Continuing Review Request Form

|  |  |
| --- | --- |
| **PI Name:**  | **IRB Number:**  |
| Title of Protocol:  |

This application is to be completed for:

* FDA-regulated studies,
* studies initially approved prior to January 21, 2019, and
* studies approved on or after that date for which the IRB has determined continuing review is required.

 If you have questions about whether or not a study may require IRB continuing review, please contact the HRPP/IRB Office at 303-398-1477.

**Section 1 – Current Status of Research**

1. Estimated study completion date:

2. Current Status of Research:

[ ]  Study is open to enrollment but no subjects have been enrolled to date.

[ ]  Study is open to enrollment and subjects have been enrolled.

[ ]  Closed to enrollment, but subjects are still “active” on the protocol regimen or undergoing procedures or interventions for the research.

[ ]  Closed to enrollment, but the research has progressed to the point that it only involves the

 following, which are part of the IRB-approved study (check all that apply):

[ ]  Long-term follow-up of subjects (or data collection)

[ ]  Accessing follow-up clinical data from procedures that subjects would undergo as part of

 clinical care

[ ]  Data analysis, including analysis of identifiable or coded

* private information
* biospecimens

[ ]  Suspended or on hold. Explain:

[ ]  Other. Explain:

**Section 2 – Funding Status**

1. Have there been any changes in funding for this study?

[ ]  No

[ ]  Yes.Please explain**:**

1. Are any changes in funding planned for or anticipated in the next 12 months?

[ ]  No

[ ]  Yes.Please explain**:**

**Section 3 – Enrollment Status**

When completing this section for a multi-center project, the numbers in this section should only include the site or sites under the control of the above noted PI for which the NJH IRB is serving as the IRB of record.

***NOTE:*** *For studies not under a waiver of consent, subjects are considered enrolled once they have provided consent.* *For studies under a waiver of consent, enrolled subjects include anyone whose data or specimen has been collected, used, studied, analyzed, or created for the purposes of the research.*

1. Total number of subjects approved for enrollment:

*Please note this number can only be increased via submission and approval of a modification request. If you have enrolled more subjects than approved this must be reported as a protocol deviation.*

1. Total number of subjects enrolled since study start:
2. Total number of subjects enrolled since last approval (initial or continuing):
3. Total number of subjects withdrawn from the study or lost to follow up:
	1. Briefly explain the reasons or circumstances related to each subject withdrawn or lost to follow up:
4. Provide the cumulative accrual by race/ethnicity and gender:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | American Indian or Alaska Native | Asian | Black or African American | Hispanic or Latino | Native Hawaiian or Pacific Islander | White | Others | Totals |
| Male |  |  |  |  |  |  |  |  |
| Female |  |  |  |  |  |  |  |  |
| Totals |  |  |  |  |  |  |  |  |

[ ]  Race/ethnicity and/or gender not collected for this study. Reason:

1. Vulnerable population accrual (cumulative):

|  |  |
| --- | --- |
| **Category** | **Total Enrolled** |
| Adults with Impaired Decision-Making Capacity |  |
| Children |  |
| Employees |  |
| Pregnant Women, Fetuses, Neonates |  |
| Prisoners |  |
| Students |  |
| Other *(describe)*:  |  |

1. Have any subjects been excluded on the basis of race, ethnicity, preferred language, socioeconomic status, education, gender, or pregnancy?

[ ]  No

[ ]  Yes.Please explain**:**

**Section 4: Progress Report**

1. Summarize any preliminary results or interim analyses or include a copy of the report, draft presentation or manuscript with this submission *(or indicate that there are none)*:

1. Briefly summarize any new and relevant information from the literature or other sources about the topic/issue under study since the last approval (initial or continuing):

1. Have adverse events occurred at the expected frequency and level of severity described in the protocol, consent, and Investigator’s Brochure (if applicable) since the last approval (initial or continuing)?

[ ]  NA – no adverse events

[ ]  Yes

[ ]  No. Explain:

1. Summarize any unanticipated problems involving risks to subjects or others (UPIRTSOs) since the last approval (initial or continuing):

*Unanticipated problems involving risks to subjects or others refer to any incident, experience, outcome, or new information that is unexpected, is related or possibly related to participation in the research, and indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized.*

1. Summarize any complaints about the research from local subjects since the last approval (initial or continuing) and any actions taken in response:

1. Summarize any issues or problems with the research since the last approval (initial or continuing) that were not captured above (e.g., difficulty with recruitment, loss of staff or other resources, etc.) and any actions taken or plans to resolve those issues or problems:

1. Since the last IRB approval (initial or continuing), has this study been audited or inspected by an external party (i.e. sponsor, FDA, OHRP, NIH, cooperative group, etc.), other than routine monitoring visits?

[ ]  No

[ ]  Yes. If the report was not previously submitted to the IRB, include a copy with this submission.

1. In the opinion of the PI, have the risks or potential benefits of this research changed?

[ ]  No

[ ]  Yes.Please explain**:**

**Section 5 – Attachments**

Please include the following items with your submission (as applicable):

[ ]  Current consent(s), information sheet(s), or script(s) **if** study is open to enrollment (or if sponsor requires re-approval)

[ ]  A redacted copy of the most recently signed consent document. If there is more than one consent (e.g., translated version), include a redacted copy of each.

[ ]  Current protocol/research plan

[ ]  Current Investigator’s Brochure

[ ]  Any un-submitted publication(s)/presentations resulting from this research

[ ]  Any un-submitted reports identified while completing this continuing review report

[ ]  Most recent DSMB or DMC report (if not provided with the Interim Report Form)

[ ]  For multi-center studies, the most recent study-wide report or update (if not provided with the Interim Report Form)

[ ]  For investigator held INDs or IDEs, a copy of the most recent annual report to the FDA

[ ]  Other *(describe)*:

**Section 6 – Other Requirements**

*Use this section to describe any additional requirements such as COI updates, documentation of training, etc. If none, delete.*

**PRINCIPAL INVESTIGATOR’S STATEMENT**

By entering my name and the date below, I certify that the information provided in this application is complete and correct.

Name Date