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 SOP 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 andAPHIS 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 (eSirius3G®). 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.

2) Surgical manipulations are performed at the University of Kentucky.

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, “The VA IACUC may not grant permission for the use of University resources where approval by the University’s IACUC is required. Similarly, the University’s IACUC may not grant permission for the use of VA resources where approval by the VA IACUC is required.”

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 eSirius3G® new joint protocol process by uploading a copy of the VA ACORP to the eSirius3G® system after approval by the VA IACUC. The investigator will then be able to access the eSirius3G® protocol to complete the required components using their eSirius3G® 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 eSirius3G® 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 Title page of the “skeleton” eSirius3G® protocol. AmendmentseSirius3G. The investigator should then be able to access the eSirius3G® protocol to complete the required components using their eSirius3G® log-on and password.
• The amendment/eSirius3G® 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 eSirius3G® 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 eSirius3G® pages/fields must be included in the amendment/eSirius3G® 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 eSirius3G® 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/eSirius3G® protocol must be submitted by the principal investigator using their eSirius3G® 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 eSirius3G® “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 eSirius3G® 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 annual review process for non-USDA covered species is deferred to the VA IACUC.

5. The VMU supervisor must be notified prior to animals being transported to and returned from UK facilities.
References:

   

2. UK/VA Memorandum of Understanding, 07/31/2009

Appendix:

1. UK/VA Memorandum of Understanding, 07/31/2009

   Approved and Adopted by the Institutional Animal Care and Use Committee
   September 16, 2009

   Administratively Revised
   October 17, 2012

   Administratively Revised
   September 17, 2014

   Administratively Revised
   September 30, 2015

   Administratively Revised
   July 19, 2017

   Approved and Adopted by the Institutional Animal Care and Use Committee
   April 18, 2018
Memorandum of Understanding
Between
The Lexington Veterans Administration Medical Center
And
The University of Kentucky
Date 7-31-2009

WHEREAS, The University of Kentucky (University) and the Lexington Veterans Administration Medical Center (VA) (collectively, Institutions) each have an Institutional Animal Care and Use Committee (IACUC) to review research protocols and perform other functions as provided by applicable laws and regulations for research projects being carried out at their respective sites; and

WHEREAS, due to the unusually close physical proximity of the parties' facilities, the University has researchers who are working on protocols at the VA site and the VA has researchers who are working on protocols at the University; and

WHEREAS, the University and the VA have agreed to cooperate with each other with regard to IACUC review and oversight of such protocols being conducted by their respective researchers, but taking place at the other institution's site; and

WHEREAS the UK and the VA share a commitment to high quality and ethical care and use of research animals, and

WHEREAS, the University and the VA have agreed to maintain separate accreditation with the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), separate registration with the United States Department of Agriculture (USDA) and separate Public Health Service (PHS) Assurance registration.

WHEREAS, the parties have previously entered into a contract for consultant veterinary and animal care services which is not affected by this agreement;

NOW, THEREFORE, in consideration of the mutual promises set forth herein, and for other good and valuable consideration, the University and the VA agree as follows:

1. Nothing in this agreement shall in any way alter or affect the parties' existing contract for consultant and veterinary service, solicitation number VA-249-08-RO-0214.
2. Nothing contained in this agreement is intended to relieve either institution of any of its duties or obligations, but sets forth the parties' understanding and processes to ensure effective oversight of animal care involving both facilities and to avoid unneeded duplication of effort. Unless otherwise agreed in writing, each party shall be responsible for its own expenses in carrying out its duties hereunder.
3. Each Institution's IACUC shall be guided by:
   a. Animal Welfare Act and all applicable state and federal statutes and other regulations relating to animals.

c. “Guide for the Care and Use of Laboratory Animals” published by the National Academy of Sciences as amended and revised.

d. The “Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching” published by the Federation of Animal Science Societies as amended and revised.

e. Public Health Service Policy on Humane Care and Use of Laboratory Animals.

f. The VA is additionally guided by the VA Handbook 1200.7.

4. Each Institution shall conduct its own semi-annual program and facility evaluations.

5. To the extent applicable to one institution’s research protocols being conducted at the other’s site, each Institution agrees to make the relevant sections of the following reports available upon request for review by the Chairperson of the other Institution’s IACUC or by another IACUC representative designated by the Chairperson.

   a. USDA inspection reports
   b. Semi-annual program evaluations.
   c. Semi-annual facility inspection reports.
   d. AAALAC accreditation correspondence.
   e. Personnel training records.
   f. Occupational Health enrollment records.
   g. Records of noncompliance investigations.

The University and the VA shall each provide a copy of the relevant sections of its semi-annual program review and facility inspection self-assessment to the other Institution’s IACUC for review in lieu of sending IACUC inspection teams to one another’s facilities. The University and the VA shall provide each other with lists of room numbers where animals are used in order to ensure that all facilities are inspected by one of the IACUCs. Each Institution shall retain the right to independently inspect any area where vertebrate animals are used on an approved protocol at that Institution. The Institutions will cooperate in all such inspection requests.

6. For all animal research protocols, including amendments, which involve the resources (personnel, facilities, supplies, funding, etc.) of both Institutions (Joint Protocols), the researcher(s) shall be required to obtain approval independently from each Institution if animals are housed for greater than 12 hours or if surgical manipulations are performed at the Institution other than where the original protocol is approved. Researchers will be required to use the forms required by and follow the policies and procedures adopted by each of the Institutions for its review, approval and amendment processes. The VA IACUC may not grant permission for the use of University resources where approval by the University’s IACUC is otherwise required. Similarly, the University’s IACUC may not grant permission for the use of VA resources where approval by the VA IACUC is otherwise required.
7. Researchers working under a Joint Protocol shall be required to comply with the applicable policies and procedures of each Institution. Each Institution shall provide researchers with reasonable access to its policies and procedures.

