

Office of Research Integrity Institutional Review Board

Report of Important Event

**Research Project Title: IRB #**

**Principal Investigator(s): Approval Expiration Date\*:**

For submission requirements, see Sections III.B.1 and IV.F of the UNE Policies, Procedures and Guidance on Research with Human Subjects.

For help completing this form, consult the IRB Administrator at **IRB@une.edu****.**

# A. DESCRIPTION OF EVENT

1. Give a detailed description of the event.
2. What was the date of the event?
3. When did it first come to your attention?
4. Did you report the event to the IRB orally and/or by email? yes no If so, when? to whom? how?
5. In your opinion, which category(ies) best characterize the type of event you are reporting?. Refer to IV.F of the UNE Policies, Procedures and Guidance on Research with Human Subjects. Check all that apply. *To check a box, double-click on it.*

Significant Protocol Violation – Complete B.1 Unanticipated Problem – Complete B.2 Serious Adverse Event – Complete B.3

# SIGNIFICANT PROTOCOL DEVIATION

1. In what way did this event deviate from the approved protocol?
2. Did the event affect a subject’s individual risk? Please explain.

yes no

1. Did the event compromise the value of the data collected or decreases the

study benefit? yes no

Please explain.

1. Did the event show evidence of willful or knowing misconduct on the part

of the responsible party? yes no

Please explain.

1. Did the event demonstrate a serious or continued noncompliance with

federal, state or local research policy, laws or regulations? yes no Please explain.

# UNANTICIPATED PROBLEM

|  |  |  |
| --- | --- | --- |
| 1. Was the problem unexpected, given the nature of the research proceduresand the subject population being studied? | yes | no |
| Please explain. |  |  |
| 2. Was the problem related or possibly related to participation in the research? | yes | no |
| Please explain. |  |  |
| 3. Did the problem place subjects or others at greater risk of harm or discomfort related to the research than was previously known or recognized? | yes | no |
| Please explain. |  |  |

* 1. **SERIOUS ADVERSE EVENT**

1. Did the event cause, or is it likely to cause, physical or psychological harm or injury that is temporarily associated with the subject’s participation in

the research? yes no

If yes, in what way? *Check all that apply.*

Is fatal or life threatening;

Results in significant or persistent disability; Requires or prolongs hospitalization;

Results in a congenital anomaly/birth defect; or

May jeopardize the subject’s health and may require medical or surgical intervention, based on appropriate medical judgment.

Please explain.

# C. CORRECTIVE ACTION

‘Corrective action’ means any steps taken to prevent a recurrence and/or to protect the safety, welfare or rights of subjects or others. In particular, please specify whether any corrective action entails substantive changes in the research protocol or informed consent process/document.

1. Describe any corrective action that has been taken.
2. Describe any corrective action that you propose to take.

# D. REQUIRED ATTACHMENTS

** Most recent Letter of Approval**

** Protocol Summary**

Using no more than one page, provide a **brief, non-technical synopsis** of the research. Identify the participant population, the recruitment procedures, and informed consent process. Describe the study location, the procedures, any interventions, and the major risks of the study.

** Current Full Protocol**

Use “track changes” or red text or underlining or highlighting to indicate noticeably all relevant or affected provisions.

** Correspondence**

Please provide copies of all correspondence pertaining to the event.

** Other Relevant Documents**

Include all other documents – for example, the Informed Consent document  that are relevant to the event or corrective action.

Primary Principal Investigator Signature Date

**Because this form is new, the Board welcomes any feedback on how this form works, any problems, and suggestions for improvement. Please email your feedback to the IRB Administrator at** **IRB@une.edu.** **It will have no effect on your application.**

# CHECKLIST OF ATTACHMENTS

**To assist Board members, please apply a label to all attachments. Please list below the label and title of each attachment:**

|  |  |
| --- | --- |
| **Label** | **Title** |
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