INDIANA TECH

Adverse/Unexpected Event Report

For Reporting Adverse and/or Unexpected Consequences to Humans Participating in Research
All forms must be typewritten, signed, and submitted via email to IRB@indianatech.edu.

When to Use this Form: The Principal Investigator (PI) 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 Serious 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. In addition, the IRB should be notified within 48 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 (e.g., misplacing a subject's research records 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; 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.

Section 1. PROTOCOL INFORMATION

1A. Principal Investigator:
1B. Project Title:

Section 2. TIMING OF EVENT

2A. Date of event:
2B. Date of its discovery by research personnel:
2C. Date of this report:

Section 3. LOCATION

3A. Where was the research activity conducted?
3B. Where did the incident (or consequent events) occur?

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Section 4. RESEARCH PERSONNEL

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

Section 5. EVENT TYPE

☐ Category A—Serious Adverse Event
☐ Category B—Other Unanticipated Event Adversely Affecting Subject or Others

Section 6. SUBJECT INFORMATION

6A. Subject ID number:
6B. Age:
6C. ☐ Male ☐ Female ☐ Other, *please specify*:
6D. Known pre-existing condition(s), if any:

Section 7. DESCRIPTION OF EVENT

7A. 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.
☐ was related to this study drug and/or biologic:
☐ was related to this study device:
☐ Other:
7B. Provide a brief narrative of the event:

Section 8. RESOLUTION

Describe any and all steps and actions taken in response to the incident or to resolve the issue:

Section 9. SUBJECT STATUS

9A. What was subject's participation level after the event?

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☐ 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:

Section 10. PREVIOUS RESEARCH

10A. Has any previous research produced this type of event or outcome? ☐ Yes ☐ No ☐ Unsure
10B. If yes, describe and reference previous reports:

Section 11. EVENT CATEGORIZATION

11A. The event is: ☐ Expected ☐ Unexpected
11B. The event is: ☐ Serious ☐ Not serious
11C. 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

Section 12. RELATION TO RISKS

12A. In the PI's judgment, was this event related to the risks as presented in the protocol or consent documents? ☐ Yes ☐ No
12B. If yes, attach copies of the research protocol and consent document(s) with relevant sections highlighted. ☐ Attached

Section 13. REVISIONS

13A. In the PI's judgment, should the research protocol or consent form(s) be revised? ☐ Yes ☐ No
13B. If yes, complete a Post-Approval Change Form and revised materials as applicable. ☐ Attached ☐ Will Follow

Section 14. NOTIFICATION OF SUBJECTS AND OTHERS

14A. 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

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☐ None
14B. If any but "None" are marked, complete a Post-Approval Change Form and revised consent or assent form(s). ☐ Attached ☐ Will Follow
14C. 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
14D. If "Yes" is marked, complete a Post-Approval Change Form and revised consent or assent form(s). ☐ Attached ☐ Will Follow

Section 15. EFFECT ON RESEARCH

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 16. REPORTS FILED

16A. Has the event been reported to any other organizations or regulatory bodies? ☐ Yes ☐ No

16B. If "Yes" is marked, indicate all that apply and attach the reports submitted to these places:

Report Filed With	Date	Report(s)	
☐ Research sponsor/coordinating site		☐ Attached	☐ Will Follow
☐ Data monitoring committee		☐ Attached	☐ Will Follow
☐ Food & Drug Administration (FDA)		☐ Attached	☐ Will Follow
☐ Office for Human Research Protections (OHRP)		☐ Attached	☐ Will Follow
☐ Other collaborators		☐ Attached	☐ Will Follow
☐ Other:		☐ Attached	☐ Will Follow

Section 17. INVESTIGATOR ASSURANCES

☐ 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).

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Principal Investigator Date

Indiana Tech Institutional Review Board
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