IACUC PROTOCOL and AMENDMENT REVIEW CHECKLISTS FOR REQUIRED CONTENT

All IACUC members should use these checklists when reviewing protocols and amendments to ensure consistency in reviews. These checklists are based on:

- The US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
- USDA Regulations 9CFR Subchapter A, Part 2, Subpart C
- PHS Policy on Humane Care and Use of Laboratory Animals (PHS 2002 or newer)
- *The Guide for the Care and Use of Laboratory Animals* (*Guide,* NRC 2011 or newer)
- *The Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*AG Guide,* ADSA/ASAS/PSA 2020 or newer)
- *AVMA Guidelines for Euthanasia of Animals:* 2020 Edition or newer

Protocol review checklist: Indicate if the protocol contains the required information, write any comments on the last page with reference to the section, and sign the last page.

Y=section complete; N=section not complete; NA=not applicable; DNR = did not review; AEs: Adverse Events; AV: Attending Veterinarian

1. General information		**Y, N, NA, DNR**
1A & 1B	Is all information complete for the PI and secondary contact person? Is the PI a member of RUSVM faculty? If No, check Section 9 for IACUC training.	
1C	Are boxes checked for type of protocol? If continuation: review previous protocol inclusive of amendments, deviations and AEs (request from IACUC administrator if not provided. Have amendments been incorporated into the new protocol, if applicable? Have issues that lead to deviations or AEs been addressed? If continuation of research: cross check rationale for increased animal numbers/experiments/duration of study; what has changed regarding power of the study (check Section 7). Is the study additional animals for power or a refinement? If pilot: check Section 2 for how pilot results will be used.	
1D	For all "No" and "N/A" confirm there is an explanation here or in further sections. Examples: Animal resources not contacted: is this a field study? Attending Veterinarian not consulted: there is no more than momentary pain? The animals do not require importation or health status review? Should the AV be consulted? No scientific review: is this based on pain, risks, etc, or is a review needed?	
1E	Is the animal information table filled in completely? If strain or specific requirements could result in welfare issues, check in project description, form 11 (i.e., if shipped mice), form 12 for how the issues are addressed. Cross check animal numbers with Section 7. Does the reuse level increase pain or distress? Can rest periods be met given reuse? Consultation with Animal Resources might be needed	
	Does the project narrative adequately address the rationale to choose category D or E? Review literature search terms to ensure alternatives to procedures resulting in D or E were searched.	

	If privately owned: is the animal owner consent form available? If purchased: review project narrative (Section 2) or Form 11 for how transportation is being handled.	
	If RUSVM animals are being used, has concurrent protocol use been noted? Has the previous protocol number been listed? If unsure if concurrent use occurs, request IACUC administrator and/or animal resources to verify. Check that any issues regarding over use and that rest periods are met.	
2. Animal Use and Procedures		
2A	Is there a clear statement of the purpose? Is there sufficient background information to understand the relevance and benefits of the study? Is the terminology used clear and understandable to a lay person? Is it clear from the description and/or literature review that the activities do not unnecessarily duplicate previous experiments or if the work is duplicative, is the need for duplication clear?	
2B	Are study day activities and major events in the study involving animals clear? Do these time points and endpoints match Section 2C? Cross check each animal use with the forms listed in Section 11.	
2C	Is the narrative clear and understandable to a lay person? Are study groups as well as endpoints clear? Cross check use/reuse with Sections 1E and 2B. Cross check with forms listed in Section 11 for missing or additional forms.	
2D	Does the study run over a break period? If yes, is it clear that veterinary care will still be available? Is the veterinarian on island/available to provide the services? If unable to determine, please request IACUC administrator assistance. Are all preventive care/screening activities that involve animal handling or sampling included in sections 2B or 2C and forms in section 11? If screening for inclusion, are these animal numbers included in section 1E?	
3. Housing		
	Are all necessary boxes checked? Cross check consent form is present; cross check with form 7.	
4. Final Disposition		
	If euthanasia is selected, is Form 1 attached? If animal returns to stock, is there a clear timeframe for this transfer after AEs are addressed (check Section 2C and Form 12)? If animal is with owner, is the end of study and liability clear in the consent form?	
5. Sharing of tissues, fluids or carcasses		
	In case of euthanasia, if material is not shared is a reason provided? Will any material being shared result in extra sampling? If yes, confirm that it is clear that another protocol will be completed.	
6. Necropsies after AEs		
	If "No", is a valid reason provided? If "N/A", cross check Form 12 AEs and who has oversight on daily care of animals in Section 2D to confirm N/A is applicable.	
7. Rationale		
	Is a rationale given including a harm/benefit analysis? Does the PI give adequate rationale to use live animals as opposed to non-animal models?	

