



SOP Title	Change or Addition of the Principal Investigator to an Approved Protocol				
Date Last Revised	09/27/2017	Date Created	06/2010	Revision #	
SOP Number	4	Required by:	<input type="checkbox"/> OHRP	<input type="checkbox"/> Funding Agency	<input type="checkbox"/> OLAW
Applicability	<input type="checkbox"/> RGC Internal	<input checked="" type="checkbox"/> Researcher	<input type="checkbox"/> Institutional		
Subgroup	<input type="checkbox"/> NKU Compliance	<input type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input checked="" type="checkbox"/> IBC	

1.0 PURPOSE

The purpose of this SOP is to describe the process for changing or adding a Principal Investigator (PI) I to an approved IBC protocol.

2.0 GENERAL INFORMATION AND SCOPE

This SOP applies to any IBC approved protocol that is changing or adding a Principal Investigator to the protocol.

3.0 PROCEDURES

In cases where the PI of an approved protocol is replaced with a new PI or a PI is added, the following steps will be taken:

1. A new investigator certification page must be signed by the new PI.
2. A fully signed copy of the BAR must be forwarded to the IBC Administrator.
3. A CV or resume for the new PI should be attached as well.
4. The IBC Administrator will serve as the liaison and forward all pertinent documentation to the IBC Chair.
5. The Chair may function as the designated reviewer and evaluate the new PI's experience as relevant to the procedures in the protocol or assign an IBC member to conduct the review.
6. If the new PI is deemed appropriate, the Chair will approve this action.
 - a. The Chair will sign the investigator certification page and forward to the IBC Administrator.
 - b. The IBC Administrator will notify outgoing PI and the new PI via email and send a formal approval notice. In cases of PI change only, the IBC Administrator will have committee authority to sign approval notice based on the Chair's approval.

4.0 REFERENCES

5.0 FORMS OR ATTACHMENTS

6.0 DEFINITIONS

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/12/2018	<input type="checkbox"/>
IBC Chair	<input checked="" type="checkbox"/>	06/12/2018	<input 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"/>	