Ascension Wisconsin Research Education and Quality Management

**Adverse Event Log Guidance Document**

This tool was created to capture if new symptoms or problems arise among study subjects.

**Tips for GCP Documentation**

* Use black ink.
* Use proper error correction method –draw a single line through the error, initial and date with today’s date and write the correct information as close to the error as possible.
* Ensure numbers are written clearly.
* Do not put a line through the number “0” and “7” when written.
* No write overs.
* Include the month, date and year when documenting a date.
* Do not use correction fluid or “white out”.
* Data much be written in each column or row, even if it is repeats. Do not use an arrow or ditto marks.

**Tips for Completing the Form**

* Print the form and maintain in the Regulatory Binder.
* Complete Investigator Name, Study Title and IRB #.

**Complete Upon Notification of an Adverse Event**

* Column 1: Complete the problem.
* Column 2: Complete the date the problem started.
* Column 3: Complete the severity of the problem.
* Column 4: Complete the date of resolution.
* Column 5: If there is a date of resolution, check resolved ; If there is not a date of resolution, check ongoing. If at a later date, the subject states the problem is resolved, return to this form and add the information.
* Column 6: Complete causality to the study.
* Column 7: Complete any interventions used for the problem.
* Column 8: Complete if the adverse event was serious.
* Column 9: Complete if the subject was dropped from the study.

**Sample**

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator:** | **Joe Smith, MD** | **Subject/Screening ID#:** | **001** |
| **Study Title/IRB #:** | **XYZ Mouthwash** | **Subject Initials:** | **ABC** |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Problem** | **Date of Onset** | **Severity\*** | **Date of Resolution** | **Outcome** | **Causality\*\*** | **Intervention** | **Serious** | **Was Patient Dropped from study?** |
| Heartburn | 01/01/16 | 1 | 01/01/16 | [x]  Resolved[ ]  Ongoing | 1 | Tums | [ ]  Yes[x]  No | No |
| Headache | 02/16/16 | 1 | 02/17/16 | [x]  Resolved[ ]  Ongoing | 0 | Tylenol | [ ]  Yes[x]  No | No |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Problem** | **Date of Onset** | **Severity\*** | **Date of Resolution** | **Outcome** | **Causality\*\*** | **Intervention** | **Serious** | **Was Patient Dropped from study?** |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |  | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |  | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |   | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |  | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |  | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |   | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |  | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |  | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |  | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |   | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |  | [ ]  Yes[ ]  No |  |
|  |  |  |  | [ ]  Resolved[ ]  Ongoing |  |  | [ ]  Yes[ ]  No |  |

Any unfavorable medical occurrence or pre-existing condition that worsens from the time the subject signs the informed consent should be recorded as an AE.

\*Severity of Problem: \*\* Causality (relation to study):

Mild 1 Not Related 0

Moderate 2 Possibly Related 1

Severe 3 Probably Related 2

 Definitely Related 3