**Institutional Review Board Office**

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**Adverse Events Form**

**For Reporting Adverse Consequences to Humans Participating in Research**

All forms must be completed, signed, and submitted as single-sided hard copy

**When to Use this Form:** The Responsible Project investigator (RPI) 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:** Science 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 Event Report (at http://www.fda.gov/cder/aers/). In addition, the IRB Office 423.236.2285; irb@southern.edu 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 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.

1. **PROJECT TITLE:**

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|  |

**IRB TRACKING NUMBER:**

**RESPONSIBLE PROJECT INVESTIGATOR (RPI) FOR SAU:**

|  |  |  |  |
| --- | --- | --- | --- |
| Last Name: | First Name: | Academic Degree(s): | |
| Dept: | Office Address: | | Mail Code: |
| Street Address: | City: | State: | Zip Code: |
| Phone: | Fax: | E-mail: | |

1. **DATE OF EVENT:**

1. **DATE OF ITS DISCOVERY BY RESEARCH PERSONNEL:**
2. **REPORT TYPE:**  Initial  Follow-up on Previously Reported Event
3. **RESEARCH SITE:** Where was the research activity conducted and where did the incident (or consequent events) occur?

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1. **RESEARCH PERSONNEL:** Who was present when the incident (or consequent events) was (were) discovered?

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1. **EVENT TYPE**  Category A – Serious Adverse Event

Category B – Other Unanticipated Event Adversely Affecting Subject or Others

1. **SUBJECT INFORMATION** Age:  Male  Female Known pre-existing condition(s) if any:

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1. **DESCRIBE THIS EVENT (CHECK ALL THAT APPLY).**

Life threatening experience  Psychological harm or injury occurred

Required emergency treatment  Social harm or injury occurred

Required transport to hospital  Economic harm occurred

Required hospitalization  Breach of confidentiality occurred

Prolonged current hospitalization  Risk of psychological, social, or economic harm increased

Persistent or significant disability/incapacity  Risk of confidentiality breach increased

Congenital anomaly/birth defect  Related to this Drug:

New diseases or problem  Related to this Device:

Death – underlying or progressive disease  Related to this Biological:

Death – research related  Other:

1. **PROVIDE A BRIEF NARRATIVE OF THE EVENT.**

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1. **DESCRIBE ANY AND ALL STEPS AND ACTIONS TAKEN IN RESPONSE TO THE INCIDENT OR TO RESOLVE THE ISSUE.**

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1. **WHAT WAS SUBJECT’S PARTICIPATION LEVEL AFTER THE EVENT?**

Subject stopped research participation  Subject had already completed research

Subject continued research participation  Subject withdrew from further participation

Subject continued participation with follow-up only  Investigator withdrew subject from further participation

Other:

1. **PROGNOSIS**

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1. **HAS ANY PREVIOUS RESEARCH THIS TYPE OF EVENT OR OUTCOME?**  Yes  No

If Yes, describe and reference previous report(s):

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| --- |
|  |

1. **MARK ONE IN BOTH A AND B TO CATEGORIZE THIS EVEN ACCORDING TO THE RPI’S JUDGMENT:**

**15A.**  Expected  Unexpected **15B.**  Serious  Not serious

1. **RELATION TO RESEARCH:** In the RPI’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 information not yet available to assess the likelihood of this

Probably Not – doubtfully related to the research

Definitely Not – clearly not related to the research

1. **RELATION TO STATE RISKS:** In the RPI’s judgment, are the probability, magnitude, and reversibility of this event consistent with the risk information in the research protocol, IRB application, and informed consent document(s) previously reviewed and approved by the IRB?

Yes  No

If Yes, attach copies of the protocol, application, and consent document(s) with relevant sections highlighted.

Attached  Will Follow

1. **REVISIONS NEEDED?** In the RPI’s judgment, should the research protocol, application, or consent form(s) be revised?

Yes  No

If Yes, complete and attach a Form B Amendment Form and revised materials, as applicable.

Attached  Will Follow

1. **NOTIFICATION OF SUBJECTS AND OTHERS:** In the RPI’s judgment, which of the following subject groups, legally authorized representatives, or parents or guardians should be notified? Check all that apply.

New subjects  Currently enrolled subjects

Subjects that have completed the research  None

If any but “None” are marked, complete and attach a Form B Amendment Form and revised consent form(s)

Attached  Will Follow

1. **RE-CONSENT/ASSENT:** In the RPI’s judgment, it is necessary to obtain anew the consent or assent of subjects, legally authorized representatives, or parents or guardians who have already given their consent or assent to participation?

Yes  No

If Yes, complete and attach a Form B Amendment Form and revised consent or assent form(s)

Attached  Will Follow

1. **AFFECT ON RESEARCH:** In the RPI’s judgment, should the research

**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 further assessed?

**be terminated** (stopped completely), with all subjects removed from research?

1. **REPORTS FILED**: To whom has the event been reported? Mark all that apply and attach report(s)

|  |  |  |
| --- | --- | --- |
| **Report Filed With** | **Date Reported** | **Report(s)** |
| Research sponsor/coordinated site |  | Attached  Will Follow |
| Data monitoring committee |  | Attached  Will Follow |
| Food & Drug Administration (FDA) |  | Attached  Will Follow |
| Office, Human Research Protections (OHRP) |  | Attached  Will Follow |
| Other collaborators |  | Attached  Will Follow |
| Other: |  | Attached  Will Follow |

1. **INVESTIGATOR ASSURANCE(S):** 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.

Responsible Principal Investigator Date Investigator Date

Investigator Date Investigator Date