

RR 403-A

IRB Report of Unexpected Internal Adverse Event	Form AE-1
Section I – Protocol Information	
IRB #: _____ Title of Protocol: _____	
Principal Investigator: _____ E-mail: _____ Address: _____	
Phone: _____	
Section II – Nature of the Adverse Event or Unanticipated Problem Involving Risks to Subjects or Others	
Submit this section if a box in each row is checked (that is, the AE is (1) unexpected and (2) related or possibly related, and (3) serious), OR the investigator determines that the event alters or potentially alters the risk of the subject. For all other events, see Section III.	
<input type="checkbox"/>	UNEXPECTED The specificity or severity of the AE is not consistent with the current investigator's brochure or with other current risk information.
<input type="checkbox"/>	RELATED OR POSSIBLY RELATED There is a reasonable possibility the AE may have been caused by the drug or intervention OR it is possible that the AE may have been caused by the drug or intervention, but there is insufficient information to determine the likelihood of this possibility.
<input type="checkbox"/>	SERIOUS (1) results in death, or (2) is life-threatening, or (3) requires inpatient hospitalization or prolongation of existing hospitalization, or (4) results in persistent or significant disability or incapacity, or (5) results in a congenital anomaly or birth defect, or (6) causes cancer, or (7) is an overdose, or (8) is any medical event which requires treatment to prevent one of the medical outcomes listed above.
SECTION III – All Other Local Adverse Events	
Reporting of all local adverse events is required. If the local adverse event does not meet the criteria as described in Section II, check box marked Yes below and complete the remainder of the reporting form.	
<input type="checkbox"/>	Yes
SECTION IV – Certification of Principal Investigator	
This submission certifies the following: All necessary information has been assessed and Section V completed in sufficient detail to facilitate IRB review. The risks of the research are minimized to the greatest extent possible. The risk-benefit relationship of the research continues to be acceptable. The consent form does not require revision. A copy of the current consent form is attached. The consent form requires revision. An <u>underlined or highlighted copy</u> and a clean original with an explanation of the changes per Section IV (10) are attached.	

RR 403-A

Signature of Principal Investigator _____

Date _____

SECTION V

Instructions: In the space provided below, please respond to each of the following questions in sequence. Each part must be addressed independently without reliance on information covered under other parts.

1. **Subject Identifier:** Identify the subject using only their patient ID number. Do not include their name.

2. **Description:** Describe the medical nature of the adverse event.

3. **Date and Time of the Adverse Event:** State the date and time the subject suffered the adverse event.

4. **Location of the Adverse Event:** State the location where the subject suffered the adverse event.

5. **Treatment of the Subject:** Describe the medical treatment of the subject who suffered the adverse event.

6. **Prognosis:** Describe the subject's prognosis.

7. **Explanation of AE Classification:**

- a. Explain your assessment of causality
 b. Explain your assessment of the severity of the AE

8. **Risk-Benefit Analysis Update:** Explain why the overall risk-benefit relationship of the research is still acceptable in light of the information concerning this adverse event report.

9. **Changes in Protocol:** In your judgment, is a change in protocol necessary to reduce or eliminate risk? If **Yes**, then attach a description of the changes to this report. Describe **each** proposed change in protocol separately in numbered sequence. The justification or rationale for each change must be included, and the investigator must advise the IRB in this report whether or not **each** proposed change that directly affects the subject requires revision of the consent or assent document(s).

10. **Informed Consent/Assent Forms:** Are any changes required in the informed consent or assent form(s) to better inform and protect the rights and welfare of the subjects? If **Yes**, then attach one copy of the **revised informed consent/assent form(s)** with the changes **underlined or highlighted** and one clean original suitable for reproduction for use during the IRB review. Upon IRB re-approval this consent/assent form will be **stamped** with the date of the valid approval period. If **No**, then provide a brief rationale and attach one copy of the **current IRB-approved consent form(s)**.

11. **Re-consent/Assent:** Is it necessary to inform subjects (or their legally authorized representatives) who have already consented to participate in the study of the adverse event with either an amendment (or addendum) to or a revision of the consent/assent form? If **Yes**, then attach one copy of the **amendment and/or revised consent/assent form(s)** with the changes underlined or highlighted and one clean original suitable for reproduction for use during the IRB review. Upon IRB re-approval this clean original will be **stamped** with the date of the valid approval period. If **No**, then provide a brief rationale.

12. **Report Requirements:** Have you complied with all applicable reporting requirements of the institution, sponsor, NIH, or FDA?
