PERFORMANCE STANDARD: The Principal Investigator (PI) is responsible for animal care & animal use as approved by the Duke IACUC and/or consistent with Duke DLAR Care SOPs.

BACKGROUND: Federal regulation, PHS Policy, and standards of AAALAC accreditation require that each research institution establish a process for management and oversight of animal care and use activities. Duke has chosen to identify the Principal Investigator as the individual who will be obligated for all animal work performed under his / her approved animal use protocol or SOP. When a sponsor is identified, these same obligations apply to the sponsor. This policy applies to all research, testing, or teaching procedures involving Duke IACUC-regulated (e.g., vertebrate & cephalopod invertebrate) animals.

ROLES:
- The IACUC will set the expectations and obligations of the Principal Investigator and Sponsors regarding care & use of animals at Duke or under a Duke IACUC-approved protocol.
- The Principal Investigator (PI) and/or Sponsor will fulfill each of their duties and responsibilities as outlined below.

POLICY:

I. Definition of a Principal Investigator: The definition of a Principal Investigator at Duke is one of the following:

   A. Duke faculty who are emeritus, tenured, tenure or research track.
   B. Duke staff veterinarians of the DLAR or the DLC.
   C. Duke staff, students (i.e., undergraduate, graduate, post-doc), adjunct faculty, visiting faculty, or third party individuals may serve as Principal Investigator when a Sponsor (See 1A or 1B above) is listed on the protocol.

II. Definition of a Sponsor: A Sponsor is an individual who qualifies as a Principal Investigator (see 1A, or 1B above), but for a specific protocol is supporting a PI who does not qualify as PI under the definition above. In addition to 1A, or 1B above, Duke non-faculty staff may serve as sponsor when appointed to do so by the Department/Center Chair and solely for the activities within that Department or Center.
III. **Responsibilities of the PI:** The PI is responsible for:

A. All animal care and use activities performed under the approved protocol, whether externally or internally funded.

B. Completing all required animal handler training, even if not directly handling the animals. Completion of training assures that the PI is properly advised on institutional expectations for animal care and use.

C. Assuring completion of training for all individuals working under his / her protocols. See the policy on Off-Site Research Involving Non-Duke Personnel.

D. Reporting unexpected or adverse events that affect animals in his / her charge as soon as practical.

   **NOTE:** In cases where the adverse event occurs during a field study, the IACUC expects timely advisement upon the PI’s return to internet access.

E. Providing required responses, assurances, and information for all IACUC documents (e.g. protocols, amendments, & reports).

F. Monitoring their ‘@duke.edu’ email account for communications from the IACUC and providing prompt responses to IACUC inquiries in a timely manner.

   **NOTE:** The IACUC generally considers one week as a timely response period. If a PI anticipates being unable to respond within one week (or if the PI expects to be out of internet access for more than one week), they should provide the OAWA/IACUC with an Alternate Contact (which may or may not be the sponsor), who will be able to respond to the IACUC on behalf of the PI during such time that the PI is out of communication. In the event of continuing inability to communicate with the IACUC in a timely fashion, the IACUC may require designation of an Alternate Contact or may close the protocol.

IV. **Responsibilities of the Sponsor:**

A. A sponsor listed on a protocol is ultimately responsible to Duke and the IACUC for PI obligations and activities of animals on the protocol.

B. Correspondence with the Principal Investigator may also be sent to the Sponsor.

   **NOTE:** Adjunct faculty must have a full faculty or emeritus faculty sponsor to ensure a point-of-contact at Duke University.
V. **Alternate Contact:** PIs may identify an Alternate Contact to assist with communication to/from the IACUC.

The Alternate Contact may / or may not be the Sponsor.

A. If a Sponsor is listed on the protocol form, then the assumption is that the Sponsor is the Alternate Contact.

B. If an individual other than the Sponsor is identified as an Alternate Contact, the PI should submit the name and contact information to mailto:iacuc@duke.edu.

C. Communications with the PI may also be sent to the Alternate Contact.

VI. **Signatures & Acceptable Routes of Submission:** The Duke animal program considers a message from a ‘@duke.edu’ email account as a valid signature of that individual.

A. Hard copy signatures, PDF signatures, or scanned documents with a hard copy signature applied to the original document are not acceptable. In rare circumstances, adjustments may be considered by the OAWA Director or Assistant/Associate Director.

B. Documents requiring submission from the PI’s ‘@duke.edu’ email account include:

1. The original protocol submission,
2. Annual Progress Reports
3. Amendments
4. Other IACUC, grant, or regulatory correspondence

C. Documents that may be submitted by a Duke Research Animal Coordinator (RAC) or PI-approved Alternate Contact from their ‘@duke.edu’ email account on behalf of the PI include:

1. Annual Progress Reports
2. Amendments
3. Other IACUC, grant, or regulatory documents.

NOTE: When the RAC or Alternate Contact submits documents on behalf of the PI, the PI must be listed in the ‘CC’ of the message. In this way, the PI has been alerted / advised of the submission of a document on their behalf.

NOTE: Grants may also be received directly from ORA or ORS representatives and/or grants managers.
VII. **When the PI is not available:** There may be occasions when the PI is not able to send an email from their ‘duke.edu’ email account (e.g., illness, death, transfer from the institution, termination of employment, sabbatical leave, not having email access, etc.). In these situations, one of the following may file an email from their ‘@duke.edu’ email account expressing the desires of the PI (or the institution) regarding a protocol action (e.g., terminate, modify activity, report):

A. Alternate Contact (identified by the PI prior to their departure)
B. Sponsor (previously listed in the approved protocol as ‘sponsor’)
C. Department Chair (of the departing PI)
D. Institutional Official

VIII. **Removing (or transferring) the role of the PI:** The following methods may be used if it becomes necessary to remove a PI from a protocol (e.g., illness, death, transfer from the institution, termination of employment, serious on-going noncompliance, etc.):

A. The IACUC may vote to suspend or terminate the protocol; or
B. One of the following may file an email from their ‘duke.edu’ email account to terminate the protocol, or to request the IACUC reassign the role of Principal Investigator to another individual. This can be performed as a Significant Change Sub-Committee approval process:
   1. Sponsor (previously listed in the approved protocol as ‘sponsor’)
   2. Department Chair (of the departing PI)
   3. Institutional Official