Virginia Department of Health

Institutional Review Board

109 Governor Street, 7th Floor

P.O. Box 2448

Richmond, Virginia 23218-2448

Request for Modification of Currently Approved Project

Part 1 – Administrative Information

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

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

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

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

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

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

Part 2 – Modification Information

1. **Please select ALL the categories of amendment(s) you are requesting.**

 \_\_\_\_\_\_ Change in Study Title

 \_\_\_\_\_\_ Change in Principal Investigator

 \_\_\_\_\_\_ Addition of/change in research personnel

 \_\_\_\_\_\_ Addition of/change in funding source

 \_\_\_\_\_\_ Change to research/study design, methods or procedures (e.g., observations, interventions, collection of biological samples or biometric information, participant tasks, etc.)

 \_\_\_\_\_\_ Addition of/change to study population

 \_\_\_\_\_\_ Addition of/change to recruitment or compensation procedure(s)

 \_\_\_\_\_\_ Addition of/change to survey(s), questionnaire(s), or other research instruments, - **Please attach revised instrument(s).**

 \_\_\_\_\_\_ Addition of/change to the identifiers collected in the study, or any others that would impact the privacy and confidentiality of the study participants

 \_\_\_\_\_\_ Addition of/change to informed consent/assent document(s) and/or procedures – **Please attach all related documents**

 \_\_\_\_\_\_ Change in the data use/analysis plan

 \_\_\_\_\_\_ Other changes (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **For each of the above selected modifications, please describe the modification that you are proposing and the reason you are making the modification.**
2. **Will the proposed modifications have an impact on the risks or benefits to the research participants? Please explain.**
3. **Attach revised protocol and/or consent (Highlight all revisions)**

Part 3 – Signature

You may submit an electronic copy of this application and required materials 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 application is correct and complete. I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the VDH Institutional Review Board.

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

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Signature of Principal Investigator Date

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Signature of Faculty Supervisor (if applicable) Date

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

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For IRB Reviewer Only:

( ) Approved: This signifies notification of IRB APPROVAL of the revision described above.

( ) Not Approved ( ) Abstain ( ) Conditionally Approved

Comments:

IRB Reviewer’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_