# Protocol Deviation

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol Number/Title:** | **PI Name:** | **Site:** | **Subject ID:** |

1. Date of deviation:
2. Date deviation identified:
3. Deviation description:
4. Deviation identified by:

If other, specify:

1. Type of deviation identified:

If other, specify:

1. Did the protocol deviation result in an AE?

Yes

No

Comments/Clarification:

1. Did the subject continue in the study?

Yes

No

Explain:

1. Does the deviation meet IRB reporting requirements?

Yes

No

Comments/Clarification:

1. Date the deviation was reported to the IRB (if applicable):
2. Action taken to resolve this deviation (if any):
3. Deviation impact (check all that apply):

Study Validity

Safety

Outcome Measures

Other (briefly describe):

1. Enter comments here:

Investigator Signature: Date:

(dd/mmm/yyyy)

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