PERFORMANCE STANDARD: All Duke animal program protocols will be reviewed for scientific merit, ethical use, and humane care & use.

BACKGROUND/PURPOSE: The National Research Council’s Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act require that the IACUC review all activities involving animals. While the responsibility for scientific merit review normally lies outside the IACUC, the committee members should evaluate scientific elements of the protocol as they relate to the welfare and use of the animals. For example, hypothesis testing, sample size, group numbers, and adequacy of controls can relate directly to the prevention of unnecessary animal use or duplication of experiments. For some IACUC questions, input from outside experts may be advisable or necessary. In the absence of evidence of a formal scientific merit review, the IACUC may consider conducting or requesting such a review. Regarding ethical (harm-benefit) analyses, the Guide for the Care and Use of Laboratory Animals indicates that for studies that have the potential for unrelieved pain or distress, there are special considerations for IACUC review. Specifically, the Guide indicates that “the IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns.” AAALAC has concluded that for studies involving the potential for pain and distress, the IACUC should conduct a “harm/benefit” analysis.

APPLICABILITY: The requirements specified in this policy apply to all protocols reviewed by the Duke IACUC.

POLICY OUTLINE:

1. Protocols submitted for Duke IACUC shall have a review for scientific merit, ethical use, and humane care & use:
   a. The review for Scientific Merit is generally considered the responsibility of the funding / granting agency. For those proposals where the funding / granting agency has not performed a scientific merit review (e.g., departmental funding), the IACUC may require a scientific merit review be performed by the Department Chair or their designee (who must not have a conflict of interest regarding the PI or the protocol).
      i. If a Scientific Merit review is required, the OAWA will coordinate the review and the person completing the review should complete and submit a “Merit Review Form” directly to IACUC@Duke.edu.
      ii. See the Duke Animal Program Guideline for performing a scientific merit review for guidance.
b. The review for **Ethical Use** shall be performed by the IACUC during its routine review processes. The main ethical principle which guides most animal use is that using animals for scientific purposes is acceptable only when any harm done to the animals is outweighed by the benefits of their use. However, it is not enough for the harm just to be lower than the benefit; harm must also be as low as possible while the benefits must be as great as possible. There are three statements which the IACUC uses to achieve the goals of an appropriate Ethical Use (Harm:Benefit) analysis:

i. **Confirm that harm caused is as low as it can be:** Protocols will be assessed for the 4’Rs to ensure that animals are only used when that they are necessary; that the correct number of animals are used to achieve the objectives of the study; and that individual animal distress is limited to that which is required for the objectives of the study.

ii. **Confirm that the anticipated outcomes are achievable and provide the maximal amount of data and outcome information:** Protocols will be assessed for the plausibility of accomplishing the proposed work.
   1. Research: How will the value of new knowledge build upon health, welfare, ecology, or conservation issues?
   2. Teaching: How will the proposed procedure enhance students’ learning regarding the learning objective being presented?
   3. Testing: Are the proposed activities legally required, or will they assess the safety or effectiveness of chemicals, drugs, medicines, vaccines and other substances?

iii. **Weigh expected harm against the anticipated benefits:** Consider the following: The greater the harm or noxiousness, the greater must be the expected benefits before a procedure can be approved.

c. The review for **Humane Care & Use** is performed by the IACUC during its routine review processes. The main issues considered during this review process includes current standards of veterinary care, current expectations of animal care in a research, testing, or teaching environment, and progressive ideas on improved animal wellbeing and welfare.