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

Form-3B

To be completed by Principal Investigator when an Adverse Event occurs in studies conducted on-site.

IRB Control #: Date:

Principal Investigator:

Study Title:

Sponsor (if applicable): Subject: ○ M ○ F Age:

Study Drug/Device/Procedure:

Provide a brief and concise description of the adverse event and the action(s) taken:

Is this event UNEXPECTED or UNANTICIPATED? (i.e. the nature, severity, or frequency of the event is not consistent with known or foreseeable risks)

○ YES ○ NO

Is there a REASONABLE POSSIBILITY that the adverse event may have been caused by the procedures involved in the research?

○ YES ○ NO

Is this a SERIOUS event or does the event suggest greater risk of harm to subjects than was previously known?

○ YES ○ NO

If you answered NO to ALL OF THE ABOVE, STOP HERE.
This event does not need to be reported immediately.
This event should be reported at the time of Continuing Review.

Have you previously reported this adverse event to the IRB?

For this study? ○ NO ○ YES Date Reported:

For this subject? ○ NO ○ YES Date Reported:

What is the total on-site enrollment for this study?

Describe the SEVERITY of the event (check all that apply)

- ☐ Death
- ☐ Life-threatening or sight-threatening
- ☐ Resulted in inpatient hospitalization or prolonged existing hospitalization
- ☐ Resulted in persistent or significant disability or incapacity
- ☐ Resulted in a congenital anomaly or birth defect
- ☐ Based upon appropriate medical judgement, may jeopardize the subject's health and may require medical or surgical intervention

In the Principal Investigator's opinion, was the reaction related to the drug/device/participation in the study?

○ UNRELATED ○ POSSIBLY RELATED ○ PROBABLY RELATED ○ DEFINITELY RELATED

What is the basis for this determination?

Is the risk of this adverse reaction described in the consent form? ○ YES ○ NO

If **No**, should this risk be described in the consent form? ○ YES ○ NO

If **Yes**, please provide Form-6 and a revised consent form with tracked changes.

If **No**, please provide justification for not including this reaction as a risk in the consent form:

Has this adverse reaction been reported to the sponsor? ○ N/A ○ YES ○ NO

Has this adverse reaction been reported to the FDA? ○ YES ○ NO

Should presently enrolled subjects be informed of this event? ○ YES ○ NO

If **Yes**, have they been informed? ○ YES ○ NO

Has this adverse reaction changed the risk to benefit ratio of the study in any way? ○ YES ○ NO

Explain:

_____

Name of Individual Preparing this Report

<u>Certification: I certify that I have reviewed this report of an on-site adverse event.</u>

_____

Signature of Principal Investigator Date

<u>Instructions:</u> Submit this form to IRB@willseye.org with the following materials: sponsor report if available and, if applicable, the revised consent form and Form-6 Amendment to Research Protocol.