WHEN AN ANIMAL USE PROTOCOL IS REQUIRED
(or when a protocol is not required)

PERFORMANCE STANDARD: All animal use must be performed in an appropriate manner with IACUC approval, oversight, and appropriate use of analgesics, anesthetics, or environmental enhancements which limit or prevent animal discomfort.

REFERENCES:
2. PHS Policy on the Care and Use of Laboratory Animals, OPRR, 1996.
3. OLAW Web Site: http://grants.nih.gov/grants/olaw/
4. AAALAC Accreditation Guidelines: http://www.aaalac.org

BACKGROUND: The institution is obligated under its USDA registration, PHS Assurance, AAALAC accreditation to assure the welfare and well-being on animals used in research, testing, or teaching. Animal protocols are generally, but not always required. Certain uses of animals do not fall under the purview of the IACUC. This policy clarifies those situations when a protocol is required, when it is not required but recommended, or when it is simply not required.

ROLES: Duke faculty, staff, or employees using animals in research, testing, or teaching are obligated for assuring necessary approvals and the well-being of animals engaged in the activity.

POLICY:
1. A protocol IS required when:
   a. Duke-owned animals are being used by Duke faculty, staff, or employees for the purpose of research, testing, or teaching.
   b. Purchase of animals used in research, testing, or teaching at Duke or other institutions where grant funds administered by Duke or Duke departmental funds are being used.
   c. Support for animals being used in research, testing, or teaching at Duke or other institutions involving grant funds administered by Duke or Duke departmental resources.
   d. Animal research, animal testing, or teaching activities involving animals on a Duke campus, regardless of funding source or ownership.
   e. Client-owned animals participate in Duke animal research, testing, or teaching (as defined above).
   f. Field Research activities.
      i. Note: Field Studies do not require a protocol. The USDA definition of Field Study vs. Field Research is used for determining the need for a protocol:
         1. Field Study: Defined as observation / data collection without an impact upon the animal;
2. **Field Research:** Defined as observation / data collection that requires capture, redirection of normal animal activities or functions, behavior modification, sedation, etc.

g. Custom antibody production in vertebrates: Antibodies are considered customized if produced using antigen(s) provided by or at the request of the investigator (i.e., not purchased off-the-shelf). An organization producing custom antibodies for an awardee must have or obtain an Assurance, or be included as a component of the awardee’s Assurance. In addition, the awardee must provide verification of project-specific IACUC approval for the production of the antibodies.

h. Use of animal tissue or materials if:
   i. Euthanasia of the animal(s) is for the purpose of obtaining or using their tissues or other materials to meet the scientific goal, OR
   ii. Project-specific antemortem manipulation of animals occur prior to euthanizing them.

2. **A protocol IS NOT Required:**
   a. No Duke funds are being used for animal purchase, or animal support, and the animals are not on the Duke campus. (Note: Any animal on a Duke campus, regardless of funding source, requires a Duke approved protocol).
   b. Animals purchased with private funds, owned by Duke employees, and used in activities outside of Duke sponsorship (e.g., personal pets, unit mascots, religious activities, etc.)
   c. Use of animal tissue or materials if:
      i. Euthanasia of the animal(s) would occur regardless of the proposed use of animal tissues or materials AND do not meet the exceptions for when a protocol is required for animal tissue or material use. Examples include: Animals are euthanized under an unrelated protocol, tissues/materials from animals euthanized at a slaughterhouse/shelter, etc. tissue/materials were previously collected and stored for an unrelated project, etc.
      ii. Custom products acquired through use of embyonated eggs (vaccines, antibodies, microbiologic, etc.), if products are harvested and the egg is destroyed prior to hatching.
   d. Work with insects or other lower taxonomic forms of animals.

   **NOTE:** All members of the PHYLUM Chordata, CLASS Vertebrata (all vertebrates), and the PHYLUM Mollusca, CLASS Cephlapoda (e.g., octopus and squid) are considered covered species and do require a protocol.

3. **Special Notes:**
   - **Recording a Decision that No Protocol Was Required:** To avoid potential animal welfare violations or funding agency restrictions in a situation when a protocol is not required, it is recommended that the Duke researcher(s) complete the brief one-page questionnaire on the web site and send the completed questionnaire to IACUC@DUKE.EDU. The OAWA will review the questionnaire, the Director, OAWA (or delegated) will reply with a signature that no protocol is required. The signed questionnaire is maintained in the animal program as evidence that a decision was made prior to performing animal activities that the work did not require a protocol. No further action is required. Note: You may use the signed questionnaire for publication assurance that no protocol was required.
a. **Publication of Activities that Did Not Require Protocol:** While the OAWA may confirm that a protocol is not required (as per this policy), selected journals may require confirmation of protocol approval prior to publication. Researchers should consider where the work will be published. Protocols cannot be approved after the work has been completed; it is important to check first! OAWA can provide a memo to the journal to affirm that the practices did not require IACUC approval (See discussion of the questionnaire above).

b. **‘Gratis’ Reviews:** The Duke IACUC will review protocols even for activities which are not required, if that activity involves Duke faculty, employee, or staff. This is a ‘gratis’ review and is not necessarily considered to be an IACUC-approval, but rather an IACUC review to reaffirm that a protocol is not required and an IACUC review to confirm no demonstrable regulatory violations are likely to occur with the proposed activity. None of the work performed without a Duke IACUC-approved protocol can be reported in any publication(s) as having been IACUC-approved by the Duke IACUC.