**Instructions:** Submit this form if your study is non-exempt and you would like to request closure of your research study and provide a final report to the IRB.

*The Principal Investigator (PI) shall complete this form for all Non-Exempt research. He/she is requested to submit on Buhooth to the PHCC IRB within 60 days of the conclusion of the study) or within 15 days of early termination. A study is concluded if all the human participants recruitment activities are completed and when access to and use of identifiable data are complete, hence the study is no longer classified as human participant research.*

|  |  |
| --- | --- |
| Study Title: |  |
| IRB Reference Number: |  |
| Principal Investigator: |  |

**REASON FOR CLOSURE**

Check the applicable options:

The study is complete

Confirm completion of all the below. All boxes must be checked for appropriate closure.

All Subjects’ recruitment & enrollment is complete. All research-related procedures, interactions or interventions including long term follow up is complete

Obtaining private identifiable information (data, specimens) is complete.

Private identifiable information can be direct (data having direct identifier like subject name, hospital record # or other identifiers..etc) or indirect (coded data that can be linked to direct identifiers and data by investigator (s)). The term investigator includes anyone involved in conducting this research.

Analyses of private identifiable information (data, specimens) are complete

Further use or access to private identifiable information (data, specimens) is no longer needed

(for example, manuscript writing, review of source documents by Sponsor …etc)

The study is cancelled (No work has been initiated, no data or samples have been collected)

State the reason(s) of cancellation:

Others; Explain:

|  |  |
| --- | --- |
| **SUBJECTS ACCRUAL STATUS SINCE LAST CONTINUING REVIEW**  Respond to the below for subjects enrolled at PHCC only | |
| Number of enrolled Subjects   *(# of subjects who signed ICF. For research with waiver of IC, # of subjects who are included; or # of samples/records)* |  |
| Were there any Subjects’ withdrawals? | Yes  No  N/A |
| Number of subjects who withdrew |  |
| Provide the reason (s) for withdrawal |  |
| Did you discontinue any Subject ’s participation?  *(PI /team stopped subject participation early before reaching the study endpoint)* | Yes  No  N/A |
| Number of discontinuations |  |
| Provide the reason (s) for discontinuing Subjects participation |  |

1. **Did the study involve the collection, storage, or use of any human biological specimens?**

Yes  No

If yes, explain what will happen with the specimens at the closure of this study:

Click or tap here to input text

**I certify that the proposed research has been completed and there will not be any further contact or pending interaction with the human participants, nor use of or access to individually identifiable information:**  Yes  No  Not applicable

1. **Is a summary of the final report on the research enclosed with this form?**  Yes  No
2. **Did this study terminate prematurely?**  Yes  No

If yes, please complete the following sections

* 1. Circumstances of early termination. What is the justification for this early termination?Click or tap here to input text
  2. Is this a temporary halt (suspension) to the study?  Yes  No

If yes, what is the justification for temporarily halting the study?*[e.g. Safety, difficulties recruiting participants, trial has not commenced, other reasons]*

Click or tap here to input text

and when do you expect the study to re-start?

Click or tap here to input text

* 1. Are there any potential implications for research participants as a result of terminating/halting the study prematurely? Please describe the steps taken to address them Click or tap here to input text

1. **Adverse events related to study procedures have occurred since the last renewal:**

☐ No

☐ Yes, these have already been reported to the PHCC IRB.

☐ No, these have NOT been reported to the PHCC IRB. Please complete and submit the “Adverse Events Reporting Form”.

1. **Deviations that took place since last continuing review.   
   The below is applicable to PHCC Site and any other site relying on IRB**

☐ No

☐ Yes, these have already been reported to the PHCC IRB.

☐ No, these have NOT been reported to the PHCC IRB. Please complete and submit the “Protocol Deviation Form”.

**RETENTION OF STUDY RECORDS:**

Confirm by checking the box that the PI will retain the records relating to research for at least 3 years after completion of the research and closure by the IRB

Confirmed

Specify the storage Location of all data/ research records (Hardcopies & Electronic)

                    