



# Protocol Deviation Report

**Protocol:** \_\_\_\_\_  
**Investigator:** \_\_\_\_\_  
**Subject Number / Identifier:** \_\_\_\_\_  
**Sponsor:** \_\_\_\_\_  
**Date of Report** \_\_\_\_\_

Describe the protocol Deviation:

Describe the reason for the protocol deviation:

Was this protocol deviation pre-approved from the sponsor?

☐ Yes ☐ No

If No; when was this protocol deviation reported to the sponsor: \_\_\_\_\_

When was this protocol deviation reported to the IRB: \_\_\_\_\_

Was this protocol deviation incurred in the immediate interest of protecting patient / subject safety?

☐ Yes ☐ No

If No; describe the preventative action that will be put in place to prevent this deviation from occurring in the future:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Form Completed by (print):** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

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