VIRGINIA STATE UNIVERSITY
INSTUTIONAL REVIEW BOARD

CONTINUING REVIEW STUDY

IRB Study No. _____

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator:_____ **Department:**_____
(Last, First, Middle Initial)

Address:_____ Phone:_____

Fax:_____ E-Mail:_____

Project Title:

Sponsor/Funding Agency:_____

SECTION II: CURRENT STUDY STATUS

☐ **ONGOING**

Date study was initiated: _____

Projected date of completion: _____

(Select one below)

☐ Enrollment of new participants or review of records/specimens continues

☐ No participants have been enrolled to date (Skip Section III)

☐ **Please check here if the study is currently suspended (temporarily) and indicate the reason(s) for the suspension:**

_____

SECTION III: SUBJECT SUMMARY

1. SUBJECT SUMMARY TABLE

Since last IRB review	Total number of subjects **CONSENTED**	
	Total number of subjects who have **WITHDRAWN** from the study	
Since beginning of study	Total number of subjects **CONSENTED**	
	Total number of subjects who have **WITHDRAWN** from the study	
Number of **ACTIVE** subjects		
Number of subjects who have **COMPLETED** the study		

If necessary, please provide further explanation regarding the subject summary: _____

2. **WITHDRAWAL.** Have any subjects withdrawn from the study since the last IRB review?

☐ No

☐ Yes, state the reasons for withdrawal:_____

3. JUSTIFICATION FOR STUDY CONTINUATION

_____

4. **Vulnerable Populations**. Are any of the subjects who have consented or enrolled in the study members of a vulnerable population **which have not previously been approved for enrollment by the IRB**? This includes children, pregnant women and human fetuses, prisoners, cognitively impaired individuals, and students.
   - ☐ No
   - ☐ Yes. Please indicate which population(s) have consented or enrolled:
     - ☐ Children
     - ☐ Pregnant Women and Human Fetuses
     - ☐ Prisoners
     - ☐ Economically/Educationally Disadvantaged
     - ☐ Cognitively Impaired
     - ☐ Students

   Please note that you must submit an amendment to the IRB to request the inclusion of these subjects.

SECTION IV: STUDY SUMMARY OF EVENTS

1. **Since the last IRB review**, did any unanticipated problems, including adverse events, protocol deviations, or subject complaints, or noncompliance occur that required prompt reporting to the IRB?
   - ☐ No.
   - ☐ Yes. Were these events reported previously to the IRB, if applicable?
     - ☐ No. Please explain why these events were not previously reported: _____
     - ☐ Yes. Provide a **summary** of these events: _____
       - ☐ Check here if the **summary** is attached.

2. Based on the above information, do you feel the validity of the data is affected?
   - ☐ No.
   - ☐ Yes. Explain:

3. Based on the above information, do you feel there is an increase in risk to subjects or others or in the frequency or severity of adverse events, protocol deviations, problems, complaints, etc. since the last IRB review?
   - ☐ No.
   - ☐ Yes. Explain: _____

4. Describe the progress of the research, including any preliminary observations and information about study results or trends: _____

   If no progress description is provided, please explain why: _____

5. Have subjects experienced any **direct** benefit(s) from their participation in the study?
   - ☐ No.
   - ☐ Yes.

   Please explain: _____

6. If any recent literature has been published or presented by you or others since the last IRB review, has it demonstrated a significant impact on the conduct of the study or the well-being of subjects?
   - ☐ N/A. There has not been any recent literature published or presented since the last IRB review.
   - ☐ No.
   - ☐ Yes. Attach a copy or explain: _____

SECTION V: REQUIRED ATTACHMENTS

All of the following documents must be included with your continuing review submission.

- Continuing review form
- Informed consent document(s), unless the IRB previously approved a waiver of consent
- Protocol
- Publications (if applicable)
- Other documentations you feel the IRB should be aware of

NOTES:

- No changes to previously approved study documents are allowed at the time of continuing review unless requested by the IRB.
- Incomplete submissions will result in a processing delay, which could result in study expiration.

Your submission of this form certifies that this study has been and will continue to be conducted in full compliance with the IRB-approved protocol, HHS regulations and VSU policies governing human subject research. You also certify that the information contained on or with this form is accurate.

Signature of Principal Investigator:_____ Date:_____

SECTION VII: IRB APPROVAL

***** For Office Use Only *****

Type of review: ☐ Full Board

☐ Expedited, Category:_____

IRB Reviewer:

☐ Check here to confirm that the most recent informed consent statement has been reviewed and no additional information needs to be provided to subjects based on any new findings.

STATUS OF STUDY: ONGOING

This continuing review has been reviewed and approved as meeting the criteria for IRB approval as outlined in 45 CFR 46.111(a) by the VSU IRB. Based on the criteria for determining the frequency of continuing review and the level of risk, this study will expire on:_____. If the study is not re-approved prior to that date all research activities must cease on that date, including enrollment of new subjects, intervention/interaction with current participants, and analysis of identified data.

Authorized IRB Signature:_____ IRB Approval Date:_____