Policy on Contracted or Subcontracted Animal Activities

This document establishes the policy requirements for contracted or subcontracted activities using vertebrate animals at facilities and institutions not under the direct control and oversight of the University of Kentucky.

Investigators at the University of Kentucky may contract to perform a variety of vertebrate animal activities 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 covered by this policy include production of custom-made polyclonal and monoclonal antibodies, creation of genetically modified animals, production of surgically modified animals, cryopreservation of embryos, as well as performance and conduct of a component of the research project as a contracted or subcontracted activity at another institution.

IACUC Approval Requirements

Instances where investigators are using vertebrate animals in their research endeavor at the University of Kentucky, in addition to the contracted or subcontracted activities, an animal use protocol must be submitted for Institutional Animal Care and Use Committee (IACUC) review and approval.

Instances where the investigator's research does not require the use of any vertebrate animals at the University of Kentucky in addition to the contracted or subcontracted activities, the abbreviated "IACUC Protocol Application Form: Contracted or Subcontracted Vertebrate Animal Activities" can be used to request IACUC review and approval.

Custom Antibody Production

The purchase of commercially available polyclonal or monoclonal antibodies does not require the submission of an animal use protocol or approval of the IACUC. Commercially available antibodies are those already produced and available through company catalogs or antibody suppliers such as Abcam (http://www.abcam.com/).

If the protocol requires the production of custom-made polyclonal and monoclonal antibodies produced either from antigen provided by the contracting investigator or through the generation of a specific polypeptide that is then used to immunize animals to produce antibodies at the contracted or subcontracted institution please see below for guidance regarding submission and approval requirements.

If the ascites method of monoclonal antibody production is to be used, sufficient information must be provided for the IACUC to "determine that (i) the proposed use is scientifically justified, (ii) methods that avoid or minimize discomfort, distress, and pain (including in vitro methods) have been considered, and (iii) the latter have been found unsuitable." (OPRR REPORTS, Number 98-01, November 17, 1997).

PHS Assured Institutions

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 reviewing an application, the OAV-IACUC office shall verify the contracted or subcontracted institution:

- Has a valid PHS assurance
- Is registered with the USDA as a Research Facility (where applicable).
- Has IACUC approval for the proposed animal activities.

In addition to items listed above, a memorandum of agreement, consent form, or other agreement may be required. Elements in the consent must include:

- Who will be responsible for non-research related health issues such as vaccination, deworming, injuries, infections, medications, and other medically related issues?
- What will be the disposition of the animal(s) at the conclusion of the project?
- Under what circumstances can the project be terminated and by whom?

Should changes to a previously established contract, memorandum of agreement, consent form, or other agreement be needed, the PI must inform the IACUC at once.

Non-PHS Assured Institutions

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

If the activity is PHS/NSF funded, the Office of Laboratory Animal Welfare (OLAW) will negotiate an Animal Welfare Assurance or 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).

If the proposed research, educational, or testing activity is not PHS/NSF supported and the contracted institution is not PHS Assured, 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 contracted or subcontracted institution must be identified, and the specific performance site of the vertebrate animal activities provided.
- The contracted or subcontracted institution must confirm that all proposed animal activities have been reviewed and approved by their IACUC (or equivalent), that they will comply with the applicable laws and regulations (including applicable animal care, husbandry, and veterinary care standards) and in the case of foreign institutions that they follow the "International Guiding

Principles for Biomedical Research Involving Animals," as developed by the "Council for International Organizations of Medical Sciences" (CIOMS) or equivalents.

- In approving the proposed animal use at the contracted or subcontracted site, the University of Kentucky IACUC remains responsible for ensuring appropriate and humane animal care and use.
- The IACUC may require additional information or documentation in fulfilling their responsibility.
- The IACUC may require on-site inspections, video inspections, additional documentation, etc.

