DEPARTMENT OF STATE HEALTH SERVICES
CENTRAL OFFICE INSTITUTIONAL REVIEW BOARD
REPORT OF SERIOUS ADVERSE EVENT OR DEATH

Protocol #: _____-_____-_____

Principal Investigator: _____

Title of Protocol: _____

Initials of Subject: _____ Date of Birth: _____

Date Enrolled (attach copy of signed consent form): _____

Site of Enrollment: _____

Treating Physician: _____

Date of Death/Serious Adverse Event: _____

Date of Oral Report to IRB: _____

Date of Report to FDA or Sponsor (if applicable): _____

If death, autopsy performed: ____ Yes ____ No Date _____

Description of serious adverse event, any treatment, and resolution: _____

_____

_____

_____

_____ _____
Signature of Principal Investigator Date

For IRB Use:
Comments:

Recommend full IRB review: ____ Yes ____ No

_____ _____
Signature of IRB Chair or Acting Chair Date