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| **Note:** Use this form for all Serious Adverse Events (SAE) and Unexpected AEs that occur at the Principal Investigator’s site. Please submit this report **within 24 hours** after a reportable event occurs. |
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| 1. **Study Information**
 |
| NA: [ ]  | Sponsor |       | Protocol Number |       |
| **Principal Investigator** |       | **IRB Log Number** |       |
| **Study Title** |       |
| Email |       | Telephone |       |
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| 1. **Report Information**
 |
| [ ]  **SAE** | [ ]  **AE** | [ ]  **Unexpected AE** | [ ]  **Protocol Deviation**[ ]  **Protocol Violation** | [ ]  **IND Safety Report from Sponsor**Date:       |
| **Date of Report** |       | Date Sponsor NotifiedNA: [ ]  |       | **SAE Onset Date** |       |
| Report Type | [ ]  Initial Report | Initial Report Date: |       |
| [ ]  Follow-up Report | Report #: |       |
| Event Outcome | [ ]  Resolved | Date: |       |
| [ ]  Stabilized | Date: |       |
| [ ]  Ongoing \***\*** If the SAE is **ongoing**, a **follow-up report must be submitted** when the SAE is resolved or stabilized. |
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| 1. **Subject Information**
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| **Subject Initial / ID / Study No.** |       | Age or Date of Birth |       | Gender | [ ]  Male[ ]  Female |
| Is the subject still an active participant in this study? | [ ]  Yes[ ]  No | If NO, date discontinued:       |
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| 1. **Description of Protocol Deviation or Violation (Please indicate the deviation date for each deviation or violation.)**
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|       |
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| **IRB USE ONLY** |
| PI Contacted By: |       | Report Phoned In On: |       |
| PI Contacted On: |       | Telephoned Report Taken By: |       |
|  | Report Received On: |       |

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| 1. **Serious Adverse Event Information**
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| **Was the event serious?** | [ ]  **Yes** | [ ]  **No** |
| [ ]  Death[ ]  Life Threatening[ ]  Persistent or Significant Disability / Incapacity[ ]  Other (please specify below):  | [ ]  Hospitalization[ ]  Congenital Anomaly / Birth Defect[ ]  Required intervention to prevent outcome listed above[ ]  Considered to be a significant incident by the PI |
|       |
| **Was the event unanticipated?** | [ ]  **Yes** | [ ]  **No** |
| [ ]  Unanticipated because the event is not identified in specificity or severity in relevant study product documents (e.g., investigator’s brochure, device manual) |
| [ ]  Unanticipated because the event is not identified in specificity or severity as a risk in the informed consent form |
| [ ]  Other (please specify): |       |
| **Was the event related to the study product (include comments as relevant)?** | [ ]  **Yes** | [ ]  **No** |
| [ ]  Definitely Related |       |
| [ ]  Probably Related |       |
| [ ]  Possibly Related |       |
| [ ]  Unknown Relationship |       |
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| **SERIOUS ADVERSE EVENT TERM(S)**Include a list of Serious Adverse Event Terms that most accurately characterize the adverse event described in narrative format below. Terms should be listed with the most important term(s) first. |       |
| **DESCRIPTION OF SERIOUS ADVERSE EVENT**Report pertinent participant health history, severity of SAE and assessment of causality, etc. |       |
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| **ACTION TAKEN** |       |
|  |  |  |  |
| **CONCOMITANT MEDICATIONS OR PRODUCTS** |       |
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| 1. **Recommendations**
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| Do you recommend a change to the protocol? (If **YES**, please attach recommended changes.) | [ ]  Yes | [ ]  No |
| Do you recommend a change to the consent form at the: |  |
| Site [ ]  | [ ]  Yes | [ ]  No | [ ]  NA  |
| Study-wide [ ]  | [ ]  Yes | [ ]  No | [ ]  NA  |
| (If **YES**, please attach a tracked consent form and sponsor approval, if applicable. If sponsor does not agree with recommended changes, please include sponsor rationale.) |  |
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| 1. **Name and Signatures**
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| **Printed Name of Reporter:** |       | **Date:** |       |
| **Principal Investigator’s Name:** |       | **Date:** |       |
| **Principal Investigator’s Signature:** |  | **Stamp:** |  |