<dd/mm/yyyy>

**<Title, First Name, Last Name>**

<Institution/Affiliation>

<Address>

|  |  |
| --- | --- |
| **Re:** | **<PELI-IRB Code>**  **<Protocol Title>** |

Dear **<TITLE, LAST NAME>:**

This is to certify that the following protocol and related documents have been granted approval under Exempt from Ethical Review process by the Peregrine Eye and Laser Institute-Institutional Review Board for implementation. The research study proposal falls under the category of less than minimal risk (state actual reason) and therefore it is exempted from review.

IRB Protocol No:

Study Protocol Title:

Study Protocol Number:

Principal Investigator:

Sponsor:

Protocol Version No.: Version Date:

ICF Version No.: Version Date:

Other Documents Reviewed:

Duration of Approval: From: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Valid Until: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Frequency of Continuing Review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator Responsibilities After Approval:

* Submit document amendments for IRB approval before implementing them.
* Submit SAE and SUSAR reports to the IRB within 7 days.
* Submit progress report every \_\_\_\_ months.
* Submit final report after completion of protocol procedures at the study site.
* Report protocol deviation/violation.
* Promptly report to the IRB any new information that may affect adversely the safety of the subjects or conduct of the trial.
* Comply with relevant international/national guidelines and regulations.
* Abide by the principles of good clinical practice and ethical research.

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

Name and Signature

IRB Chair

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