

TAMU Institutional Animal Care and Use Committee (IACUC)

Protocol Review Checklist

(See accompanying AUP Help Text Addendum)

(Blue highlighted text indicates topics emphasized during 2023-24 AAALAC site visits)

Also see TAMU-S-009 for more information on performance of AUP and Amendment review.	
1	Personnel Identification and Qualifications
	Are personnel conducting procedures appropriately qualified and trained in those procedures (or is an explanation given that includes who will be training them and how they will be trained)? (also see TAMU-G-029 ⁱ)
2	Project Description and Procedures
	Lay Summary: Are the study objectives clearly written in lay language? Does the study benefit human or animal health, advancement of knowledge or society in general? Does the response include procedure or study details which should be removed and placed elsewhere in the submission? Section includes Help Text.
	Animal Justification: Is the rationale for the use of live animals adequate? Section includes Help Text.
	Species Justification: Is the justification for the species selected adequate? Section includes Help Text.
	Animal Number Justification: Is there appropriate justification for all test groups or teaching conditions as described in the Experimental Design section? Section includes Help Text.
	Experimental Design: Is the sequence/timeline of procedures in live animals clear, concise and sequential for each aim, experiment, or study as described in the section instructs/help text? Can you determine what is happening to each animal and when to adequately assess animal welfare? Are pilot study and training activities clearly defined? Are any procedures missing from the timeline(s) that appear elsewhere in the submission? Are the animal numbers consistent between this section, the Animal Number Justification and Pain and Distress sections? Section includes Help Text.
	Procedures: Is the list of procedures complete when compared to the Experimental Design section and include sufficient clear and concise detail to determine what is occurring to the live animal? Has pain and distress been minimized where possible? If used, is the open drop method of anesthesia described and ensure no contact of anesthetic compound with animal? Is the euthanasia method description complete including secondary method to ensure death, consistent with AVMA standards, and inclusive of neonates (if applicable)? Note that surgery is not to be described here. Section includes Help Text. (Animal identification – also see TAMU-G-014) (Genetically modified animals/Genotyping – also see TAMU-G-007 ⁱⁱ) (Rodent breeding – also see TAMU-G-040 ⁱⁱⁱ) (Zebrafish – also see TAMU-G-008) (Pilot studies - also see TAMU-G-030) (Pain and distress – also see TAMU-G-023)
	Procedures Table: Does the table indicate where surgery is performed (if applicable)?
	Prolonged Restraint: Does the section only describe prolonged restraint in awake animals? Is prolonged restraint scientifically justified; duration, frequency, and acclimation to restraint described; and removal criteria for animals which do not adapt to restraint included? Section includes Help Text. (also see TAMU-G-051 ^{iv})
	Blood/Tissue/Other Samples Collected: Are all samples and methods of collection from live animals described? Are the routes, volumes and frequencies of blood collection consistent with published guidelines or IACUC Guidance? (also see TAMU-G-017 ^v)
	Clinical Signs: Are possible clinical signs described (including negative phenotype) and applicable to procedures described? Section includes Help Text.
	Monitoring and recording procedures...: Are criteria for evaluating animal health & well-being appropriate? Is the frequency of monitoring described and appropriate/reasonable? Section includes Help Text.
	Animal Removal from Study: Is the criteria for animal removal, palliative intervention, or euthanasia clear and appropriate? Are humane endpoints described for animals that will experience unrelieved pain & distress? Is monitoring increased to apply removal criteria? Section includes Help Text. (also see TAMU-G-001)
	Is death (without euthanasia) a planned endpoint? If yes, is the required scientific justification, description of palliative therapy, monitoring, clinical signs with timeline, and records maintained as appropriate? (also see TAMU-G-001)

