



SOP Title	IACUC Holding Procedures				
Date Last Revised	07/17/2024	Date Created	9/21/2021	Revision #	1.1
SOP Number	27	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 checked="" type="checkbox"/> Institutional		
Subgroup	<input type="checkbox"/> NKU Compliance	<input type="checkbox"/> IRB	<input checked="" type="checkbox"/> IACUC	<input type="checkbox"/> IBC	

1.0 PURPOSE

The purpose of this SOP is to provide a mechanism for holding animals not assigned to an active Northern Kentucky University (NKU) approved protocol or animals on a protocol under investigation for potential issues of non-compliance, where the welfare or well-being of the animals is in question.

2.0 GENERAL INFORMATION AND SCOPE

A. BACKGROUND

All animals maintained by NKU for teaching or research purposes must be covered by an active, approved Institutional Animal Care and Use Committee (IACUC) protocol. The IACUC has the responsibility to ensure all IACUC protocols meet federal law, Public Health Service policy and internal regulations and procedures. This SOP specifically addresses the holding of animals on a global animal holding protocol. This Holding Protocol does not expire and does not require Annual Renewal.

B. ROLES

Researcher/Principal Investigator (PI): The investigator should work with the IACUC to ensure that protocols are active and current and will remain so for the duration of the research or teaching activity. The PI will continue to serve as the PI for animals transferred to the protocol in all cases, except when there are concerns regarding animal well-being.

IACUC: Provide a mechanism for rapid transfer of animals in cases where it is necessary to protect animal welfare or reduce unnecessary use.

IACUC Chair: Serve as the temporary Principal Investigator for animals transferred to the holding protocol if the animals are on a protocol under investigation for potential issues of non-compliance where the welfare or well-being of the animals is in question. In a case where the IACUC chair is under investigation as a PI for concerns regarding non-compliance and the chair’s animals need to be assigned to the holding protocol, the Institutional Official will appoint another IACUC member who is an animal user (preferably one not from the IACUC chair’s department) to oversee the holding protocol or care for animals covered by the IACUC chair’s protocols in question.

3.0 PROCEDURES

A. ELIGIBILITY

Use of the Holding Protocol is intended to be temporary; permission must be obtained from the IACUC Chair or IO in the event of a conflict involving the IACUC chair prior to approval of the Holding Protocol use. Situations which may result in the use of this protocol include:

1. Animals ordered/acquired without an approved protocol (potential non-compliance situation);
2. Animals originating from terminated protocols;
3. Expired or lapsed protocol;
4. Animals on a protocol under investigation for potential issues of non-compliance, where the welfare or well-being of the animals is in question;
5. Investigators without an approved NKU protocol who have animals that may require immediate housing at NKU;
6. Investigators that are leaving NKU and do not yet have the necessary approvals or ability to transfer animals to the new institution.

B. REQUEST

The PI requesting the use of the NKU IACUC Holding Protocol must follow these instructions to request use of the holding protocol:

1. Email IACUC@nku.edu to notify the IACUC that you will be requesting use of the Holding Protocol.
 - a. You will receive an email back which will grant access to the NKU Holding Protocol in Mentor IACUC.
2. Access Mentor IACUC and click "IACUC" from the dropdown.
3. In the left-hand column, click "My Protocols".
4. Click "NKU IACUC Holding Protocol".
5. Click "New Amendment +" at the bottom of the screen.
6. Select "Holding Protocol Request".
7. Click "Create Amendment".
8. Click "Answer" and answer all questions that appear.
9. Click "Save Answers".
10. Click "Return to Protocol Page".
11. Click "Submit" (If an additional box pops up, click "OK").
 - a. This will submit the holding protocol request to the IACUC. You will either be contacted by the IACUC Chair or receive approval via the Mentor system.

C. APPROVAL

Only the IACUC Chair (or IO in the case of a conflict of interest with the IACUC chair) is authorized to approve the transfer of animals to the Holding Protocol. Once approval has been received, all actions involving the Holding Protocol will be reported to the IACUC at the next regularly scheduled meeting.

D. MANAGEMENT/MAINTENANCE OF ANIMALS ON THE HOLDING PROTOCOL

1. No experimental or instructional procedures are allowed on animals maintained on the Holding Protocol.
2. Breeding to maintain viability of specific lines may occur under this protocol. Expansion of colony breeding is not authorized.
3. Selected procedures or specialized husbandry condition may continue at the discretion of the IACUC Chair in order to ensure animal health (e.g. maintenance on a special diet, care of chronically implanted catheters or enhanced monitoring).
4. While the IACUC chair or other designated PI will oversee the holding protocol, this person may delegate responsibility for the daily care of animals on the protocol to another PI or animal user with greater expertise in the needs and care of specific species or to the laboratory animal care technician.
5. Feeding, sanitation and environmental enrichment will be maintained as appropriate for the species and conditions in accordance with *The Guide for the Care and Use of Laboratory Animals*.
6. Documentation of Animals Placed on the Holding Protocol: If animals are transferred to the holding protocol from an existing protocol, then the PI of the original protocol will remain responsible for tracking/counting the animals.
7. If euthanasia is required for the animals in Holding Protocol, the IACUC Chair or their designee will perform it using appropriate methods.
8. Other methods of disposition, as appropriate, may also be pursued to ensure the welfare of the animals. Examples could include transfer to an active protocol or adoption by approved users.
9. The IACUC Chair must be notified in writing of any pre-existing conditions of note for all animals transferred onto the Holding Protocol. Examples include but are not limited to:
 - a. Existing surgical implants
 - b. Zoonotic and/or infectious disease potential, including viral vectors
 - c. Chemical or radiation hazard potential
 - d. Special dietary and care needs
 - e. Past surgical history
 - f. Genetic anomalies that affect the appearance, health or normal behavior of the animal
 - g. Poor fecundity

E. TIME LIMIT

Animals should be removed from the holding protocols as soon as possible. The maximum time for an animal to stay on the Holding Protocol is two months. A return of the animals to an approved protocol by the previous PI will be prioritized, once the issues triggering the need for the holding protocol have been resolved. If this does not occur, then animals are to be transferred to another protocol, adopted out, or euthanized after two months on the holding protocol.

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	09/15/2022	<input type="checkbox"/>
IACUC Chair	<input checked="" type="checkbox"/>	09/15/2022	<input type="checkbox"/>
IACUC Committee	<input checked="" type="checkbox"/>	09/15/2022	<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 checked="" type="checkbox"/>	07/07/2024	<input type="checkbox"/>	Menter userface update
IACUC Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>	