**Noncompliance Report**

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| --- | --- |
| Category | □ Protocol Violation □ Non-Compliance to SOPs |
| Trial IRB No. |  | Investigator Name |  |
| Type | □ Critical □ Major □ Minor |
| Date Violation/Non-Compliance Occurred | [ ] [ ] [ ] [ ] /[ ] [ ] /[ ] [ ] YYYY/MM/DD | Date Local Investigator was informed/became aware of event | **[ ] [ ] [ ] [ ] /[ ] [ ] /[ ] [ ]** YYYY/MM/DD |
| Description of violation/non-compliance (include participant study numbers, how it was identified, who it was reported to): |  |
| Significance of violation/non-compliance to Subject Safety (as assessed by Investigator): |  |
| Significance of Deviation to Integrity of Data (as assessed by Investigator): |  |
| Corrective action (if applicable): |  |
| Preventative action (if applicable): |  |

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| --- | --- | --- | --- | --- | --- |
| Written by |  |  |  |  |  |
|  | Name, Title |  | Signature |  | Date(YYYY-MM-DD) |
|  |  |  |  |  |  |
| Confirmed by |  |  |  |  |  |
|  | Name, Title |  | Signature |  | Date(YYYY-MM-DD) |