Were any amendments to the protocol submitted to the IRB during this review period?  Yes  No *(If yes, summarize)*

Are you amending the protocol/consent form at the time of this continuing review?  Yes  No *(*If yes, submit with this continuing review a Request for Modification/Amendment to Approved Protocolform and include a copy of the summary of protocol changes, (if applicable) consent **with changes highlighted and a consent without the highlighting for stamp.** *)*

***Safety Information***

Did this study encounter any serious adverse events during this review period, that met the criteria for reporting?  Yes  No If yes, number:

Were these events reported to the IRB?  Yes  No  NA

If no, complete a “Report of Serious or Unexpected Adverse Event” form and submit with this continuing review.

Did this study encounter any unanticipated problems during this review period?  Yes  No

If yes, describe the unanticipated problem(s) and include actions that were taken and plans to prevent a recurrence in the future.

Were any unexpected benefits to subjects discovered during this review period?  Yes  No

If yes, explain.

Describe what is being done to ensure subject privacy and research data confidentiality

Did any protocol deviations potentially affecting risk to subjects occur during this review period?  Yes  No

If yes, was the deviation(s) reported to the IRB?  Yes  No

List or attach a list of all other protocol deviations not affecting risk to subjects occurring during this review period.

***Additional Comments***

Provide any additional comments that the IRB should be aware of that may impact the safety of the subjects involved in this research

|  |  |
| --- | --- |
|  |  |
| Signature | Date |