Vanderbilt University Institutional Review Board

Notification of Noncompliance with the Protocol

*Non-compliance, adverse events, and/or unanticipated problems to participants or others may be reported to the IRB by anyone. It does not require the signature of the Principal Investigator.

NOTE: This form is NOT for adverse events or unanticipated problems involving risk to participants or others (See IRB Policy III.L).

☐ Noncompliance Report: An incident involving non-adherence to the protocol. NOTE: This definition may not match the PI or Sponsor’s definition.

1. Noncompliance Description. Please describe in detail the nature of the noncompliance including the date of occurrence.

2. Explain why or how the noncompliance occurred.

3. Indicate the outcome of the noncompliance.

4. Did the noncompliance result in a violation of the participant’s rights, safety, or welfare?
   ☐ Yes ☐ No If “No”, please provide a rationale for this assessment:

5. Did the noncompliance affect the integrity of the study?
   ☐ Yes ☐ No If “No”, please provide a rationale for this assessment:

6. Please provide an explanation of the plan to prevent future noncompliance.

7. Has the PI been notified of this noncompliance and received a copy of this report? The PI should be notified of all noncompliance with the protocol, adverse events, and/or unanticipated problems involving risks to participants or others. The PI is responsible for the accurate documentation, investigation and follow-up of all noncompliance, adverse events and/or unanticipated problems involving risks to participants or others that are possibly related to study participation.
   ☐ Yes ☐ No

8. Is the PI requesting the study be placed on Administrative Hold? ☐ Yes ☐ No

9. Has this been reported to the sponsor?
   ☐ Yes ☐ No If “No”, please provide rationale for not reporting:

10. Sponsor’s response (if applicable).

_________________________________________________  ________________________
Principal Investigator’s Signature     Date

_________________________________________________  ________________________
*Other Signature       Date

Role in Study