

INTERNAL Serious/Unexpected Adverse Event

Instructions: PDF Version

Submit this form within 72 hours of the adverse event.

This form is for events at a site for which this IRB is directly responsible (e.g. UHB, KCHC). For reports of events at other sites (e.g. those forwarded by a sponsor), use the External Serious/Unexpected Adverse Event Form

This format is designed for those who wish to print the form and complete it with a typewriter. If you would prefer to complete the form on a computer, please choose a different format.

If you need additional room to answer any questions, attach a separate page.

If you have any questions, contact the IRB Office at 718-270-2680.

Protocol #

SUNY Health Science Center at Brooklyn
Kings County Hospital Center
Institutional Review Board

INTERNAL Serious/Unexpected Adverse Event

(Use for events at a site for which this IRB is directly responsible.)

Principal Investigator:

Dept:

Box:

How should we contact you?

Name (if not PI):

Email:

Ph:

Fax:

Cell:

Page:

Protocol Title:

Date of Onset:

Date of Resolution:

Subject's Initials

What is the likelihood that the adverse event was caused by the study intervention?

- Definitely Yes**
 Probably Yes
 Probably Not
 Definitely Not

YES NO

- Is this a follow-up to a previously reported event?**
- Is there a DSMB (Data Safety Monitoring Board) or similar central safety review board in place for this study?**
- Should changes be made to the protocol?**
If YES, attach a form for Amendment
- Should changes be made to the "Risks" section of the consent form?**
If YES, attach a revised consent form.
- Is this protocol externally funded?**
If YES, provide the date adverse event was reported to sponsor:
- Does this protocol involve a locally-held IND/IDE?**
If YES, attach a copy of the FDA adverse event form and date of filing with FDA or written notice to the holder of the IND/IDE:

Below, or as an attachment, please provide a typed summary of the adverse event and its significance. Please provide as much context as possible (e.g. number of similar adverse events, total number of adverse events, number of participants enrolled).

Principal Investigator

Date

Internal AE Form 11/1/01 PDF

Summary of Adverse Event and Significance: