Collaborations with External Entities: Standard Operating Procedure

Overview/Purpose

According to the Guide (Eighth Edition):

“Inter-institutional 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). In addition, IACUCs from the participating institutions may choose to review protocols for the work being conducted.”

Ohio State IACUC is responsible for oversight of animal activities occurring at Ohio State and for studies in which funding is coming to Ohio State regardless of the location of the activity (i.e. subcontracted to another institution). In all cases, the goal is to provide clear responsibility of oversight to the collaborating entities per federal requirements. This document states what is needed when these collaborations occur at The Ohio State University.

This SOP does not include training and consulting activities conducted at other institutions or private facilities by Ohio State personnel. Ohio State personnel would be required to comply with the external entities policy and should consult with the external IACUC if the work involves animal use there.

Definitions

1. Collaboration – to work with another individual/entity outside Ohio State that involves the joint care, use and/or handling of animals
2. Memorandum of Understanding (MOU) - A document indicating responsibilities of respective entities

Requirements

1. The Office of Responsible Research Practices (ORRP) will serve as the coordinating agency for collaborations with external entities that involve the Ohio State Animal Care program. Investigators must consult with the ORRP staff to determine the need to complete an Ohio State IACUC protocol, develop a Memorandum of Understanding with the collaborating entity, or if submission of the entities approved IACUC protocol would be appropriate.

2. The Office of the Attending Veterinarian (OAV) must be notified by the external institution prior to animal movement to assess the health status and ensure proper medical care and health maintenance.

3. The required documents depend on the funding and location of animal use as indicated below:
   a. The animals will be housed in OSU facilities:
      i. An OSU IACUC protocol must be submitted and approved.
      ii. If animals are to be housed in ULAR facilities, an animal order form must be submitted prior to animal movement. For housing in non-ULAR areas, the clinical veterinarian for the facility should be contacted directly prior to animal movement.

   b. No animal activities are performed at Ohio State, but funding for work with animals is subcontracted by Ohio State:
i. The external IACUC approval letter for the animal activities being performed at the external institution is required. The external IACUC (or equivalent animal research ethics committee) will be asked to assume full responsibility for the animal activities in its facilities including responsibility for ongoing protocol review and animal facility inspections.

c. Some animal activities are conducted at Ohio State however funding is through an external entity:
   i. Ohio State IACUC will require a copy of the external institution’s IACUC protocol
   ii. A memorandum of understanding (MOU) will be executed to document the respective responsibilities of Ohio State and the external institution and whether a separate Ohio State protocol is required. The IACUC staff will work with the Ohio State PI, the OAV and institutional officials to secure this agreement.
   iii. The OAV must be notified by the external institution prior to animal movement to assess the health status and ensure proper containment procedures and health maintenance.

d. Some animal activities supported with Ohio State funding are conducted at an external entity:
   i. The Ohio State IACUC protocol should clearly describe all planned animal research activities to be conducted at the subcontracted site(s). The Ohio State IACUC may rely on the approval of an external IACUC for the animal activities being performed at the external institution. This can occur when the external institution has an NIH/OLAW approved Animal Welfare Assurance and, if necessary, an active registration with the USDA. In most cases, the external IACUC (or equivalent animal research ethics committee) will be asked to assume full responsibility for the animal activities in its facilities including responsibility for ongoing protocol review and animal facility inspections.
   ii. A memorandum of understanding (MOU) will be executed to document the respective responsibilities of Ohio State and the subcontracted institution. The IACUC staff will work with the Ohio State PI, the OAV and institutional officials to secure this agreement.

4. Animal work funded by NIH must be conducted at facilities that meet the following requirements:
   a. Have an NIH/OLAW approved Animal Welfare Assurance
   b. Have an active registration with the USDA (if applicable)
   c. Accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). The IACUC staff will work with the OSU PI, the OAV and institutional officials to secure this agreement.

5. Unaffiliated Personnel Conducting Animal Research in Ohio State Facilities must be listed on the Ohio State protocol and comply with the requirements of a study team member. For teaching
protocols, a listing of credentials of personnel involved in instructional activities may be included in the protocol rather than individual names.

Applicable Regulations

1. Health Research Extension Act of 1985 and Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals

History of Revisions

016-00 - new policy approved 10/2002
016-01 - brief summary of revisions approved 02/26/2007
102-00 – changed to an SOP and changed previous title “Inter-institutional activities”, reformatted, clarified requirements, approved 03/27/2015