

For Official Use Only:

IRB Log #\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_

 Institutional Review Board

 Adverse Incident Reporting Form

Directions to Researchers: This form must be completed any time a research subject experiences an adverse reaction to, or unexpected event following, an intervention by a researcher as part of the IRB reviewed protocol. Report any serious adverse event **POSSIBLY RELATED** to the study design or procedures that is unanticipated, meaning its occurrence was not cited in the protocol application reviewed by the IRB. An event is considered serious if it potentially affects the rights, welfare or safety of subjects in the study. This form must be submitted to the IRB chair and IRB Coordinator within 48 hours of becoming aware of the event.

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| --- | --- |
| Title of Research ProposalClick here to enter text. | Principal Investigator/Project DirectorClick here to enter text. |
| PhoneClick here to enter text. | EmailClick here to enter text. |

**Adverse Event**

Onset Date:Click here to enter text. Date investigator/director learned of event: Click here to enter text.

Report Type: [ ]  Initial [ ]  Follow-up

Event Status: [ ]  Resolved [ ]  Ongoing

Please describe the event, any treatment, and the outcome. Include pertinent subject history (provide additional pages if needed).

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| Click here to enter text. |

Do you recommend changes to the protocol? No [ ]  Yes [ ]  ; if yes, attach proposal

Do you recommend changes to the consent form? No [ ]  Yes [ ]  ; if yes, attach proposal

By signing this form, the Primary Investigator certifies that he/she has disclosed to the IRB all relevant information concerning this Unanticipated/Adverse Event.

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| Primary Investigator Signature | Date |

**Routing Instructions**

 1) Institutional Review Board Chair, A242

 2) Institutional Review Board