# 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)

V3.0 2020-10-20