



Amending the Animal Use Protocol

1. Consider one-on-one virtual sessions including iRIS screen share for customized, comprehensive support for any AUP submission. Contact the Animal Welfare Office at 979.845.1828 or animalcompliance@tamu.edu to schedule.
2. Find all referenced documents, tools, and instructions on the TAMU IACUC Guidance page (requires TAMU authentication): <https://vpr.tamu.edu/animals-in-research-and-teaching/texas-am-iacuc-guidance/>
3. Follow IRIS-M-003 *How to Create an Amendment* to start an Amendment in iRIS, or contact AWO staff for assistance
4. Use the **amendment form** in iRIS to select requested modifications by type and communicate justification for the request. The AUP/IACUC Application (Animals) form is considered a “living document”. A new version of the AUP with requested modifications/amendment details incorporated into the relevant sections is required.
5. See the instructions (also listed in Section 2.3 of the amendment) and tips below for the various types of amendments commonly requested. The types of modifications below coincide with the options in the iRIS AUP Amendment form.

Type of modification	Applicable AUP sections to revise + tips <i>(section numbers may vary depending upon selections made in AUP section 5.4 Project Activities, so only section titles are listed below)</i>
1. Combine AUPs	<ul style="list-style-type: none"> ❖ All/most AUP sections may require revision. Additional Tips: <ul style="list-style-type: none"> ✓ The title and lay summary should be broad enough to encompass the multiple projects and should not contain acronyms or scientific jargon. ✓ See AWO-O-073 <i>Tips for Combining AUPs</i>
2. New Funding Source	<ul style="list-style-type: none"> ❖ Project Identification, subsection: IACUC Funding Questions. (If additional funding will require adding animals, procedures, administered agents, hazards, etc., check all of the selections that apply in section 2.1 of the amendment form and revise appropriate sections of the IACUC Application). Additional Tips: <ul style="list-style-type: none"> ✓ Enter sponsor(s). Include M# from Maestro in the IACUC Funding section. ✓ Note: Multiple funding sources are allowed on one AUP, however, we recommend that you keep any DOD/ACURO funded projects on a separate AUP to avoid delays caused by additional ACURO review times. ✓ May require additional revisions to other sections of the AUP if adding animals or modifying procedures, drugs, or hazards.
3. Additional Animals and/or Species	<ul style="list-style-type: none"> ❖ Project Identification, subsection: Species table; Project Description and Procedures (including subsections: Species Justification; Animal Number Justification; Experimental Design); Pain and Distress table and Euthanasia information subsection; and all subsections of Animal Procurement and Maintenance Information. ❖ Other sections as applicable: Privately Owned Animals; Project Description and Procedures (including subsections: Procedures, Samples Collected, Clinical Signs, Monitoring, Animal Removal and associated tables); Pain and Distress (subsections: Alternatives Search (if category D or E) and subsequent sections for Relief Measures); Field Studies/Wild Capture including permits; Transgenic Animal Information. Additional Tips: <ul style="list-style-type: none"> ✓ Total should match that in Species and Pain & Distress sections. ✓ Describe statistical method or cite references to justify number of animals/group for each study/aim/class.
4. Animal Housing or Procedure Location	<ul style="list-style-type: none"> ❖ Project Description and Procedures (including subsections Procedures Table (for adding procedure location); Animal Procurement and Maintenance Information (subsection: Housing Information table (for adding housing)); Non-survival or Survival Surgery sections AND Procedures Table (for adding a surgery location).

	<p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ Add new locations to the Procedures and/or Housing table (list all procedures in one line per individual location). ✓ Select housing locations for each species unless animals are housed under another (home/facility) AUP. If animals are housed under another AUP, transfer to/from other approved AUP must be selected as a source and final disposition of animals.
<p>5. Procedure (add or modify)</p>	<ul style="list-style-type: none"> ❖ Project Description and Procedures (including subsections: Experimental Design; Procedures including table; Clinical Signs; Monitoring and Recording Procedures; Animal Removal from Study). ❖ Other sections as applicable: Privately Owned Animals (and owner consent form); Blood/Tissue/Other Samples Collected; Drug/Agent Administration including nonpharmaceutical grade and controlled substances, if applicable; Pain and Distress; Alternatives Search (if category D or E) and subsequent subsections for Relief Measures; Field Studies (and wildlife permit); Animal Procurement and Maintenance Information (subsections: Husbandry (special conditions required such as metabolic cages, single housing, special husbandry for tamoxifen procedures); and Transportation); EHS or other Safety sections; Biosafety. <p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ Indicate in the Personnel table which staff members will perform new/modified procedure(s) and update their experience/training for that activity. If adding new staff to perform the new procedure(s), submit a Personnel Change Request form concurrently along with the amendment. ✓ Include new procedures in Experimental Design and Workflow/Timeline. Where does the new procedure fit in with the rest of the study? See AWO-O-069 <i>AUP Tool - Experimental Design and Workflow</i>. ✓ Add procedure descriptions/details in the Procedures section including limits (max number of times performed on one animal and how often). See AUP Help Text for the type of information needed for several common procedures. ✓ For blood/tissue collection, add flexibility in the Samples table by using ranges or phrases such as “up to X mL” and “not more often than X times/week”. See also TAMU-G-017 <i>Guidelines on Blood Collection</i> and TAMU-G-007 <i>Guidelines on Genetically Modified Animals and Genotyping</i>. ✓ Describe clinical signs (risks)/monitoring/early removal criteria for the new procedure in those applicable AUP sections. See TAMU-G-001 <i>Guidelines on Choosing Appropriate Endpoints</i>, AWO-O-072 <i>AUP Tool - ERC Worksheet</i>, and AUP Help Text for those sections. ✓ For cat. D & E procedures, perform an alternatives search and include relief measures in the Pain & Distress sub-sections. See AWO-O-074 <i>AUP Tool - NonDrug Relief</i> for options. ✓ Add drugs and hazards to the applicable sections. ✓ Select/describe options for husbandry requirements and exceptions (such as single housing or modified diet/water). <ul style="list-style-type: none"> ▪ Include the monitoring plan for animals while under each restriction/exception. ✓ Browse the IACUC Guidance webpage for guidance on animal procedures applicable to your project, as well as for choosing humane endpoints and early removal criteria
<p>6. Surgery (add or modify)</p>	<ul style="list-style-type: none"> ❖ Project Identification, subsection: Project Activities; Project Description and Procedures (including subsections Experimental Design; Procedures including table; Clinical Signs; Monitoring; Animal Removal from Study); Drugs/Agents including controlled substance questions (if applicable); Pain and Distress (including table and subsections: Alternatives search and associated relief measures subsections); Survival and/or non-survival surgery section; Animal Procurement and Maintenance Information (subsection: Husbandry requirements (if post-op requires special care)).

	<ul style="list-style-type: none"> ❖ Other sections as applicable: Standard of Care (for privately owned animals); Blood/Tissue/Other samples collected. <p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ In addition to the applicable suggestions in #5 above: <ul style="list-style-type: none"> ▪ Select Survival or Non-Survival surgery in project activities section 5.4 to populate those sections of the AUP. ▪ Include anesthesia risks, infection, and wound dehiscence in clinical signs/monitoring/removal criteria sections; mortality rates can also be included if death is a possible risk. ▪ In applicable surgical section: <ul style="list-style-type: none"> • Check the box for pre-operative assessment & care (determine that animals are healthy before surgery). • For survival surgery check the box for pre-emptive analgesia or provide scientific justification for not providing. See TAMU-G-002 <i>Guidelines on the use of Anesthesia and Analgesia</i>. • Describe surgical procedures including the anesthesia protocol. • Address when suture/staples are removed. Are they removed under sedation? • Select the planned assessment options for adequate anesthesia, physiological supports during surgery/recovery, and aseptic practices. • Select and describe applicable post-op monitoring practices and potential post-op complications. ✓ Other documents applicable to surgery: TAMU-G-003 <i>Guidelines for the Safe Use of Inhalant Anesthetics</i>, TAMU-G-003 <i>Guidelines for the Safe Use of Inhalant Anesthetics</i>, TAMU-G-018 <i>Guidelines for Performing Surgical Procedures in Non-Rodent Mammals</i>, TAMU-G-022 <i>Guideline for Non-survival Surgery</i>, TAMU-G-049 <i>Guidelines for Performing Surgery in Amphibians and Reptiles</i>.
<p>7. Drugs/Agents (add or modify)</p>	<ul style="list-style-type: none"> ❖ Project Identification, subsection: Species table (if requesting additional animals); Project Description and Procedures (including subsections: Experimental Design; Procedures including table; Clinical Signs; Monitoring; and Animal Removal); Drugs/Agents including nonpharmaceutical grade and controlled substance questions (if applicable); Pain and Distress table (if requesting additional animals); Chemical Safety Details. <p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ List all substances administered to animals including peri-operative substances such as eye lube, supplemental fluids, anesthesia/analgesia, and pre-emptive analgesia.
<p>8. Biological or Chemical/Radiation Hazard (add or modify)</p>	<ul style="list-style-type: none"> ❖ Project Description and Procedures (including subsections: Experimental Design; Clinical Signs; Monitoring and Recording Procedures; Animal Removal from Study); and Radioactive Materials Information, Chemical Safety Details, or Biosafety sections (including all subsections). <p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ Select applicable biohazard use in AUP section 5.4 Project Activities and complete the populated Biohazard section at the end of the protocol/application. ✓ If AUP modification requires IBC permit modification, submit IBC amendment concurrently.
<p>9. Method of Euthanasia or Disposition (add or modify)</p>	<ul style="list-style-type: none"> ❖ Method of Euthanasia: Project Description and Procedures (including subsections: Experimental Design; Procedures; Procedures Table); Drug/Agent Administration including nonpharmaceutical grade and controlled substance questions, if applicable; Pain and Distress, subsection Euthanasia Information. ❖ If requesting to change your current method of euthanasia from one AVMA approved method to another, please contact CMP veterinarians as noted in the instructions above for a VVC (not available for Houston & Kingsville campuses).

