

	Peregrine Eye and Laser Institute	
	Institutional Review Board	
	SOP 6B	
	Management of Protocol Resubmissions	
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SOP 6B Management of Protocol Resubmissions

1. Purpose

To describe the review procedures for protocol resubmissions.

2. Scope

This SOP pertains to the resubmission of revised or modified protocols that have been previously reviewed by the IRB. The procedure begins with the receipt of the revised protocol documents and ends with filing of the documents in the protocol file and the entry of the submission in the protocol database.

3. Responsibility

The IRB shall ensure that the researcher addresses the modifications it requires of a protocol before its approval not later than four (4) weeks after receipt of the decision letter. Modifications may be minor or major modifications. Minor modifications shall undergo expedited review while major modifications shall undergo full review.

4. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive protocol resubmission and enter in the logbook	Staff Secretary	on day of receipt
2	Code resubmitted protocol documents and notify Chair	Staff Secretary	on day of receipt
3	Evaluate resubmission or notify Technical Reviewer and Primary Reviewers	Chair Staff Secretary	3 days
4	Review the resubmission	Primary Reviewers	1-2 weeks upon receipt
5	Communicate IRB Decision	Chair and Staff Secretary	3 days after final decision
6	File the documents in the Protocol File Folder and update the database	Staff Secretary	

5. Detailed Instructions

Step 1 The Staff Secretary receives the study document, checks the nature of the document and ensures that the submission is properly logged.

Step 2 The Staff Secretary indicates the code assigned to the protocol when it was initially submitted and the date of receipt on all the documents.

Step 3 The Staff Secretary Retrieves **Form 2.5** Notification of IRB Decision that pertains to the original protocol and informs the Chair about the resubmission and about the nature of the modifications required from the researcher. Given the necessary information, the Chair either evaluates the resubmitted protocol at his/her level or directs the Staff Secretary to inform the reviewers concerned and to forward to them the necessary documents.

Step 4 The assigned reviewers conduct review of the resubmitted protocol by noting the different recommendations made by the IRB and evaluating whether these were satisfactorily addressed in the resubmitted protocol. The reviewers submit their report and recommendations in **Form 2.9** Review of Study Modifications to the Chair for inclusion in the next regular meeting. SOP 10 Full Board Review.

Step 5 For Resubmissions approved at the level of the Chair: The Chair dictates his/her decision to staff secretary for preparation of the draft approval letter **Form 2.6** Document Decision Form, finalization and sending to the Principal Investigator. For the resubmissions that underwent Full Review, refer to SOP 28 Communicating IRB Decisions.

Step 6 The Staff Secretary gathers all the pertinent documents related to the resubmission (revised protocol, assessment forms, excerpts of minutes, approval letter) and enters the relevant information on resubmission in the appropriate protocol database.