Research Ethics Board

# Adverse Event Report Acknowledgement Form

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| 1. PRINCIPAL INVESTIGATOR (LAST NAME, FIRST NAME)    | 2. INSTITUTION, DEPARTMENT      | 3. PHONE NUMBER      |
| 4. LOCATIONS WHERE THE RESEARCH HAS BEEN CARRIED OUT:[ ]  VCC Broadway Campus [ ]  VCC Downtown Campus [ ]  Other:      |
| 5. PROJECT TITLE:      |

INSTRUCTIONS:

1. Page 1 of this form, when signed on behalf of the VCC Research Ethics Board, is your acknowledgement of the adverse event reports listed below.
2. A copy of each report cited below must be attached to this form for the Research Ethics Board’s permanent file. Details of local adverse events may be reported under Item 9 below in lieu of attachments.
3. Report on only incident per form.
4. You may submit additional information, but please refer to the appropriate numbered items in any addenda or attachments.
5. Submissions must include the principal investigator’s assessment under Item 10 below.

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| 6. BRIEF DESCRIPTION OF THE INCIDENT:      | 7. PROJECT NUMBER(S) AFFECTED:      |
| 8. REPORT DATE(S):      | 9. REPORT NUMBER(S)/DESCRIPTION(S) [e.g. “Quarterly Report”]      |
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| 10. PRINCIPAL INVESTIGATOR’S ASSESSMENT OF THE SERIOUSNESS AND CAUSALITY OF THE SIDE EFFECTS AND WHETHER THESE COMPROMISE ON ETHICAL GROUNDS THE CONTINUATION OF THE STUDY: IF A CHANGE TO THE CONSENT FORM IS REQUIRED, PLEASE ATTACH A COPY WITH THE CHANGES HIGHLIGHTED. |
| Related to medication/medical procedure?Serious?Should the study continue?Should the consent documentation be revised?IS THIS A FOLLOW-UP REPORT? |   [ ]  Yes / Possible [ ]  Yes [ ]  Yes [ ]  Yes [ ]  YES | [ ]  No / Unlikely[ ]  No[ ]  No[ ]  No[ ]  NO | [ ]  Unknown |
| 13. ADDITIONAL INFORMATION:      |
| 14. CONTACT PERSON AND INFORMATION FOR CORRESPONDENCE:     [ ]  PLEASE SUBMIT A COPY TO CONTACT AT:      E-MAIL:       |
| 15. ATTACHMENTS:[ ]  Copies of adverse event reports[ ]  A copy of the revised, highlighted consent form |