CHS CIRB Protocol Deviation/Violation Report Form
(Form Date 4/2011)

Date:

Protocol:

Principal Investigator: Subject ID:

Event Date:

Describe protocol deviation/violation:

Provide an explanation whether the protocol deviation affected the safety of the subject or the integrity of the study data. List corrective actions below, including measure taken to ensure that similar deviations will not occur in the future.

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.

_____ _____

Signature Principal Investigator 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.