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	SOP: Collaborative Work with Outside Institutions		
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Purpose

The intent of this Institutional Animal Care and Use Committee (IACUC) standard operating procedure is to outline the procedures governing review of projects involving collaborative work with live animals at outside organizations (called “Collaborative Organizations”).

Background

If work with live vertebrate animals is being done at a Collaborative Organization through an award, sub-award, contract, or sub-contract from Lehigh University (LU), LU is accountable for ensuring that the work being conducted on the project meets all applicable regulations and LU policies regarding the humane care and use of animals. Therefore, such projects are subject to review and approval by the LU IACUC. The Office of Laboratory Animal Welfare (OLAW) and the Animal and Plant Health Inspection Service (APHIS) 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.

Policy

The LU IACUC determines the extent of its review on a protocol-by-protocol basis, with its minimum level of review being an administrative review as described herein to assure that adequate controls are in place at the performance site. The LU IACUC will typically perform an administrative review and approval of projects involving live vertebrate animal work being done at Collaborative Organizations. Under certain conditions, the project may be recommended for LU IACUC committee review. The extent of the review may depend upon the following factors:

- The nature of the proposed work to be conducted at the Collaborative Organization
- A demonstrated ability by the Collaborative Organization to maintain the highest standards of humane care and use of animals, as evidenced by a current accreditation with the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) or an equivalent international accreditation. If the Collaborative Organization does not have an AAALAC or equivalent international accreditation, other accreditations or certifications will be considered. These include current Animal Welfare Assurance (PHS Assurance) with OLAW, or an active certification with the United States Department of Agriculture (USDA) or equivalent certifications. Foreign organizations should comply with the International Guiding Principles for Biomedical Research Involving Animals developed by the Council for International Organizations of Medical Sciences (CIOMS) or equivalent.
 - When such evidence is available, the LU IACUC will, in most cases, elect not to perform duplicate review of the proposed animal use to be conducted at the Collaborative Organization.


The LU Principal Investigator (PI) is responsible for the work with live animals that is conducted as part of his or her LU work and for ensuring that such work is compliant with the LU PHS Assurance and applicable regulations and laws. IACUC administrative review and any further IACUC review assist the PI in fulfilling this responsibility.

If projects are funded by the Public Health Service (PHS) or the National Science Foundation (NSF), the Collaborative Organization must hold a current PHS Assurance with OLAW. For projects using USDA covered species in the United States, the Collaborative Organization must be certified by the USDA. Equivalent certification may be required for foreign Collaborative Organizations.

LU PIs are encouraged to contact the IACUC office for assistance if they are considering engaging an outside organization for some or all of the live animal work on their project.

Procedure

1. If the live animal work proposed at the Collaborative Organization is approved by its IACUC, and the Collaborative Organization has a current AAALAC accreditation, PHS Assurance, or other acceptable accreditations or certifications, the LU IACUC may elect not to perform duplicate

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review and instead enter into an administrative Authorization Agreement (Agreement) with the Collaborative Organization.

2. Examples of Agreements are provided in Appendices A through D. The LU IACUC will determine which Agreement is appropriate on a case-by-case basis. The following procedure applies:
 - a. The LU PI on the project submits an IACUC Protocol Application Form: Contracted or Subcontracted Vertebrate Animal Activities (Appendix E).
 - b. The LU IACUC office will initiate an Agreement, requesting from the Collaborative Organization:
 - i. A copy of the Collaborative Organization's protocol sections describing the animal work proposed in the grant proposal, and approved by the Collaborative Organization's IACUC.
 - ii. An approval letter from the Collaborative Organization's IACUC for the proposed animal use.
 - iii. The Collaborative Organization's applicable certifications, including:
 1. Current OLAW Assurance number
 2. AAALAC certification status
 3. Current USDA registration
 - c. The LU Manager of Research Integrity and the IACUC Chair review the protocol and the Agreement, and the Agreement is signed by the Manager of Research Integrity once all criteria have been met.
 - d. If the Collaborative Organization does not have the certifications/accreditations listed above, the LU IACUC will decide on a case-by-case basis whether LU sponsored work with live vertebrate animals at such an organization is permitted and the terms and conditions under which such work can be conducted.
 - e. Once the Agreement is signed by all parties, LU IACUC staff approves the protocol administratively and includes the Agreement with the protocol file.
 - f. The LU IACUC staff reports the approval of the protocol to the LU IACUC at a subsequent meeting.
 - g. The LU PI's post-approval responsibilities are as follows:
 - i. When informed of any serious incidents of animal concern or non-compliance, such as incidents reported to the Collaborative Organization's IACUC or external regulatory agencies, report them promptly to the LU IACUC.
 - ii. Submit approval letters from the Collaborative Organization's IACUC on an annual basis, prior to the protocol expiration date.
 - h. If the LU IACUC has significant concerns about the welfare or humane treatment of animals at the Collaborative Organization, if there is evidence of loss of accreditation, citations by regulatory agencies or other significant events, the LU IACUC may require additional details from the LU PI or the Collaborative Organization and the LU IACUC may elect to revoke the Agreement.

References

1. National Institutes of Health, Office of Extramural Research, Office of Laboratory Animal Welfare. Grants Policy: Office of Laboratory Animal Welfare, Frequently Asked Questions: PHS Policy on Human Care and Use of Laboratory Animals (2015).
<http://grants.nih.gov/grants/olaw/faqs.htm#621>