

Office of Research, Grants and Contracts Standard Operating Procedures (SOP)

SOP Title	(IACUC) PI- Reporting Protocol Deviations and Adverse Events							
Date Last Revised	07/03/2024	Date Created		11/2010		Revision #		2.3
SOP Number	15	Required by:		OHRP	□Funding Agency ⊠OL			LAW
Applicability	RGC Interna	iC Internal 🛛 🖾 Researche		- 🛛 Institutional				
Subgroup	🛛 NKU Comp	liance		⊠IACUC		JIBC		

1.0 PURPOSE

The purpose of this SOP it 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 noncompliance 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

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

3.2 ACCESSING MENTOR IACUC

- 1. Go to the Mentor website.
- 2. If prompted, the 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 dropdown.
- 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 "Deviations/Adverse Events". Select the "Protocol Deviations/Adverse Events" tab.
- 5. Click "New Deviations/Adverse Events +".
- 6. Change the date to reflect the date of the incident. If there are multiple dates, choose the

earliest date.

- 7. Type any comments you would like to include (this is not required).
- 8. Click "Save".
- 9. Click "Start Survey"
- 10. Answer the questions that appear.
- 11. Click "Save Answers and Close".
- 12. Click "Back".
- 13. If not already there, click the "Deviations/Adverse Events" tab.
- 14. Click "Sign Electronically".
- 15. Click "Submit".

Approvals

Title	Approved	Date Approved	Not Applicable	
Manager of Research Compliance	\boxtimes	06/17/2019		
IACUC Chair			\boxtimes	
Institutional Official			\boxtimes	

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	\boxtimes	08/10/2020		Formatting approved by A. Southwick
IACUC Chair			\boxtimes	
Institutional Official			\boxtimes	

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	\boxtimes	07/03/2024		Mentor interface update
IACUC Chair			\boxtimes	
Institutional Official			\boxtimes	