USE OF DLAR HOLDING PROTOCOL

PERFORMANCE STANDARD: To provide a mechanism for holding animals not on study or assigned to current Duke protocols.

BACKGROUND/PURPOSE: All Institutional Animal Care and Use (IACUC) protocols are within federal guidelines and meet all institutional expectations. All animals maintained by Duke University Medical Center (DUMC) must be covered by an active, approved IACUC protocol. The IACUC has the responsibility to ensure all animal use activity meets federal law, Public Health Service policy, and AAALAC, i accreditation expectations. This policy specifically addresses the holding of animals on a global animal holding protocol.

ROLES:
- **Researcher**: The investigator should work with the IACUC to ensure that protocols are active and current and will remain so for any anticipated or ongoing animal use.
- **IACUC**: Provide a mechanism for rapid transfer of animals in cases where it is necessary to protect the wellbeing, welfare, or prevent the wastage of the animals.
- **Attending Veterinarian or designee**: Will maintain a Holding Protocol for the purpose of receipt of animals that would otherwise be euthanized for lack of an existing protocol.

PROTECTIVE MEASURES REQUIRED: Personnel protective equipment is required; appropriate to the species and any treatments being given.

POLICY:

1. **Eligibility for Participation Under this Policy**: Use of the Holding Protocol is intended to be temporary.
2. **Situations which may result in the use of this protocol, might include:**
   a. Animals ordered without an approved protocol (non-compliance situation)
   b. Animals originating from inactive (or terminated) protocols.
   c. Animals on a protocol under investigation for potential issues of non-compliance where the welfare or well-being of the animals is in question. Animals associated with a non-compliance item that does not impact their welfare can be maintained on their parent protocol until the non-compliance item is resolved. IACUC should be notified ASAP of the non-compliance event.
   d. Investigators without an approved Duke protocol having animals that may require immediate housing at Duke.
   e. Investigators that are leaving Duke and do not have the necessary approvals for transfer to the new institution.
3. **Requests to place animals on the DLAR Holding protocol will be generated by the PI, the IACUC Chair, IACUC Vice Chair, the OAWA Director, OAWA Associate Director, or the AV (or designee).**
4. **An investigator requesting the use of the DLAR Holding protocol must complete**
the “DLAR Holding Protocol Request Form” and submit to the DLAR Director or designee.

5. **Transfer Required Due to Termination of Approved Protocol:** IACUC- and OAWA-authorized transfers from expiring protocols will be generated through currently produced monthly reports: Protocol Expiration Memo and New Numbers for Expiring Protocols. These reports will be generated and sent to DLAR within 2 business days after the IACUC Full Committee meeting. These reports are the authorizing source documents for DLAR staff to transfer animals to the DLAR Holding Protocol.

6. **Transfer Required Due to Non-Compliant / Adverse Event:** The IACUC Chair, IACUC Vice Chair, the OAWA Director, the OAWA Associate Director, or the Attending Veterinarian (or designee) are authorized to initiate the transfer of animals from an active protocol to the Holding Protocol. These actions will be reported to the IACUC at the next regularly scheduled meeting.

7. DLAR will transfer animals within 3 business days of receipt of transfer request from the PI or monthly reports from IACUC and OAWA.

8. Management of Animals on the Holding Protocol (what can be done):
   a. No experimental procedures are allowed on animals maintained on the DLAR Holding Protocol.
   b. Breeding performed to maintain viability of specific lines may occur under this protocol. Expansion colony breeding is not authorized. DLAR will perform all procedures necessary to maintain colony viability.
   c. Feeding, sanitation, and environmental enrichment will be provided according to the approved protocol.

9. DLAR must be notified of any pre-existing conditions of note prior to transfer of animals onto the Holding protocol (for PI-initiated actions); and will coordinate with the PI concerning any special conditions when the transfer request is initiated by the IACUC or OAWA. Examples include but are not limited to:
   a. Existing surgical implants.
   b. Zoonotic disease.
   c. Special dietary needs.
   d. Past surgical history.
   e. Viral vectors.
   f. Poor fecundity.

10. Fees: Per diem, procedure, or the fees for support of the animals on the Holding Protocol will be charged to the investigator (or department) while their animals are on the Holding Protocol. DLAR may place a surcharge for animals on the DLAR Holding Protocol. The Director, DLAR may waive this surcharge as appropriate.

NOTE: Federal grant funds may NOT be used for support of any animals in a holding protocol status due to non-compliance or failure to obtain IACUC approval for a 3 year replacement protocol.

NOTE: New faculty transfers to Duke may use federal funds for support of animals on a holding protocol, until such time that a protocol is approved.

11. A copy of the form to request transfer to the holding protocol by principal investigators is located on the DLAR website.