IRB Identifier:_____
(To be assigned by the IRB)

VIRGINIA STATE UNIVERSITY
ADVERSE EVENT REPORTING FORM

The Responsible Project Investigator (RPI) should complete and sign this form and submit it with related attachments for any event that falls into either Category A or Category B (see page 2)

Responsible Project Investigator Information		
RPI First Name:		**RPI Last Name:**
Department:		**Office Address:**
Phone:	**Fax:**	**Email:**
Complete Title of Research Project:		
Research Site: Where was the research activity conducted and where did the incident (or consequent event) occur?		
Subject Information: [ ]Age [ ] Male [ ] Female		
Known pre-existing condition(s) if any:		
Research Sponsoring Agency (e.g. NIH, NSF, etc):		

Description of Event	
Date of Event: _____/_____/_____	**Time of Event: ____:____ AM or PM (circle one)**
Location:	**Attending Physician:**
Hospital or Site of Medical Care:	
Provide a brief description of the event. Attach any additional documentation that may be helpful (lab or x-ray reports):	
Medical Treatment Received:	
Describe the Subject's Prognosis and Outcome. Attach any follow-up reports if the outcome is indeterminable at the time of this report.	

IRB Identifier:_____
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Nature of the Event

Event Type: ☐ Category A – Serious Adverse Event
☐ Category B – Other Unanticipated Event Adversely Affecting Subject

Serious - *A serious adverse event is any event occurring that results in any of the following outcomes. Check the outcome that applies:*

- ☐ **death**
- ☐ **life-threatening event**
- ☐ **in-patient hospitalization**
- ☐ **prolongation of existing hospitalization**
- ☐ **a persistent or significant disability/incapacity**
- ☐ **a congenital anomaly/ birth defect (pregnant subjects only)**

An unexpected adverse event – *the event or outcome was not described as a risk of participation in the research**, or,** through described as a risk, the event or outcome has occurred with unexpected severity or frequency.*
Unexpected? Yes ☐ No ☐

Probable (The adverse event is *likely related* to the study.) Probable? Yes ☐ No ☐
Possible (The adverse event *may be related* to the study.) Possible? Yes ☐ No ☐
Unlikely (The adverse event is *doubtfully related* to the study.) Unlikely? Yes ☐ No ☐
Unknown? ☐

Provide a brief rationale for your assessment. State whether the same adverse event has occurred previously and provide incidence data whenever relevant.

What Was Subjects Participation Level After the Event?

☐ Subject stopped research participation
☐ Subject had already completed research
☐ Subject continued research participation
☐ Subject withdrew from further participation
☐ Subject continued participation with follow-up only
☐ Investigator withdrew subject from further participation

Impact on Study

Protocol Changes. In your judgment, is a change in the protocol necessary to reduce or eliminate the risk?

☐ **Yes. Attach a Protocol Amendment.**
☐ **No. Provide a brief rationale in the space provided.**

Informed Consent Document. Are any changes required in the informed consent document(s) to better inform and protect the rights of subjects enrolled hereafter?

☐ **Yes. Attach <u>two</u> (2) revised consent forms.**
☐ **No. Provide a brief rationale in the space provided.**

Impact for Existing Subjects. Should/will subjects and/or guardians who have already consented to participate in the study be informed of this new information?

☐ **Yes. Attach an information sheet or consent addendum form.** ☐ **No. Provide a brief rationale in the space provided.**
NOTE: This form must be completely filled out. **Incomplete forms will be returned to the RPI for the completion of missing information.**

Signature of Responsible Project Investigator:	**Date Signed:** **_____/_____/_____**
Consulting Physician Report **(required for "Serious" Adverse Events whether expected or unexpected)**	
Please describe the severity of the event, the likelihood in your judgment that it was related to the research protocol, and any other information you feel would be important:	
Signature of Consulting Physician (if required):	**Date Signed:** **_____/_____/_____**
***** FOR IRB USE ONLY ***** **FINAL DISPOSITION**	
Review Category: ☐ **Expedited** ☐ **Full**	**Action:** ☐ **Approved** ☐ **Disapproved**
Recommendations:	
Signed by IRB Chair:	**Date Signed: _____/_____/_____**
Continuing Review Deadline: _____/_____/_____	