

**MEHARRY MEDICAL COLLEGE SERIOUS ADVERSE EVENT FORM
(TO BE COMPLETED BY PRINCIPAL INVESTIGATOR)**

Principal Investigator: _____ IRB# _____

Exact Title of Project _____

Subject age: ____ Gender: ____M ____F Date of most recent IRB approval _____

New report _____ Follow-up report _____ If Follow-up, date of first report _____

Description of Adverse Reaction:

Event onset: _____ Is event continuing: ____Yes ____No*

*Event termination: _____

Check all appropriate items:

____Resulted in hospitalization or prolonged an existing hospitalization

____Resulted in permanent disability

____Subject died If so, was an autopsy performed: ____Yes ____No

Findings, if relevant (Use additional sheets)

Other:

Possibility of this event having been caused by the subject's participation in this study is:

____None ____Low ____Moderate ____High ____Unknown

Action Taken (i.e. describe status of the subject's participation):

Cause of event (if not related to research):

____Underlying disease ____Concomitant medication

____Disease progression ____Other: (Describe _____)

Has the same reaction occurred previously in this study? ____Yes ____No

If yes, how often? _____

Is event currently listed in consent/assent form? ____Yes ____No

Should consent/assent form be revised to inform subject of event? ____Yes/No

IRB Policy requires submission of internal SAE reports within 48 hours of the PI's knowledge of the event. If this report does not meet this requirement, explain on an additional sheet why it is late.

If YES, attach revised form for review.
If NO, explain why:

Should presently enrolled subjects be informed of event? _____Yes _____No

If yes, have they been informed? _____Yes _____No

Signature of Principal Investigator

Date

NOTE: Submit one original and one copy of this form and a revised consent/assent form, if applicable, to Cynthia G. Weaver or James L. Potts, M.D, Chair of the Institutional Review Board, in the Office of Grants Management. Note: If necessary, submit one highlighted copy of the revised consent/assent form and one clean copy without highlighting.

Is project extramurally funded? _____Yes _____No

If yes, which agency/company? _____

IRB ACTION/OFFICIAL USE ONLY:

Reviewed by: _____ Date _____
Comments:

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