**Baton Rouge Community College**
**Institutional Review Board
Adverse Event Report**

Submit this form to the IRB Chair within 48 hours of the event/within 48 hours of when the event was reported to the Principal Investigator.

**Date of Adverse Event:**

**Principal Investigator:**

**Study Title:**

**Adverse Event:** Describe the adverse event associated with this research study.

**Ethical Concerns**: Describe any ethical concerns regarding this research study that have come to light as a result of the adverse event.

**Complete the following regarding the unanticipated event:**

1. How many subjects were involved in the adverse event?

2. Has any similar adverse event occurred in this study? If yes, describe:

3. Has the study been discontinued due to the adverse event? If yes, why?

4. In your opinion, in what manner was the adverse effect related to the research study? Explain your response.

Unrelated

Related

Unknown

5. Describe how you propose to protect other participants from exposure to this harm.

**Principal Investigator’s Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name (Printed):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Routing Signatures

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IRB Chair Date

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Vice Chancellor for Academic Affairs Date

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Chancellor Date