

Institutional Animal Care and Use Committee (IACUC) INSTRUCTIONS for

Protocol Amendments for the Use of Animals

These instructions are to be used when completing an IACUC protocol amendment application.

Please remember that ALL protocol and amendment submissions take time to process. Category B, C and D amendments are eligible for DMR, but may be called for FCR at any point in the review process (defined below). Amendments adding new Category E procedures/models and amendments adding paralytics are almost always required to undergo FCR. Submissions should be received on the 15th of the month prior to the IACUC meeting (usually the first Wednesday of every month). Upon receipt, an administrative pre-review is conducted before the amendment is sent on to the designated IACUC member(s) for review. Veterinary review occurs concurrently with IACUC review.

Definitions:

FCR (Full Committee Review) – If FCR is required, approval of those protocols may be granted only after review at a convened meeting of the IACUC with a quorum of members present. Following FCR, members may vote to approve or if modifications are required to secure approval, may send the review of subsequent revisions to DMR (as defined below).

DMR (Designated Member Review) - If FCR is not required, at least one member of the IACUC, designated by the IACUC Chair and qualified to conduct the review, shall review the protocol and have the authority to approve, require modifications (to secure approval), or request FCR of the protocol. These types of protocols are processed as rolling reviews with no set deadlines. However, submission timing should be planned with consideration of the possibility that any IACUC member can call for FCR at any point in the review process.

An amendment is any change to an existing WVU IACUC approved protocol (e.g., adding drugs, changes to procedures, addition of animal numbers, adding personnel, change to procedure rooms, etc.).

- 1. Use the **most current Word document version** of your WVU IACUC approved protocol forms when submitting an amendment. If old versions are used, the amendment will be sent back to you for correction. If you are unsure what version is needed, please contact the Office of Animal Welfare (OAW).
- 2. Submit a brief summary of the amendment in Word format. The summary should include a description of the changes and a rationale/justification for the requested changes. This summary can alternatively be provided within the body of your email, if it is brief.
- 3. Submit the amended forms in Word format.



- 4. Remove all previous changes (i.e. highlighting and strikethroughs from previous amendments), if applicable.
- 5. Highlight any changes being made (such as changes in procedures, compounds used, etc.).
- 6. If you are <u>changing</u> your animal numbers (Section 5), use the strikethrough to cross out the old number and <u>highlight</u> the new number.
- 7. If you are <u>removing</u> any information from the body of the main form or an appendix (such as personnel, procedures, drugs, etc.), use the <u>strikethrough</u>. Do not delete the information at this time.
- 8. If you are adding Personnel and choose to use the IACUC Personnel Addition Form, it can be found on the <u>Protocols</u> page under Personnel Additions.
 - a. Please be sure to provide the following:
 - i. The specific procedure(s) that the individual will be performing (e.g. behavioral studies, surgery, euthanasia, colony management, tissue harvest, etc.). "ALL" is no longer acceptable.
 - ii. The specific species that the individual will be working with.
 - iii. The experience and/or qualifications for each person as they relate to the species and procedures indicated on this form.
 - iv. If the personnel being added does not have prior experience with species and/or procedures, indicate who will be responsible for properly training the individual. Note: It is the responsibility of the PI to ensure and document that all personnel performing procedures are qualified and proficient prior to unsupervised work.
- 9. If you are submitting a <u>NEW</u> Appendix form, <u>highlight</u> the title only.

For more specific instructions on any sections of the protocol, please refer to **Protocol Instructions**.

If you have questions or concerns, please contact the Office of Animal Welfare at iacuc@mail.wvu.edu.