



## CSUSM SEMIANNUAL PROGRAM REVIEW CHECKLIST

**Please indicate:** *NA-Not applicable; A-Acceptable; M-Minor deficiency; S-Significant Deficiency; C – change in program (PHS Policy IV.A.1.a.-1.)*(include in semiannual report to IO and in annual report to OLAW)

### INSTITUTIONAL POLICIES AND RESPONSIBILITIES

NA	A	M	S	C	<u>Animal Care and Use Program</u>
	X				Responsibility for animal well-being is assumed by all members of the program ( <i>Guide, p 1</i> ) [must]
	X				IO has authority to allocate needed resources ( <i>Guide, p 13</i> )
	X				Resources necessary to manage program of veterinary care are provided ( <i>Guide, p 14</i> ) [must]
	X				Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> ( <i>Guide, pp 11, 15</i> )
	X				Program needs are regularly communicated to IO by AV and/or IACUC ( <i>Guide, p 13</i> )
	X				Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site ( <i>Guide, p 14</i> ) [must]
	X				Inter-institutional collaborations are described in formal written agreements ( <i>Guide, p 15</i> )
	X				Written agreements address responsibilities, animal ownership, and IACUC oversight ( <i>Guide, p 15</i> )
NA	A	M	S	C	<u>Disaster Planning and Emergency Preparedness</u>
	X				Maintains a disaster plan and business continuation plan for all locations (including satellites) that takes into account both personnel and animals and plans include <i>Guide, p 35, p 75</i> [must]: provisions for euthanasia ( <i>Guide, p 35</i> ) [must] triage plans to meet institutional and investigators' needs ( <i>Guide, p 35</i> ) actions to prevent animal injury or death due to HVAC or other failures ( <i>Guide, p 35</i> ) preservation of critical or irreplaceable animals ( <i>Guide, p 35</i> ) essential personnel and their training ( <i>Guide, p 35</i> )

	X				Animal facility disaster plans are approved by the institution and incorporated into overall response plan ( <i>Guide</i> , p 35)
	X				Emergency personnel are provided a copy and integration with overall plan is in place ( <i>Guide</i> , p 35); copy is posted on animal facility door to enable law enforcement access to plan
NA	A	M	S	C	<u>IACUC General Considerations, Membership, and Functions</u>
	X				IACUC Meets as necessary to fulfill responsibilities ( <i>Guide</i> , p 25) [must]
	X				IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions ( <i>Guide</i> , p 26) [must]
	X				Continuing IACUC oversight after initial protocol approval is in place ( <i>Guide</i> , p 33)
	X				IACUC evaluates the effectiveness of training programs ( <i>Guide</i> , p 15)
	X				At least 5 members, appointed by the CEO or Designated Authority (IO) (PHS Policy, <a href="#">IV.A.3.</a> )
	X				Members include veterinarian, scientist, non-scientist, and non-affiliated/non-lab animal user( <i>Guide</i> , p 24)
	X				IACUC organizationally reports to the Institutional Official (PHS Policy, <a href="#">IV.A.1.b.</a> )
	X				Institution provides training and resources to assist IACUC member in understanding and evaluating issues brought before the committee
	X				IACUC authority and resources for oversight and evaluation of institution's program are provided ( <i>Guide</i> , p 14)
	X				Conducts semiannual evaluations of institutional animal care and use program (PHS Policy, <a href="#">IV.B.</a> )
	X				Conducts semiannual inspections of institutional animal facilities (PHS Policy, <a href="#">IV.B.</a> )
	X				Methods for reporting and investigating animal welfare concerns are in place ( <i>Guide</i> , p 23) [must] Reviews and investigates concerns about animal care and use at institution (PHS Policy, <a href="#">IV.B.</a> )
	X				Has procedures for review, approval and suspension of animal activities (PHS Policy, <a href="#">IV.B.</a> ). Animal protocols contain all required information
	X				Has procedures for review and approval of significant changes to approved activities (PHS Policy, <a href="#">IV.B.</a> )
	X				Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS ( <i>Guide</i> , p 30) [must]
	X				Has policies for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) ( <i>Guide</i> , p 27-32)

