

IACUC POLICIES, PROCEDURES, and GUIDELINES

APPROVAL OF VERTEBRATE ANIMAL ACTIVITIES CONTRACTED OR SUBCONTRACTED BY THE UNIVERSITY OF KENTUCKY

120.1 Purpose

Investigators at the University of Kentucky may contract to perform a wide variety of vertebrate animal activities, funded by a number of different sources, at sites outside of the University of Kentucky. Any contract or subcontract that directly involves the use of vertebrate animals at an institution other than the University of Kentucky requires compliance with this policy. The types of vertebrate animal activities can vary from contracted custom antibody production ([see IACUC 107 - ANIMAL PROTOCOL REQUIREMENTS FOR THE PRODUCTION OF CUSTOM ANTIBODIES](#)), the creation of genetically modified animals, the production of surgically modified animals, the cryopreservation of embryos, to the performance and conduct of a significant component of the research project at a contracted or subcontracted institution. Additionally, the various funding agencies and federal regulatory agencies impose differing oversight and documentation requirements on the Institution and the IACUC, further complicating the task of identifying and complying with the various requirements. This policy establishes the requirements for the approval of the use of vertebrate animals at facilities and institutions not under the direct control and oversight of the University of Kentucky.

120.2 Regulatory Requirements

The University of Kentucky has established an Institutional Program for Animal Care and Use under Administrative Regulation AR7:5 that is “*applicable to all research, teaching, and testing activities involving vertebrate animals (animal activities) conducted at the University facilities or under University sponsorship, regardless of species or source of funding.*” This administrative regulation requires compliance with the Animal Welfare Act Regulations (AWARs), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the *Guide for the Care and Use of Laboratory Animals* (ILAR Guide), and the *Guide for the Care and Use of Agricultural Animals* (Ag Guide). The administrative regulation also states that “an animal use protocol must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) prior to initiating any animal activity. For sponsored projects involving animal activities, the animal use protocol shall be approved before an account will be established.” (University of Kentucky Administrative Regulations, AR 7:5, <http://www.uky.edu/Regs/files/ar/ar7-5.pdf>)

The Public Health Service states that “the applicant/grantee is responsible for the humane care and treatment of animals in NIH grant-supported activities. The

Policy implements and supplements the U.S. Government Principles for the Care and Utilization of Vertebrate Animals used in Testing, Research, and Training. The Policy also requires the applicant to establish appropriate policies and procedures for the humane care and use of animals, based on the Guide for the Care and Use of Laboratory Animals, and to comply with the Animal Welfare Act and its implementing regulations.” [NIH Grants Policy Statement (12/03) - Part II: Terms and Conditions of NIH Grant Awards - Subpart A:

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part5.htm] Accordingly, the applicant/grantee is responsible for animal activities conducted at contracted and subcontracted sites and must provide verification of IACUC approval of all vertebrate activities to the NIH prior to the agency making an award.

120.3 IACUC Approval Requirements

- **120.3.1** If the protocol requires the production of custom polyclonal or monoclonal antibodies at the contracted or subcontracted institution please refer to [IACUC 107 - ANIMAL PROTOCOL REQUIREMENTS FOR THE PRODUCTION OF CUSTOM ANTIBODIES](#) for specific instructions and guidance regarding submission and approval requirements.
- **120.3.2** If the contracted or subcontracted institution has a PHS assurance then the University of Kentucky IACUC may defer the majority of the protocol review and project oversight to the contracted or subcontracted institution (<http://grants.nih.gov/grants/olaw/references/dc95-3.htm>). In doing so, the IACUC retains responsibility to obtain documentation indicating the activity was reviewed and approved by the IACUC of the contracted or subcontracted institution that is a registered facility with the USDA, if applicable, and possesses a valid PHS Assurance. In instances where investigators are using vertebrate animals in their research endeavor and must submit an animal use protocol for IACUC review and approval, this can be easily accomplished in the e-Sirius[®] protocol system. One of the last sections in the e-Sirius[®] protocol asks the investigator to indicate if they are contracting for off-site contracted vertebrate animal activities and if they respond “yes” requests the necessary additional information for IACUC approval. In instances where the investigator’s research does not require the use of any vertebrate animals in addition to the contracted or subcontracted activities, and a copy of the protocol approved by the contracted or subcontracted IACUC can be attached, the abbreviated “IACUC Protocol Application Form: Contracted or Subcontracted Vertebrate Animal Activities” can be used to request IACUC review and approval.

