***This form must be completed for non-exempt research only***

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| --- | --- |
| Study Title: |  |
| IRB Reference No: |  |
| Principal Investigator: |  |
| IRB Expiry date: |  |

*Instructions: Submit this application when you would like to request continuing review of your research study (i.e. a request to renew the IRB approval period).*

*Submit with this application:*

* *Current approved version of the study protocol*
* *IRB Approvals from any collaborating site (if applicable)*

**Study Status**

**Please indicated what best reflects your research from the options below: [click the applicable checkbox]**

The research study did not start yet

New participant recruitment is still in progress.

Enrollment closed, but research-related procedures, interactions or interventions including long term follow up are still ongoing.

Remaining study activity is limited to analysis of private identifiable information (data/specimens) only.

Collection and analyses of private identifiable information is still ongoing *(for studies involving Subjects' data/specimens that are collected and analyzed under a waiver of IC)*

**Please complete the table below. If you have multiple subject pools (e.g., parents and children) indicate how many total participants have been recruited for each separate group. For studies determined to be more than minimal risk, please submit a completed “Notice of Amendment Form” if you need to increase or decrease enrollment for the study.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Participant Group:** | **# Enrolled** | **# Completed** | **# Withdrawn/ Dropped terminated by PI:** |
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| --- | --- |
| Date of last visit or contact with subject for research purposes | /       /  DD MMM YYYY |

1. **Please explain why the research was never initiated: (if applicable)**

Click or tap here to input text

1. **To your knowledge, since the last protocol approval date, has there been any new information, either through the study itself or through outside sources (e.g., literature, journal articles, conferences, etc.) that may indicate an increased risk to subjects in this study, including social, physiological, or physical harm)?**

Yes  No

If yes, Summarize the new information or attach supporting documentation:

Click or tap here to input text

1. **Provide a summary of your progress to date:**

Click or tap here to input text

1. **Please provide a succinct narrative (no more than 2 paragraphs) about the interim study results and preliminary findings**

Click or tap here to input text

1. **Has any data from this study been disseminated by the investigator in a peer-reviewed forum (e.g., conference, abstract, publication, etc.)?**

Yes  No

If yes, please provide an appropriate citation for the published manuscript**:**

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 “Serious 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”.

1. **Do you have any proposed changes/amendments to your application that need to be submitted for the PHCC IRB review and approval?**

No modifications at this time.

I have modifications that need approval. A Notice of Amendment Form is included with my submission.

***Please note:*** *If modifications are needed, submit a separate “Notice of Amendment Form” to explain the proposed changes and the track changes copy of the revised documents . The modification will be reviewed for approval with this renewal. Changes may not be implemented until you receive IRB approval.*

1. **Please specify the documents that have been revised and submitted with this form:**

Research Proposal submission form

Survey(s), questionnaire(s)

Interview guide(s)

Consent/Assent form(s)

Recruitment materials (flyers, emails, etc.)

Updated any expired CITI certificates

Others (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_