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-AC ¹, 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.

OLAW ² 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.

AAALAC ³ 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. If the offsite facility is not accredited, AAALAC requires UCSD to describe the offsite facility’s animal care and use program and facilities in its own AAALAC Program Description and annual report and include it in the AAALAC site visit—specifically those areas that are related to the animals owned by UCSD. This includes all housing, support and procedure areas.” Even if the off site facility is geographically far away, AAALAC will evaluate it as part of UCSD’s site-visit process. When the contract or offsite facility is not accredited, AAALAC recommends that UCSD ramp up the intensity of its oversight, including a facility inspection as part of the IACUC’s semiannual review, along with other forms of long-distance monitoring.
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.

<table>
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<tr>
<th>Funding</th>
<th>Animal Housing and/or Procedures</th>
<th>IACUC Review</th>
<th>UCSD Protocol Type or Requirements</th>
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<td>UCSD</td>
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<td>UCSD Animal Protocol</td>
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<tr>
<td>Non-UCSD</td>
<td>UCSD</td>
<td>Both institutions</td>
<td>• Reciprocal Protocol form</td>
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| AAALAC Accredited YES | UCSD                             | UCSD IACUC will not approve non-AAALAC institutions to perform animal studies on this campus. [Existing contracts as of 6.20.07 shall have until 12.31.08 for the off site location to procure AAALAC accreditation.]
| Non-UCSD AAALAC Accredited NO | UCSD                             | UCSD IACUC will not approve non-AAALAC institutions to perform animal studies on this campus. [Existing contracts as of 6.20.07 shall have until 12.31.08 for the off site location to procure AAALAC accreditation.]
| (SD)VA or UCSD | (SD)VA or UCSD                   | (SD)VA or UCSD | • Online application MOU application |
| UCSD        | Offsite facility that is PHS Assured & AAALAC-accredited | UCSD IACUC will not approve off site animal work at a non-AAALAC facility. [Existing contracts as of 06.20.07 shall have a period until 12.31.08 for the off site location to procure AAALAC accreditation. If UCSD personnel work at such non-accredited sites during this period, UCSD EH&S must review hazards involved.]
| UCSD        | Offsite facility: PHS Assured NO AAALAC Accredited YES | UCSD IACUC will not approve off site animal work at a non-AAALAC facility. [Existing contracts as of 06.20.07 shall have a period until 12.31.08 for the off site location to procure AAALAC accreditation. If UCSD personnel work at such non-accredited sites during this period, UCSD EH&S must review hazards involved.]
| UCSD        | Offsite facility: PHS Assured NO AAALAC Accredited NO | UCSD IACUC will not approve off site animal work at a non-AAALAC, non-PHS-assured facility. |
| UCSD        | Offsite Facility Field Studies   | UCSD IACUC   | • Online application MOU application |
| UCSD        | Offsite Facility Field Studies   | UCSD IACUC   | • UCSD IACUC will review on a case-by-case basis. |
APPENDIX ONE
OFF SITE ANIMAL ACTIVITIES

Definition of Offsite:
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.

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)

Online Memorandum of Understanding Application:
An online Memorandum of Understanding Application is required in circumstances where funding is issued to a UCSD PI and animal studies are subcontracted to another institution (see table). All questions must be answered and specific language must be included regarding ownership of animals, day to day responsibility for animals, housing, care, staff training, transportation, safety, and monitoring. If an Inter-Institutional Assurance must be negotiated by OLAW, or if a site must be included in the UCSD AAALAC Program Description, specific and detailed language must cover the individual institution responsibilities and all topics in a standard PHS Assurance and/or AAALAC Program Description.

APPENDIX TWO
RECIPROCAL PROTOCOLS (DONE AT UCSD)

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.

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.

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.
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](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](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](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.

UCSD IACUC review and approval
The UCSD IACUC will review the above documents (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.

References:
3. AAALAC Connection Spring 2003 “Who’s Responsible for Offsite Animals?”