NA	A	M	S	C	IACUC Protocol Review – Special Considerations
	X				<p>Information included in animal protocols:</p> <p>a) Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide</i>, <a href="#">p 27</a>)</p> <p>b) For pilot studies, a system to communicate with the IACUC is in place (<i>Guide</i>, <a href="#">p 28</a>)</p> <p>c) For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide</i>, <a href="#">p 28</a>)</p> <p>d) Prolonged restraint protocols include description and justification of restraint devices used (<i>Guide</i>, <a href="#">p 29</a>) [must], consideration of alternatives to physical restraint (<i>Guide</i>, <a href="#">p 29</a>), evidence that the period of restraint is the minimum to meet scientific objectives (<i>Guide</i>, <a href="#">p 29</a>), description of training of animals to adapt to restraint that is provided (<i>Guide</i>, <a href="#">p 29</a>), confirmation that animals that fail to adapt are removed from study (<i>Guide</i>, <a href="#">p 29</a>), description of appropriate observation intervals of restrained animals (<i>Guide</i>, <a href="#">p 29</a>), verification that veterinary care is provided if lesions or illness result from restraint (<i>Guide</i>, <a href="#">p 30</a>) [must], verification that explanations of purpose and duration of restraint are provided to study personnel (<i>Guide</i>, <a href="#">p 30</a>)</p> <p>e) Protocols with multiple surgical survival procedures contain justification of multiple surgical procedures and how outcomes will be evaluated (<i>Guide</i>, <a href="#">p 30</a>). The IACUC evaluates major versus minor on a case-by-case basis (<i>Guide</i>, <a href="#">p 30</a>). Multiple survival procedure justifications in non-regulated species conform to regulated species standards (<i>Guide</i>, <a href="#">p 30</a>)</p> <p>f) Protocols involving food or fluid restriction (e.g. for behavioral studies) includes how and how often animals are monitored to ensure nutritional needs are met (<i>Guide</i>, <a href="#">p 31</a>), that body weights are taken at least weekly while on restriction (<i>Guide</i> p 31), that daily written records are maintained and where these are kept (<i>Guide</i> p 31).</p> <p>g) Pharmaceutical grade chemicals are used , when available, for animal-related procedures (<i>Guide</i>, <a href="#">p 31</a>) and non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (<i>Guide</i>, <a href="#">p 31</a>)</p> <p>h) Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (<i>Guide</i>, <a href="#">p 32</a>)</p> <p>i) Disposition plans are considered for species removed from the wild (<i>Guide</i>, <a href="#">p 32</a>)</p> <p>j) Toe-clipping only used when no alternative, performed aseptically and with pain relief (<i>Guide</i>, <a href="#">p 75</a>)</p>

