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

SOP Title	(IRB) PI – Reporting Unanticipated Problems or Adverse Events				
Date Last Revised	07/11/2024	**Date Created**	11/2010	**Revision #**	1.1
SOP Number	1	**Required by:**	☒OHRP ☐Funding Agency ☐OLAW		
Applicability	☐ RGC Internal	☒Researcher	☐Institutional		
Subgroup	☒ NKU Compliance	☒IRB	☐IACUC	☐IBC	

1.0 PURPOSE

The purpose of this SOP it to describe the process for submitting unanticipated problems with human subjects research.

2.0 GENERAL INFORMATION AND SCOPE

This SOP applies to any investigator involved with human subjects research.
The Institutional Review Board (IRB) has established this written policy, as mandated by federal regulations, to guide Principal Investigators (PI) through the process of reporting unanticipated problems involving risk to research subjects or any other serious non-compliance as related to an IRB protocol previously approved by the IRB committee.

3.0 PROCEDURES

1. The Principal Investigator (PI) is responsible for reporting unanticipated problems or non- compliance via Mentor IRB within ten (10) business days of receipt of the information, unless there are extraneous circumstances (out of country, etc.).
2. A report is required to be submitted in Mentor IRB by:
    - Logging into Mentor IRB;
    - Select the appropriate protocol;
    - Select the "Adverse Events" tab at the bottom of the screen and click on the "New Adverse Event" button.
3. The PI should describe the unanticipated problem in detail using the IRB application in Mentor IRB as a reference.
4. Answer the questions that appear in Mentor IRB.
5. The IRB will review the submitted report and respond within 10 business days. Additional time may be needed if a Full Board Review is required.
6. Based on the review, the IRB may:
    - Reconsider the approval of the study.
    - Require modifications to the study.
    - Revise the timetable or increase continuing review as part of the study approval.
7. Based on the review, further reporting to NKU administration may be required.
8. If the study is federally funded (e.g., by the Department of Health and Human

Services) additional IRB reporting requirements may be in effect.

4.0 REFERENCES

45 FR 46.103 (5)45 CFR 46.103

5.0 DEFINITIONS

Unanticipated Problems (from OHRP) - OHRP considers unanticipated problems, in general, to include any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	☒	06/15/2017	☐
IRB Chair	☐		☒
Institutional Official	☐		☒

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☒	07/11/2024	☐	Updated template & Mentor UI
IRB Chair	☐		☒	
Institutional Official	☐		☒	