IACUC FORMS AND REVIEW PROCESS

1. Animal Use Protocol Submission

All testing, instructional and research proposals utilizing living vertebrate animals must be submitted for evaluation by the Institutional Animal Care and Use Committee (IACUC). Exceptions include animals used in agricultural instruction and the use of privately owned animals determined to be exempt from IACUC review by the College of Veterinary Medicine’s Clinical Research Advisory Committee. Animal Use Protocol (AUP) submissions must also be submitted when utilizing dead vertebrate animals or animal parts if the animal was both sacrificed and procured solely and specifically for a research, teaching, or testing purpose. Work utilizing such living vertebrate animals and/or dead vertebrate animals or animal parts at The Ohio State University may not be initiated until notification of IACUC approval has been received. To initiate an AUP submission, go to: https://eprotocol.osu.edu/. General information on the e-Protocol system can be obtained at: http://researchonline.osu.edu/animal-research/e-iacuc/; e-Protocol training (in the form of downloadable PDF user guides) is available at: http://researchonline.osu.edu/e-protocol/training/.

2. Submission Deadline

AUPs should be submitted to the IACUC office by the submission deadline (available at: http://orrp.osu.edu/iacuc/iacucmeetings/) to be evaluated at the next convened meeting.

3. Personnel Requirements

The IACUC maintains several requirements that each individual listed on a protocol must complete. The e-Protocol system is programmed to block a protocol from being submitted in which any individual on the protocol is missing or is out of date on any of the requirements listed below:

- **Animal Usage Orientation Course:** This training must be updated no less than every three years. The online “Animal Usage Orientation Course” is available at https://rf.osu.edu/secure/education.

- **Occupational Health and Safety Course:** This training is available at https://rf.osu.edu/secure/education. This training must be updated no less than every three years.

- **Occupational Health Risk Assessment:** This can be completed via the Occupational Health Registry (available at https://rf.osu.edu/secure/ochre/). The registry must be reviewed every year.
The Ohio State University Financial Conflict of Interest Screening/Disclosure: This can be completed at https://rf.osu.edu/secure/e-coi.

4. Principal Investigator Assurances and Endorsement

The PI submitting an AUP for review must verify that the information provided in the AUP is accurate and complete and acknowledge his or her ultimate responsibility for the ethical performance of the research, instruction, or testing, the welfare of the animals involved, and strict adherence to any conditions imposed by the IACUC. This requirement is satisfied by the agreement of the PI to several assurances listed as part of the electronic submission process.

5. Review and Endorsement by the ULAR Clinical Veterinarian

Protocol review and endorsement by a ULAR clinical veterinarian is required prior to submission of an AUP to the IACUC. This can be initiated by pressing “Forward for Vet Review” under “My Activities” from the workspace of the protocol. Please note that only the PI can submit a document for review. The veterinarian endorsement will automatically forward the protocol for department endorsement.

6. Departmental Endorsement

The endorsement by the chairperson or appropriate alternative from the college department or administrative unit in which an AUP originates is required prior to submission to the IACUC. Once the endorsement is granted, the protocol is forwarded directly to the IACUC staff for processing.

7. Animal Use Protocol Review

In its review of protocols involving animals (whether by designated member review or by full Committee review), the IACUC will determine if the proposed activities are congruent with the “U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training” as outlined in the PHS Policy, “The Guide for the Care and Use of Laboratory Animals,” and “The Animal Welfare Act.”

Protocols proposing activities that do not involve major survival surgery on a USDA-covered species, unrelieved pain or distress (including prolonged restraint), death as an endpoint, multiple survival surgeries or use of primates (exceeding pure observation) may be evaluated by designated member review. Access to a copy of the entire protocol is provided to all IACUC members. The protocol is then evaluated by a designated reviewer if no IACUC member calls for full Committee review within a specified time. Designated reviewers are assigned by the IACUC Chair with the
assignments distributed among all IACUC members. The designated member reviewer has 3 options regarding protocol evaluation:

1. Approve  
2. Require Further Information  
3. Refer to Full Committee Review

Protocols proposing activities involving major survival surgery on a USDA-covered species, unrelieved pain or distress (including prolonged restraint), death as an endpoint, multiple survival surgeries or use of primates (along with any other protocols for which an IACUC member has called for full committee review) are evaluated at a convened IACUC meeting. Convened IACUC meetings typically occur once per month. A quorum for a meeting must be maintained to pass motion on any Committee actions and is considered to be a simple majority of the current membership of the IACUC.

