Institutional Review Board (IRB)
840 Walnut Street
Philadelphia, PA 19107
Phone: 215-440-3155
Email: IRB@willseye.org

Form-1: New Study Submission

Do not use this form for research involving only existing patient records and/or specimens.
For this type of research, use Form-1A.

A. Complete the following fill-in items according to the instructions given in INSTRUCTIONS FOR COMPLETION OF WILLS EYE HOSPITAL IRB FORM-1.

1. **Research Study Identifying Information**

Study Title:

Principal Investigator:

Service or Department:

Preferred Mailing Address:

PI Phone: PI Email:

Coordinator Name:

Coordinator Phone: Email:

Co-Investigator(s):

Sponsorship: ◯ Industry: _____

Industry-sponsored studies will incur a one-time Review Fee.

◯ Federal/State/Local Government: _____

◯ Research Foundation/Grant: _____

◯ None

2. What type of IRB review are you requesting for this Research Study Proposal?

   ◯ Standard Review

   ◯ Expedited Review (Attach a letter to the IRB Chairman specifying the reasons you believe that your Research Study Proposal meets the requirements for expedited review.)

3. Was this Research Study Proposal ever reviewed previously by the Wills Eye Hospital IRB?

   ◯ NO

   ◯ YES

   If YES, what was the IRB #?

4. Does the study involve research activities (including enrollment, consent, and study treatment) to be conducted at the Wills Eye Emergency Room?

   ◯ NO

   ◯ YES

   If YES, approval of Jefferson IRB is required for this study. Contact the IRB Office for additional guidance.

5. Are you requesting a waiver or alteration of the Written Informed Consent Form or Process?

   ◯ NO

   ◯ YES

   If YES, compose a letter to the IRB Chairman specifying the reason(s) you believe that a waiver or alteration of the Written Informed Consent Form is applicable to your Research Study Proposal and submit it with this Form-1.

6. (a) Does this Research Study Proposal involve the use of any drugs or biologics or vaccines?

   ◯ NO

   ◯ YES

   If YES, list drugs to be used in this Research Study Proposal:

(b) Are all drugs/biologics/vaccines

(i) approved by the FDA?	NO	YES	N/A
(ii) for the use indicated?	NO	YES	N/A
(iii) for the dose indicated?	NO	YES	N/A

If NO to any of the above, complete a Form-1 IND**.**

(c) Are the drugs/biologics/vaccines listed in the Wills Eye Hospital Formulary?

NO

YES

N/A

(d) If NO, are these drugs/biologics/vaccines being dispensed on the 7th Floor of Wills Eye Hospital?

NO

YES

N/A

(e) Will the Sponsor provide the drugs/biologics/vaccines for the study?

NO

YES

N/A

If NO to (d) or (e), complete a Form-2 Drug Statement.

7. (a) Does this Research Study Proposal involve the use of a medical device(s)?

NO

YES

If YES, list device(s) to be used in this Research Study Proposal:

(b) Has this device been approved by the FDA for the use indicated?

- ◯ NO
- ◯ YES
- ◯ N/A

If NO, provide the Investigational Device Exemption ("IDE") and Sponsor for each device:

OR, provide a letter from the Sponsor or evidence from the scientific literature justifying why an IDE is not needed and summarize such justifications below:

(c) Is this a Non-Significant Risk (NSR) or Significant Risk (SR) device?

- ◯ NSR
- ◯ SR
- ◯ N/A

8. Does this Research Study Proposal involve an investigational procedure?

- ◯ NO
- ◯ YES

If YES, provide a description of the procedure:

9. Does this Research Study Proposal involve radiation exposure(s); or the use of any radioactive substance(s) other than standard diagnostic radiography, radionuclide scanning or radiation therapy; or require additional radiation exposure(s) from any of the foregoing solely as a result of participation in the Study?

- ◯ NO
- ◯ YES

If YES, this study must also be approved by the Radiation Safety Committee. Attach a copy of your approval letter for this radiation exposure or use of radioactive substance.

10. Does this Research Study Proposal involve use of rDNA, synthetic nucleic acid, nanotechnology, stem cells, infectious agent (pathogen), or biological toxin?

- ◯ NO
- ◯ YES

If YES, this study must also be approved by the Institutional Biosafety Committee. Attach a copy of your approval letter when submitting this application.

11. Does this Research Study Proposal involve research to be performed at/in/with another institution?

- ◯ NO
- ◯ YES

If YES, provide a list of the collaborating institutions:

12. Does this Research Study Proposal involve research to be performed involving any special subject populations?

- ☐ NO, children, prisoners, pregnant women/fetuses/neonates will be excluded.
- ☐ Children
- ☐ Prisoners
- ☐ Pregnant Women/Fetuses/Neonates
- ☐ Others (please specify):

What potential risks or discomforts do you anticipate for these special subject populations?

13. What is the level of risk for participants in this study?

- ◯ Minimal Risk
- ◯ Greater Than Minimal Risk

14. Will notices or advertisements be employed to recruit participants into this Study?

- ○ NO
- ○ YES

If YES, such notices/advertisements must be attached for approval by the IRB.

15. (a) Are you, or any co-investigator, receiving any compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of this study or in the form of compensation tied to sales of the product, such as a royalty interest?

- ○ NO
- ○ YES

If YES, please explain:

(b) Do you, or any co-investigator, when aggregated with a spouse and any dependent children, have any ownership interest (including stock and stock options) or other financial interest in the sponsor of this study whose value cannot be readily determined through reference to public prices (generally, interests in a non-publicly traded corporation that exceeds $5,000 determined through reference to public prices or other reasonable measure of fair market value (and does not represent more than a five percent ownership interest in any single entity) during the time of the study and for one (1) year following the completion of the study?

- ○ NO
- ○ YES

If YES, please explain:

(c) Do you have any property or other financial interest in the product, including, but not limited to, a patent, trademark, copyright, royalties, or licensing agreement?

- ○ NO
- ○ YES

If YES, please explain:

(d) Have any payments or contributions been made, directly or indirectly, by the sponsor of this study to you or to any co-investigator (when aggregated with a spouse and any dependent children), or to the institution, of $5,000 or more to support activities, exclusive of the costs of conducting the clinical study or other clinical studies (e.g., a salary, royalty, grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria, or other payments) during the time of the study and for one (1) year following the completion of the study?

○ NO

○ YES

If YES, please explain:

B. **Research Study Protocol.** Describe your Proposed Research Study and complete your Informed Consent Form in a separate document according to **Instructions For Completion of Wills Eye Hospital IRB Form-1.** Submit this document when submitting Form-1.

C. **Research Study Written Informed Consent Form.** Compose your Informed Consent Form according to the **IRB's Policy and Procedure Regarding Informed Consent.** Attach the completed informed consent document or a letter to the IRB Chairman requesting a waiver or alteration to the requirement to obtain informed consent when submitting Form-1.

D. **Principal Investigator's Statement.** As Principal Investigator, I certify that:

- The information provided in this Research Study Proposal is accurate and complete as of the date of this submission;
- I have read the IRB Policy and Procedures Manual;
- I understand the federally mandated responsibility of a research investigator in conducting a clinical protocol and will conduct this clinical protocol in accordance with these responsibilities;
- I have, and each one of the co-investigators has, completed/passed the mandatory training program;
- I will obtain consent from all subjects with an IRB-approved Informed Consent Form, if applicable to the project, and store the Consent Form in a satisfactory repository;
- I will provide all subjects with a copy of their signed Informed Consent Form;
- I have disclosed all conflicts of interest.

Signature of Principal Investigator Date

Instructions: Have each Co-Investigator sign an Investigator Statement Form and submit the completed application with all signatures present and all required documentation. Incomplete applications will be returned and must be resubmitted in full.

Submission Checklist

* required

Form-1 with separate Signature Page(s) for Co-Investigator(s)*
Protocol*
Informed Consent or Letter Requesting Waiver/Alteration*
Supplementary Documents (where applicable)
- Letter requesting Expedited Review
- Investigator Brochure
- Drug/Device Information
- Correspondences (FDA, OHRP, between investigators, sponsor, advisor, etc.)
- Recruitment Materials (ads, brochures, letters, etc.)
- Data Collection Sheet

Submission Instructions (All signatures must be present):

Mail to:

Wills Eye Hospital IRB
840 Walnut Street
Philadelphia, PA 19107

OR

Email to:

IRB@willseye.org with "New Study Submission" in the subject line.
Attach all required forms and documentation to email.