



INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

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IACUC GUIDELINE: INTER-INSTITUTIONAL AGREEMENT ON THE USE OF ANIMALS IN RESEARCH SETTINGS

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**Purpose:**

The UCSB Institutional Animal Care and Use Committee (IACUC) recognizes that an increasing number of UCSB Principal Investigators (PIs) are collaborating on animal research studies with other academic and non-academic institutions. Similarly, a growing number of investigators from other academic institutions are using UCSB facilities, including the Natural Reserve System (NRS), to conduct their animal research activities. This Guideline provides the framework for decision-making about the institutional responsibilities for the care and use of live animals, including inter-institutional collaborations and studies performed by non-UCSB personnel at UCSB and off-campus sites (e.g., Santa Cruz Island, Sedgwick Ranch, Sierra Nevada Aquatic Research Laboratory (SNARL), and Valentine Eastern Sierra Reserve (VESR)). Further, a written agreement (e.g., memorandum of understanding) may be created to more specifically define each institution's roles and responsibilities for animal care and use, animal ownership, and IACUC review and oversight.

Each institution shall be responsible for notifying the other of any instances of non-compliance reportable to OLAW/NIH or USDA with respect to care and treatment of animals that are involved with research activities covered by the Memorandum of Understanding.

**Background:**

When UCSB owns animals at an offsite host institution, or when animals owned by other institutions are housed or used at this campus, UCSB is subject to rules and guidelines of the USDA (for species regulated by the Animal Welfare Act/Regulations); the Office of Lab Animal Welfare (OLAW) (for PHS funded projects) and AAALAC. The PHS status of the offsite facility may impact whether the UCSB IACUC is required to obtain Inter-Institutional PHS Assurance, include the facility in the UCSB Program Description, and conduct semi-annual facility inspections and

program reviews, or other oversight requirements. In all instances, the UCSB IACUC requires conformity to all federal, state, local, and institutional regulations and policies.

**USDA-APHIS-AC<sup>1</sup>** assigns responsibility for animal care and use to the institution that owns the animals. With an inter-institutional collaboration, responsibility for animal care and use is not well defined, but probably will reside with the institution that is providing the animal housing and care and is involved in the planning and execution of the animal study. For its part, UCSB must ensure that animal studies involving covered species that are performed on non-UCSB sites, are performed by institutions that are registered with USDA-APHIS-AC, have an approved Veterinary Care Program in place, and have an IACUC which reviews the program of animal care and use and conducts semi-annual facility inspections. Further, the UCSB IACUC may request to review these semi-annual inspection and program review reports.

**OLAW<sup>2</sup>** requires that the awardee's institution be responsible for ensuring that all terms and conditions of the award, including the PHS animal welfare policy, are met. Jurisdiction in this case is based on the source of funding, not ownership of the animals. The PHS Policy requires that all awardees and each performance site hold an approved Animal Welfare Assurance. OLAW negotiates Inter-institutional Agreement Assurances of Compliance when an awardee institution without an animal care and use program or IACUC will rely on the program of an Assured institution. Assured institutions also have the option to amend their Assurance to cover non-assured performance sites, which effectively subjugates the performance site to the Assured institution and makes the Assured institution responsible for the performance site. If both institutions have full PHS Assurances, they may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be performed. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees. Similarly, IACUCs partnered by inter-institutional collaborations should share any significant questions or issues raised during a semi-annual program review and facilities inspection.

**AAALAC<sup>3</sup>** follows ownership in terms of defining who is responsible for animals at an offsite facility. If both institutions are AAALAC-accredited, then UCSB can defer to the oversight of the offsite facility's IACUC. If animals are legally transferred to the off-site facility, with UCSB surrendering ownership, then the responsibilities of UCSB are diminished.

### **Applicability:**

#### *Inter-institutional Collaborations:*

For projects that involve inter-institutional collaborations (i.e., sub-awards) where UCSB PIs receive federal funding for activities involving animal research projects conducted by the sub-awardee at an off-site location, the collaborating institution must provide the UCSB IACUC Office with a copy of the approval letter of the corresponding protocol covering the animal activities described in the grant and verify that the institution has a current and valid PHS Assurance, and USDA-APHIS registration for covered species (if applicable).

