**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 |       | HispanicOr Latino |       | American Indian orAlaskan Native |       |
| Female |       | Not HispanicOr Latino |       | Asian |       |
| Unknown |       | Unknown |       | Black or AfricanAmerican |       |
|  |  |  |  | Native Hawiian orOther 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 |