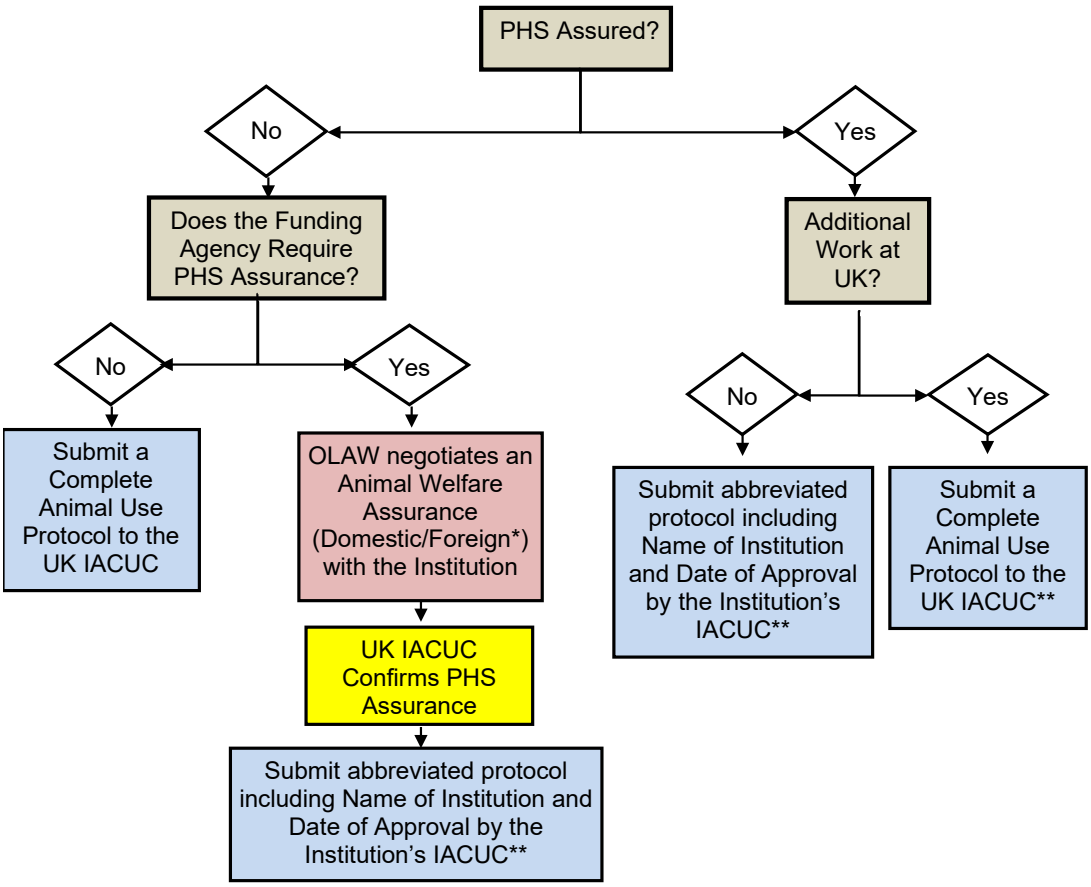
Exemptions to this Policy

It is recognized that there may be instances where exemptions 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, exemptions to the above policies and procedures may be made on a case by case basis, by the IACUC Chair and the Attending Veterinarian.

Training Requirements

- Initial training requirements for staff listed in an abbreviated protocol is limited to the AALAS Learning Library (ALL) course "Working with the IACUC".
- Continuing education requirement is limited to the ALL course "Refresher: Working with the IACUC" every three years.
- Individuals working with unfixed animal tissues, body fluids, etc. may be required to participate in the Occupational Health and Safety Program.
- Individuals conducting research under new protocol submissions shall complete (as established by the Office of the Vice President for Research) the web-based Responsible Conduct of Research (RCR) basic course training through the Collaborative Institutional Training Initiative (CITI). A Refresher RCR is required biennially.
- In cases where vertebrate animal activities are to be conducted at UK, a full protocol is required and all education and OHS requirements as listed in IACUC Policy 106 will apply.

Approved and Adopted by the IACUC:
January 18, 2023



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

Blue-Investigator

Yellow-IACUC

Red-Institution

The IACUC may require on-site inspections, video inspections, or additional documentation to ensure that the applicable animal care, husbandry, and veterinary care standards are met.

*The IACUC will verify that the institution complies with the International Guiding Principles for Biomedical Research Involving Animals and that the institution's IACUC equivalent has reviewed and approved the activities

** In instances where PHS funding supports work at UK AND the contracted/subcontracted institution, the corresponding UK protocol may be amended to include the subcontract/sub-award.

IACUC Protocol Application Form: Contracted or Subcontracted Vertebrate Animal Activities

Please complete applicable sections of this form if these conditions apply:

- Your research requires contracting or subcontracting an outside PHS assured institution (including the production of custom-made antibodies).
- Additional vertebrate animal work is not being conducted at the University of Kentucky.

Please type in your answers!

Protocol Title: (For custom-made antibodies, please complete this title by listing your proteins for which antibodies are required):

Principal Investigator: First Name Middle Initial Last Name

Campus Address:

Email:

Phone:

Funding Source/Agency:

Fund Title:

Sponsor Grant Number:

PI on Grant (If different than PI on Protocol): First Name Middle Initial Last Name

Institution/Clinical Research Organization Name:

PHS Assurance #:

USDA # (if applicable):

Synopsis: Explain in layman's terms, how this research relates to human and/or animal medical, physical, physiological or psychological diseases or problems. (Very brief)

Will animal tissues or parts be sent to UK for this work?

PI experience and qualifications for training profile:

CUSTOM ANTIBODY PRODUCTION ONLY:

Literature Search (Please search antibody databases to assess commercial availability. Recommend (http://www.abcam.com/) –

Databases Searched:

Date Searches Were Conducted:

Results of Search for Unnecessary Duplication (Please indicate whether the antibodies you are requiring are commercially available or not:

If the antibody or antibodies are commercially made and your research requires custom-made antibodies, please provide scientific justification for their use here:

Antibodies source(s) name (State the name(s) of the facility/institution producing the custom-made antibodies and a contact name and phone number):

Will the Ascites method be used? Select one: Yes No

If the Ascites method will be used, please provide justification for using this method:

Please attach a copy of the outside contracted/subcontracted institution's IACUC approved protocol.

Additional information may be requested by UK's IACUC for review (especially if the ascites method of antibody production is used).

Please date and sign below.

Date:

By signing here, _____I certify that I am the Principal Investigator of this IACUC protocol; that I am verifying that all information in the protocol is correct and accurate to the best of my knowledge.

Please send this document to the OAV-IACUC Office:

Jennifer Brown: Jennifer.Brown@uky.edu (7-2934)
Rebecca Florence: Rebecca.Florence@uky.edu (3-4169)