 <b>ROSS UNIVERSITY</b> SCHOOL OF VETERINARY MEDICINE	<b>IACUC PROTOCOL REVIEW CHECKLIST FOR          REQUIRED CONTENT          Pol.012</b>	Issued	February 2017
		Revised	Sept 2020
		Authority	IACUC


## IACUC PROTOCOL REVIEW CHECKLIST FOR REQUIRED CONTENT

**All IACUC members should use this checklist when reviewing protocols to ensure consistency in reviews. This checklist is 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
- *The Guide for the Care and Use of Laboratory Animals*
- AVMA Guidelines on Euthanasia

Indicate if the proposal contains the required information, write any comments on the last page with reference to the section, and sign the last page. Please use ☒ to copy and paste when needed.

<b>1. General information</b>		
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.	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N
1C	Are boxes checked for type of protocol?  If continuation: review previous protocol. 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). If pilot: check Section 2 for how pilot results will be used.	<input type="checkbox"/> Y <input type="checkbox"/> N
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? No scientific review: is this based on pain, risks, etc, or is a review needed?	<input type="checkbox"/> Y <input type="checkbox"/> N
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?	<input type="checkbox"/> Y <input type="checkbox"/> N
	Does the project narrative adequately address the rationale to choose category D or E? Review literature search to ensure alternatives to procedures resulting in D or E were searched.	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
	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.	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A

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	If RUSVM animals are being used, has concurrent protocol use been noted? Has the previous protocol number been listed? If this protocol describes a major procedure, review previous protocols on which the animals have been assigned to make sure that 2 major procedures are not being performed on the same animal. Check that any issues regarding over use and that rest periods are met.	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A
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**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? Is it clear that the activities do not unnecessarily duplicate previous experiments or if the work is duplicative, is the need for duplication clear?	<input type="checkbox"/> Y <input type="checkbox"/> N  <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N  <input type="checkbox"/> Y <input type="checkbox"/> N
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.	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N
2C	Is the narrative clear? 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.	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N
2D	Does the study run over a break period? If yes, is it clear that veterinary care will still be available? 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?	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N  <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N

**3. Housing**

	Are all necessary boxes checked? Cross check consent form is present; cross check with form 7.	<input type="checkbox"/> Y <input type="checkbox"/> N
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**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?	<input type="checkbox"/> Y <input type="checkbox"/> N  <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N
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**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.	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> Y <input type="checkbox"/> N
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**6. Necropsies after AEs**

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	If "No", is a 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.	<input type="checkbox"/> Y <input type="checkbox"/> N
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**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?	<input type="checkbox"/> Y <input type="checkbox"/> N
	Does the PI provide adequate rationale for the specific species of animal being used as opposed to a lower phylogenetic species?	<input type="checkbox"/> Y <input type="checkbox"/> N
	Is there a statistically sound justification given 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.	<input type="checkbox"/> Y <input type="checkbox"/> N

**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? Are diverse databases 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?	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> NA
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**9. Personnel qualifications and training**

	Are personnel appropriately qualified and trained in the procedures and species? Is anyone non-RUSVM? 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)? Cross check roles with what are stated in the project narrative (Section 2C) and Section 11 Forms.	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> NA
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**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?	<input type="checkbox"/> Y <input type="checkbox"/> N
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**11. Additional Forms (forms 1-12)**

All forms	Are any forms missing? 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?	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> Y <input type="checkbox"/> N
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?	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N

**Owner consent**

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	Has the IACUC approved form been used and is it written in a way that the intended audience can clearly understand it? <input type="checkbox"/> Y <input type="checkbox"/> N Are the following included? <input type="checkbox"/> Y <input type="checkbox"/> N <ul style="list-style-type: none"> <li>• Purpose of project (short)</li> <li>• Manipulations to animal with indication of risk, pain, etc.</li> <li>• Benefit(s)</li> <li>• Responsibilities/obligations/voluntary</li> <li>• Statement that withdrawal can occur and no impact on vet services</li> <li>• Costs</li> <li>• Confidentiality</li> <li>• Sufficient contact info is available</li> </ul>
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Record any deficiencies or comments here; use additional pages as needed.

This Policy is subject to annual review.

**Policy Approval:**

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**Signed**

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**Date**