



NU-IREC: Adverse Event/Unanticipated Problem Reporting Form

The form is intended for reporting adverse consequences to humans participating in research. All forms must be typewritten, signed, and submitted via email to resethics@nu.edu.kz.

DEFINITIONS

Unanticipated Problem: Any event or information that (1) was **unforeseen** given the approved research procedures and subject population; (2) **related or probably related** to participation in the research or if the incident probably or definitely affects subjects; and (3) suggests that the research places subjects or others at a **greater risk of harm** that was previously known or recognized.

Adverse event: Any physical, psychological, or social harm to subjects during the study.

Unexpected: An event is “unexpected” when its specificity and severity are not accurately reflected in the informed consent document.

Related to the research: An event is “related to the research procedures” if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current participants.

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 the Course of the Study.

Serious adverse events are those that result in death, a life-threatening experience, hospitalization, or prolongation of existing hospitalization, a persistent or significant disability or capacity, or a congenital anomaly. 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 NU IREC (resethics@nu.edu.kz) should be notified within 48-72 hours of the 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 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, or it is *reasonable to conclude* that the event or outcome was related to participation, or *it is 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. Protocol Number:

1C. 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?

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 in Biomedical Research
- Category B - Other Unanticipated Event Adversely Affecting Subject or Others in Social and Behavioral Research



Section 6. SUBJECT INFORMATION

6A. Subject ID number:
6B. Age:
6C. <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other, <i>Please specify:</i>
6D. Known pre-existing condition(s), if any:

Section 7. DESCRIPTION OF EVENT

7A. This event (check all that apply): <ul style="list-style-type: none"><input type="checkbox"/> caused psychological harm or injury.<input type="checkbox"/> caused physical harm or injury.<input type="checkbox"/> caused congenital anomaly/birth defect.<input type="checkbox"/> caused social harm or injury.<input type="checkbox"/> caused economic harm.<input type="checkbox"/> caused a breach of confidentiality.<input type="checkbox"/> increased risk of psychological, social, or economic harm or injury.<input type="checkbox"/> increased risk of breach of confidentiality.<input type="checkbox"/> was a life-threatening experience.<input type="checkbox"/> required emergency treatment.<input type="checkbox"/> required transport to the hospital.<input type="checkbox"/> required hospitalization.<input type="checkbox"/> prolonged a current hospital stay.<input type="checkbox"/> death occurred due to an underlying or progressive disease, not related to research.<input type="checkbox"/> death occurred related to research.<input type="checkbox"/> was related to this study drug and/or biologic:<input type="checkbox"/> was related to this study device:<input type="checkbox"/> Other:
7B. Provide a brief narrative of the event:

Section 8. RESOLUTION

Describe all steps and actions taken in response to the incident or to resolve the issue:
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Section 9. SUBJECT STATUS

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

- 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 and attach an [Appendix G: IREC Protocol Amendment 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 representatives, or parents/guardians should be notified? Check all that apply.

- New subjects
- Currently enrolled subjects
- Subjects that have completed the research
- None

14B. If any but "None" are marked, complete and attach an [Appendix G: IREC Protocol Amendment 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 representatives, or parents/guardians who have already given their consent or assent to participate?

Yes No

14D. If "Yes" is marked, complete and attach an [Appendix G: IREC Protocol Amendment Form](#) and revised consent or assent form(s). Attached Will Follow

Section 15. AFFECT 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)
<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"/> 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. PRINCIPAL 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).

 Principal Investigator

 Date

Acknowledgement in the development of the form: University of Illinois, Office for the Protection of Research Subjects.