



SOP Title	(IACUC) PI – Reporting Protocol Deviations and Adverse Events				
Date Last Revised	06/13/2019	Date Created	11/2010	Revision #	2.0
SOP Number	15	Required by:	<input type="checkbox"/> OHRP	<input type="checkbox"/> Funding Agency	<input checked="" type="checkbox"/> OLAW
Applicability	<input type="checkbox"/> RGC Internal	<input checked="" type="checkbox"/> Researcher	<input type="checkbox"/> Institutional		
Subgroup	<input checked="" type="checkbox"/> NKU Compliance	<input type="checkbox"/> IRB	<input checked="" type="checkbox"/> IACUC	<input type="checkbox"/> IBC	

## 1.0 PURPOSE

The purpose of this SOP is to describe the process for submitting protocol deviations and adverse events for protocols approved by the IACUC.

## 2.0 GENERAL INFORMATION AND SCOPE

The Institutional Animal Care and Use Committee (IACUC) has established this written policy, as mandated by federal regulations, to guide Principal Investigators (PI) through the process of reporting protocol deviations and adverse events or any other serious non-compliance as related to an IACUC protocol.

## 3.0 PROCEDURES

The Principal Investigator (PI) is responsible for reporting protocol deviations, adverse events or non-compliance via Mentor IACUC within ten (10) business days of receipt of the information, unless there are extraneous circumstances (out of country, etc.).

### 3.1 COMPLETE FORM

1. Complete the NKU IACUC Protocol Deviation/Adverse Event Report form.

### 3.2 ACCESSING MENTOR IACUC

1. Go to the [Mentor website](#).
2. Institution ID = NKU.
3. Click “Log in”
4. Use your NKU ID (NKU email username) and NKU password to log in.

### 3.3 SUBMITTING UNANTICIPATED PROBLEMS OR ADVERSE EVENTS IN MENTOR

1. After logging into Mentor, click “IACUC” in the black banner.
2. Click “My “Protocols”. All of your protocols will be listed here.
3. Select the appropriate protocol.
4. At the bottom, there are three tabs, “Annual Reports”, “Amendments” and “Protocol Deviations/Adverse Events”. Select the “Protocol Deviations/Adverse Events” tab.
5. Click “New Protocol Deviation/Adverse Events”.
6. Change the date to reflect the date of the incident. If there are multiple dates, choose the earliest date.

7. Click "Choose File" and upload the Protocol Deviation/Adverse Event Report form.
  8. Type any comments you would like to include. This is not required.
  9. Click "Save". You will be returned to the protocol page.
  10. Upload any other relevant documents by clicking the paper icon next to "Additional Documentation" at the bottom of the page.
  11. Click "Sign Electronically" next to the PI name.
  12. Click "Submit Protocol Deviation/Adverse Events."
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Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/17/2019	<input type="checkbox"/>
IACUC Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input type="checkbox"/>		<input type="checkbox"/>	
IACUC Chair	<input type="checkbox"/>		<input type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>	