

University of Louisville
University Committee for Animal Welfare
Policies and Procedures

Research Involving Collaborations and Contracted Research

Policy:

Investigators at the University of Louisville (UofL) may collaborate with non-UofL entities, including contracting the performance of a wide variety of vertebrate animal activities or the production of “custom antibodies,” at sites outside of UofL. Any collaboration, contract, or subcontract that directly involves research with vertebrate animals at an institution other than UofL requires compliance with this policy. The relationship between UofL Principal Investigators (PIs) and collaborating institutions, including the production of “custom antibodies,” must be clearly defined in an IACUC (or comparable oversight body) *Proposal*. In addition, UofL PIs contracted and funded by an outside organization through a subaward, subgrant, or subcontract to perform animal work must include details in the IACUC *Proposal* outlining the animal work. The use of UofL facilities (e.g., fee-for-service use of Core Animal Laboratories) by non-UofL investigators also requires UofL Committee for Animal Welfare (UCAW) approval. The level of oversight required for such studies will depend upon 1) ownership of the animals, 2) the award recipient for sponsored projects, and 3) the regulatory status of the collaborating institution. A written agreement (e.g., memorandum of understanding) clearly delineating the responsibilities of each institution may be required for UCAW approval.

Exemptions:

The following do **not** require oversight by the UCAW:

1. Use of commercial suppliers for animals, surgically manipulated animals, or animal-derived materials (e.g., antibodies) considered “off-the-shelf” (i.e., for which the products are available to non-UofL Principal Investigators). However, the inclusion of surgically manipulated animals, or animal-derived materials, must be described in an approved UCAW Proposal.
2. Transfer of naïve breeding stock, e.g., genetically-engineered murine (GEM) strains, to a collaborating institution for which animal ownership is specifically transferred does not require UCAW review or approval but may require negotiation via Material Transfer Agreement(s) (contact the Office of Technology Transfer; 502-852-2965; thinker@louisville.edu).

Background:

Regulatory agencies recognize that although “review of a research project or evaluation of a program or facility by more than one recognized IACUC (or a comparable oversight body and henceforth referred to as IACUC) is not a federal requirement... It is imperative that institutions define their respective responsibilities (1).” According to *PHS Policy*, any performance site associated with a PHS grant must hold an approved “Animal Welfare Assurance.” Research using USDA-regulated species (i.e., mammals, excluding laboratory-bred rats and mice, and research involving agricultural animals for production research) must be performed at a facility that is registered with the USDA. AAALAC's Rules of Accreditation extend to all institutionally owned animals.

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Procedures, Guidelines, and Exceptions:

1. Use of UofL Facilities by Non-UofL Investigators

- a. UCAW-recognized Core Animal Laboratories (Cores) receiving requests for fee-for-service use of their facilities and services by non-UofL entities must document all requests in the “Collaborating Institutions” section of the Core’s UCAW-approved *Proposal* for review and approval. A copy of the animal research protocol(s) approved by the prospective user's IACUC and documents attesting to the approval of the protocol must also be attached for review. These protocols should include a description of the use of the Core. The UCAW review of the protocol will be limited to the use of the Core. If requested procedures are not explicitly described in the approved Core *Proposal*, the *Proposal* must be amended to include the procedures. If the ownership of the animals is retained by the non-UofL entity, no additional action is necessary.
- b. UCAW-recognized Cores receiving requests to serve as collaborators on outside-sponsored projects, *i.e.*, for which the Core personnel will provide substantial scientific input, must submit a *Proposal* by a UofL-recognized PI.
- c. All other use of UofL facilities must be described in a UCAW-approved *Proposal* submitted by a UofL-recognized PI.

2. Conduct of Animal Studies at Non-UofL Sites with No IACUC (Excluding Field Studies)

- a. Direct requests by UofL PIs to entities that have no IACUC to perform specific services are ***prohibited***.
- b. Services to be performed by entities with no IACUC must be explicitly described in a UCAW *Proposal* for review and approval. The description should also include methods of transporting animals to the contracting location, if applicable.
 - 1) Research with USDA-covered species is prohibited.
 - 2) Research with other vertebrates on studies sponsored by PHS may only be conducted if the UCAW accepts complete responsibility of the site in its animal care program. This requires that UofL amend its “Assurance” with OLAW to cover the non-assured performance site and involves considerable resources and elevated risk. This option requires UCAW oversight and semiannual inspections of the facility and is generally only available for local institutions.
 - 3) Research with other vertebrates for which the contracting institution accepts ownership of the animals, and which are not funded by PHS, may be approved. The use of the facility must be explicitly described in the UCAW *Proposal*. The UCAW will determine approval based on the nature of the studies and procedures.

3. Conduct of Animal Studies at Non-UofL Sites with an IACUC

- a. Projects involving research with animals at UofL ***and*** a collaborating institution, including the creation of custom antibodies or GEM strains, require that the following information be described in the “Collaborating Institutions” section of the UCAW *Proposal* for review and approval:
 - 1) A brief description of the procedures to be performed at the collaborating location and the method of transporting animals to/from the collaborating locations.
 - 2) Institutional information, which may be reviewed administratively (e.g., during importation of GEM strains):

