**Study XXX: [STUDY NAME]**

**protocol DEVIATION Form**

|  |  |
| --- | --- |
| **QUALIFIED (SITE) INVESTIGATOR:**  | **Site Name:**  |
| **PARTICIPANT NUMBER:\*** | **PARTICIPANT LETTER CODE:\*** |
| \* [Note to template: If more than one participant, include details in Description of Deviation section below.] |
| **[ ]  REQUEST**  | **[ ]  NOTIFICATION** |
| **Protocol Date & Version:**  |  |
| *If the deviation affects the inclusion/exclusion criteria, add the following:*  |
| **Inclusion No.:**  | **Exclusion No.:** |
| **Description of Deviation:**[If deviation involves more than one participant, include Participant # and Letter Code in this section]1. Date of Deviation (if previously occurred)
2. Brief description of the deviation
3. Reason for deviation
4. Explain measures/corrective actions to prevent re-occurrence (for unintentional/unanticipated deviations)
 |
| **Did the deviation result in an adverse event:**  | **[ ]  YES [ ]  NO [ ]  NA** (deviation request) |
| **Did the deviation result in an SAE:**  | **[ ]  YES [ ]  NO [ ]  NA** (deviation request) |
| **Did the deviation result in participant being withdrawn from the study:** | **[ ]  YES [ ]  NO [ ]  NA** (deviation request) |
| **Deviation reported to REB/IEC:** | **[ ]  YES [ ]  PLAN TO REPORT** **[ ]  NOT REQUIRED** |
|  |
| **Qualified (site) Investigator:** | ***(Signature)*** |  | ***(dd/mmm/yyyy)*** |
| **PM Notified By:** |  | **Notification Date:** |  |
|  |  |  | ***(dd/mmm/yyyy)*** |

***Email/fax to [study PM] at [Email address / fax #]***

|  |
| --- |
| ***The following section to be completed by Sponsor/SI or Medical Monitor*** |
|  |
| **REVIEW REQUIRED BY:** | **[ ]  Sponsor/SI [ ]  Medical Monitor\***\*if SI is also QI |
| **REQUEST APPROVED / NOTIFICATION ACCEPTABLE:** | **[ ]  YES [ ]  NO** |
|  |
| **Comments and Recommendations. If request is not approved Action(s) Required:** |
|  |
| **[ ]  Sponsor/SI** **[ ]  Medical Monitor** |
|  |  |  |  |  |
| ***(Name)***  |  | ***(Signature)*** |  | ***(dd/mmm/yyyy)*** |