PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute Institutional Review Board**
PELI-IRB-SOP-06-02-2026	
Version No. 2	**SOP 05 Exemption from Ethical Review**
Approval Date: March 9, 2026	
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SOP 05 Exemption from Ethical Review

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall ensure that all IRB members, officers, independent consultants, technical reviewers, and administrative staff receive initial and continuing training appropriate to their roles, to maintain competence in the ethical and scientific review of research involving human participants.

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) recognizes that certain research activities may be exempt from ethical review, provided that they meet established exemption criteria and pose no more than minimal risk to participants, if any.

1. The PELI-IRB shall apply exemption from ethical review only to research protocols that meet nationally accepted criteria for exemption, in accordance with the National Ethical Guidelines for Health and Health-Related Research (NEGHHR) and other applicable ethical standards.
2. Determination of exemption shall be based on a documented assessment of the nature of the research, the level of risk involved, and the extent to which human participants, identifiable data, or biological materials are involved.
3. Protocols that qualify for exemption shall include, but are not limited to, research that:
    a. does not involve human participants or identifiable human biological materials or data;
    b. involves institutional quality assurance, program evaluation, public health surveillance, or educational evaluation activities that present no more than minimal risk;
    c. involves observation of public behavior or interactions where participant identity cannot readily be ascertained and confidentiality is protected; or

d. uses publicly available data or information.

4. Exemption from review shall not be presumed by investigators. All claims of exemption must be submitted to and formally determined by the PELI-IRB through its designated authority.
5. All protocols determined to be exempt shall be formally documented, assigned an official exemption status, and issued a Certificate of Exemption from Ethical Review.
6. Records of exempted protocols shall be properly filed, tracked, and reported to the full board for information, to ensure transparency, institutional oversight, and quality assurance.
7. The PELI-IRB reserves the right to reclassify a protocol initially deemed exempt if subsequent information indicates that the research no longer meets exemption criteria**.**
8. The IRB Vice-Chair shall have primary responsibility for supervising the Staff Secretary in the implementation of this SOP and ensuring compliance with all documentation and reporting requirements.

II. Purpose

To describe the procedures for handling of protocols that are qualified for exemption from review.

III. Scope

This SOP applies to protocols that the IRB Chair has deemed qualified for exemption from review. This SOP follows the same steps as SOP 04 – Management of Protocol Submissions and enumerates the criteria that allow exemption from ethical clearance by the IRB. It ends with the filing of documents and updating of the database.

IV. Responsibility

The IRB Chair is responsible for assessing any protocol that qualifies for exemption from review. The Checklist for Exemption from Ethical Review (Form 5) should be used to determine whether the protocol qualifies for exemption.

V. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	See Step 1 of SOP 4 – Management of Protocol Submissions		
5	Inform the PI and issue the Certificate of Exemption from Ethical Review	Chair and Staff Secretary	1-3 calendar days

6	File the original protocol package in a properly coded Protocol File Folder and update the database	Staff Secretary	1-3 calendar days
7	Include the exempted protocol in the agenda of the next full board meeting for information	Staff Secretary	1-3 calendar days

VI. Detailed Instructions

Step 1 The IRB communicates its decision to the PI through Form 4.7 (see SOP 27 Communicating IRB Decisions) and the Chair issues a Certificate of Exemption from ethical clearance for the Staff Secretary to send to the PI.

Step 2 The Staff Secretary files the original package in a properly coded Protocol File Folder and updates the database.

Step 3 The protocol exempted from review is included in the next full board agenda to inform the IRB Members of the matter.

VII. Forms

1. Form 4.7 Notification of IRB Decision
2. Form 5 Checklist for Exemption from Ethical Review

VIII. References

1. 2020 PHREB SOP Workbook
2. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
3. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
4. National Ethical Guidelines for Health and Health-related Research (NEGHHR) 2017

IX. Revision Index

Version	Date	Reasons For Revision
1	July 16, 2022	Initial Release
2	March 9, 2026	○ Revised and reclassified as SOP 5 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics

		○ Added a Policy section to define the governing principles and general guidelines of the SOP.