CHS CIRB Adverse Event Report Form
(Form Date: 4/2011)
(All Adverse Event Reports must be reviewed by the Principal Investigator)

Date:

Protocol:

Adverse Event-Internal ☐

Principle Investigator: **Subject ID:**

Event date: **Date Reported to PI:**

Enrollment Site: ☐ **CH** ☐ **SMMC** ☐ **SCH**

☐ **Initial Report** ☐ **Follow-up Report**

Causality: ☐ **Definite** ☐ **Probable** ☐ **Possible** ☐ **Unrelated**

Event Severity Classification: ☐ **Serious Unexpected** ☐ **Moderate Unexpected**
☐ **Serious Expected** ☐ **Moderated Expected**

Provide brief description of event and action taken:

Adverse Event – External ☐ **Submit report only if required by the sponsor**

Attach the completed Summary of External Adverse Events form – do not attach Sponsor's Safety Report

The CHS CIRB will not formally review these reports. The Adverse Event Report Form will be stamped a "Received" with the date and a copy will be returned to the investigator.

DECLARATION: I certify that I have reviewed the attached report and conclude that the risk-benefit ratio of the research continues to be acceptable, and that the risks are minimized to the greatest extent possible.

Principal Investigator's Signature: _____ Date: _____

NOTE: The CHS IRB requires the original signature of the Principal Investigator. Approval will not be sent to the Principal Investigator until the CHS IRB office has received the original signature on this document.