Animal Research Performed Offsite

The Institutional Animal Care and Use Committee (IACUC) is charged with ensuring that the use of live vertebrate animals for testing, research and/or training purposes conforms to the ethical and humane standards for animal care and use, federal laws and regulations, regulatory policies and guidelines, and institutional policies and procedures. This mandate applies to the use of live vertebrate animals performed under the direction of EVMS personnel or supported by EVMS-managed funds, and includes work performed at EVMS, as well as work performed at offsite locations. Animals owned by EVMS are the responsibility of the Institution, and, at a minimum, a copy of the IACUC-approved protocol, IACUC approval letter, and IACUC-approved annual reviews must be on file with the IACUC Office.

The United States Department of Agriculture (USDA) assigns responsibility for animals based upon ownership. If more than one institution is involved, responsibility is shared by the institution providing housing and care and the institution involved in planning and execution of the animal-use project. The Public Health Service (PHS) assigns responsibility based upon funding. The PHS Policy requires that all awardees and each performance site maintain an approved Animal Welfare Assurance (domestic institutions) or a Statement of Compliance (foreign institutions) on file with the Office of Laboratory Animal Welfare (OLAW). The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) assigns responsibility based upon the institution responsible for the animals at the offsite location. In all cases, the IACUC requires that all animal-use activities are performed in compliance with federal, ethical, and institutional standards.

Purpose:
The Institution encourages all EVMS personnel to conduct animal research onsite, unless sufficiently justified. The purpose of this policy is to define those situations in which the justified offsite use of live vertebrate animals must be reviewed and approved by the IACUC.

Definitions:
1. An offsite institution/location is any non-EVMS facility.
2. "EVMS Personnel" applies to any faculty (whether such faculty member is fully-salaried, partially-salaried, or non-salaried), faculty agent, staff, student, investigator, fellow, or trainee who conducts animal research under the guidance of the EVMS IACUC using EVMS-managed funds.

Policy:
Any work involving live vertebrate animals performed entirely or in part at EVMS must be reviewed and approved by the IACUC, prior to the use of animals. Likewise, if EVMS personnel use EVMS-managed funds to support the offsite use of live vertebrate animals or engage in activities that fall under the auspice of the Institution, the IACUC must review and approve the work to be performed at an offsite location, prior to the use of animals. An appropriate agreement between EVMS and the offsite institution may be required, prior to IACUC approval, for non-PHS-funded, unfunded, or intramurally-funded offsite activities.

Examples of offsite activities involving EVMS personnel that are covered by this policy include, but are not limited to, the following:
1. participation in a collaborative or non-collaborative project as part of an EVMS-based research effort in which live vertebrate animals are subjected to testing, research, and/or training procedures at an offsite institution;
2. provision of live vertebrate animals housed at EVMS to an investigator at an offsite institution for use in a collaborative project;
3. receipt of live vertebrate animals that have been subjected to testing, research, and/or training procedures by an investigator at an offsite institution as part of a collaborative project;
4. use of EVMS-managed funds to support a collaborative or non-collaborative project in which live vertebrate animals are subjected to testing, research, and/or training procedures at an offsite institution;
5. use of EVMS-managed funds to contract for research services to be performed by an outside vendor or to purchase animal materials (i.e. custom antibodies, etc.) from an outside vendor.
6. use of an investigator’s EVMS association in any publication or public presentation resulting from a project involving live vertebrate animals subjected to testing, research, and/or training procedures at an offsite institution.

1NIH/OLAW has made the following interpretation of PHS Policy regarding IACUC approval when antibodies are purchased of antibodies: In the case that standard reagent antibodies (e.g. mouse-antihuman) are produced by a commercial supplier using their own resources and offering them for general sale, for example, through a catalogue, the institution may consider the antibodies to be “off-the-shelf” reagents, and the supplier is not required to file an Assurance with OLAW. If, on the other hand, a supplier or contractor produces custom antibodies using antigen(s) provided by or at the request of a principal investigator, the antibodies are considered “customized” and the vendor or subcontractor must file an Assurance with OLAW. Usually, it is known in advance that someone intends to perform this kind of work under a PHS grant. In such cases, the applicant must mark the PHS Grant Application (PHS Form 398) “yes” for vertebrate animal involvement and include the appropriate Animal Welfare Assurance number(s), verification of project-specific date of IACUC protocol review, and the identification of all project performance sites. All animal-related activities supported by the PHS must be conducted at Assured institutions and must be reviewed and approved by an IACUC. When both the PHS Grantee and its Contractor hold OLAW-approved Assurances, some latitude is allowed in determining which IACUC (if not both) will review the proposal. However, the institution which subcontracts or subgrants and animal activity regains partial accountability for providing effective oversight mechanisms to ensure compliance with the PHS Policy. Part of that responsibility includes ensuring that subgranted/subcontracted animal-related activities are conducted only at an Assured institution.

The PHS Policy requires that all awardees and each performance site maintain an approved Animal Welfare Assurance (domestic institutions) or a Statement of Compliance (foreign institutions) on file with the Office of Laboratory Animal Welfare (OLAW). This requirement does not apply to projects supported by non-federal funds; however, an appropriate agreement between EVMS and the offsite institution may be required.

The IACUC may accept approval by the offsite institution’s IACUC or comparable regulatory agency if the following conditions are met and if appropriate documentation (i.e. a copy of the IACUC-approved protocol, IACUC approval letter, IACUC-approved annual reviews, etc.) is presented to the IACUC for review: 1. the offsite institution has a PHS Assurance Number; 2. the offsite institution has a duly constituted IACUC and an Attending Veterinarian; 3. the offsite institution is AAALAC-accredited.

Even if these conditions are met, the IACUC may require additional conditions for approval. If the offsite institution’s approval is accepted, it is the responsibility of the EVMS personnel involved in the project to provide evidence of annual continuing review and approval to the IACUC for the life of the project.
EVMS is an AAALAC-accredited institution. If the offsite institution is AAALAC-accredited and the EVMS investigator turns over ownership of the animals to the offsite institution, the IACUC may defer oversight of the animals to the offsite institution. If the offsite institution is not AAALAC-accredited, the IACUC must develop a reporting program to obtain required program and facility status information. Also, documentation of animal use must be conducted at one or both locations.

The mechanism used by the IACUC to determine review of proposed offsite use of live vertebrate animals will be determined by a variety of factors. The compliance status of the offsite institution may impact whether the IACUC is required to conduct semi-annual site inspections and program reviews. The EVMS investigator involved in the offsite research will be responsible for the costs of the offsite inspections and program reviews.

Investigators who are contemplating any involvement in offsite animal research activities should contact the IACUC to determine whether the proposed procedures are subject to prior review and approval by the IACUC.