Policy:
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 (PIs), does not require additional regulatory oversight by the UofL IACUC. Transfer of breeding stock, e.g., genetically-engineered murine (GEM) strains, to a collaborating institution for which animal ownership is specifically transferred, may require negotiation via Material Transfer Agreement(s), but does not require IACUC review or approval. Otherwise, the relationship between UofL Principal Investigators (PIs) and collaborating institutions, including the production of “custom antibodies,” must be clearly defined in an IACUC Proposal. The level of oversight required for such studies will depend upon: 1) ownership of the animals, 2) award recipient for sponsored projects, and 3) 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 IACUC approval.

Background:
Regulatory agencies recognize that although “review of a research project or evaluation of a program or facility by more than one recognized 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 rats and mice and agricultural animals used 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.

Procedures, Guidelines, and Exceptions:

1. Use of UofL Facilities by Non-UofL Investigators
   a. IACUC-recognized Core Animal Laboratories (CALs) receiving requests for fee-for-service use of their facilities and services must forward copies of animal use protocols approved by the prospective user's IACUC and documents attesting to the approval of the protocol. These protocols should include a description of the use of the CAL. Submission of the hosting protocol should include a cover letter by the CAL Director assuring the IACUC that procedures will comply with the IACUC-approved CAL’s Proposal. UofL IACUC review of the protocol will be limited to the use of the CAL. If requested procedures are not explicitly described in the approval CAL 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. IACUC-recognized CALs receiving requests to serve as collaborators on outside-sponsored project, i.e., for which the CAL 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 UofL IACUC-approved Proposal submitted by a UofL-recognized PI.
2. **Conduct of Animal Studies at 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 the UofL IACUC Proposal for review. The description should also include methods of transporting animals to the contracting location, if applicable.
      1) Use of USDA-covered species is prohibited.
      2) Use of other vertebrates on studies sponsored by PHS may only be conducted if the UofL IACUC accepts complete responsibility of the site in its animal care and use program.
      3) Use of 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 IACUC Proposal. The IACUC will determine approval based on the nature of the studies and procedures.

3. **Conduct of Animal Studies at Sites with an IACUC**  
   a. Projects involving the use of a collaborating institution, including the creation of GEM strains, require that the following information is forwarded for IACUC review:
      1) A brief description of the procedures to be performed at the collaborating location and method of transporting animals to/from the collaborating locations.
      2) Institutional information, which may be reviewed administratively (e.g., during importation of GEM strains):
         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 involving USDA-covered species must be conducted at locations registered with the USDA as Research Facilities.
   c. For studies funded by PHS, it is preferred that collaborating institutions maintain their own full “PHS Assurance.” In some cases, UofL may negotiate an “Inter-institutional Agreement Assurances of Compliance” with OLAW, which requires that the UofL IACUC 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 Research Resources Facilities. Though involving considerable resources and elevated risk, the University may also choose to amend its “Assurance” to cover non-assured performance sites, which effectively subjugates the responsibility of the performance site to UofL.
   d. Ownership of the animals, although not necessarily the intellectual property obtained from use of 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 responsibility by the USDA. Approval for such circumstances will be made by the IACUC on a case-by-case basis.
   e. The UofL IACUC must be informed of any changes in the use of animals at the collaborating unit. This includes any changes in USDA Registration, PHS Assurance, and/or AAALAC accreditation status.
   f. For circumstances where the UofL IACUC has accepted the oversight provided by the collaborating IACUC, the UofL IACUC 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 used, 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
5) AAALAC Site Visit results
6) Disaster, Emergency Preparedness, and Contingency Plans

References:


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