Federal regulations applying to human subjects research include the responsibility of the investigator(s) to report adverse events of any kind. As related to the study, these may be: 1) an unexpected change in the subject; 2) something that causes harm (e.g., physical or psychological injury, loss of confidentiality or anonymity); or 3) something contrary to what is approved in the protocol.

This form is meant as a guide in reporting adverse events to the VDSS IRB. For assistance, contact irb@dss.virginia.gov.

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| Section I. Study and Principal Investigator information |

1. Study Title:

Click here to enter text.

1. VDSS IRB Number Click here to enter text.
2. Principal investigator (PI) name: Click here to enter text.
3. Faculty supervisor name, if applicable: Click here to enter text.
4. PI Email: Click here to enter text.
5. PI Telephone Number: Click here to enter text.

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| Section II. Information about the Adverse Event |

1. Describe the adverse event. Click here to enter text.
2. Date/Time and location were the event happened

Click here to enter text.

1. Describe actions taken and dates in response to the event.

Click here to enter text.

1. Who from the study stuff witnessed the event? Click here to enter text.
2. How many research subjects were involved in the event? Click here to enter text.
3. Have research subjects been informed, explain why or why not?

Click here to enter text.

1. Has the event been reported to any other authority? If yes, describe; if no, why not?

Click here to enter text.

1. What “follow-up with subjects/situation has been arranged? And when will it occur?

Click here to enter text.

1. In your judgement, why did this event happen?

Click here to enter text.

1. What could be done to prevent it the next time?

Click here to enter text.

1. Do you plan to modify the study protocol or other materials to address concerns? Please explain.

Click here to enter text.

1. What else should the IRB know about this event?

Click here to enter text.

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| Section III. Attestation and Signature(s) |

The \*Principal Investigator certifies that the information provided in this Adverse Event Form is correct and complete.

|  |  |
| --- | --- |
| PI Signature | DateClick here to enter a date. |

\*If the principal investigator is a student, the faculty supervisor must sign this form.