**FORM 4.3E ADVERSE EVENT REPORT REVIEW FORM**

**IDI REC TRACKING#**

[ ] Sponsor Report [ ]  Investigator Report [ ]  Follow-Up Report

Test Article:

Investigator:

Participant Initials:

Age:

Sex: [ ]  Male [ ]  Female

Summary of Event(s):

|  |  |  |
| --- | --- | --- |
| AE Code:  | Onset: Date and time | **DESCRIPTION** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Further Action Required**? [ ]  **No**  [ ]  **Yes**

**IF YES:**

 [ ] Full IDI REC Review [ ]  Notify Participants of Risk [ ]  Amend Protocol

 [ ] Letter [ ] Addendum to ICF [ ]  Other

Signature of Chair or Designee Date

**Instructions for Acknowledgement:**

[ ] Investigator Acknowledgement [ ]  Sponsor Acknowledgement

[ ] Other Instructions:

[ ] **ACKNOWLEDGED**