IRB APPROVAL NUMBER:_____ AMENDMENT NUMBER_____
(For IRB Use Only)

VIRGINIA STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
STUDY AMENDMENT FORM

This form must be typed and submitted Virginia State University, Office of Sponsored Research and Programs, P. O. Box 9407, Petersburg, VA 23806.

Section I: Investigator Information		
Principal Investigator:	**Department:**	
P. O. Box:	Phone:	E-Mail:

Co-Principal Investigator:		
P. O. Box:	Phone:	E-Mail:

Project Title:

Sponsor/Funding Agency:

Section II: Amendment Description

1. Provide a complete description of the proposed change(s) included in this amendment:

2. Is the study sponsored/funded? Please mark **(X)** the appropriate line below.

☐	NO

☐	YES, Check the appropriate line below and provide with this amendment, as applicable:	
	☐	a copy of the sponsor's amendment, if the amendment came from the sponsor
	☐	a copy of your notice to the sponsor of this change, if you initiated the amendment
	☐	a copy of the approved amendment will be sent to the sponsor.

3. Do the proposed change(s) described in this amendment alter the risk to benefit assessment?

☐	NO
☐	YES, Please describe how the assessment is altered:

4. Do the proposed change(s) described in this amendment affect any of the following documents?

☐	Authorization	☐	Advertisement, fliers, etc.	☐	Research Protocol, thesis, or dissertation	☐	Other, Please describe:

NOTE: Any document selected above must be included with the submission of the amendment.

5. Do the proposed change(s) described in this amendment require changes to the informed consent and/or assent document(s) or process? Please mark **(X)** the appropriate line below.

	The new informed consent and/or assent document(s) are <u>in addition</u> to the current one(s).
	The new informed consent and/or assent document(s) <u>replace</u> the current one(s).
	The new informed consent and/or assent document has been waived for this study.

A. Will enrolled subjects be informed of the change(s) described in this amendment?

	YES
	NO. Please explain why not:

	YES. Will enrolled subjects be re-consented and/or re-assented?
	NO. Please explain how enrolled subjects will be notified:

6. Amendment includes: (check all that apply)

	Informed Consent and/or Assent, dated:
	Protocol, dated:
	Notice to Sponsor, dated:
	Advertisement, dated:
	Other, dated:

NOTE:

1. **Only include documents that were checked in items 4 and 5 above (as being changed because of the amendment).**
2. **Listing document dates are optional and only necessary if required by the investigator or sponsor.**

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NOTE TO INVESTIGATORS: Study amendments *may not* be instituted until approval from the IRB is given.

Signature of Investigator:	Date:
Signature of Co- Investigator:	Date:

Section III: IRB Approval

This amendment, including documentation noted in item 7 above, has been reviewed and approved as meeting the criteria for IRB approval as outlined in 45 CFR 46.111(a) by VSU's IRB. I agree with the investigator's assessment regarding the above statement, unless otherwise noted.

Authorized IRB Signature:_____ IRB Approval Date:_____