

**NDNU Institutional Review Board (IRB)  
REPORT OF UNANTICIPATED PROBLEM OR SERIOUS ADVERSE EVENT**

All unanticipated problems and/or serious adverse events having to do with participant safety and well-being in IRB-approved research must be reported *promptly* to the IRB. Note that such incidents can include physical harm *and/or* social/behavioral harm, e.g., breach of confidentiality or undue stress/anxiety.

Initial reports may be made via phone, email, fax, or mail, and must be reported as soon as possible, but **within no more than 1 week (7 calendar days)** of learning of such an event/problem. Furthermore, the Principal Investigator must submit this form to the IRB, with any additional sheets needed to provide a complete description of the event and actions taken with regard to the subject and the study, as soon as possible but **within no more than 2 weeks (14 calendar days)** of learning of such an event/problem.

NDNU Principal Investigator (Faculty):	Phone, Email:
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NDNU Student Investigator:	Phone, Email:
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IRB Approval Number:	Study Title:
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Date of Incident:	Date of Its Discovery by Research Personnel:	Date of This Report:
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Details/Description of problem; Treatment and/or steps taken; Timing of events. (Attach additional information if needed.)

Unanticipated problem/ adverse event *appears* to be (check one):

Directly related to the research     Indirectly related to the research     Unrelated to the research

Has this type of adverse/unanticipated effect been reported before?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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Is this type of effect likely to occur again?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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Are changes needed in the protocol and/or consent form?	<input type="checkbox"/> Yes**	<input type="checkbox"/> No
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\*\* If yes, a Research Modification Form should accompany this report.

What other agencies (e.g., sponsor, FDA) have been notified of this unanticipated problem/adverse event? In writing?

Signature of NDNU Principal Investigator:	Date :
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<u>IRB Committee Responses</u> Reviewer:	Date:
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Assessment & actions to be taken; Notifications needed, if any: