

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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<input type="checkbox"/> Subject stopped research participation <input type="checkbox"/> Subject withdrew from further participation <input type="checkbox"/> Investigator withdrew subject from further participation <input type="checkbox"/> Subject had already completed research <input type="checkbox"/> Subject continued research participation <input type="checkbox"/> Subject continued participation with follow-up only <input type="checkbox"/> Other:
9B. Describe the subject's prognosis:

Section 10. PREVIOUS RESEARCH

10A. Has any previous research produced this type of event or outcome? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure
10B. If yes, describe and reference previous reports:

Section 11. EVENT CATEGORIZATION

11A. The event is: <input type="checkbox"/> Expected <input type="checkbox"/> Unexpected
11B. The event is: <input type="checkbox"/> Serious <input type="checkbox"/> Not serious
11C. In the PI's judgment, was there a relationship between the event and the research? <input type="checkbox"/> Definitely: clearly related to the research <input type="checkbox"/> Probably: likely related to the research <input type="checkbox"/> Possibly: may be related to the research but not enough information is available to assess this <input type="checkbox"/> Probably not: doubtfully related to the research <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No
12B. If yes, attach copies of the research protocol and consent document(s) with relevant sections highlighted. <input type="checkbox"/> Attached

Section 13. REVISIONS

13A. In the PI's judgment, should the research protocol or consent form(s) be revised? <input type="checkbox"/> Yes <input type="checkbox"/> No
13B. If yes, complete a Post-Approval Change Form and revised materials as applicable. <input type="checkbox"/> Attached <input type="checkbox"/> 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 <input type="checkbox"/> New subjects <input type="checkbox"/> Currently enrolled subjects <input type="checkbox"/> Subjects that have completed the research

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<input type="checkbox"/> None
14B. If any but "None" are marked, complete a Post-Approval Change Form and revised consent or assent form(s). <input type="checkbox"/> Attached <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No
14D. If "Yes" is marked, complete a Post-Approval Change Form and revised consent or assent form(s). <input type="checkbox"/> Attached <input type="checkbox"/> Will Follow

Section 15. EFFECT ON RESEARCH

<p>In the PI's judgment, the research should:</p> <p><input type="checkbox"/> Continue as planned with no changes to the research protocol or consent process.</p> <p><input type="checkbox"/> Continue with changes to the research protocol or consent process, as previously noted on this form.</p> <p><input type="checkbox"/> Suspend new subject enrollment until the event is assessed further.</p> <p><input type="checkbox"/> Be terminated (stopped completely) with all subjects removed from research.</p>
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Section 16. REPORTS FILED

16A. Has the event been reported to any other organizations or regulatory bodies? <input type="checkbox"/> Yes <input type="checkbox"/> No		
16B. If "Yes" is marked, indicate all that apply and attach the reports submitted to these places:		
Report Filed With	Date	Report(s)
<input type="checkbox"/> Research sponsor/coordinating site		<input type="checkbox"/> Attached <input type="checkbox"/> Will Follow
<input type="checkbox"/> Data monitoring committee		<input type="checkbox"/> Attached <input type="checkbox"/> Will Follow
<input type="checkbox"/> Food & Drug Administration (FDA)		<input type="checkbox"/> Attached <input type="checkbox"/> Will Follow
<input type="checkbox"/> Office for Human Research Protections (OHRP)		<input type="checkbox"/> Attached <input type="checkbox"/> Will Follow
<input type="checkbox"/> Other collaborators		<input type="checkbox"/> Attached <input type="checkbox"/> Will Follow
<input type="checkbox"/> Other:		<input type="checkbox"/> Attached <input type="checkbox"/> Will Follow

Section 17. INVESTIGATOR ASSURANCES

<input type="checkbox"/> 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).
<div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> Principal Investigator Date </div>

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