|  |  |  |
| --- | --- | --- |
| SOP Number:  [SOP NUMBER] – [VERSION] | Page Number:  1 of [X] | Effective Date:  [DATE] |

|  |  |  |
| --- | --- | --- |
| Originated by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |
| Reviewed by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |
| Approved by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |

##### Standard Operating Procedure (SOP)

**Safety Reporting and Managing Adverse Events**

***Please note that italic font is used within templates to indicate areas where site-specific information must be included and to describe the type of information needed.***

1. SCOPE

The scope of this SOP applies to the reporting requirements for any adverse events occurring in any clinical study of an investigational new drug or biologic during all phases, including Phase 4, of development.

[Also identify the owner, functional group/business unit impacted by the SOP and/or describe the range of effort described within the SOP, including limitations, boundaries and goals. Explicitly identify any out-of-scope items.]

1. PURPOSE

The purpose of this SOP is to describe how to manage, document and report safety events.

1. DEFINITIONS AND/OR ABBREVIATIONS & ACRONYMS (optional)
2. **Safety event** is any injury or adverse event that occurs in a participant taking part in a clinical trial.
3. **Adverse event (AE)** is any untoward medical occurrence in a clinical trial of a pharmaceutical/biologic product; an AE may or may not have a causal relationship with the investigational product.
4. **Serious adverse event (SAE)** is any untoward medical occurrence that at any dose:
   1. Results in death
   2. Is life-threatening
   3. Requires inpatient hospitalization or prolongation of existing hospitalization
   4. Results in persistent or significant disability/incapacity
   5. Results in a congenital anomaly/birth defect

[**NOTE:** Important medical events that may not result in death, be life-threatening or require hospitalization may be considered serious when, based on appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.]

1. GENERAL STANDARDS (Optional)

General information related to the SOP should be included in this section.

Add federal regulation references here.

1. PROCESS & PROCEDURES
2. Identifying and Assessing the Adverse Event/Safety Event
3. Review adverse change from baseline (pre-treatment) condition.
   1. Intercurrent illness that occurs during a clinical study after treatment has started, whether considered related to treatment or not.
   2. Any effect that is unintended and unfavorable, such as a:
      1. Sign, observed by clinicians
      2. Symptom, reported by a participant/parent
      3. Laboratory abnormality
      4. Disease
4. Ensure that the following are appropriately investigated:
   * 1. Spontaneous reports by participants
     2. Observations by clinical research staff
     3. Reports to research staff by family or medical care providers
     4. Review of study participant diaries, if applicable
     5. Possible AEs documented in medical records, progress notes etc.
     6. Reports of a participant’s death within four weeks of stopping treatment or during the protocol defined follow-up period, whichever is longer, whether considered treatment related or not
5. Only the PI or sub-investigator:
   1. Performs clinical assessment
   2. Orders appropriate laboratory tests and diagnostic prodedures and/or studies
   3. Confers with medical/surgical consultants as needed
6. Clinical Management of the Adverse Event/Safety Event
7. The investigator, sub-investigator and study coordinator ensure that all appropriate resources are directed toward participant safety and wellbeing and institute therapeutic intervention/support measures.
8. The investigator, sub-investigator and study coordinator review the protocol for instructions regarding the investigational drug management.
9. The investigator, sub-investigator and study coordinator will follow up and assess the adverse event until patient is stabilized and/or the event is resolved.
10. Documenting the Adverse Event/Safety Event
11. The investigator completes the appropriate AE worksheet, noting the:
12. Nature and severity of the event
13. Probable relationship of the AE to the investigational product
14. Date and time of AE onset
15. Date and time of AE resolution, if available
16. The study coordinator:
17. Interviews participant and/or parent/guardian, if available
18. Reviews participant records
19. Records all therapeutic interventions, diagnostic procedures, laboratory tests, concomitant medications, dosage adjustments and interruptions
20. Collects source documents for laboratory tests/procedures
21. Completes the appropriate case report form (CRF)
22. The investigator or sub-investigator:
23. Provides medical interpretation of laboratory tests and/or diagnostic procedures
24. Reviews CRF
25. Signs CRF
26. Reporting Adverse Events/Safety Events
27. Sponsor reports for an SAE must be reported via telephone, fax or e-mail no later than 24 hours of staff becoming aware of the events.
28. Provide as much information as is available.
29. Provide additional documents that support the SAE.
30. Keep sponsor informed throughout management of the event and as details become available.
31. If additional information cannot be obtained for whatever reason, this should be documented.
32. Sponsor should be informed when no other information is expected.
33. Reporting SAEs to the IRB by *[Insert the title of the person responsible for submission]*
34. *Include your IRB’s reporting requirements*
35. Receiving IND Safety Reports from sponsors
36. *Include your IRB’s reporting requirements and any internal process(es) you have for reviewing IND safety that are sent by the sponsor.*
37. Supporting Documents
38. 21 CFR 312 Subpart B – Investigational New Drug Application (IND)
39. 21 CFR 314 Subpart H – Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses
40. 21 CFR 812 Subpart C – Responsibilities of Sponsors
41. ICH Good Clinical Practice Guideline Sections 4 and 5
42. REFERENCES

Include both local and federal regulations cited to create the SOP.

1. ATTACHMENTS
2. Attachment 1 – Attachment title: Adverse Event Reporting Template
3. REVISION HISTORY

Major changes should be identified. Show history in descending order of versions.

|  |  |  |
| --- | --- | --- |
| Version Number | Summary of Changes | Replaces |
|  |  | Document Number, Revision Number |
| 02 | Enter the summary of changes in a bulleted list, highlighting the major changes | SOP XXX-###, 01 |
| 01 | Original document |  |

1. FOOTER

[Version number], [Version date], [Page count], [Any sort of a confidentiality statement]