**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 (if applicable) 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| **Did the deviation result in participant being withdrawn from the study?** | | | | | **YES  NO  NA** (deviation request) | | | |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)*** |