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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 Notified  NA: | | |  | | **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** | | | | | | | | | | | | | | | | |
| **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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| **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** | | | | | | | | | | | | | |
| **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 |  | | | | | | | | | | | | |
|  | | | |  | | | | | | | | | |
| **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** | | |  | | | | | | | | | | |
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| **CONCOMITANT MEDICATIONS OR PRODUCTS** | | |  | | | | | | | | | | |
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| 1. **Recommendations** | | | | | | | | | | | | | |
| 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.) | | | | | | | |  | | | | | |
|  | |  | |  | | | | |  | | | | |
| 1. **Name and Signatures** | | | | | | | | | | | | | |
| **Printed Name of Reporter:** | |  | | | | **Date:** |  | | | | | | |
| **Principal Investigator’s Name:** | |  | | | | **Date:** |  | | | | | | |
| **Principal Investigator’s Signature:** | |  | | | | **Stamp:** |  | | | | | | |