3	<p>Drug/Agent Administration (Anesthesia/Analgesia – also see TAMU-G-002^{vi}, TAMU-G-003^{vii}) (General drugs – also see TAMU-G-010) (Neuromuscular blockers – also see TAMU-G-011) (MS222 – also see TAMU-G-021)</p>
	<p>Is the list of agent(s) complete including drugs used for euthanasia? Is the dosage, route of administration (including specifics for gas anesthesia – e.g. open drop vs vaporizer), and frequency listed and appropriate? Are there agents listed which are not found elsewhere in the AUP?</p>
	<p>Does the section <u>only</u> describe administration of non-pharmaceutical grade compounds or pharmaceutical grade drugs which have been modified (in <u>live</u> animals)? Is the use justified, and did the PI describe the number of animals affected, how pH, sterility, and stability will be assured? Did the PI address the availability of pharmaceutical grade compounds (including anesthesia and euthanasia) and provide scientific justification for why they have selected non-pharma grade? Section includes Help Text.</p> <p>References: (also see - TAMU-G-010^{viii}) Orange Book (human): https://www.accessdata.fda.gov/scripts/cder/daf/ Green Book (animal): https://animaldrugsatfda.fda.gov/adafda/views/#/search</p>
4	<p>Pain and Distress (also see TAMU-G-023)</p>
	<p>Table: Is the pain classification appropriate for the procedures described? (also see TAMU-C-008b)</p>
	<p>If category D or E</p> <ul style="list-style-type: none"> • Has the PI considered alternatives to procedures that may cause more than momentary or slight pain or distress, and provided a description of the methods and sources used to determine that alternatives were not available? • If alternatives are available, has scientific justification been given for why their use is not appropriate? • Have the 3Rs have been addressed?
	<p>If category D: Is the use of non-drug pain/distress relief described?</p>
	<p>If category E: Is unrelieved pain & distress described for all applicable procedures and justified? Is the use of non-drug pain/distress relief described? Did the PI provide complete scientific justification for withholding analgesia which addresses all possible drug classes? Section includes Help Text.</p>
5	<p>Euthanasia Information (varies by species, also see TAMU-G-025^{ix}, TAMU-G-028, TAMU-G-047, TAMU-G-048)</p>
	<ul style="list-style-type: none"> • Is the method of euthanasia described consistent with the AVMA Guidelines? Are AVMA deviations justified for scientific reasons in the Procedures section? • Are all methods of euthanasia described in the Procedure section also listed here (and vice versa)? Does the description include the secondary method used to verify death? Note CO₂ must include a secondary method of euthanasia.
6	<p>Wildlife Studies</p>
	<ul style="list-style-type: none"> • If permits are required, are they attached, or description provided for “pending”? • Does transportation of animals conform to section instructions and permit requirements (if any)?
7	<p>Animal Procurement/Maintenance/Husbandry/Disposition</p>
	<p>Source of Animals: Does the Source match information provided elsewhere in the AUP (Experimental Design, Procedures)? For Transfer, does the Experimental Design section indicate (at a high level) what has happened to the animals prior to transfer so that an assessment may be made as to the full impact of all activities on animal welfare?</p>
	<p>Housing Information: Has the PI attached a PI satellite housing SOP (if applicable)? (also see TAMU-G-005)</p>
	<p>Husbandry Requirements: If applicable, has the PI provided a complete response, including scientific justification, as directed in section instructions for all special husbandry?</p> <ul style="list-style-type: none"> • Is single housing of social species justified, duration minimized, and additional enrichment provided or justified if withheld? • Is general lack of enrichment justified and duration minimized? • Has the PI described how effectiveness of hand sanitation will be confirmed for hand washed items? <p>(Single housing/environmental enrichment - also see TAMU-G-012, TAMU-G-027^x)</p>

