

UCUCA Policy: Review for Scientific Merit of Animals in Use Categories 7, 8, and 9

I. Background

The University of Michigan defines Use Categories 7, 8, and 9 as those procedures in which “animals might experience pain, discomfort or distress for which anesthetics, analgesics, or tranquilizers would customarily be given, but these drugs cannot be used because their use would adversely affect the experimental results or interpretation or are unavailable”. Protocols with animals in Use Categories 7, 8, or 9 are thus unique (compared to Use Categories 1-6) in that pain or distress is induced in animals, but is not relieved. It is therefore especially important that this pain or distress be essential for the validity of the procedure and the scientific goals of such protocols be so meritorious that this pain or distress is justified. It falls within the scope of the UCUCA review of protocols and modifications to assess this proportionality. Certainly, the national and international trend is that the scrutiny of animal experiments, particularly those that involve pain or distress, is continually increasing. Both investigators and the University, as represented by the University Committee on the Use and Care of Animals (UCUCA), have an obligation to justify the scientific merit of all animal experiments, but especially those in Use Categories 7, 8, and 9, to other investigators, to regulatory bodies, and to the general public. The criteria for establishment of scientific merit for animals in Use Categories 7, 8, and 9 are described below. *Procedures for review of protocols with Use Categories 1-6 animals remain unchanged.*

II. *Scientific merit can be established by external review.* Four different pathways (A-D) may be used. These applications will be reviewed for animal use concerns as we do now, and can be approved for as long as three years.

A. Scientific merit can be established if the experiments included in an animal use application are funded by an external, not for profit, agency. (No change from present policy.)

B. Scientific merit can be established if the experiments have not been funded, but have ranked in the top 50th percentile, after review from an external, not for profit, agency. (This includes any grant application that received a priority score from an NIH review, even if the percentile is slightly less than the 50th.) To establish this, the applicant must provide the review document that indicates the percentile ranking. This allows review for scientific merit by a mechanism that was not utilized in previous policies.

C. *In a few cases, scientific merit can be established by examination of review comments from an external, not for profit, agency.* Some applications that are not scored by the NIH, or are not in the upper 50th percentile after an external review, are nevertheless meritorious. If the applicant feels that the reviewer comments are

supportive of the proposed work including Use Category 7, 8, or 9 animals, he or she can request a special review. The applicant must provide copies of all review documents. UCUCA will evaluate the review documents provided to determine if they indicate strong scientific merit of the proposed experiments.

D. *Scientific merit can be established by a "Statement of Assurance" from an external, for profit organization (usually a "contract").* The Statement of Assurance should discuss the strong scientific merit of the proposed protocols, and the necessity for animals in Use Categories 7, 8, or 9. The Statement of Assurance will be considered in the overall evaluation of the animal use application.

III. *Scientific merit for projects can be established by internal reviews.*

Animal use applications which are funded by departments or other internal funds must be accompanied by a letter from the Department Chair or designate that describes what materials were reviewed for determination of scientific merit (in general, the animal use application alone is not adequate for determination of scientific merit) and what aspects of the proposed experiments are sufficiently meritorious that they justify the use of animals in Use Categories 7, 8, or 9. This letter might also address some of the issues listed in the document, "[Guidelines for Unit Heads in Assuring Scientific or Instructional Merit in Proposals for Animal Use in Research or Teaching](#)". Alternatively, in lieu of a letter from the Department Chair, written reviews of the proposed work from OVPR, BMRC, the Phoenix Project, the Rackham Graduate School, etc. can be appended.

Additionally, animal use applications that include animals in Use Categories 7, 8, or 9 and are funded by departments or other internal funds may be reviewed as pilot projects. These pilot projects will be approved for no more than one year, and for a very limited number of animals in Use Category 7, 8, or 9. To assist UCUCA in its determination of an appropriate number of animals, investigators may want to submit review documents from external or internal organizations that comment specifically on the need for preliminary experiments using animals in Use Category 7, 8, or 9.

IV. *Modifications of animal use protocols that involve animals in Use Category 7, 8, or 9.*

All modifications that increase the number of animals in Use Categories 7, 8, or 9, or significantly change procedures on animals in Use Category 7, 8, or 9, will be reviewed by members of UCUCA. Such a review requires a minimum of 4 weeks to complete.