8. Each Institution agrees to make the following documents available upon request for review by the Chairperson of the other Institution's IACUC or by other IACUC representatives designated by the Chairperson: applications, approved protocols, applicable portions of IACUC meeting minutes, and personnel training records that pertain to a Joint Protocol. The IACUC from each institution will provide written documentation of verification of approval of Joint Protocols matching funded grants administered by the VA Research and Development office or the University Office of Sponsored Projects for forwarding to appropriate granting agencies.

9. Each Institution agrees that the Chairperson of the other Institution's IACUC or other IACUC representatives designated by the Chairperson shall be permitted to inspect the site(s) of any work being conducted under a Joint Protocol at any time. Both Institutions agree to cooperate in such inspections.

10. Each Institution agrees to cooperate with and assist the other in preparing accurate, non-duplicative reports of animal counts for the USDA, AAALAC, and Office of Laboratory Animal Welfare. Researchers working under a Joint Protocol shall be allowed to move animals between the two institutions for approved procedures. Oversight will be provided by the Institution where the animals were originally housed unless the animals stay for more than 12 hours in the other facility. If animals are moved for a period lasting over 12 hours, they must be transferred to the Joint Protocol at the other facility for oversight.

11. The parties agree that the Veterinary Medical Unit (VMU) of the VA will decide upon optimal food, caging, and husbandry practices for animals housed in VA animal facilities, and that the VA will be responsible for the provision of adequate veterinary care. The VA will retain authority for decisions related to such care, including emergency euthanasia as may deemed appropriate by VA personnel. University agrees to abide by all VA Standard Operating Procedures (SOPs) with regards to animals brought to the VA.

12. The parties agree that the Division of Laboratory Animal Resources (DLAR) of the University will decide upon optimal food, caging, and husbandry practices for animals housed in University animal facilities, and that the University will be responsible for the provision of adequate veterinary care. The University will retain authority for decisions related to such care, including emergency euthanasia as may deemed appropriate by University personnel. The VA agrees to abide by all University Standard Operating Procedures (SOPs) with regards to animals brought to the University.

13. Each Institution agrees to immediately notify the other in the event of an infectious outbreak within their facility. This may result in temporary stoppage of movement of
animals between the Institutions until reasonable risk of spreading the infection is minimized. Veterinarian(s) from the University and the VA consulting veterinarian(s) will determine appropriate action in consultation with the respective IACUCs.

14. In the case of a serious accident, animal welfare concern, or incident of non-compliance with an approved Joint Protocol, the initial responsibility for investigation and fact finding shall reside in the Institution that controls the site of the incident. The parties agree that serious accidents, credible animal welfare concerns, and allegations of non-compliance involving a Joint Protocol shall be reported to the Chairperson of the IACUC of the other Institution within 24 hours of initiating an investigation. Upon agreement of both IACUC Chairpersons or their representatives, continued investigation of the incident may proceed by one of the following:

a. Designation of the IACUC of the Institution controlling the site of the incident as the primary IACUC responsible for the investigation, documentation of findings, and recommended corrective actions, if any. The Chairperson of the secondary IACUC shall be provided an opportunity to review and comment on any investigative subcommittee report prior to its submission to both IACUC’s for discussion and final resolution and recommendations to the respective Institutional Officials.

b. Establishment of a joint subcommittee for investigation of the incident. This subcommittee shall consist of a minimum of 2 members from each IACUC and shall, as a representative of both IACUC’s, be responsible for the investigation, documentation of findings, and recommended corrective actions, if any. The joint subcommittee’s report shall be presented to both IACUC’s for discussion and final resolution and recommendations to the respective Institutional Officials.

c. Establishment of separate investigations by each IACUC. Each Institution agrees to cooperate with the other in investigating the incident including providing requested documentation, reasonable access to facilities, and not obstructing access to personnel. The Chairperson of the other Institution’s IACUC shall be provided with an opportunity to review and comment upon the report prior to submission of the report to the respective IACUC for action.

In cases where the IACUC Chairpersons or their representatives cannot agree upon the establishment of a primary investigating IACUC or a joint subcommittee for investigation, separate investigations by each IACUC shall be required. It is the responsibility of the Chairperson of each IACUC to forward the notification of investigation and subsequent documents to the Institutional Official. Reporting of findings to all applicable agencies will be the responsibility of the Institution(s) investigating the incident.

15. Each Institution shall comply with all applicable federal, state, and local laws and regulations.
16. This Agreement will continue unless the Agreement is terminated by one or both of the Institutions by written notice from the Institution Official. Termination shall occur six months after written notification by either Institution.

17. The Agreement and any amendments may not be extended, renewed, or otherwise amended except in writing and signed by the Institutional Official of both Institutions.

18. This Agreement will be governed by and construed in accordance with the laws of the Commonwealth of Kentucky to extent consistent with U.S. Federal Law.

This Agreement will become effective upon the date of the last signature below.

Agreed to and Approved by:

Sandy J. Nielsen, FACHE
Director
Veterans Affairs Medical Center

John S. Thompson, M.D.
Associate Chief of Staff for Research & Development
Veterans Affairs Medical Center

James W. Tracy, Ph.D.
Vice President for Research
University of Kentucky

Harold F. Stills, DVM
Director, Laboratory Animal Resources
University of Kentucky

Date

Date

Date

CC: VISN Director