Each AUP handled in full Committee is evaluated by a team of two primary reviewers. Committee discussion is initiated by the primary reviewers and is then opened for discussion by the full Committee. After review, the IACUC has 4 options regarding protocol evaluation at the full Committee meeting:

1. Approve  
2. Require Further Information  
3. Defer  
4. Disapprove

For full Committee review, a majority vote of the quorum present is required to pass a motion for any of these proposed actions. The count of the vote is recorded in the Minutes of the meeting. Members who vote against an action of the Committee are encouraged to identify the reasons for their vote. They may also submit a written minority report. Members of the IACUC are instructed to disclose any real or perceived conflicting interests and to leave the meeting room during the IACUC’s discussion and vote of such protocols.

At the time of review, the Committee specifies which reviewers will evaluate the PI’s response to any requested protocol clarifications or modifications. The Committee may select any number of reviewers to evaluate the investigator’s response or request that responses be reviewed by the convened committee at its next scheduled meeting. In the case of designated member review, the designated reviewer evaluates the investigator’s response whenever clarifications other than completion of administrative requirements are needed. In cases when only completion of administrative requirements (completed housing request, completed chemical hygiene plan, or approval by the Institutional Biosafety Committee) are needed, the IACUC staff will coordinate final approval. (See [IACUC Required Clarifications, Modifications, and
Revisions to Animal Use Protocols}). All committee members are able to view investigator’s responses within the eProtocol system during the review process.

8. Continuing Annual Reviews (First and Second Year)

The IACUC requires submission of annual reviews of approved AUPs by the first and second anniversaries of an AUP’s approval date (for protocols that were reviewed and approved prior to the launch of e-Protocol, the annual review due dates are calculated from the date of initial IACUC review). The annual review form prompts the PI to verify that the current information on the protocol is accurate and to make study team or protocol changes (via amendment) as necessary. The e-Protocol system sends an automated reminder e-mail 60, 30, 15, and 7 days prior to the protocol’s annual review deadline. However, the PI is ultimately responsible for submitting annual review materials in advance of the annual review due dates to ensure continuing IACUC approval. Failure to submit an annual review may result in the early termination of the AUP. See [Annual Reviews] for further information.

9. Protocol Renewals (Third Year)

Animal Use Protocols are approved for a maximum period of 3 years. To continue an AUP beyond the three year approval period, a new AUP submission is required. To avoid a lapse in IACUC approval, a completed renewal AUP must be submitted and approved by the IACUC prior to the expiration date of the AUP. A renewal protocol can be initiated by clicking on the “Create Renewal” in the protocol workspace. This will create a copy of the currently approved protocol and maintain the currently assigned protocol number followed by –R1 (or the number of the renewal –R2, R3 etc). To allow sufficient time for the review and approval process, the IACUC recommends that a renewal AUP be submitted two meetings in advance of the AUP expiration date. The e-Protocol system will send automated reminders 90, 60, 30, and 15 days prior to the protocol’s expiration date. However, the PI is ultimately responsible for submitting AUP renewal materials by the renewal submission deadline to ensure continuing IACUC approval. The renewal AUP is processed using the initial submission review process as detailed above.

10. Approval Periods

Federal regulations do not permit the IACUC to extend any approval periods. If a renewal protocol has not been processed and approved by the expiration date of the AUP, IACUC approval for the work under the AUP will expire. Should IACUC approval expire, all activities involving the care and use of animals must cease immediately and any animals remaining under the protocol must either be transferred to the IACUC holding protocol or be euthanized according to a method approved on the protocol. Any activities conducted under the protocol after expiration will be in direct violation of federal regulations and institutional and IACUC policies.