WillsEye Hospital

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

Form-3A

To be completed by Principal Investigator when an Adverse Event occurs in studies conducted off-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 reaction 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 drug/device/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 ANY 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:

How many times has this reaction occurred in individual subjects participating in this study? *(usually in the company narrative)*:

What is the total national/international enrollment for the study?

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

In the Principal Investigator's opinion, was the reaction drug-related or caused by the procedures associated with this protocol?

○ 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:

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:

Has this adverse event been submitted for review and analysis by a monitoring entity, such as the Sponsor, a coordinating or statistical center, or a DSMB/DMC?

○ YES ○ NO

If **Yes**, what was the recommendation of the monitoring entity?

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Name of Individual Preparing this Report:

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

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Signature of Principal Investigator Date

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