Virginia Department of Health

Institutional Review Board

109 Governor Street, 7th Floor

P.O. Box 2448

Richmond, Virginia 23218-2448

Adverse Event Report

Part 1 – Administrative Information

IRB #: \_\_\_\_\_\_\_\_

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator (PI): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_

Faculty Supervisor (if PI is a student) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Part 2 – Information on Adverse Event

1. Please describe the adverse event(s). Include details such as the number of events, the dates of occurrences, number of participants involved, any known or potential impact on participants, and any other relevant information.
2. Please describe the known or possible cause(s) for the event.
3. Please describe the actions, if any, that you have taken in response to the event. Include the dates of those actions.
4. Have you submitted or do you plan to submit for IRB review, a modification to the study as a result of the adverse event? If yes, briefly describe the modification. (The Request for Modification Form is located at <http://www.vdh.virginia.gov/OFHS/policy/irb.htm#forms>. If no, please explain why you believe that an amendment is not required.
5. Do you plan to inform the participants who are already enrolled in your study about the adverse event or any safety or procedure related information as a result of this event? If yes, describe what will be communicated, and when and how it will be communicated. If the communication will be in writing, please provide the text of the communication to the VDH IRB. If no, please explain.

Part 3 – Signature

You may submit an electronic copy of this form by clicking on the attestation box below and entering name and date. After clicking on the attestation box, please save a copy of the form before emailing the form and required materials to VDHIRB@vdh.virginia.gov

**Principal Investigator**

I certify that the information I provided in this adverse event report is correct and complete.

\_\_\_\_ Attestation of Principal Investigator \_\_\_\_Attestation of Faculty Supervisor (if applicable)

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Signature of Principal Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Faculty Supervisor (if applicable) Date

(If the principal investigator is a student, the faculty supervisor must also sign)