**IACUC RECORDS AND REPORTING REQUIREMENTS**

NA	A	M	S	C	<u>Reports to Institutional Official:</u>
	X				Submits report on semiannual program reviews and facility inspections, which includes minority IACUC views, every 6 months to the IO (PHS Policy, <a href="#">IV.B.</a> )
	X				Compiles program review and facility inspection(s) results (includes all program and facility deficiencies). Report distinguishes significant from minor deficiencies and includes plan and schedule for correction of each deficiency identified and includes minority IACUC views
	X				Report describes departures from Guide or PHS Policy and reason(s) for departure
NA	A	M	S	C	<u>Reports to OLAW/USDA</u>
	X				Annual reports include any minority IACUC views in relation to semiannual reviews (PHS Policy, <a href="#">IV.F.</a> )
	X				Annual reports to OLAW and USDA are complete providing all required information
	X				Promptly advises OLAW of serious/ongoing Guide deviations or PHS Policy noncompliance ( <a href="#">NOT-OD-05-034</a> )
	X				USDA reporting mechanism in place for IACUC-approved exceptions to regulations and standards (Included in report to IO and in annual report to USDA)
	X				Promptly advises OLAW and/or USDA of any suspension of activity by the IACUC as appropriate ( <a href="#">NOT-OD-05-034</a> )
	X				Reports to OLAW and/or USDA, within 15 days, failure to adhere to timetable for correction of deficiencies
NA	A	M	S	C	<u>Records (PHS Policy, <a href="#">IV.E.</a>):</u>
	X				Minutes of IACUC meetings and semiannual reports maintained for 3 years
	X				IACUC review documentation maintained for 3 years after end of study
	X				IACUC review of activities involving animals includes all required information
NA	A	M	S	C	<u>Personnel Security</u> <b>NEW</b>
	X				Preventive measures in place include pre-employment screening, and physical and IT security ( <i>Guide</i> , <a href="#">p 23</a> )
NA	A	M	S	C	<u>Investigating &amp; Reporting Animal Welfare Concerns</u> <b>NEW</b>
	X				Preventive measures in place include pre-employment screening, and physical and IT security ( <i>Guide</i> , <a href="#">p 23</a> )
	X				Methods for investigating and reporting animal welfare concerns are established ( <i>Guide</i> , <a href="#">p 23</a> ) <b>[must]</b>
	X				Reported concerns and corrective actions are documented ( <i>Guide</i> , <a href="#">p 24</a> )
	X				Mechanisms for reporting concerns are posted in facility and at applicable website with instructions ( <i>Guide</i> , <a href="#">p 24</a> )
	X				Includes multiple contacts ( <i>Guide</i> , <a href="#">p 24</a> )
	X				Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection ( <i>Guide</i> , <a href="#">p 24</a> )

## PERSONNEL QUALIFICATIONS AND TRAINING (INCLUCING IACUC)

NA	A	M	S	C	General Considerations
	X				Institution has established and implemented an effective training program. <b>Training is documented</b> ( <i>Guide, p 15</i> )
	X				All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: <b>[must]</b> <ul style="list-style-type: none"> <li>• Training program includes IACUC and veterinary/ professional/management/supervisory personnel (<i>Guide, p 15-17</i>)</li> <li>• Training program includes animal care personnel (<i>Guide, p 16</i>)</li> <li>• Training program includes research investigators, instructors, technicians, trainees, students (<i>Guide, pp 16-17</i>)</li> </ul>
	X				Continuing education for program and research staff provided to ensure high quality care and reinforce training ( <i>Guide, pp 16-17</i> )
	X				Training is available prior to starting animal activity ( <i>Guide, p 17</i> )
NA	A	M	S	C	Training program content includes( <i>Guide, p 17</i> ):
	X				Humane practices of animal care (housing, husbandry, handling, etc.)
	X				Humane practices of animal use (research procedures, use of anesthesia, pre/post op care, aseptic surgical techniques and euthanasia ( <i>Guide, p 17</i> ) )
	X				Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, <a href="#">IV.A.1.g.</a> )
	X				Research/testing methods that minimize animal pain or distress (PHS Policy, <a href="#">IV.A.1.g.</a> )
	X				Use of hazardous agents, including access to OSHA chemical hazard notices where applicable. ( <i>Guide, p 20</i> )
	X				Specific training on waste anesthetic gas.
	X				Methods for reporting concerns ( <i>Guide, p 17</i> )
	X				Animal care and use legislation, IACUC function, Ethics of animal use and Three R's ( <i>Guide, p 17</i> ),
NA	A	M	S	C	IACUC Member training includes:
	X				Formal orientation to institution's program ( <i>Guide, p 17</i> )
	X				Training on legislation, regulations, guidelines, and policies ( <i>Guide, p 17</i> )
	X				Training on how to inspect facilities and labs where animal use or housing occurs ( <i>Guide, p 17</i> )
	X				Training on how to review protocols as well as evaluate the program ( <i>Guide, p 17</i> )
	X				Ongoing training/education ( <i>Guide, p 17</i> )

