



POLICY

Prior to approving a research or teaching protocol utilizing animals, the Institutional Animal Care and Use Committee (IACUC) will review the application to determine if the following criteria are adequately addressed:

- 1) Is the purpose and potential value of the proposed animal use clear and acceptable;
- 2) Is there documentation to support that unnecessary duplication was adequately considered;
- 3) Is there a clear, sequential and complete description of all procedures (surgical and non-surgical) to be performed on animals;
- 4) Is there adequate justification for the selected species;
- 5) Is there adequate justification for the number of animals requested;
- 6) Is the use of analgesics, anesthetics, and tranquilizing drugs appropriate to minimize discomfort and pain to animals;
- 7) Is there adequate peri-operative and/or peri-procedure care in accordance with established veterinary medical practices;
- 8) Is there a clear description and criteria for timely intervention for animals that would otherwise experience pain or distress beyond that anticipated and described in the research endpoints;
- 9) Is there a clear description and rationale for the selected study endpoints;
- 10) Are all applicable exceptions to the Guide and/or USDA Regulations listed and appropriately justified;
- 11) Is the disposition of animals/method of euthanasia appropriate, including a method to ensure death;
- 12) Is there adequate information to assess that alternatives or alternative methods that incorporate replacement, reduction, or refinement of animal use to minimize animal pain and distress were considered;
- 13) Is there adequate documentation of training and experience or proposed training for all personnel for all listed responsibilities;
- 14) Is the use of hazardous materials adequately outlined and provisions in place to ensure a safe working environment?

Upon receipt of an acceptable submission addressing the criteria listed above, a final harm/benefit analysis is conducted weighing the potential adverse effects of the study against the potential benefits that are likely to accrue as a result of the research. If it is determined that the benefits outweigh, or balance, the harms and the protocol is in compliance with the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals, USDA Regulations (where applicable), the Guide for the Care and Use of Laboratory Animals, and the UNO IACUC Animal Welfare Assurance, Guidelines and Policies, approval and release to conduct the study is issued.

REGULATION (including but not limited to the following)

- The animals selected... for a procedure should be of an appropriate species and quality... to obtain valid results.” (USGP III)
- “The number of animals selected... should be the minimum required to obtain valid results.” (USGP III)
- “Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.” (PHS Policy at IV.C.I.a.)
- The IACUC should evaluate scientific elements of the protocol...e.g. hypothesis testing, sample size, group numbers and adequacy of controls (The Guide, pg 26)
- Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. ...” (USGP IV)
- “Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesic, or anesthesia, unless the procedure is justified for scientific reasons ...” (PHS Policy at IV.C.I.b.)
- Avoidance of “unnecessary duplication of experiments”. (The Guide: 8th Edition, pg. 26)
- “Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.” (PHS Policy at IV.C.I.f.)
- “Applications and proposals...shall contain...a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research...” (PHS Policy at IV.D.I.d.)
- “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.” (USGP II)
- “A proposal...must contain a rationale for involving animals...” (USDA 9 CFR 2.31(e)(2))
- “A proposal... must contain... identification of the species... and a rationale for the appropriateness of species...” (USDA 9 CFR 2.31 (e)(1)(2))
- “A proposal...must contain...the approximate number of animals to be used... and a rationale for... numbers of animals to be used.” (USDA 9 CFR 2.31 (e)(1)(2))
- “Alternatives...include... methods that reduce the number of animals to the minimum required to obtain scientifically valid data...” (USDA Policy 12, March 25, 2011)
- “The principal investigator must provide written assurance that the activities do not unnecessarily duplicate previous experiments.” (USDA 9 CFR 2.31(d)(iii))
- “No animal will be used in more than one major operative procedure from which it is allowed to recover unless justified for scientific reasons... or is required to protect the health and well being of the animal as required by the attending veterinarian...” (USDA 9 CFR 2.31(d)(x))



- “ A proposal... must contain a description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research...” (USDA 9 CFR 2.31 (e)(4))
- “Procedures that may cause more than momentary or slight pain or distress...will be performed with appropriate sedatives, analgesics or anesthetics unless withholding such agents is justified for scientific reasons...” (USDA 9 CFR 2.31(d)(iv)(A))
- “...all scientists...and other personnel... are qualified to perform their duties...” (USDA 9 CFR 2.32(a))
- “...the IACUC is expected to weigh the objectives of the study against potential animal welfare concerns” (The Guide, pg 27)
- AAALAC International expects the IACUC (or other oversight body), as part of the review process, “will weigh the potential adverse effects of the study against the potential benefits that are likely to occur as a result of the research.” This analysis should be performed prior to final approval of the protocol and should be a primary consideration in the review process. AAALAC International site visitors will assess whether the IACUC has conducted this analysis. (AAALAC FAQs, September, 2011)
- The IACUC’s harm/benefit analysis should be documented for protocols involving pain and discomfort (AAALAC, J. Bradfield, January 9, 2012)