**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**