# OCCUPATIONAL HEALTH AND SAFETY PERSONNEL

NA	A	M	S	C	<u>Institutional Program For A Safe And Healthy Workplace</u>
	X				Program is established and implemented and is consistent with federal, state, and local regulations ( <i>Guide, p 17</i> ) [must]
	X				Covers all personnel who work in laboratory animal facilities ( <i>Guide, p 18</i> )
	X				Based on hazard identification and risk assessment (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) ( <i>Guide, p 20</i> )
	X				Personnel training (pregnancy/illness/immunosuppression/allergy precautions, zoonoses, hazards)
	X				Personal hygiene procedures are in place and posted (work clothing, eating/drinking/smoking policies) ( <i>Guide, p 20</i> )
	X				Procedures in place for use, storage and disposal of hazardous biologic, chemical, and physical agents ( <i>Guide, p 21</i> )
	X				Specific procedures for personnel protection (shower/change facilities, injury prevention) ( <i>Guide, p 19</i> )
	X				Personal Protective Equipment for the work area is appropriate and available ( <i>Guide, p 21</i> ) (e.g., Hearing protection is provided in high noise areas ( <i>Guide, p 22</i> ) and Respiratory protection is available when performing airborne particulate work ( <i>Guide, p 22</i> )) and Hazardous facilities are separated from other areas and identified as limited access ( <i>Guide, p 19</i> )
NA	A	M	S	C	<u>Program For Medical Evaluation And Preventive Medicine For Personnel</u>
	X				Pre-employment evaluation including health history ( <i>Guide, p 22</i> )
	X				Immunizations as appropriate (rabies, tetanus, etc.) and tests ( <i>Guide, p 22</i> )
	X				Zoonosis surveillance as appropriate (Q-fever, tularemia, Hantavirus, plague, etc.) ( <i>Guide, p 23</i> )
	X				Promotes early diagnosis of allergies including preexisting conditions ( <i>Guide, p 22</i> )
	X				Considers confidentiality and other legal factors as required by federal, state and local regulations ( <i>Guide, p 22</i> ) [must]
	X				Occupational safety and health of field studies is reviewed by OSH committee or office ( <i>Guide, p 32</i> )
NA	A	M	S	C	<u>Procedures for reporting and treating injuries, including bites, etc. (<i>Guide, p 23</i>)</u>
	X				Special precautions for personnel who work with primates and/or primate serum, tissues or bodily fluids ( <i>Guide, p 21 and 23</i> , to include tuberculosis screening provided for all exposed personnel, appropriate PPE according to species, and appropriate care if exposure occurs according to species.
	X				Training and implementation of procedures for needle sticks and splashes
	X				Education regarding <i>Cercopithecine herpesvirus 1</i> (Herpes B) for personnel working with macaque serum or tissues, to include Training and implementation of procedures for bites, scratches, or injuries associated with macaques and Injuries associated with use of macaque tissues/fluids are carefully evaluated and treatment implemented

### GENERAL VETERINARY CARE

NA	A	M	S	C	General Considerations
	X				Institutional arrangement for veterinarian with training or experience in lab animal medicine, including in species used ( <i>Guide, p 15</i> ) [must], and in facility administration/management ( <i>Guide, p 15</i> )
	X				Veterinary access to all animals ( <i>Guide, p 14</i> ) [must]
	X				Provision for backup veterinary care. Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use ( <i>Guide, p 14</i> ) [must]. If part time /consulting veterinarian, visits meet programmatic needs ( <i>Guide, p 14</i> ) and regular communication occurs between veterinarian and IACUC ( <i>Guide, p 14</i> )
	X				Veterinarian provides guidance on handling, immobilization, sedation, analgesia, anesthesia, euthanasia
	X				Veterinarian provides guidance/oversight on surgery programs and oversight of post-surgical care
	X				Veterinary authority to oversee all aspects of animal care and use
	X				Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol ( <i>Guide, p 5</i> ) [must] and provides consultation when interventional control is not possible ( <i>Guide, p 5</i> ) [must]

