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

SOP Title	(IRB) Non-Compliance and Suspension or Termination of a Protocol					
Date Last Revised	09/21/2017	Date Created	10/09/2017	Revision #	1.0	
SOP Number	3	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 is to describe the process for suspension or termination of an IRB approved protocol.

2.0 General Information and Scope

As required by Federal Regulation (45 CFR 46), Northern Kentucky University's Institutional Review Board (IRB) for the Protection of Human Subjects has established this procedure to define the criteria and procedural guidelines for suspension or termination of an active, approved IRB research protocol.

All allegations of potential non-compliance will be reviewed by the IRB Administrator in consultation with the IRB Chair. Based on the severity and/or legitimacy of the noncompliance issue(s), the IRB Chair and Administrator will refer an issue of (1) minor noncompliance to the IRB Administrator for resolution or (2) serious and/or serious ongoing noncompliance to the Institutional Review Board as a whole for discussion and resolution. When the issue involves serious and/or serious ongoing noncompliance, the IRB Administrator will advise the Institutional Official of the noncompliance and of actions taken by the Institutional Review Board as a whole to address the issue.

3.0 Procedures

Minor noncompliance: Usually inadvertent failure of Principal Investigator (PI) and/or research staff to abide by guidelines.
Serious noncompliance: Isolated incident(s) of inadvertent or intentional noncompliance by Principal Investigator and/or research staff that increases risk to or adversely affects the welfare and rights of research participants.
Serious ongoing noncompliance: A consistent pattern of intentional noncompliance by the Principal Investigator and/or research staff that increases risk to or adversely affects the welfare and rights of research participants.

Northern Kentucky University's Institutional Review Board reserves the authority to suspend or terminate an active IRB research protocol due to noncompliance. The IRB will notify the Principal Investigator (PI) of any suspension or termination of an active IRB research protocol, in writing, which will include a statement explaining the reasons for the suspension or termination.

Suspension: An action taken by the IRB mandating that all research activities stop temporarily until the IRB investigates the alleged noncompliance and lifts the suspension or terminates the study. Suspended IRB protocols will retain initial IRB approval status, but the Principal Investigator must cease all research activities until the IRB has reviewed and approved continuing the research.
Termination: An action taken by the IRB mandating that all research activities and activities that constitute research misconduct stop permanently.

The events that may lead to the suspension or termination of an active IRB protocol include, but are not limited to, the following:

1. Non-compliance with Northern Kentucky University, Commonwealth of Kentucky, or federal guidelines or regulations which may include but are not be limited to:
    a. Failure to apply for approval to continue conducting an ongoing, active IRB protocol beyond the approved expiration date.
    b. Failure to request approval of revisions to an ongoing, active IRB protocol.
    c. Conducting research not approved by the IRB.
    d. Failure to receive an exemption from the IRB.
    e. Failure to follow the procedures of the active IRB approved protocol.
    f. An increase or change in risk to a research participant.
    g. An unanticipated problem involving serious risk or harm to a research participant.
    h. Inadequate oversight of ongoing research by the Principal Investigator.
2. Continuing issues with a suspended IRB which may include, but are not limited to:
    a. Failure to respond to previous IRB expressed concerns of noncompliance.

The determination to suspend an active, approved IRB protocol will be made:

1. By a majority vote of Institutional Review Board members attending a convened meeting at which a quorum of members must be present or
2. By the IRB Chair if the circumstances require immediate action (e.g., elevated risk of harm to Participants, etc.), and a convened IRB meeting is not possible.

When a study is suspended by a convened meeting of the Institutional Review Board, the IRB Administrator, will notify the Institutional Official immediately and provide information pertaining to the suspension decision.

When a study is suspended by the IRB Chair, the IRB Administrator will notify the Institutional Review Board as a whole and provide information pertaining to the suspension decision. The Institutional Review Board will convene a meeting within 10 working days to review and discuss the suspension. By a majority vote of Institutional Review Board members attending this convened meeting at which a quorum must be present, the IRB may (1) continue or (2) end the suspension.
The IRB Administrator will notify the Institutional Official immediately and provide information pertaining to the suspension decision.

Following a suspension by the IRB chair or by the IRB as a whole, the IRB may decide to:

1. Reinstate the project as approved if concerns leading to the suspension have been addressed satisfactorily
2. Terminate the project if concerns leading to the suspension have not been addressed satisfactorily, or
3. Continue the suspension if concerns leading to the suspension are in the process of being addressed by the Principal Investigator.

The determination to terminate an IRB study will be made only by:

1. A majority vote of Institutional Review Board members attending a convened meeting at which a quorum of members is present
2. The Principal Investigator

Other recommendations that may accompany a suspension or termination include:

1. Review by IRB and Institutional Official of Principal Investigator privileges to conduct human subject research.
2. Review by the Institutional Official of the Principal Investigator's acceptance of federal grant money related to human subject research.

All decisions will be made available to the Principal Investigator in writing within 10 working days. The Principal Investigator has the right to appeal an IRB decision to suspend approval of or terminate an active IRB protocol according to the procedures outlined in SOP #3 (IRB) Appeal Suspension or Termination of a Protocol found on the NKU IRB website.

Approvals

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