**LINCOLN UNIVERSITY Adverse Event Report Form**

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| **IRB Protocol Number:** | **Date:** |
| **Project Title:**  |
| **Principal Investigator:** | **Phone:** |
| **IRB Contact:** | **Phone:** |

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| --- | --- | --- |
| 1. Adverse Event Details
 | 1. Agency
 | 1. Date Aware of Event:
 |
| 1. Type of Report Initial follow up
 | 1. Outcome of Event
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| 1. Nature of Adverse Event
 | 1. **SERIOUS**

DeathLife Threatening Hospitalization (Initial or Prolonged) Disability (persistent or significant) Requires treatment or intervention to preclude impairment or damage to a subjectMedically SignificantOther:  | 1. **RESULT**

 Unanticipated Anticipated |
| 1. **RELATIONSHIP TO STUDY**

Definitely related Unlikely RelatedProbably Related UnrelatedPossibly Related Unknown |
| 1. **MONITORED BY EXTERNAL DSMB**

 No Yes |
| 1. Assessment of Adverse Event
 | 1. **RISK BENEFIT RATION AFFECTED**
 | YES If YES, explainNO |
| 1. **PROTOCOL CHANGES REQUIRED**
 | YES If Yes, explainNO |
| 1. **CONSENT CHANGES REQUIRED**
 | YES If Yes, explainNO |
| 1. **RECONSENT OF SUBJECTS REQUIRED**
 | YES, If Yes, explainNO |

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| DECLARATION: I attest that I have carefully reviewed the external event attached to this form.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Principal Investigator’s Signature Date |

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| **IRB Office Action:** Refer to IRB Chair Refer to full IRB Meeting Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_IRB Staff Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| IRB Chair recommendation: No further action required. Report accepted as submitted Refer to full IRB Committee Additional information requestedComments: IRB Chair Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| IRB Full Board Recommendation: No further action required. Report accepted as submitted. See attached stipulations.IRB staff signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Definition of Adverse Events**

* **Unanticipated Problems Involving Risks to Subjects or Others (UPX)**

*Any incident, experience, or outcome that meets all of the following criteria:*

* *Unexpected*
* *Related or possibly related to participation in the research*
* *Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized*
* **Adverse Events (AEs) / Serious Adverse Events (SAEs)**
* *Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related (OHRP).*
* *Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research (FDA)*
* *An AE is serious (SAE) if it adversely alters the relationship between risks and benefits (e.g., inpatient/ prolongation of hospitalization, life-threatening reactions, persistent or significant disability/incapacity or permanent harm or disability, congenital anomaly/birth defect in offspring of subject, jeopardizes subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition, breach of confidentiality that may have a negative consequence, results in death or place subject in immediate risk of death)*
* **Unanticipated Adverse Device Effects (UADEs)**

*Any serious adverse device effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.*

* **Protocol Deviations or Errors**

*Occasions when protocol-required procedures are accidentally or intentionally not met. No regulatory language defining events that must be reported. Report to IRB is often driven by sponsor/monitor requests or PI/research staff concerns*

* **Noncompliance**

*Failure to follow federal, state or local regulations governing human research, requirements or determinations of the IRB, or institutional policies. This definition may include action of any University employee or agent, such as investigators, research staff, IRB members, IRB staff, employees, or Institutional Officials.*

Serious Noncompliance

*An action or omission by an individual (investigator, research staff, IRB member, IRB staff, employee, or Institutional Official) that any other reasonable individual would have foreseen as compromising the rights and welfare of a subject or others.*

Continuing Noncompliance

*A pattern of repeated actions or omissions by an individual (investigator, research staff, IRB member, IRB staff, employee, or Institutional Official) that:*

* *Indicates a pattern of deficiency in the ability or willingness of an individual to comply with federal regulations, LU HHS policy, or determinations or requirements of the LU HHS;*
* *If allowed to continue could reasonably be expected to develop into serious noncompliance; or*
* *Recurs after a report of the activity has been evaluated and corrective action has been mandated*