	(Food/fluid restriction or manipulation – also see TAMU-G-031 ^{xi}) (Housing density – also see TAMU-G-040) (Sanitation - also see TAMU-G-026 ^{xiii})
	Transportation of Animals: Is the method of transportation appropriate to the species? (also see TAMU-G-016)
	Veterinary Details: Is emergency veterinary support/care indicated and appropriate?
	Completed Experiment: Is the final disposition of animals described, including adoption procedures (if applicable)? (adoption - also see TAMU-G-020)
8	Surgery (Surgery – varies by species, also see TAMU-G-013 ^{xiii} , TAMU-G-018 , TAMU-G-022 , TAMU-G-035 , or TAMU-G-049) (Expired Medical Materials - also see TAMU-G-024) (Anesthesia, Analgesia, and other Drugs – see references in Drug/Agent Administration section)
Non-survival surgery	
	Does this section describe a euthanasia procedure rather than non-survival surgery and should be removed? Is there a perfusion described? Perfusions with secondary procedures, or data collections increasing anesthetic time fall under this section (Perfusion alone = euthanasia).
	Is the description and support practices adequate? Is only one surgery described per section?
Survival Surgery	
	Are Multiple Survival Surgeries (MSS) scientifically justified?
	Are pre-op assessments and care appropriate? Is pre-emptive analgesia provided or scientific justification provided for withholding?
	Is the surgery description adequate and appropriate? Is surgical site preparation appropriate to maintain asepsis or justification provided for exception? Is only one surgery described per section? Is a neuromuscular block used without anesthesia? Section includes Help Text.
	Are inter-op assessments, support and care, and aseptic practices adequate? Are anesthesia recovery assessments adequate? Is thermoregulatory support provided or justified for withholding?
	Has the PI adequately justified requested exceptions from standards, including the use of expired medical materials and lack or modification of aseptic technique (if applicable)?
	Is post-operative care, frequency of observation, support, and responsible staff described and appropriate? Is analgesia provided or scientific justification provided for withholding? Section includes Help Text.
	Is documentation maintenance appropriate? Are post-operative complications and management described?
Environmental Health & Safety, Radioactive Materials, Chemical Safety, Physical Safety, Field Safety, Biosafety, and Transgenic Animal Information will be reviewed by appropriate compliance units	
Completion of Review: For USDA Categorization – see TAMU-C-008c	

All exceptions require justification.

- ⁱ [TAMU-G-029](#): Common exceptions include request for waiver from CITI course requirements and study specific training (external participants only) for individuals with professional training
- ⁱⁱ [TAMU-G-007](#): Common exceptions to meet stated scientific goals include tail biopsy in excess of stated maximum, lack of anesthesia for older rodents (tail biopsy), and toe clipping in older rodents
- ⁱⁱⁱ [TAMU-G-040](#): Common exceptions include the housing of multiple litters in the same enclosure and exceeding space requirements to maximize breeding efficiency especially for underproducing strains (exception described in Section 8)
- ^{iv} [TAMU-G-051](#): Common exceptions include lack of acclimation to restraint and lack of enrichment for singly housed restrained social animals to meet stated scientific goals of study
- ^v [TAMU-G-017](#): Common exceptions to meet stated scientific goals include exceeding volume or frequency for blood sampling, lack of anesthesia based on age for distal tail amputation
- ^{vi} [TAMU-G-002](#): Common exceptions include delivering analgesia in drinking water based on formulation and using euthanasia solution for procedural anesthesia when commonly utilized in private veterinary practice
- ^{vii} [TAMU-G-003](#): Common exception for open drop method of gas anesthesia
- ^{viii} [TAMU-G-010](#): Common exceptions include use of non-pharmaceutical grade when pharmaceutical grade is available due to dose, formulation or additive concerns, and not testing for purity, sterility, pH, etc. based on grade selected, use of expired drugs and compounds when utilized for non-survival procedures
- ^{ix} [TAMU-G-025](#): Common exceptions to meet stated scientific goals include the use of a physical method of euthanasia in awake



animals and humane killing in place of euthanasia

^x [TAMU-G-012](#) & [TAMU-G-027](#): Common exceptions include single housing to meet stated scientific research goals or for husbandry purposes and withholding of enrichment regardless of housing density to meet stated scientific goals

^{xi} [TAMU-G-031](#): Common exceptions to meet stated scientific goals include the use of a nutrient deficient diets, food or water restriction outside of standard frequency, lack of body weight monitoring and record collection

^{xii} [TAMU-G-026](#): Common exceptions include the lack of sanitation of PI devices to meet stated scientific goals

^{xiii} [TAMU-G-013](#): Common exceptions for survival surgery includes the use of tips only aseptic practices due to the type of surgery performed and lack of preemptive analgesia to meet stated scientific goals

