

IACUC POLICIES, PROCEDURES, and GUIDELINES

REVIEW OF JOINT VA-UK PROTOCOLS

Purpose:

This document establishes policies and procedures for the IACUC review of animal use activities that are primarily located at the Lexington Veterans Affairs Medical Center (Lexington VA) but involve activities requiring review and oversight by the University of Kentucky and the University of Kentucky IACUC (UK IACUC). This policy does not apply to non-surgical procedures in research animals lasting less than 12 hours.

Background:

Investigators at the Lexington VA have established collaborative relationships with University of Kentucky investigators or share the use of equipment located at the University of Kentucky. These investigators house their animals at the Lexington VA Veterinary Medical Unit (VMU) under animal use protocols reviewed and approved by the Lexington VA Subcommittee on Animal Studies (VA IACUC). In pursuing the collaborative arrangements or use of shared equipment, they transport vertebrate animals to facilities under the jurisdiction and oversight of the University of Kentucky and the University of Kentucky IACUC. This requires that the investigator submit and receive approval from both the VA IACUC and the UK IACUC for the animal activities and places the respective IACUCs in the position of possibly reviewing animal activities approved at another Institution.

As stated in NOT-OD-01-017 (February 12, 2001),

“OLAW and APHIS agree that review of a research project or evaluation of a program or facility by more than one recognized IACUC is not a federal requirement.....

If both institutions have full PHS Assurances, they may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be performed. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees. Similarly, an IACUC would want to know about any significant questions or issues raised during a semiannual program inspection by another IACUC of a facility housing a research activity for which that IACUC bears some responsibility or exposure.”

The Lexington VA uses the standard paper-based VA Animal Component of Research Protocol (ACORP) form. The University of Kentucky uses an electronic protocol submission and approval system (Electronic Protocol Processing System). This document establishes procedures designed to permit each Institution to fulfill their responsibilities and review the appropriate components of a specific vertebrate animal research proposal without posing a greater burden than is necessary upon the investigator or the respective IACUCs.

Responsibilities:

The Memorandum of Understanding between the University of Kentucky and the Lexington Veterans Affairs Medical Center establishes the requirements for IACUC review, approval, and oversight for protocols involving the resources of both Institutions. The following two criteria require that a Lexington VA investigator obtain review, approval, and oversight by the UK IACUC for an animal activity primarily performed under a protocol approved by the VA IACUC:

- 1) The animal is housed at the University of Kentucky for greater than 12 hours during any period of 48 hours or more.
- 2) Surgical procedures are performed on university property .

In both of these situations, the investigator is subject to review, approval, and oversight by the UK IACUC and is subject to the rules and regulations of the University of Kentucky. As stated in the Memorandum of Understanding section D, Subsections D2 and D3 activities under oversight of the VA “may not begin (at the VAMC or at the University) until after the VAMC IACUC approves the activity and the VAMC Associate Chief of Staff for Research and Development (ACOS/R&D) notifies the Principal Investigator (PI) in writing that the work has been granted approval by all applicable VAMC sub-committees and by the VAMC R&D Committee (VHA Directive 1200.01, ref. C.8, above, and VHA Handbook 1200.07, ref. C.10, above). This document also establishes that “Parties agree that for any research that is considered "University research", the use of animals may not begin until after the activity is approved by the University's IACUC.

Procedures for Joint Protocol Processing

1. Investigators with approved VA ACORPs desiring to add components requiring UK IACUC approval must submit either an amendment/modification or new protocol (which ever the case may be) requests to both the UK IACUC and the VA IACUC. In the case of an amendment, these requests should be submitted simultaneously because approval from both IACUCs is required prior to the initiation of any activities requested in the amendment/protocol. In the case of a new protocol, the VA protocol must be approved first so that the approved ACORP may be attached to the UK protocol.
 - Investigators planning to submit a new joint protocol to the UK IACUC must first notify the VMU supervisor. The supervisor will initiate the UK IACUC new joint protocol process by uploading a copy of the VA ACORP to the Electronic Protocol Processing System after approval by the VA IACUC. The investigator will then be able to access the protocol to complete the required components using their Electronic Protocol Processing System log-on and password
 - If the investigator is amending an existing joint protocol, the amendment’s reason/purpose should state “UK/VA joint protocol” followed by the amendment’s identification number. Unlike in the UK Electronic Protocol Processing System, the original VA ACORP is not automatically modified to reflect amendments approved after the initial protocol approval. VA amendments and modifications are sequentially numbered and attached to the ACORP with the appropriate appendices and approvals associated with each modification. Prior to submission of an amendment requesting UK IACUC approval of an activity listed in a VA-approved ACORP, an electronic copy of the complete approved VA ACORP (Adobe Acrobat PDF format), including all amendments, must be attached by the VA Research Staff to the “skeleton” protocol. The investigator should then be able to access the protocol to complete the required components using their Electronic Protocol Processing System log-on and

password.

- The amendment/ protocol should describe the animal-related activities proposed to be performed at the University of Kentucky. The investigator does not need to complete the entire Electronic Protocol Processing System protocol form as the attached VA-approved protocol will provide adequate details regarding the other protocol activities at the VA to permit review by the UK IACUC. The following Electronic Protocol Processing System pages/fields must be included in the amendment/ protocol to permit UK IACUC review and approval:
 - i. Experimental Design: Animal Methodology: Description of the activities proposed to be performed at the University of Kentucky. This section should be limited to only those activities being performed at the University of Kentucky and for which UK IACUC approval is being sought. For new joint protocols, the activities proposed should be identical to those approved in the VA ACORP while for amendments, the activities should be identical to those requested under question #3 of the VA form “Modification of the Animal Component of Research Protocol (ACORP).”
 - ii. Surgery: If the protocol or amendment includes surgery to be conducted at UK, the surgery section of the UK Electronic Protocol Processing System protocol form must be completed.
 - iii. Species: Animal Usage Location Where the animals will be held (>12 hours) or be surgically manipulated. This is required to ensure that the site(s) is (are) included in the UK IACUC semiannual facility and program review.
 - iv. Personnel: Any personnel not listed on the VA ACORP and involved in the animal activities at the University of Kentucky must be listed.
- 2. The amendment/ protocol must be submitted by the principal investigator using their Electronic Protocol Processing System logon and password. The submitted amendment/new protocol will be reviewed by the UK IACUC following standard policies and procedures for all amendments/new protocols using the designated review process. The UK IACUC Office will ensure that the appropriate VA documents have been attached to the Electronic Protocol Processing System “skeleton” protocol prior to submitting the request for IACUC review and approval via Designated Review. The investigator will receive e-mail communications regarding the UK IACUC review through the Electronic Protocol Processing System.
- 3. The UK IACUC will be responsible for ensuring that the University of Kentucky animal housing and usage sites listed on the protocol are included in the UK semiannual facility and program review.
- 4. The VMU supervisor must be notified prior to animals being transported to and returned from UK facilities.

References:

1. Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, National Academy Press, Washington, D.C., 2011.
 - a. Office of Laboratory Animal Welfare, National Institutes of Health, U.S. Department of Health and Human Services. 2001 Office of Extramural Research Guidance Regarding Administrative IACUC Issues and Efforts to Reduce Regulatory Burden.
[\[https://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-017.html\]](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-017.html)

2. UK/VA Memorandum of Understanding, is available upon request from the Office of the Attending Veterinarian.

Approved and Adopted by the Institutional Animal Care and Use Committee
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