

**UNIVERSITY OF CALIFORNIA SAN DIEGO
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

Policy and Guidelines on Inter-Institutional Animal Research

Purpose:

The UCSD Institutional Animal Care and Use Committee (IACUC) recognizes that an increasing number of investigators are performing animal housing or procedures at offsite locations, or conversely, other institutions are performing animal work at the UCSD campus. This policy provides a framework for decision-making about the institutional responsibility for the care of the animals.

Background:

When UCSD owns animals at an offsite host institution, or when animals owned by other institutions are housed or used at this campus, UCSD 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 or AAALAC status of the offsite facility may impact whether the UCSD IACUC is required to obtain Inter-Institutional PHS Assurance, include the facility in the UCSD Program Description, conduct semi-annual facility inspections and program reviews, or other oversight.

USDA-APHIS-AC¹, in most cases, assigns responsibility for offsite animals to the institution that owns the animals. If more than one institution is involved, responsibility for the animals being used is shared by the institution providing housing and care and the institution that is involved in the planning and execution of the study. If an owning institution has a say in how offsite animals are used, then that institution has responsibility for the animals. UCSD must ensure that the offsite facility is a registered Research Facility with USDA-APHIS-AC, has an approved Veterinary Care Program in place, and has an IACUC which reviews the program of animal care and conducts facility inspections.

OLAW² requires that the awardee 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. 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, an IACUC needs to know about any significant questions or issues raised during a semi-annual program inspection by another IACUC of a facility housing a research activity for which that IACUC bears some responsibility or exposure.

AAALAC³ follows ownership in terms of defining who is responsible for animals at an offsite facility. If both institutions are AAALAC-accredited, then UCSD can defer to the oversight of the offsite facility's IACUC. If animals are legally transferred to the off-site facility, with UCSD surrendering ownership, then the responsibilities of UCSD are diminished.

In many circumstances this requires IACUC decision making on a case-by case basis. In all cases, the UCSD IACUC requires conformity to all federal, state, local and institutional regulations and policies. The following table is a general guide for determining the type of protocol and type of institutional IACUC review needed in varying circumstances. The IACUC/AWP/ACP staff are responsible for making decisions in individual cases.

	Funding	Animal Housing and/or Procedures	IACUC Review	UCSD Protocol Type or Requirements
1	UCSD	UCSD	UCSD	UCSD Animal Protocol
2	Non-UCSD AAALAC Accredited YES	UCSD	Both institutions	<ul style="list-style-type: none"> • Reciprocal Protocol • Non-UCSD animal protocol and approval letter
3	Non-UCSD AAALAC Accredited NO	UCSD		UCSD IACUC will not approve non-AAALAC institutions to perform animal studies on this campus.
4	(SD)VA or UCSD	(SD)VA or UCSD	(SD)VA or UCSD	Refer to 7.12.01 MOU document
5	UCSD	U.S. Offsite facility that is PHS Assured & AAALAC-accredited	No UCSD review needed if other institution's IACUC has approved	UCSD PI must provide the other Institution's protocol and approval letter to UCSD IACUC for file and potential review.
6	UCSD	U.S. Offsite facility: PHS Assured NO AAALAC Accredited YES	UCSD IACUC	<ul style="list-style-type: none"> • UCSD Animal Protocol • In general, the IACUC will not approve such situations, but each situation will be reviewed on a case-by-case basis.
7	UCSD	U.S. Offsite facility: PHS Assured YES AAALAC Accredited NO		UCSD IACUC will not approve off site animal work at a non-AAALAC facility.
8	UCSD	U.S. Offsite facility: PHS Assured NO AAALAC Accredited NO		UCSD IACUC will <u>not</u> approve off site animal work at a non-AAALAC, non-PHS-assured facility.
9	UCSD	Field Studies	UCSD IACUC	<ul style="list-style-type: none"> • UCSD Animal Protocol • UCSD IACUC will review on a case-by-case basis.
10	UCSD	Foreign Institution	UCSD IACUC	<ul style="list-style-type: none"> • Foreign institution must have Foreign PHS Assurance. • UCSD PI must provide Foreign IACUC (or IACUC-equivalent) approval letter in original language and English translation. • Foreign institution must be AAALAC-accredited. If not AAALAC-accredited, the physical ownership of animals must be ceded to the foreign institution.

