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| **When to Use this Form:** The Principal Investigator (PI) may use this form to report any Unanticipated Problems or Serious Adverse event as defined below. This form may also be used to report other issues of noncompliance by anyone witnessing such an event. |
| ***Unanticipated Problem***  **Any Unanticipated Problem for which *All Three* of the Following are True:**   1. **Unexpected Event**: The event or outcome *was not described as a risk* of participation in the research protocol or consent form, or, though described as a risk, the event or outcome has occurred with *unexpected severity or frequency.* This includes adverse events which are also unanticipated problems. 2. **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). 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. 4. Submit Unanticipated problems within 10 working days of the occurrence. Note some adverse events will also be Unanticipated problems and must be reported within 10 working days to the IRB. |
| ***Serious Adverse Event***  Serious adverse events are serious medical occurrences 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. Submit this report within 5 working days of the occurrence. |
| ***Other Issues of Noncompliance***  Noncompliance is defined as any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with federal or state regulations, requirements of the NEOMED IRB Standard Operating Procedures Manual, institutional policies governing human subjects research or the requirements or determinations of the IRB. Examples include, but are not limited to, failure to obtain IRB approval, inadequate supervision, failure to follow recommendations made by the IRB, failure to report unanticipated problems and adverse events or protocol changes made without IRB approval. |

**PROTOCOL INFORMATION**

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| **Principal Investigator of study:** |
| **Person completing this form:** |
| **IRB Protocol Number:** |
| **Project Title:** |
| **Is this study open to enrollment? Yes**  No |

**TIMING OF EVENT**

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| --- |
| **Date of event:** |
| **Date of its discovery:** |
| **Date of this report:** |

**LOCATION**

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| --- |
| **Where was the research activity conducted?** |
| **Where did the incident (or consequent events) occur?** |

**RESEARCH PERSONNEL**

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

**EVENT TYPE- as defined above**

|  |
| --- |
| Unanticipated Problem  Serious Adverse Event  Other Noncompliance Issue |

SECTION I

Complete section 1 is you are reporting an unanticipated problem or serious adverse event as defined above. If you are reporting other issues of noncompliance, please go to Section II.

**SUBJECT INFORMATION**

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| **Subject ID number:** |
| **Age:** |
| Male  Female  Other, *please specify*: |
| **Known pre-existing condition(s), if any:** |

**DESCRIPTION OF EVENT**

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| **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.  subject complaint about conduct of research.    Other: |
| **7B. Provide a brief narrative of the event:** |

**RESOLUTION**

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

**SUBJECT STATUS**

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| --- |
| **What was the 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:** |

**PREVIOUS RESEARCH**

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

**EVENT CATEGORIZATION**

|  |
| --- |
| **The event is:**  Expected  Unexpected |
| **The event is:**  Serious  Not serious |
| **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 |

**RELATION TO RISKS**

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

**REVISIONS**

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| --- |
| **In the PI’s judgment, should the research protocol or consent form(s) be revised?**  Yes No |
| **If yes, complete and attach an** [**Amendment Form**](https://oprs.research.illinois.edu/forms-templates/forms/amendment-form) **and revised materials, as applicable.**  Attached Will Follow |

**NOTIFICATION OF SUBJECTS AND OTHERS**

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| **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 |
| **If any but “None” are marked, complete and attach an** [**Amendment Form**](https://oprs.research.illinois.edu/forms-templates/forms/amendment-form) **and revised consent or assent form(s).**  Attached Will Follow |
| **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 |
| **“Yes” is marked, complete and attach an** [**Amendment Form**](https://oprs.research.illinois.edu/forms-templates/forms/amendment-form) **and revised consent or assent form(s).**  Attached Will Follow |

**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 II Noncompliance

Complete Section II for other Noncompliance issues which are not unexpected problems or serious adverse events:

**Noncompliance Information**

1. Provide an explanation of the facts surrounding the noncompliance, including a timeline of occurrence of noncompliance and discovery.

1. Provide an assessment of the increased risk (if any) to subjects resulting from the noncompliance.

1. Explain the corrective measures taken in response to the noncompliance and explain any preventive measures that will be taken to prevent the noncompliance from occurring in the future (if possible).

**Investigator Action**

Please indicate any actions that will be taken as a result of this report.

1. The informed consent process or document will be revised. Please submit an amendment requesting the revisions:

The informed consent document will **NOT** be revised. Please explain:

1. The protocol’s methods/procedures will be revised. Please submit an amendment requesting the revisions.
2. Currently enrolled subjects will be notified of the changes to the protocol. Please attach a copy of the notification.
3. Other corrective and/or preventive action will be taken. Please explain:
4. The event compromised the validity of the data. Please explain:

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SECTION III Reporter/Principal Investigator Statement

For Noncompliance issues reported by someone other than the Principal Investigator:

**Do you wish to remain anonymous if possible? Please note we cannot guarantee anonymity but your name will be held in confidence.**

**No**

**Yes →** Please explain why you wish to remain anonymous:

|  |
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For Unanticipated Problems, Adverse Events, and Noncompliance Reported by the Principal Investigator**:**

Recorded in the Minutes of:

**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 |

**For IRB Use Only**

The event described in this report is an:

An Unanticipated Problem/adverse event requiring reporting to OHRP

An adverse event not requiring OHRP reporting.

Serious or Continuing Noncompliance requiring OHRP reporting

NEITHER Serious nor Continuing Noncompliance

Authorized IRB Signature: Date: