IRB Protocol No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ACTION REQUESTED:

 \_\_\_\_\_ Renew: New participant accrual to continue

 \_\_\_\_\_ Renew: Enrolled participant follow up only

 \_\_\_\_\_ Terminate: Protocol discontinued

1. Any amendment since the last review: \_\_\_\_No \_\_\_\_\_Yes

 If yes, describe briefly: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Any change in participant population, recruitment or selection criteria since the last review:

 \_\_\_\_ No \_\_\_\_Yes: Explain the changes: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Any change in the Informed Consent process or documentation since the last review:

 \_\_\_\_ No \_\_\_\_Yes: Explain the changes: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Is there any new information in recent literature or similar research that may change the risk/benefit ratio for participants in this study?

 \_\_\_\_ No \_\_\_\_Yes: Discuss and attach the narrative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. An unexpected complication or side effect noted since the last review:

\_\_\_\_ No \_\_\_\_Yes: Discuss and attach the narrative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Did any participant withdraw from the study since last approval:

\_\_\_\_ No \_\_\_\_Yes: Reasons for withdrawal:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Any new investigator that has been added to or removed from the research team since the last review?

\_\_\_\_ No \_\_\_\_Yes

1. Are there any new collaborating sites that have been added or deleted since the last review?

\_\_\_\_ No \_\_\_\_Yes: Please identify the sites and note the addition or deletion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Summary of protocol participants:

Accrual ceiling set by IRB: #\_\_\_\_\_\_\_\_

New participants accrued since last review: #\_\_\_\_\_\_\_\_

 Total participants accrued since protocol began: #\_\_\_\_\_\_\_\_\_

 Accrual Exclusions:

 \_\_\_\_None

 \_\_\_\_Male: #\_\_\_\_\_\_\_

 \_\_\_\_Female: #\_\_\_\_\_\_

 Impaired Participants:

 \_\_\_\_\_ None

 \_\_\_\_\_ Physically: #\_\_\_\_\_\_\_

 \_\_\_\_\_ Congenitally: #\_\_\_\_\_\_\_

 \_\_\_\_\_ Both: #\_\_\_\_\_\_\_\_

*To be filled out by the IRB:*

Date received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Received by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Primary Reviewer’s Name and Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| Changes to the protocol recommended: \_\_\_\_\_ Yes \_\_\_\_\_ NoComments: |
| Changes to the informed consent form recommended: \_\_\_\_\_ Yes \_\_\_\_\_ NoComments: |
| Recommendations:\_\_\_\_Take note and no further action\_\_\_\_Request an amendment to the protocol\_\_\_\_Request an amendment to the informed form.\_\_\_\_Request further information.\_\_\_\_Suspend or terminate the study\_\_\_\_Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Type of review:\_\_\_\_\_ Expedite Review\_\_\_\_\_\_Full board Review Date of Meeting: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

IRB Final Decision: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Certified By:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and Signature

PELI IRB Chair

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_