Application for Renewal

CPHS Log #

Principal Investigator(s):

Study Title:

Date study was approved by CPHS:

What is the current status of the study? (check one)

 The study did not start and human subjects data was never collected. Skip all questions. Sign and return to CPHS.

 Data collection has not yet begun, but it is expected to commence in the next year. Complete the form (in the progress report section, explain why the project was delayed), sign, and return to CPHS. If any part of the study detailed in the original application has changed (no matter how minor), you must also submit an Application for Revision.

 The project is currently ongoing. Complete the form, sign, and return to CPHS. If any part of the study detailed in the original application has changed, you must also submit an Application for Revision.

 The project concluded in the past year. Complete the form, sign, and return to CPHS. What was the date the project concluded?

Human Subjects

Tell us about the number of human subjects participating in your study:

Since the first day of data collection, how many subjects have participated?

Was an Informed Consent signed by each subject who participated or his or her legal representative since the beginning of data collection?

If no, please explain:

On what date was the first Informed Consent signed?

In the past year (since the last review), how many human subjects participated?

How many subjects have completed the study?

How many subjects have dropped out or not completed the study?

Please explain why these subjects did not complete the study:

How many subjects were approved for the project in your original application PLUS any revisions?

How many additional subjects do you anticipate will participate in the next year?

If this number puts you over the number you are approved for, you must attach an Application for Revision.

Progress Report

Summarize your progress on this study to date. You may enclose a report or abstract based off of this data. If the study is complete, summarize the results of the study.

Has anything changed about any part of the study since it was last reviewed (no matter how minor)?

If yes, you must attach an Application for Revision.

How much longer is this study anticipated to continue?

Were there any Serious Adverse Events that occurred during the last year? If yes, you must attach a letter detailing the event(s).

Did anything unanticipated happen or were there any problems that involved risk to subjects or to others (including new knowledge that brought to light previously unknown risks of your procedures)?

If yes, please explain

Did any subject offer complaints or negative comments about the study? If yes, please explain

Is there anything else that CPHS needs to know about any part of the study in order to adequately evaluate the study?

Signature of PI:

Date: