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

Form-4 Continuing/Final Review of Research

This form must be completed and submitted within one month of expiration of your current approval term.

PART I

IRB #:
Type of Review: ◯ Continuing/Annual Review ◯ Final Review
Date of Original IRB Approval:
Date of Last IRB Renewal:
Initial Review was: ◯ Full ◯ Expedited

Study Title:

Goal(s) of study:

Principal Investigator: Service/Department:
Co-Investigator(s):

PART II

Do not include screen failures, withdrawals, or terminations in this section.

	Since last approval	Total to date
1. Current enrollment of study		
2. Total number of subjects enrolled into study (On-site WEH only)		
(Other sites)		
3. Number of subjects with major adverse reactions at WEH (These risks are currently noted in the consent form)		
4. Number of subjects with major adverse reactions at WEH (These risks are not currently noted in the consent form)		
5. Number of subjects with any adverse reactions at other sites.		

○ This report of continuing review *does not include* increased risks to subjects currently enrolled in the protocol. Current subject risk profile remains unchanged.

○ This report of continuing review *does include* increased risks to subjects currently enrolled in the protocol. Consent form risk profile has been revised. Please explain revisions below.

PART III

Progress Narrative: IRBs are federally mandated to review a progress report for all continuing studies. Provide a brief narrative summarizing the past year's on-site research and subject progress. Include subject response to treatment/procedures, withdrawals from study, data analysis, and presentations/ publications of research. Indicate any changes in key personnel:

Risk/ Benefit Ratio: Has any information appeared in the literature or has any similar research been presented at meetings that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?

○ YES
○ NO

If **Yes**, please explain:

Enrollment:

What was the projected enrollment for this study?
Has the enrollment for the past year been greater or less than projected?
If the enrollment has been less than projected, explain why, and has this impacted on the statistical validity of this study?

Have there been any modifications to recruitment procedures?

Demographics:

Do not include screen failures, withdrawals, or terminations in this section.

	Native American	Asian	Black Non-Hispanic	Hispanic	White Non-Hispanic	Other/ Unknown	Total
Female							
Male							
Children							
Unknown							
TOTAL							

PART IV

Current Study Status

Please check <u>one</u> of each of the following, unless otherwise instructed:

1. ◯ Study is active
   ◯ Study is completed and closed
   ◯ Study is withdrawn or terminated
   ◯ Study never started

   If withdrawn, terminated, or never started, please explain:

2. ◯ Enrollment is open
   ◯ Enrollment is closed

3. Which consent forms do you request to renew?

   ◯ All consents on file
   ◯ Only the following:

   ◯ None

4. Date-collection

   ◯ Data-collection is complete.
   ◯ Data-collection is ongoing.

General Comments

1. Were there any grievances or complaints concerning this research protocol? Please explain.

2. Did anyone withdraw or terminate from the protocol? How many? Why?

PART V

Certifications: We certify that the information contained above is correct, that the consent form currently reflects any and all modifications since the last approval by the Institutional Review Board, and that (*check where relevant*):

☐ Under federal mandate, there is a signed consent form on file with the Principal Investigator for every subject studied at WEH. *If this is not true, please provide a brief explanation in the Progress Narrative. Do not check if no subjects enrolled.*

AND

☐ Under federal mandate, each subject at WEH has received a signed copy of the consent form used in the study. *If this is not true, please provide a brief explanation in the Progress Narrative. Do not check if no subjects enrolled.*

OR

☐ The Institutional Review Board approved the study without a need to obtain written consent from the subjects.

_____

Signature of Principal Investigator Date

_____

Telephone and/or Pager Number

Instructions: Submit this Form with the completed Annual ICF Table (unless written consent was waived). Attach any new or amended consent forms for review.

Wills Eye Hospital IRB
840 Walnut Street
Philadelphia, PA 19107

IRB Control #:_____

ANNUAL REVIEW
CONSENT FORM REPORT

Include all subjects who signed a consent form, including those who were withdrawn or terminated from the study due to screen failures.

Subject ID#	Date Subject Signed and Received ICF	Date Subject Enrolled Into Study	Date of First Treatment	Date Subject Signed and Rcv'd Revised ICF	Subject Status in Study (i.e. active, completed, withdrawn)

Attach additional sheets if necessary, using the same table headers as above.