



<b>SOP Title</b>	(IRB) Appeal Suspension or Termination of a Protocol				
<b>Date Last Revised</b>	06/07/2017	<b>Date Created</b>	04/26/2017	<b>Revision #</b>	1.0
<b>SOP Number</b>	4	<b>Required by:</b>	<input checked="" type="checkbox"/> OHRP	<input type="checkbox"/> Funding Agency	<input type="checkbox"/> OLAW
<b>Applicability</b>	<input type="checkbox"/> RGC Internal	<input type="checkbox"/> Researcher	<input checked="" type="checkbox"/> Institutional		
<b>Subgroup</b>	<input type="checkbox"/> NKU Compliance	<input checked="" type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input type="checkbox"/> IBC	

### 1.0 Purpose

The purpose of this SOP is to describe the process for a Principal Investigator of human subjects research to appeal a suspension or termination of an approved IRB protocol.

### 2.0 General Information and Scope

As required by Federal Guidelines, the Institutional Review Board (IRB) has established this written policy to establish the criteria and procedure for appealing a suspension or termination of an IRB approval.

If the investigator believes that the proposal has been suspended or terminated because of incorrect, unfair, or improper evaluation by the Institutional Review Board (IRB), the investigator may appeal to the IRB and request reconsideration and a hearing of the proposal by the board.

### 3.0 Procedures

#### Appeal Process

Within ten (10) business days after a negative decision, the PI must show cause in writing or at a designated hearing as to why the board's decision should be reversed.

1. Report is required in writing, dated and signed by PI.
2. Submit the report to the IRB via Research, Grants and Contracts IRB Administrator within ten (10) business days of receipt of the IRB decision, unless there are extraneous circumstances (out of the country etc.).

#### Appeal Decision

The IRB will review the written report and respond within 10 business days. Additional time may be needed if a Full Board meeting is not currently scheduled.

The IRB may take one of the following actions:

1. Reinstatement of an IRB Approval with or without additional monitoring or reporting
2. Require modification to a suspended or terminated IRB; or
3. Confirm suspension or termination of IRB approval.

### 4.0 References

45 CFR 46

5.0 Forms or Attachments

6.0 Definitions

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Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/15/2017	<input type="checkbox"/>
Institutional Official	<input checked="" type="checkbox"/>	06/15/2017	<input type="checkbox"/>