Applicability:

Any housing or use of animals for the purpose of research, testing or teaching, conducted in whole or in part offsite (including field studies), must be reviewed and approved/registered by all applicable UCSD entities prior to initiation if it satisfies any of the following criteria:

1. It is conducted by or under the direction of UCSD personnel in connection with his or her UCSD responsibilities
2. It uses UCSD property, facilities, or resources to support or carry out the activity
3. The name of UCSD is used in applying for funds (intra or extramural)

Definition of Off Site:

Occurring outside of UCSD owned, operated, or leased facilities (including international sites). For purposes of research oversight, private facilities located on UCSD land are considered offsite locations

Definition of Off Site Animal Activities:

Any housing or use of animals for the purpose of research, testing, teaching, field studies, or related purposes that is conducted in whole or in part at a non-UCSD institution, company, contracting laboratory, contract research organization or similar facility.

Definition of a Reciprocal Protocol:

A Reciprocal Protocol is an online application for UCSD IACUC Approval of a non-UCSD Protocol (i.e. funding is not received through a UCSD investigator). This application must include the approved protocol from the submitting institution's IACUC. A UCSD Faculty Member must electronically sign the application and agree to take full responsibility for the animal(s), procedures, and personnel while at UCSD. The UCSD IACUC will review the Reciprocal Protocol, Non-UCSD Protocol, approval letter, and PQs at a regularly scheduled IACUC Meeting. The IACUC may require conditions to approval. If any hazards are associated with the animals to be transported to UCSD, the Reciprocal Protocol must be reviewed and approved by UCSD Environmental Health and Safety. All Reciprocal Protocols require consultation with and monitoring by UCSD Veterinary Services.

Reciprocal Protocol Criteria for the Submitting Institution:

1. The Institution must have a duly constituted IACUC and attending veterinarian
2. The Institution must be accredited by AAALAC.
3. The PI of the Reciprocal Protocol must have an appointment at his/her home institution equivalent to that of a UCSD PI.
4. The Reciprocal Protocol must be submitted by the PI listed on the protocol of his/her home institution.

Reciprocal Protocol Criteria for the responsible UCSD Faculty Sponsor:

1. To be eligible to sponsor a Reciprocal Protocol, the responsible UCSD faculty member must be a P.I., i.e. qualified to submit a UCSD grant proposal under PPM 150-10 with appropriately approved animal space.

Custom Antibodies produced Off Site:

1. 'Custom antibody' refers to instances when the Principal Investigator provides specific preparations to off-site vendors to produce antibodies from live animals.
2. Custom Antibodies may only be subcontracted to vendors which are PHS-assured, AAALAC-accredited, (and USDA-registered if rabbits or other USDA-covered species are used).
3. A Tissue Transfer Application must be submitted to and approved by the IACUC before contracting with the vendor.

Personnel Qualifications (PQ) Forms

1. Everyone with animal contact at a UCSD facility must submit a Personnel Qualifications Form (PQ).
2. Non-UCSD employees may be required to register as volunteers with Human Resources, and provide evidence of medical monitoring at the home institution. In some cases, enrollment in the UCSD OHSP Medical Monitoring program will be required. The Staff Volunteer Appointment form can be found at <http://www-hr.ucsd.edu/~qwl/policies/pdf/sp3vol.pdf> and the Oath and Patent forms can be found at <http://blink.ucsd.edu/Blink/External/Topics/Policy/0,1162,4397,00.html>. The occupational Health Policy for all employees with research animal contact can be found at <http://blink.ucsd.edu/Blink/External/Topics/Policy/0,1162,13516,00.html>.
3. The UCSD Orientation to Animal Research, as well as other training classes, may be required based on the review of the PQ form.

References:

1. 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.
2. 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>.
3. AAALAC Connection Spring 2003 "Who's Responsible for Offsite Animals?"