	Does the PI provide adequate rationale for the specific species of animal being used as opposed to a lower phylogenic species?	
	Does the PI provide a statisticall justification for the group sizes and number of animals to be used? In the case of teaching, do the animal numbers match the ratio of students:animal, number of students/semester and number needed over 9 semesters? Cross check with Sections 1E and 2C.	
8. Literature review		
	Does the protocol meet the criteria for a literature exemption? Are the search dates within 30 days of submission of the protocol application? Do key words focus on the methods as well as the objectives/subject? Is more than one database used? If duplication or alternatives were located, are these discussed in the project narrative (Section 2) or rationale (Section 7) regarding why the research is needed or alternatives are not used?	
9. Personnel qualifications and training		
	Are personnel appropriately qualified and trained in the procedures and species? Is anyone non-RUSVM (if unsure, consult with IACUC administrator)? If so, do they meet RUSVM requirements? If not all personnel are identified, has the PI indicated how they will be added to the protocol (e.g., via amendment)?	
10. Teaching Syllabus/Materials		
	Do the uses/procedures, student:animal ratios, and supervision match what is stated in Sections 2A, B & C, Section 7, and in the Forms?	
11. Additional Forms (forms 1-12)		
All	Are any forms missing based on the procedures described in section 2? Do quantities (e.g., substance administration, sample collection) and frequency match Sections 2B&C, if specified in these sections? Do responsible personnel match Section 9?	
Form 12	Have reasonable efforts been made to identify AEs based on the procedures? Are reporting of AEs, assessment of AEs, and withdrawal/endpoints clear?	
Owner consent		
	Has the IACUC approved form been used and is it written in a way that the intended audience can clearly understand it? Are the following included? • Purpose of project (short) • Manipulations to animal with indication of risk, pain, etc. • Benefit(s) • Responsibilities/obligations/voluntary • Statement that withdrawal can occur and no impact on vet services • Costs • Confidentiality • Sufficient contact info is available	

Record any deficiencies or comments here; use additional pages as needed.

Sign and date:

Amendment review checklist: Prior to reviewing any amendment, ensure the approved protocol and amendments are available for cross-checking. Indicate if the amendment contains the required information, write any comments on the last page with reference to the section, and sign the last page.

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	Y, N, NA, DNR
Do the types of changes indicate those stated on page 2? Do any of the changes impact the original objectives? If yes, is a new literature search required or should a new protocol be completed?	
<u>Change in personnel</u> Is a signature page with indication of training attached or is some means of documented training available?	
<u>Change in species</u> Do the housing, feed, drugs, rest periods, Form 12 AEs, etc. apply to the new species? If not, have these sections of the protocol been amended to reflect the new species? Does the change in species require a new literature review? Does the change in species change the objective of the study? If yes, is a new protocol required?	
<u>Change in surgical procedure</u> Is the change justified? Does it change the pain category? Is a new literature search required for alternatives and pain management? Does it change the drugs needed or potential AEs? If yes, are the forms amended?	
<u>Change in animal housing</u> Is the housing still within the guidelines? If not, how is it justified and does it impact welfare?	
<u>Change in funding</u> Is a protocol to grant comparison required by the funding agency?	
<u>Change in veterinary care</u> Is care still available throughout the period of animal use?	
<u>Change in category of animal use</u> Is a new literature review required?	
<u>Change in animal numbers</u> Research: is the change justified statistically? Have AEs or variance resulted in the request for additional animals and, if yes, have protocol changes been implemented to decrease these? Teaching: is the change justified?	
<u>Addition/deletion of procedures</u> Does the addition/deletion impact the protocol objectives? If it adds to the objectives, is a new literature search or explanation of the animal use/benefit needed? If it is not related to the original objectives, is a new protocol or literature search needed? Does the change impact the animal category, reuse, resting periods, etc that might require a literature search for alternatives? Does the change involve change in medications that need to be clarified? Is the procedure clear?	

Does the change impact potential AEs and endpoints?	
Change in anesthesia or analgesia Does the change impact pain or risk of AEs?	
Change in euthanasia Is the method an approved AVMA method? If not, what is the justification?	
Substance administration Can the substance impact pain category, welfare or AEs? Is a H&E review needed?	
Other For all other changes, are these in line with the original protocol objectives, pain categories, literature review, etc.	

Record any deficiencies or comments here; use additional pages as needed.

POLICY REVIEW

This Policy will be reviewed and updated once the IACUC transition to the Cayuse cloud platform is complete.

Policy Approval:

Jennifer K Ketzis

03 November 2023

Signed **Date**

Revision History

Previous version released: March 2019, reviewed March 2020 with no revisions, reviewed in November 2023 with no major revision. Current version to go into effect: 03 November 2023

Revisions made

1. In 1E it is indicated that for rest periods Animal Resources might need consulting.
2. In 2D availability of veterinarian clarified
3. A place for the reviewer's signature has been added.
4. This revision history section added.
5. Formatting revisions throughout for consistency and change of check boxes to Y, N, NA or DNR.
6. Clarifications throughout regarding need to consult with IACUC administrator.