**REPORT OF ADVERSE EFFECTS ASSOCIATED WITH RESEARCH**

To be filed within 24 hours of occurrence of the event.

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| --- | --- | --- | --- |
| Name of Project: |  | | |
| IRB Protocol Number: | |  | |
| Principal Investigator: | |  | |
| Subject Studied: | |  | |
| Date of Complication: | | / / | |
| Type of Complication: | |  | |
|  | |  | |
| Action Taken: | |  | |
|  | |  | |
| Present Status of Subject: | | |  |
|  | |  | |
| Prognosis: | |  | |
|  | |  | |

Additional information:

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|  |

Potential of this complication explained in Informed Consent signed by subject?

Yes

No

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| PI Name: |  | | | |
| Signature: | |  | Date: | / / |