	<ul style="list-style-type: none"> ❖ Final Disposition: Animal Procurement and Maintenance Information and Additional Exceptions, subsection: Completed Experiment (Final Disposition of Animals) <p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ Describe new planned and emergency euthanasia methods for each species. ✓ Recommend including multiple euthanasia methods to maximize flexibility (e.g. “CO2 asphyxia + physical secondary method”; “Anesthesia + physical secondary method”, etc.) ✓ See the following IACUC euthanasia guidance documents for more information: TAMU-G-025 <i>Guidelines on Physical Methods of Euthanasia in Warm Blooded Species</i>, TAMU-G-028 <i>Guidelines on Euthanasia Using Carbon Dioxide</i>, TAMU-G-047 <i>Guidelines on Inhaled and Non-inhaled Agents of Euthanasia</i>, TAMU-G-048 <i>Euthanasia of Fish Amphibians and Reptiles</i>.
<p>10. Exception: Painful or distressful procedures</p>	<ul style="list-style-type: none"> ❖ Project Description and Procedures (including subsections: Experimental Design; Procedures; Procedures Table; Clinical Signs; Monitoring; and Animal Removal); Pain and Distress, including subsections: Pain and Distress Category Table; Alternatives Search; and associated Cat. D or E Relief Measures). <p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ In addition to the applicable recommendations in section #5 above: <ul style="list-style-type: none"> ▪ Complete all fields for Pain & Distress category D & E procedures. ▪ The Animal Welfare Information Center may be able to provide assistance with alternatives searching and addressing the 3Rs. https://www.nal.usda.gov/awic
<p>11. Exception: Single housing of social species</p>	<ul style="list-style-type: none"> ❖ Project Description and Procedures (including subsections: Experimental Design; Procedures; Procedures table); Animal Procurement and Maintenance Information (subsection: Husbandry Requirements). <p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ Describe/justify planned single housing. Include duration (limit to minimum period required), plan for additional enrichment, monitoring, removal criteria, and return to social housing. See TAMU-G-027 <i>Guidelines on Enrichment, Single Housing - Biomedical Species</i>.
<p>12. Exception: Prolonged restraint</p>	<ul style="list-style-type: none"> ❖ Project Description and Procedures (including subsections: Experimental Design; Procedures; Procedures Table, and Prolonged Restraint question); Pain and Distress, subsections: Pain and Distress Categories Table; Alternatives Search. <p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ Provide rationale, frequency, duration, monitoring, removal criteria and complete the prolonged restraint field (below the Procedures table). ✓ See AUP Help text for this section as well as TAMU-G-051 <i>Guidelines on the Use of Physical Restraint</i>.
<p>13. Exception: Use of Non-pharmaceutical grade substances</p>	<ul style="list-style-type: none"> ❖ Project Description and Procedures (including subsections: Experimental Design; Procedures; Drugs/Agents including non-pharmaceutical grade questions; Pain and Distress subsection: Alternatives search) <p>Additional Tips:</p> <ul style="list-style-type: none"> ✓ Address/describe/justify the use of non-pharmaceutical grade substances beneath the Drug table. See TAMU-G-010 <i>Guidelines for the Use of Pharmaceutical and Non-Pharmaceutical Grade Drugs and Compounds</i>.
<p>14. Exception: Non-AVMA approved method of euthanasia</p>	<ul style="list-style-type: none"> ❖ Project Description and Procedures (including subsections: Experimental Design; Procedures; Procedures table); Drug/Agent Administration including nonpharmaceutical grade and controlled substance questions, if applicable; Pain and Distress, subsections: Alternatives search; Euthanasia Information. <p>Additional Tips:</p>

