|  |  |
| --- | --- |
| **[Insert Study Name & HRPO#]** | |
| **Site Number:**  **Pt\_ID:** | **Visit Date**  / / 2 0  d d m m m y y y y |
|  | |

# Did this participant have any protocol deviations? Yes No

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Description of Protocol Deviation:** | **Deviation Category\*** | **Deviation Code\*\*** | **Date Deviation Occurred:** (dd/mmm/yyyy) | **Date IRB Notified (if applicable):** | **Principal Investigator’s Signature** | **Date Signed**  (dd/mmm/yyyy) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**\*DEVIATION CATEGORIES:**

1. Safety
2. Informed Consent
3. Eligibility
4. Protocol implementation
5. Other, specify in log

\*\*DEVIATION CODES: Numbers listed by the sample protocol deviations Safety (Category A)

* 1. Not reporting an SAE within 24 hours
  2. Laboratory tests not done
  3. AE/SAE is not reported to IRB
  4. Other, specify in log

Informed Consent (Category B)

* 1. Failure to obtain informed consent
  2. Consent form used was not current IRB-approved version
  3. Consent form does not include updates or information required by IRB
  4. Consent form missing
  5. Consent form not signed and dated by participant
  6. Consent form does not contain all required signatures
  7. Other, specify in log

Eligibility (Category C)

* 1. Participant did not meet eligibility criterion
  2. Randomization of an ineligible participant
  3. Participant randomized prior to completing Baseline Assessment, etc.
  4. Randomization and/or treatment of participant prior to IRB approval of protocol
  5. Other, specify in log

Protocol implementation (Category D)

* 1. Failure to keep IRB approval up to date
  2. Participant receives wrong treatment
  3. Participant seen outside visit window
  4. Use of unallowable concomitant treatments
  5. Prescribed dosing outside protocol guidelines
  6. Missed assessment
  7. Missed visit
  8. Other, specify in log