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 recovered  Date 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 \_\_\_\_\_ No  Comments: | |
| Changes to the informed consent form recommended: \_\_\_\_\_ Yes \_\_\_\_\_ No  Comments: | |
| 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 Review  Date of Meeting: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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

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

Printed Name over Signature