Date:

This is to certify that the following protocol and related documents have been granted approval by the Peregrine Eye and Laser Institute-Institutional Review Board for implementation.

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:

Type of Review: \_\_\_\_\_\_Full Board \_\_\_\_\_\_Expedited

Meeting Date:

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_