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 \_\_\_\_\_ No  Comments: | |
| Changes to the informed consent form recommended: \_\_\_\_\_ Yes \_\_\_\_\_ No  Comments: | |
| 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_