PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 12/08-0-2022	
Version No. 8	**SOP 12** **General Recruitment Practices and Advertisements**
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SOP 12 General Recruitment Practices and Advertisements

1. Purpose

To describe the acceptable methods of general recruitment practices and the standard operating procedures on review and approval advertisements employed in research studies.

2. Scope

Recruitment of participants into a study shall not begin until the study has secured final IRB approval. The IRB must approve all recruitment methods and materials (flyers, letters, brochures, email advertisements, radio announcements, etc) prior to use. Material must be submitted for review and re-approval at the time of continuation. Examples of acceptable methods of recruitment include general advertisements in print, radio or televised format, mailings using purchased lists available to the public, class announcements, email list-serve, or participations in health fairs. Investigators may re-contact participants from a previous study if the request for permission to re-contact for future studies was part of the consent process in the original study. For studies that involve recruitment of patients from a medical practice or a treatment facility, it is not acceptable for investigators not affiliated with that practice or facility to directly recruit patients. The initial contact must be initiated by the physician or an employee of the practice or facility. Recruitment can take the form of a flyer posted in the waiting area or handed to potential participants by a physician or employee of the practice or facility.

3. Responsibility

It is the responsibility of the IRB/Chair/designated Member to review and approve study advertisements.

4. Process Flow/ Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE

1	Submit recruitment methods and study advertisements for review	PI	One month before full-board meeting
2	Receive documents, and refer to Primary Reviewers of the protocol	Staff Secretary	One week upon receipt of submitted documents
3	Determine type of review	Chair	
4	If expedited, review study advertisements and make recommendations.	Primary Reviewer/Chair	1 week upon receipt
5	Discuss at full board, if necessary	Members	
6	Communicate IRB decision to PI	Staff Secretary	1-3 days upon being informed
7	File documents in the protocol file folder and update database	Staff Secretary	

5. Detailed Instructions

Step 1 Prior to use, the PI must have the study advertisements approved by the IRB. For IRB approved studies, the PI should submit the study advertisement along with **Form 3.2** Protocol Amendment Form one month before the quarterly full board meeting to the Staff Secretary.

Step 2 The Staff secretary receives the study advertisement submission, logs the submission in the Receiving logbook and forwards the submission to the Primary Reviewers of the protocol one (1) day upon receipt of the documents.

Step 3 The Chair determines if the proposed advertisements and recruitment methods are for expedited review or for full board review.

Step 4 The Primary reviewers perform expedited review of the study advertisements and make recommendations. See SOP 9 Expedited Review. Below are the guidelines for reviewing study advertisements:

- The content of recruitment materials and the method for communicating it cannot contain misleading or exculpatory language or tactics that create undue influence.
- Advertisements should contain limited information that provides enough detail to allow the prospective participant his/her eligibility and interest. Visual effects that may create undue influence cannot be used, example, placing the phrase "GET PAID P1,000" in all capital letters while the rest of the ad is in lower case is not acceptable.
- Generally the elements of any advertisement to recruit participants should be limited to the following:

    - The name of the PI and institution
    - An accurate description of the condition under study and/or research purpose
    - In summary form, the key eligibility criteria that will be used to admit (or exclude) participants into the study
    - A straightforward and truthful description of the benefits
    - If applicable, a statement that compensation is available or a statement of how much compensation is available
    - The amount/length of time or other commitment required of the participants;
    - The location of the research and contact information for obtaining additional information
- Advertisements cannot incorporate elements that:
    - State or imply a certain favorable outcome or other benefit beyond what is in the informed consent form
- For FDA-regulated studies
    - Make claims that the drug, device or biologic is safe and effective for the purpose under investigation or that is known to be equivalent or superior to any other drug, device, or biologic
    - Use terms such as new treatment, new medication, or new drug without identifying it as investigational
- The IRB must review and approve the final taped version of any radio or TV advertisement. The ad may be granted approval-pending amendments based on the script, but the final product must be submitted for additional review and approval to ensure consistency with the language and tone presented in the script.

- Advertisements including TV and radio ads may be reviewed through the expedited process. The IRB reserves the right to require full board review of any recruitment material.

Step 5 If necessary, the study advertisements may be referred to the full board for final decision.

Step 6 Inform the PI about the IRB decision. For approved ads, they must display the IRB validation stamp, unless an exception has been granted by the IRB. If it is not feasible to make copies of the validated version, it is acceptable to use the exact wording on the validation stamp: “PELI-IRB, Approval On (Date), Approved until (date), and Approved by (initials)”.

Step 7 File copies of the documents in the protocol file folder and update database.