



Duke University Animal Care & Use Program Policy



IACUC REVIEW AND APPROVAL PRACTICES (Clearance requirements from OESO, EOHW, and others)

PERFORMANCE STANDARD: Proposed activities involving animals are reviewed as efficiently as possible, to facilitate the research effort and funding agency needs. Investigators are provided the maximum amount of support with funding agency needs, while restricting actual animal activities until approval and required clearances are completed.

BACKGROUND:

1. The institution has a responsibility to assure only IACUC approved animal procedures are conducted, and that these practices are conducted in a safe manner for its employees.
2. Funding agencies often have a time sensitive need for IACUC certification of protocol approval, placing the principal investigator in a difficult position between the institution and the funding agency.
3. Researchers and research staff may have a number of OESO or Employee Health issues that require resolution prior to beginning the work with animals, some of which may take days to week to fully resolve.
4. The IACUC has the federal obligation to review animal care and use, with a peripheral responsibility to assure appropriate health and safety concerns for the individuals working with or around animals.
5. The IACUC meets only once a month and has a limited number of options to facilitate clearances.
6. OAWA (under IACUC direction) is able to delay issuing the IACUC approval notice while coordinating other office clearances (OESO, EOHW, etc) and if required, provide a certification letter to the appropriate funding agency; thereby easing regulatory burden while facilitating the process for the institution, funding agencies, and the principal investigator.

POLICY:

1. The IACUC will review animal use applications without consideration of the status of OESO or EOHW reviews, final approval of the Medical Center Transport Sub-Committee, or signatures from DLAR, VAMC, DUPC, CCIF, Principal Investigator, and Co-Investigator.
2. If the animal use concerns are resolved, the IACUC will 'APPROVE' the proposed application for animal use.
3. The 'APPROVAL DATE' will be the date of IACUC action without regard to the state of OESO or EOHW clearance. The 3-year life of the protocol will begin with the date of IACUC approval.
4. The IACUC assigns to OAWA the administrative responsibility for assuring clearance of OESO and EOHW, final approval of the Medical Center Transport Sub-Committee, or signatures from DLAR, VAMC, DUPC, CCIF, Principal Investigator, and Co-Investigator (as necessary).

5. The method of task accomplishment is as follows:
 - a. The OAWA will not issue the 'IACUC APPROVAL LETTER' to the Principal Investigator until receiving clearance from any or all of the aforementioned activities.
 - b. The OAWA will not enter an 'APPROVED' status in the animal ordering software (GRANITE) until receiving clearance from any or all of the aforementioned activities.
 - c. The OAWA may (if requested) submit a funding certification letter to the appropriate funding agency to facilitate the needs of the Principal Investigator and the funding agency.
6. Animal use activities, including purchasing of animals or breeding of animals, can begin only after the OAWA issues the APPROVAL LETTER (and sets the GRANITE database to allow animal ordering).
7. **Exception to this policy:**
 - a. The IACUC Chairman, or designee, may issue the APPROVAL LETTER in extraordinary circumstances. An extra-ordinary circumstance is defined as lacking a clearance not the cause or responsibility of the PI, but rather the result of institutional actions (or lack thereof). In this case, the PI will provide an email acknowledgement not to proceed with the affected activity until OESO clearance is received. Other unaffected work can proceed.
8. **Post-Approval Signatures:**
 - a. **Removing the authority of the PI:** When an investigator is not able to provide the required signatures (e.g. death, terminated from the institution), the Institutional Official shall serve as the signatory agent for the required action.
 - b. **Modifications to existing work:** The animal program accepts 'electronic signatures' when an investigator is not able to provide an original signature. An Email from the Principal Investigator's Duke Email account will serve as the 'electronic signature' for the action under consideration.