For reporting Adverse Consequences to Humans Participating in Research

All forms must be typewritten, signed, and submitted via email to y.abusamra@scnm.edu

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| **When to Use this Form:** The Principal Investigator (PI) should complete and sign this form and submit it with related attachments for any event that falls into either Category A or Category B, below: |
| **Category A: Any *Serious Adverse Event* that Occurs within 48 Hours of Participation in the Research**    Serious adverse events are those resulting in death, a life-threatening experience, hospitalization or prolongation of existing hospitalization, a persistent or significant disability or capacity, or a congenital anomaly or birth defect. Every serious adverse event must be reported on this form, even if the event does not appear to be associated with the research protocol. If applicable, also file an FDA Adverse Report. In addition, the IRB Office should be notified within 24 hours of discovery of any serious adverse event. |
| **Category B: Any Event for which *All Three* of the Following are True:**   1. **Subject or Risks to Subject or Others Adversely Affected:** An event or outcome has occurred that has *resulted in harm* to the subject, has *affected the subject detrimentally*, has *worsened* as a result of their participation, or that has resulted in *increased risk to the subject or to others,* whether or not the risk has actually resulted in harm (for example, misplacing a subject’s research records would constitute an increased risk event that should be reported). 2. **Unexpected Event**: The event or outcome *was not described as a risk* of participation in the research, or, though described as a risk, the event or outcome has occurred with *unexpected severity or frequency.* 3. **Possibly, Probably, or Definitely Related Event:** The event or outcome was *definitely related* to participation in the research or it’s *reasonable to conclude* that the event or outcome was related to participation, or *it’s possible* the event or outcome was related but not enough information is available at this time to assess the likelihood of this possibility. |

**Section 1. PROTOCOL INFORMATION**

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| **1A. Principal Investigator:** |
| **1B. Protocol Number:** |
| **1C. Project Title:** |

**Section 2. TIMING OF EVENT**

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| **2A. Date of event:** |
| **2B. Date of its discovery by research personnel:** |
| **2C. Date of this report:** |

**Section 3. LOCATION**

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| **3A. Where was the research activity conducted?** |
| **3B. Where did the incident (or consequent events) occur?** |

**Section 4. RESEARCH PERSONNEL**

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| **Who was present when the incident (or consequent events) was (were) discovered?** |

**Section 5. EVENT TYPE**

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| Category A—Serious Adverse Event  Category B—Other Unanticipated Event Adversely Affecting Subject or Others |

**Section 6. SUBJECT INFORMATION**

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| **6A. Subject ID number:** |
| **6B. Age:** |
| **6C.**  Male  Female  Other, *please specify*: |
| **6D. Known pre-existing condition(s), if any:** |

**Section 7. DESCRIPTION OF EVENT**

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| **7A. This event (check all that apply):**  caused psychological harm or injury.  caused physical harm or injury.  caused congenital anomaly/birth defect.  caused social harm or injury.  caused economic harm.  caused a breach of confidentiality.  increased risk of psychological, social, or economic harm or injury.  increased risk of breach of confidentiality.  was a life-threatening experience.  required emergency treatment.  required transport to hospital.  required hospitalization.  prolonged a current hospital stay.  death occurred due to an underlying or progressive disease, not related to research.  death occurred related to research.  was related to this study drug and/or biologic:  was related to this study device:  Other: |
| **7B. Provide a brief narrative of the event:** |

**Section 8. RESOLUTION**

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| **Describe any and all steps and actions taken in response to the incident or to resolve the issue:** |

**Section 9. SUBJECT STATUS**

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| **9A. What was subject’s participation level after the event?**  Subject stopped research participation  Subject withdrew from further participation  Investigator withdrew subject from further participation  Subject had already completed research  Subject continued research participation  Subject continued participation with follow-up only  Other: |
| **9B. Describe the subject’s prognosis:** |

**Section 10. PREVIOUS RESEARCH**

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| **10A. Has any previous research produced this type of event or outcome?**  Yes  No  Unsure |
| **10B. If yes, describe and reference previous reports:** |

**Section 11. EVENT CATEGORIZATION**

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| **11A. The event is:**  Expected  Unexpected |
| **11B. The event is:**  Serious  Not serious |
| **11C. In the PI’s judgment, was there a relationship between the event and the research?**  Definitely: clearly related to the research  Probably: likely related to the research  Possibly: may be related to the research but not enough information is available to assess this  Probably not: doubtfully related to the research  Definitely not: clearly not related to the research |

**Section 12. RELATION TO RISKS**

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| **12A. In the PI’s judgment, was this event related to the risks as presented in the protocol or consent documents?**  Yes No |
| **12B. If yes, attach copies of the research protocol and consent document(s) with relevant sections highlighted.**  Attached |

**Section 13. REVISIONS**

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| **13A. In the PI’s judgment, should the research protocol or consent form(s) be revised?**  Yes No |
| **13B. If yes, complete and attach an Amendment Form and revised materials, as applicable.**  Attached Will Follow |

**Section 14. NOTIFICATION OF SUBJECTS AND OTHERS**

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| **14A. In the PI’s judgment, which of the following subject groups, legally authorized representative, or parents/guardians should be notified? Check all the apply**  New subjects  Currently enrolled subjects  Subjects that have completed the research  None |
| **14B. If any but “None” are marked, complete and attach an Amendment Form and revised consent or assent form(s).**  Attached Will Follow |
| **14C. In the PI’s judgment, is it necessary to obtain a new consent or assent of subjects, legally authorized representative, or parents/guardians who have already given their consent or assent to participate?**  Yes No |
| **14D. If “Yes” is marked, complete and attach an Amendment Form and revised consent or assent form(s).**  Attached Will Follow |

**Section 15. AFFECT ON RESEARCH**

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| **In the PI’s judgment, the research should:**  **Continue as planned** with no changes to the research protocol or consent process.  **Continue with changes** to the research protocol or consent process, as previously noted on this form.  **Suspend new subject enrollment** until the event is assessed further.  **Be terminated** (stopped completely), with all subjects removed from research. |

**Section 16. REPORTS FILED**

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| **16A. Has the event been reported to any other organizations or regulatory bodies?**  Yes No | | |
| **16B. If “Yes” is marked, indicate all that apply and attach the reports submitted to these places:** | | |
| **Report Filed With** | **Date** | **Report(s)** |
| Research sponsor/coordinating site |  | Attached Will Follow |
| Data monitoring committee |  | Attached Will Follow |
| Food & Drug Administration (FDA) |  | Attached Will Follow |
| Office for Human Research Protections (OHRP) |  | Attached Will Follow |
| Other collaborators |  | Attached Will Follow |
| Other: |  | Attached Will Follow |

**Section 17. INVESTIGATOR ASSURANCES**

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| I have reviewed the contents of this form, with attachments, and I certify that the information provided is complete and accurate to the best of my knowledge. |
| **The original signature of the PI is required before this form can be processed (electronic signatures are acceptable).**    Principal Investigator Date |