**REPORT OF ADVERSE EFFECTS ASSOCIATED WITH RESEARCH**

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

|  |  |
| --- | --- |
| 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:  |  / / |