PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 07/01-0-2022	
Version No. 1	**SOP 07** **Exemption from Review**
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Not Applicable	

SOP 7 Exemption from Review

1. Purpose

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

2. Scope

This SOP applies to protocols that the IRB Chair has deemed to be qualified for exemption from review. This SOP starts with the same steps as SOP 6 Management of Protocol Submissions, and enumerates the criteria that allows exemption from ethical clearance by the IRB. It ends with filing of documents and updating of the database.

3. Responsibility

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

4. Process Flow/ Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1-4	See Steps 1-4 of SOP 6A Management of Protocol Submissions		
5	Inform PI and issue certificate of exemption from ethical clearance to PI and	Chair and Staff Secretary	1-3 days upon receipt
6	File original package in a properly coded Protocol File Folder and update database	Staff Secretary	1-3 days upon receipt

7	Include in agenda of next board meeting to inform board of exempted protocol	Staff Secretary	1-3 days upon receipt

5. Detailed Instructions

Step 1-4 Initial protocol submission procedures are similar to STEPS 1-4 of SOP 6A Management of Protocol Submission.

The following are protocols exempt from ethical review according to the National Ethical Guidelines for Health and Health Related Research (NEGHHR) 2017 "The Research Ethics Review Process Guideline 3.1":

a. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols).

b. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests, provided that they do not involve more than minimal risks or harms.

c. Research that only includes interactions involving procedures, or observation of public behavior (including visual or auditory recording) if there will be no disclosure of the participants' responses outside the research and the information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained.

d. Protocols that involve the use of publicly available data or information.

The Chair uses the checklist in **Form 2.2.3** Study Protocol Assessment form for Exemption from Ethical Review to determine if a protocol is qualified for exemption in Step 4 of SOP 6

Technical approval is given by the Technical Reviewer in Step 6, forwarded to the Chair in Step 7 of SOP 6

Step 8 The IRB communicates its decision to the PI through **Form 2.5** (see SOP 28 Communicating IRB Decisions) and the Chair issues a Certificate of Exemption from ethical clearance for the Staff Secretary to send to the PI

Step 9 The Staff Secretary files the original package in a properly coded Protocol File Folder and updates the database

Step 10 The protocol exempted from review is included in the next full board agenda to inform the Members of the matter