

EXTERNAL Serious/Unexpected Adverse Event

Instructions: PDF Version

This form is for reports of events at sites for which this IRB is not directly responsible (e.g. those forwarded by a sponsor). For events at local sites, use the Internal 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.

Submission Checklist:

In your submission to the IRB, please include the following:

- _____ External Serious/Unexpected Adverse Event Form
- _____ Material from sponsor and/or site at which event occurred

Protocol #

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

EXTERNAL Serious/Unexpected Adverse Event

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

Principal Investigator:

Dept:

Box:

How should we contact you?

Name (if not PI):

Email:

Ph:

Fax:

Cell:

Page:

Protocol Title:

Dates or control numbers for the Adverse Event, Sponsor, or DSMB (Data Safety Monitoring Board) Reports submitted:

YES NO

- Is there a DSMB or similar central safety review board in place for this study?**
- Are any of the reported events *possibly* related to the study intervention?**
- 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.**

If you are submitting multiple reports, please provide a summary list by event title and patient number or initials.

Principal Investigator

Date