

**PLEASE NOTE:** If this is an unanticipated problem or an adverse event related to study participation, please complete the [Unanticipated Problem/Adverse Event Form](#).

Principal Investigator:  
Protocol Number (IRBNet):  
Project Title:

**Question 1: Describe the protocol deviation.**

**Question 2: When did the deviation occur?**

**Question 3: Please provide details resulting in the protocol deviation.**

**Question 4: Why was the IRB not notified regarding changes to the protocol?**

**Question 5: Describe the steps taken to avoid recurrence of the deviation/violation.**

**NOTE:** Please have both the staff member completing this report and the Principal Investigator for this protocol electronically sign the IRBNet package prior to submitting this report in IRBNet.