	<ul style="list-style-type: none"> ✓ Scientific justification must be provided, and the campus Attending Veterinarian (or designee) consulted for proposing the use of non-AVMA approved or physical methods of euthanasia without anesthesia.
15. Exception: Withholding enrichment	<ul style="list-style-type: none"> ❖ Project Description and Procedures (including subsection: Experimental Design); Animal Procurement and Maintenance Information (subsection: Husbandry); Pain and Distress, subsection: Alternatives search. Additional Tips: ✓ Scientific justification must be provided for withholding environmental enrichment for biomedical species. See TAMU-G-027 <i>Guidelines on Enrichment, Single Housing - Biomedical Species</i>. ✓ Environmental enrichment is not required for agricultural species used in research and teaching activities related to food or fiber production, breeding, management or production efficiency, however, suggestions are available. See TAMU-G-012 <i>Suggestions for Environmental Enrichment of Agricultural Species</i>.
16. Exception: Other exception	<ul style="list-style-type: none"> ❖ Other exception (please define in section 2.2 of the Amendment form and contact AWO staff for guidance regarding applicable application sections to revise) to teaching activities to prevent over-use. Colony/herd manager should be listed as personnel in 6.1 for access to the AUP. Additional Tips: ✓ Any exception to care standards in the Animal Welfare Regulations, ILAR/Ag Guide, or IACUC Guidance must be justified and described in the Husbandry Requirements section including monitoring and plan to return to standard conditions.
17. Other	<ul style="list-style-type: none"> ❖ Please define in section 2.2 of the Amendment form and contact AWO staff for guidance regarding applicable application sections to revise. Additional Tips: ✓ All other changes; could include incorporating PAM suggestions. Contact AWO staff for assistance.
18. Pilot Study Update	<ul style="list-style-type: none"> ❖ Provide a pilot study summary in section 2.4 of the Amendment form, including: <ul style="list-style-type: none"> ▪ A description of the pilot study (please copy/paste from the approved IACUC Application form) ▪ The results of the pilot study Additional Tips: ✓ This section applies to AUPs in which the IACUC approved a pilot study on a small cohort of animals. The summary must be completed by the PI, submitted to and approved by the IACUC, before commencing with the remainder of the study. ✓ See TAMU-G-030 <i>IACUC Guidelines for Performance of Pilot Studies for additional information</i>.

- ❖ For the TAMU College Station, Galveston and Dallas campuses, some minor changes *may be* confirmed by the Attending Veterinarian (AV) or designee via the Veterinary Verification and Consultation (VVC) process instead of by IACUC-reviewed Amendment. For more information see AWO-O-028 *VVC Explained* or call AWO staff.
- ❖ **AUP tools & iRIS manuals:** Browse the TAMU IACUC Guidance page for these and other tools and guidance at: <https://vpr.tamu.edu/animals-in-research-and-teaching/texas-am-iacuc-guidance/> (Use your TAMU Net ID credentials):
 - IRIS-M-003 How to Create an Amendment [PI]
 - TAMU-S-003 Significant and Minor Changes to Approved Animal Activities
 - AWO-F-032 AUP Off-line Worksheet
 - AWO-O-069 AUP Tool - Experimental Design and Workflow



- AWO-O-072 AUP Tool - ERC Worksheet
- TAMU-C-008a Addendum - AUP Help Text* (continuous listing of all available AUP Help Text by section)
- TAMU-C-008b Addendum - Pain & Distress Categorization

***We highly recommend utilizing the Help Text available for many AUP sections! Help Text demonstrates IACUC expectations by providing clarifying details, examples, and in some cases customizable text for many AUP sections.**

Additional notes: Concurrent IACUC review of multiple amendments on one AUP is not allowed. The IACUC can only review one amendment at a time per AUP.