

3. Did the deviation occur in order to eliminate an apparent hazard to the subject: Yes No
If yes, describe the circumstances surrounding the hazard (e.g., time, place, manner, situation, etc.):

4. Considering this deviation:

a. Do you recommend any change to the protocol: Yes No
 If yes, attach recommended changes (marked in the protocol or a detailed summary).

b. Do you recommend a change to the consent document/template: Yes No
 If yes, attach the consent changes, marking the changes in the document.

c. Has the study sponsor reviewed these recommended changes: Yes No

As Principal Investigator, I understand that deviations from a protocol can have serious effects on the integrity of human research. As the Principal Investigator, I am responsible for oversight of all procedures performed for this protocol and will endeavor to prevent protocol deviations.

Date: _____

Principal Investigator Signature

Printed Name of Principal Investigator