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

IRB Protocol No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 1: To be filled out by the PI**

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

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

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

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

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

 Name of the study medicine/device: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| Subject I.D. *(Site and eCRF IDs)*: | Age: | Sex: | Site:[ ]  On-site (SAE that occur **in study participant enrolled in study site** that has ethical clearance from Peregrine Eye and Laser Institute- Institutional Review Board)[ ]  Off-site (SAE that occur in study participants **enrolled in a different study site** that has ethical clearance from Peregrine Eye and Laser Institute- Institutional Review Board) |
| SAE Report Type:[ ]  Initial [ ]  Initial and Final Report

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. of initial submitted report per patient  |  |  | No. of initial submitted report per patient  |  |
| No. of Initial submitted report per study |  |  | No. of Initial submitted report per study |  |

 [ ]  Follow-up of data [ ]  Final Report | Onset of SAE: | <DD/MMM/YYYY> |
| Date of Initial Report to Sponsor (If applicable): | <DD/MMM/YYYY> |
| Date of Initial Report to IRB | <DD/MMM/YYYY> |
| **MEDICAL HISTORY (list relevant medical history):**[ ] Tick box if not applicable |
| **Condition** | **Start Date**(dd/mmm/yyyy) | **End date**(dd/mmm/yyyy) | **Ongoing**(Yes/No)  | **Current Medication required**(Yes/No)(If yes, pls. indicate list of **ongoing medication** information such as the generic name, dosage strength, frequency, start and end date) |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| **Event Details:** |
| **Narrative Report of SAE:** | **Diagnosis:** |
|  |  |
| **Seriousness Criteria** (check all that are relevant to the event):[ ]  Participant died [ ]  Inpatient hospitalisation or prolongation of existing inpatient hospitalisation[ ]  Life-threatening [ ]  Involved persistent or significant disability or incapacity[ ]  Congenital anomaly/ [ ]  Other significant medical events (as defined in protocol) birth defect |

|  |
| --- |
| **Study intervention** |
| **Device/Drug** | **Start date**(dd/mmm/yyyy) | **End date**(dd/mmm/yyyy) | **Relationship** ***Tick either unrelated or possibly related*** | **Expected** (Yes/No) |
| **Unrelated** | **Possibly**  | **Probably** | **Definitely** | **Unknown** |
|  |  |  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| **Relevant test/laboratory findings** *(include only the results relevant to the SAE diagnosis or course of SAE)* |
| **Test/lab finding**  | **Unit**  | **Date**(dd/mm/yyy) | **Value** | **Date**(dd/mm/yyyy) | **Value**  | **Date**(dd/mm/yyyy) |
| 1. |  |  |  |  |  |  |
| 2. |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |
| 4. |  |  |  |  |  |  |
| Comment on test/laboratory findings (if none, mark as N/A) |
| **Concomitant drugs relevant to the SAE***(do not include therapy used to treat the SAE)*[ ] Tick box if no relevant concomitant medication |
| **Drug name** | **Dose/schedule** | **Route of administration** | **Reason for use** | **Start date**(dd/mm/yyyy) | **End date**(dd/mm/yyyy) | **Continued**(Yes/No) |
| 1. |  |  |  |  |  |  |
| 2. |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |
| 4. |  |  |  |  |  |  |
| **Action taken (***check all that are relevant to the SAE***)**  |
| [ ]  No action taken  | [ ]  Device/Drug permanently discontinued due to this SAE | [ ]  Concomitant medication taken  |
| [ ]  Drug/Device schedule adjusted/ temporarily interrupted *If multiple devices used, please record which deivce(s) have been adjusted/interrupted:* | [ ]  Non-drug therapy given | [ ]  In-patient hospitalization [ ]  Prolonged in-patient hospitalization  |
| **Outcome of SAE** |
| [ ]  Completely recoveredDate of recovery <dd/mm/yyyy> | [ ]  Condition still present and unchanged | [ ]  Recovered with sequelae Date: <dd/mm/yyyy> |
| [ ]  Condition deteriorated | [ ]  Condition improving | [ ]  Death Date of death <dd/mm/yyyy>Post mortem was done Yes [ ]  No [ ]  |

**Section 2: To be filled up by the designated IRB representative**

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

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

Recommendations:

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

IRB Final Action : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Chair : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed Name over Signature