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- a) Institution/Facility name
- b) USDA Registration number, if applicable
- c) PHS/OLAW Assurance number, if applicable
- d) AAALAC-accreditation status
- e) Documents attesting to the approval of the work in question by the collaborating IACUC
- b. Studies that involve subcontracted animal work performed **solely** at a non-UofL institution **with an IACUC** through funding (subaward, subgrant, subcontract, etc.) from UofL must be documented in a UofL UCAW *Proposal*. A copy of the approval letter **and** approved IACUC protocol from the subcontracted IACUC must be attached for review. For example, a UofL PI has contracted a non-UofL institution/investigator to perform the entirety of a live-animal project (this contracted work will be performed exclusively at the non-UofL institution; animal research will not be conducted at UofL). If animals will be transported between UofL and the non-UofL entity, or subcontracted animal work will be performed solely at a non-UofL institution **without** an IACUC, then a UCAW *Proposal* must be filled out and explicitly describe the collaboration (see 2b and 3a).
 - i. In instances where investigators are also working with vertebrate animals for research at UofL and must submit a UCAW *Proposal* for review and approval, the details of subcontracted animal work may be included in the “Collaborating Institutions” section of the *Proposal*.
- c. Studies involving USDA-covered species must be conducted at locations registered with the USDA as Research Facilities.
- d. For studies funded by PHS, it is preferred (and may be required by OLAW) that collaborating institutions maintain their own full “PHS Assurance.” In some cases, UofL may negotiate an “Interinstitutional Assurance” with OLAW, which requires that the UCAW provide direct oversight for the project; this is routinely done when non-UofL entities (*e.g.*, sponsors) will perform work with UofL faculty within the Comparative Medicine Research Unit. Though involving considerable resources and elevated risk, UofL may also choose to amend its “Assurance” to cover non-assured performance sites, which effectively subjugates the responsibility of the performance site to UofL. This option requires UCAW oversight and semiannual inspections of the facility and is generally only available for local institutions.
- e. Ownership of the animals, although not necessarily the intellectual property obtained from research with said animals, should be transferred in writing to the collaborating institution. If ownership cannot be transferred, then the collaborating unit must be considered part of UofL's AAALAC-accredited program and may be considered UofL's responsibility by the USDA. Approval of such circumstances will be made by the UCAW on a case-by-case basis.
- f. The UCAW must be informed of any changes in work with animals at the collaborating unit. This includes any changes in USDA Registration, PHS Assurance, and/or AAALAC accreditation status.
- g. For circumstances where the UCAW has accepted the oversight provided by the collaborating IACUC, the UCAW retains the authority to require video or direct inspection of the collaborating institutions. Copies of the following may also be required, based on the level of input and involvement of the UofL PI, species, nature of the studies and procedures, and perceived regulatory and public relations risks:
 - 1) Applicable IACUC-approved protocols
 - 2) Pertinent safety unit review and approval of hazardous agent use
 - 3) IACUC Semi-Annual Reports
 - 4) USDA Inspection Report

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- 5) AAALAC Site Visit results
- 6) Disaster, Emergency Preparedness, and Contingency Plans

4. *Conduct of Animal Studies at UofL Contracted/Funded by Non-UofL Entities (e.g., sponsors)*

- a. Projects involving research with animals at UofL that are contracted and funded through a subcontract, subgrant, or subaward from a non-UofL institution (e.g., sponsors) must be explicitly described in a UCAW *Proposal* for review and approval. The following information should be described in the “Collaborating Institutions” section of the *Proposal*:
 - 1) Contracting (Awardee) Institution/Facility Name
 - 2) Contracting Institution PHS/OLAW Assurance Number, USDA Registration, and AAALAC-accreditation status
 - 3) Funding Institution
 - 4) Awardee Investigator
 - 5) Grant Number
 - 6) UofL Subcontract/Subaward Number
- b. If the collaborating institution that is subcontracting and funding the animal work at UofL does not have a PHS Assurance, UofL may negotiate an “Interinstitutional Assurance” (IIA) with OLAW. OLAW will contact the awardee institution to initiate the IIA process. The IIA requires that the UCAW provide direct oversight for the project; this is routinely done when non-UofL entities (e.g., sponsors) subcontract animal work to be performed by UofL faculty at UofL.

5. *Memoranda of Understanding (MOU)*

The *Guide for the Care and Use of Laboratory Animals* states, “Interinstitutional collaboration has the potential to create ambiguities about responsibility for animal care and use. In cases of such collaboration involving animal use (beyond animal transport), the participating institutions should have a formal written understanding (e.g., a contract, memorandum of understanding, or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight (AAALAC 2003)” (p. 15).

- a. In addition to the requirements listed above for collaborations and contracted research, an MOU may be required detailing animal care and use responsibility, animal ownership, and IACUC review and oversight. The Office of Animal Welfare (UCAW@louisville.edu) will assist PIs in obtaining an MOU during the UCAW *Proposal* review process.

References:

1. *Guidance Regarding Administrative IACUC Issues and Efforts to Reduce Regulatory Burden* (Office of Extramural Research, February 12, 2001 [Notice: NOT-OD-01-017], National Institutes of Health.
2. OLAW Frequently Asked Question. A. Applicability of the PHS Policy. 2. Does the PHS Policy apply to the production of custom antibodies or to the purchase of surgically modified animals? http://grants.nih.gov/grants/olaw/faqs.htm#App_2
3. OLAW Frequently Asked Question. D. Protocol Review. 8. When institutions collaborate, or when the performance site is not the awardee institution, which IACUC is responsible for review of the research activity? <http://grants.nih.gov/grants/olaw/faqs.htm#d8>
4. Who's Responsible for Offsite Animals? AAALAC Connection. Spring 2003. AAALAC, International. http://www.aaalac.org/publications/Connection/Spring_2003_lowres.pdf
5. National Research Council, *Guide for the Care and Use of Laboratory Animals*, 8th Ed., National Academy Press, Revised 2011.

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