When UCSB is the awardee and a sub-award is to a foreign institution, PHS animal welfare requirements are applicable. The foreign institution must have or obtain a foreign PHS Assurance from OLAW in order to conduct animal research activities. The foreign institution must also follow the *International Guiding Principles for Biomedical Research involving Animals* and comply with all applicable laws, regulations, and policies governing animal care and use for their country of jurisdiction. The UCSB PI identified on the grant must provide the foreign IACUC (or IACUC-equivalent) approved protocol and approval letter in the original language and English translation. The IACUC may accept, as its own, the approval of the foreign institution's IACUC; however UCSB remains responsible for the animal activity conducted at the foreign site.

The UCSB IACUC will be notified when a sub-award involving animal research is being conducted by a non-UCSB PI at non-UCSB facilities. Further, the UCSB IACUC/Staff/Research Integrity Office will determine on a case-by-case basis whether a written memorandum of understanding should be initiated between the collaborating institutions.

*Use of UCSB Facilities or Locations by Non-UCSB PIs:*

The UCSB IACUC may accept another institution's approved animal protocol for animal studies performed at UCSB off-campus locations (i.e., Natural Reserves), by non-UCSB PIs, provided that the institution supplies a copy of the approved protocol and approval letter (and any other requested materials, including but not limited to, verification of training and occupational health and safety enrollment, corresponding permits, hazard authorizations, etc.) and the institution complies with all federal, state, local laws, policies and guidelines on animal care and use. The UCSB IACUC will determine on a case-by-case basis whether a memorandum of understanding should be initiated between the institutions.

The following table is a general guide for determining the type of IACUC review required in various scenarios<sup>4</sup>:

<i>Funding</i>	<i>Animal Housing and/or Procedures</i>	<i>IACUC Review</i>	<i>UCSB Protocol Type or Requirements</i>
UCSB	UCSB	UCSB IACUC	UCSB animal protocol
UCSB (Prime); Sub-award to Non-UCSB	Non-UCSB, domestic (U.S.A.) facility PHS Assured and AAALAC-accredited	Notification to UCSB IACUC	UCSB PI to provide the other Institution's approval letter to UCSB IACUC for file. MOU may be initiated
UCSB (Prime); sub-award to Non-UCSB	Non-UCSB, domestic (U.S.A.) facility PHS Assured and non AAALAC accredited	Notification to UCSB IACUC	UCSB PI to provide the other Institution's approval letter to UCSB IACUC for file. MOU may be initiated. DOD funding may not be used to support non-AAALAC accredited offsite-facilities conducting animal research
UCSB (Prime); sub-award to Non-UCSB	Non-UCSB, domestic (U.S.A.) facility Non PHS Assured	N/A	UCSB cannot distribute federal funding to sub-awards that are not PHS-assured.

UCSB (Prime); sub-award to Non-UCSB foreign component	Foreign Institution	UCSB IACUC	Foreign institution must provide verification of Foreign PHS assurance. UCSB PI must provide Foreign IACUC (or equivalent) approved protocol and approval letter in original language and English translation. MOU is required for animal care and use responsibilities and oversight.
Non-UCSB (Prime); sub-award to UCSB	UCSB	UCSB IACUC	UCSB animal protocol. MOU may be initiated at Prime's request.
Non-UCSB (regardless of funding)	UCSB Natural Reserves	To be determined on a case-by-case basis	UCSB IACUC will verify animal activities occurring at reserve and determine if a MOU is required between institutions.

\*Note for scenarios not identified in this table, please contact the IACUC Office to determine IACUC review requirements. Any projects involving USDA-covered species, the institution housing the animals is responsible for maintaining their USDA registration and reporting annual animal usage, unless otherwise specified in the MOU between the institutions.

<sup>1</sup> Code of Federal Regulations, Title 9 (Animals and Animal Products), Chapter 1, Subchapter A (Animal Welfare). The Animal Welfare Act of 1966 (P.L. 89-544)-as amended by the Animal Welfare Act of 1970 (P.L. 91-579); 1976 Amendments to the Animal Welfare Act (P.L. 94-279). Available from: Regulatory Enforcement and Animal Care, APHIS, USDA, Unit 85, 4700 River Road, Riverdale, MD 20737-1234.

<sup>2</sup> Health Research Extension Act of 1985, Public Law 99-158, November 20, 1985, "Animals in Research ". Available from: OLAW, National Institutes of Health, RKL1, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, Maryland 20892-7982 (for express or hand delivered mail, use zip code 20817) or visit the OLAW website at <http://grants.nih.gov/grants/olaw/olaw.htm>.

<sup>3</sup> AAALAC Connection Spring 2003 "Who's Responsible for Offsite Animals?"

<sup>4</sup> Adapted from UCSD Policy 21 Interinstitutional Animal Research