This guideline should complement the IACUC Policy “Scientific merit, ethical, and Humane Care and Use Reviews of Animal Use Protocols.” Duke University supports the judicious use of animals in research, education, and testing in the interests of human and animal welfare. At the same time, it insists on humane and ethical treatment of those animals.

In compliance with University policy and federal statutes, the Institutional Animal Care and Use Committee (IACUC) provide supervision, coordination, and review of every project proposed to include the use of animals. Although formal scientific or instructional merit review normally lies outside the IACUC, the IACUC’s charge includes compliance with the “US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training,” Principle II of which states that “procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.” Thus, the IACUC must assure scientific or instructional merit in the projects it approves.

IACUC considers a funding decision by external peer review to be adequate evidence of scientific merit. However, proposed projects that are not subjected to external peer review (such as internally funded projects, industry contracts or gifts, and instructional use of animals), must provide alternative evidence of scientific or instructional merit. Toward that end, IACUC requires the Department Chair or their designee of the home department/unit to assure the scientific or instructional merit of any project to be undertaken prior to external review and approval, provided that this individual does not have a conflict of interest regarding the PI or the protocol.

In accord with US Government Principle II, the Department Chair or their designee is required to assure that the project is meritorious, that is, that it is likely to benefit human or animal health, the advancement of knowledge, or the good of society. The Department Chair or their designee’s electronic submission of their review via email form their Duke email address documents that assurance.

To assist Department Chair or their designee on unit-level committees in evaluating scientific merit in a proposed research project, the IACUC concludes that, in addition to meeting the criteria in US Government Principle II, at least the following questions should be considered:

1. Has the investigator formulated appropriate long-term scientific goals for the proposed work?
2. Does the proposed work have clearly-defined short term objectives?
3. Is the experimental method appropriate for answering the question?
4. Is there reasonable probability that interpretable data will be obtained?

Additionally, the chair/director may wish to consider the following:

1. Does the proposed work have the potential for publication in a peer-reviewed journal?
2. If not, is it a pilot study that will likely lead to an external peer-reviewed grant application or publication?

To assist chairs/directors or unit-level committees in evaluating instructional merit in a proposed instructional project, the UCUCA suggests that the following questions be considered:

1. Has the instructor formulated appropriate long-term instructional goals for the course?
2. Does the course have clearly-defined specific learning objectives?
3. Is the proposed instructional use of animals appropriate for illustrating the principle or topic being taught?
4. Is there a reasonable probability that the student will be provided with a meaningful learning experience?

If you have questions regarding these guidelines, please contact the Office of Animal Welfare Assurance at IACUC@DUKE.edu