



## 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 transfer), 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.”

The 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). The intent of this SOP is to define responsibility of oversight to the collaborating entities per federal requirements.

### Definitions

1. **Collaboration** – to work with another individual/entity outside Ohio State that involves the joint care, use and/or handling of animals. This does not include the transfer of animals to another facility when there have been no procedures conducted on the animals at the originating facility.
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 office 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 entity's 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 unless an MOU has been signed that indicates only one institution will review the protocol in cases where animals will only be housed at Ohio State.
    - ii. If animals are to be housed in ULAR facilities, an online animal order form must be submitted prior to animal movement. For housing in non-ULAR areas, the clinical veterinarian 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. Confirmation of the external IACUC approval 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 IACUC function and animal activities in its facilities including responsibility for ongoing protocol review and animal facility inspections. This information may be included in the sponsored program agreement between the two entities.
  - c. Animal activities are conducted at Ohio State for less than 24 hours :
    - i. The Ohio State IACUC will require confirmation of approval by an 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. Procedures to be conducted at the external site should be described in the Ohio State protocol timeline section. 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. An 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 or Foreign Assurance
  - b. Have an active registration with the USDA (if applicable)
  - c. Accredited by AAALAC, International. If the facility is not accredited, additional information may be required by the IACUC on a case by case basis. The information could include the approved protocol and standard operating procedures at the external entity. The ORRP staff will work with the OSU PI, the OAV and institutional officials to secure these documents.
5. Names and/or credentials of unaffiliated individuals conducting activities approved on the OSU IACUC protocol at external facilities or locations should be indicated in the external collaboration section of the protocol. Additional information may be required if external entities are not overseen by an IACUC.

## **Applicable Regulations**

1. Health Research Extension Act of 1985 and Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals
2. National Research Council *Guide for the Care and Use of Laboratory Animals*, Eighth Edition. National Academy of Sciences, 2011
3. USDA Animal Welfare Act
4. USDA Animal Welfare Inspection Guide page 7-41

## **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

102-01 –changed to clarify information required when external facilities are involved approved 08/17/2018