

ST. VINCENT HOSPITAL RESEARCH & REGULATORY AFFAIRS
Unanticipated Problems and Protocol Deviations
Involving Risks to Human Subjects or Protocol Violations

This form should be utilized under the following circumstances:

- When there is a change in risk to human subjects (even slight) and there exists a:
 Protocol deviation or Unanticipated problem that does not meet the criteria for an adverse event
- Protocol Violations (e.g. enrollment that does not fit within inclusion/exclusion criteria)
- HIPAA Violations (e.g. disclosure of PHI without consent, storage breach)

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator: _____ **IRB Study Number:** _____
 Address: _____ Department: _____
 Phone: _____ Fax Number: _____ E-Mail: _____
 Research Coordinator Name: _____ Phone Number: _____
 Research Proposal Title: _____
 Research R Number: _____
 Sponsor/Funding Agency: _____
 Sponsor and/or Funding Agency(s): _____ Sponsor Number: _____

SECTION II: PROBLEM, DEVIATION, OR VIOLATION CATEGORY

The problem, deviation, or violation involved (check all that apply):

Subject safety

Was the subject(s) adversely affected? Yes No

If yes, check to see that criteria for adverse event has not been met, if met fill out adverse event form.

Subject/study data reliability or validity

HIPAA Violation

Other, explain:

SECTION III: PROBLEM, DEVIATION OR VIOLATION INFORMATION

Subject ID: (*do not list names*): _____ Problem, Deviation, or Violation Date(s): _____

Date problem, deviation, or violation was first discovered by the PI or study personnel: _____

Date of report to RRAD: _____ Date of report to IRB: _____

Explanation of problem, deviation, or violation (what, when, where and why):

Corrective Measure(s) Taken (to prevent problem, deviation, or violation from occurring again):

Will an amendment to the protocol be submitted?

No. Provide rationale:

Yes.

Research Study Title:

Research R Number:

SECTION IV: NOTIFICATION INFORMATION

Was the sponsor notified of the problem, deviation, or violation?

N/A. This study is not sponsored.

No. Explain:

Yes. Date of Notification:

Signature of Principal Investigator: _____ Date: _____

FOR IRB OFFICE USE ONLY

This information has been reviewed and should be filed with the appropriate study and reported to the IRB/IBC.

This information should be reviewed at the next full IRB/IBC meeting.

Additional Comments: _____

Authorized IRB Signature: _____ Date: _____

Authorized IBC Signature: _____ Date: _____
(if applicable)