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| **Protocol Deviation** |
| **Protocol Number/Title:** Click here to enter text. | **PI Name:** Click here to enter text. | **Site:** Click here to enter text. | **Subject ID:** Click here to enter text. |

1. Date of deviation: Click here to enter a date.
2. Date deviation identified: Click here to enter a date.
3. Deviation description: Click here to enter text.
4. Deviation identified by: Choose an item.
 If other, specify: Click here to enter text.
5. Type of deviation identified: Choose an item.

 If other, specify: Click here to enter text.

1. Did the protocol deviation result in an AE?
 [ ]  Yes
 [ ]  No
 Comments/Clarification: Click here to enter text.
2. Did the subject continue in the study?

[ ]  Yes
[ ]  No
Explain: Click here to enter text.

1. Does the deviation meet IRB reporting requirements?

[ ]  Yes
[ ]  No
Comments/Clarification: Click here to enter text.

1. Date the deviation was reported to the IRB (if applicable): Click here to enter a date.
2. Action taken to resolve this deviation (if any): Click here to enter text.
3. Deviation impact (check all that apply):
 [ ]  Study Validity
 [ ]  Safety
 [ ]  No Impact
 [ ]  Outcome Measures
 [ ]  Other, specify: Click here to enter text.

Investigator Signature: Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (dd/mmm/yyyy)