

VCU IRB

ADVERSE EVENT / SAFETY REPORTING FORM

Today's Date: _____ VCU IRB #: _____
 PI Name: _____ Signature: _____
Print Last, First, Middle Initial
 Title of Project (w/ Sponsor Protocol #): _____

Completing this form fulfills the investigator's obligation to ensure "prompt reporting to the IRB...of any unanticipated problems involving risk to the subjects or others..." as in accordance with 45 CFR 46.103(b)(5) and 21 CFR 56.103(b)(5). This form is also used for communicating submissions of anticipated and non-serious events as well as safety reports (IND safety reports, etc.), although reporting in these cases is not required.

Class(check one:) **Required Reporting Investigator Actions** (You must check at least one of the following actions:)

| | | |
|--|---|--|
| <input type="checkbox"/> Class 1a: <i>serious, unexpected, and related or possibly related – VCU SITE</i> | Report immediately at occurrence (using this form). Submit 20 copies. | <input type="checkbox"/> After considering risk/benefit ratio, <i>NO CHANGES</i> are currently proposed to research protocol or consent form. <input type="checkbox"/> After considering risk/benefit ratio, <i>CHANGES</i> are proposed to research protocol and/or consent form. The VCU IRB Study Reporting Form is attached with proposed changes to protocol or consent form. |
| <input type="checkbox"/> Class 1b: <i>serious, unexpected, and related or possibly related – NON-VCU SITE</i> | Report immediately at notification of occurrence (using this form). Submit 20 copies. | <input type="checkbox"/> DSMB Review Documentation Attached (Required for Non-VCU adverse events reviewed by a DSMB) <input type="checkbox"/> After considering risk/benefit ratio, <i>NO CHANGES</i> are currently proposed to research procedures or consent form. <input type="checkbox"/> After considering risk/benefit ratio, <i>CHANGES</i> are proposed to research protocol and/or consent form. The VCU IRB Study Reporting Form is attached with proposed changes to protocol or consent form. |

For all Class I Events:

Subject ID (initials): _____

Subject Age & Gender: _____

Date of Occurrence: _____

SAE Brief

Description: _____

Check One

Initial Report

Follow-up Report

Check One

Resolved

Ongoing

| | | |
|--|--|--|
| <input type="checkbox"/> Class 2: <i>mild or moderate, unexpected, and related or possibly related – VCU SITE</i> | Reporting required only if changes are proposed. | <input type="checkbox"/> After considering risk/benefit ratio, <i>CHANGES</i> are proposed to research protocol and/or consent form. The VCU IRB Study Reporting Form is attached with proposed changes to protocol or consent form. <input type="checkbox"/> Investigator is taking no action. |
| <input type="checkbox"/> Class 3: <i>other non-class 1 and 2 events.</i> | Reporting required only if changes are proposed. | <input type="checkbox"/> After considering risk/benefit ratio, <i>CHANGES</i> are proposed to research protocol and/or consent form. The VCU IRB Study Reporting Form is attached with proposed changes to protocol or consent form. <input type="checkbox"/> Investigator is taking no action. |

For VCU IRB USE ONLY

Acknowledged: _____ Date: _____

Comments: _____

Expedited Review: _____ Date: _____

Comments: _____

Full Panel Review: _____ Date: _____

Comments: _____