In reviewing an application the IACUC office shall verify that the contracted or subcontracted institution has a valid PHS assurance and, if applicable, that the agency or firm is registered with the United States Department of Agriculture as a Research Facility. A copy of the

contracted agency or firm's IACUC protocol approval and date shall be included in the e-Sirius[®] protocol file as an attachment.

- **120.3.3** If the contracted or subcontracted institution does not have a PHS assurance then the University of Kentucky IACUC does not have the discretion of deferring the protocol review and oversight to the institution's IACUC (<http://grants.nih.gov/grants/olaw/references/dc95-3.htm>).

- **120.3.3.1** If the proposed research, educational activity, or testing is biomedical and the contracted or subcontracted institution is domestic (located within the United States) then:

- The contracted or subcontracted institution must contact the Office of Laboratory Animal Welfare (OLAW) of the National Institutes of Health (NIH) to establish a PHS assurance. This would allow the University of Kentucky IACUC to defer protocol review and oversight to that institution as detailed above.

or

- The University of Kentucky's PHS assurance must be amended to include the performance site of the contracted or subcontracted institution. A complete animal use protocol must be submitted to the IACUC for review and approval. This option requires IACUC oversight and inspections of the facility and is generally only available for local institutions.

- **120.3.3.2** If the proposed research, educational activity, or testing is biomedical and the contracted or subcontracted institution is foreign then:

- If the funding is of PHS origin, the Office of Laboratory Animal Welfare (OLAW) will negotiate a Foreign Animal Welfare Assurance with the contracted or subcontracted institution. If the contracted or subcontracted institution was listed as a performance site in the application, the responsible Institute/Center (IC) should request that OLAW negotiate the assurance. Otherwise, the request should come from the grants management personnel in the Office of Sponsored Programs Administration (OSPA).
- Following confirmation of a PHS assurance at the contracted or subcontracted institution, the University of Kentucky IACUC will defer the review of the

protocol activities and oversight of activities occurring at that institution to the institution.

- If the funding is not of PHS origin, the University of Kentucky IACUC must review and approve all animal activities occurring at the contracted or subcontracted foreign site.
 - A complete animal use protocol must be submitted to the IACUC for review and approval.
 - The foreign site must indicate that they are guided by the “International Guiding Principles for Biomedical Research Involving Animals,” as developed by the “Council for International Organizations of Medical Sciences” (CIOMS).
 - The foreign site must confirm that all proposed animal activities have been reviewed and approved by the IACUC equivalent of the institution.
- **120.3.3.3** If the research, educational, or testing focus is not biomedical:
 - A complete animal use protocol must be submitted to the IACUC for review and approval.
 - The contracted or subcontracted institution must be identified and the specific performance site of the vertebrate animal activities provided.
 - The contracted or subcontracted institution must indicate that they will comply with the applicable laws and regulations of the jurisdiction in which they are located and that they will fully comply with the applicable animal care, animal husbandry, and veterinary care standards.
 - In approving the proposed animal use at the contracted or subcontracted site, the University of Kentucky IACUC remains responsible for assuring appropriate and humane animal care and use (Ag Guide).
 - The IACUC may require additional information or documentation in fulfilling their responsibility.

- The IACUC may require on-site inspections, video inspections, additional documentation, etc.

120.4 Exceptions to this Policy

It is recognized that there may be instances where exceptions to the policies and procedures detailed in this document may be necessary or mandatory for completion of the research, educational, or testing procedures. In these cases, exceptions to the above policies and procedures may be authorized by a majority vote of a quorum of the full IACUC and the approval of the Institutional Official, the Vice President for Research.

Approved and Adopted by the
Institutional Animal Care and Use Committee
August 18, 2010

Colors are used to indicate the actions of various groups and organizations in the process:

Blue-Investigator

Yellow-IACUC

Red-Institution