### VETERINARY MEDICAL CARE

NA	A	M	S	C	Clinical Care and Management <b>NEW</b>
	X				Veterinary program offers high quality of care and ethical standards ( <i>Guide, p 105</i> ) [must]
	X				Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia ( <i>Guide, p 106</i> )
	X				Veterinarian provides oversight to surgery and perioperative care ( <i>Guide, p 106</i> )
	X				Veterinary care program is appropriate for program requirements ( <i>Guide, pp 113-114</i> )
	X				Vet (s) is familiar with species and use of animals and has access to medical and exp. treatment records ( <i>Guide, p 114</i> )
	X				Procedures to triage and prioritize incident reports are in place ( <i>Guide, p 114</i> )
	X				Procedures are in place to address: Problems with experiments to determine course of treatment in consultation with investigator( <i>Guide, p 114</i> ) Recurrent or significant health problems with the IACUC and doc. of treatments and outcomes ( <i>Guide, p 114</i> ) Veterinary review and oversight of medical and animal use records ( <i>Guide, p 115</i> )
	X				Procedures established for timely reporting of animal injury, illness, or disease ( <i>Guide, p 114</i> ) [must]
	X				Procedures established for veterinary assessment, treatment, or euthanasia ( <i>Guide, p 114</i> ) [must]
	X				Veterinarian is authorized to treat, relieve pain, and/or euthanize ( <i>Guide, p 114</i> ) [must]



NA	A	M	S	C	Preventive Medicine/Animal Procurement & Transportation
	X				Evaluation of animal vendors ( <i>Guide</i> , <a href="#">p 106</a> )
	X				Procedures for lawful animal procurement ( <i>Guide</i> , <a href="#">p 107</a> ) [must], evaluation of animals, and transport ( <i>Guide</i> , <a href="#">p 106</a> ), to include linking procurement to IACUC approval, sufficient expertise and facilities confirmed prior to procurement, appropriate procurement records maintained, movement of animals is planned to minimize transit time, ensure safety and minimize risk and deliveries are planned to ensure receiving personnel are available ( <i>Guide</i> , <a href="#">pp 107- 108</a> ) at appropriate receiving facilities ( <i>Guide</i> p 109)
	X				Breeding colonies are based on need and managed to minimize numbers ( <i>Guide</i> , <a href="#">p 107</a> )
	X				Procedures for quarantine, stabilization/acclimation to include zoonoses prevention ( <i>Guide</i> , p110, 111)
	X				Procedures for compliance with animal transportation regulations, including international requirements, are in place ( <i>Guide</i> , <a href="#">p 107</a> ) [must],
	X				Procedure on separation by species, source, health status ( <i>Guide</i> , <a href="#">pp 109, 111-112</a> )
	X				Procedure for isolation of sick animals ( <i>Guide</i> , <a href="#">p 112</a> )
	X				Program of surveillance, diagnosis, treatment, and control of disease to include daily observation ( <i>Guide</i> , <a href="#">p 112</a> )
	X				Availability of diagnostic resources for preventive health program ( <i>Guide</i> , <a href="#">p 112</a> )
	X				Provision for emergency, weekend, and holiday veterinary care
NA	A	M	S	C	Surgery
	X				Procedures for monitoring surgical anesthesia and analgesia, including assessment of surgical outcomes and making corrective changes when needed ( <i>Guide</i> , <a href="#">p 115</a> )
	X				Pre-surgical plan (identify space, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping, conduct pre-op exam, define post-op care) includes veterinary input ( <i>Guide</i> , p116)
	X				Appropriate training or experience of personnel in surgery and anesthesia to ensure good technique and ensure appropriate monitoring of surgical anesthesia and analgesia ( <i>Guide</i> , <a href="#">p 115, 119</a> ) [must]
	X				Major procedures distinguished from minor ( <i>Guide</i> , <a href="#">pp 117-118</a> )
	X				Use of effective aseptic procedures for survival surgery ( <i>Guide</i> , <a href="#">pp 118-119</a> )
	X				Aseptic surgery is conducted in dedicated facil. or spaces, unless exception justified and IACUC approved ( <i>Guide</i> , <a href="#">p 116</a> )
	X				Implemented procedures for using/scavenging volatile anesthetics
	X				Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs ( <i>Guide</i> , <a href="#">p 119</a> )
	X				Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) ( <i>Guide</i> , <a href="#">pp 119-120</a> )




	X				For nonsurvival surgery (excluding perfusion or acute tissue collection), the site is clipped, gloves are worn and instruments and area are clean ( <i>Guide</i> , <a href="#">p 118</a> )
	X				For aquatic species, skin surfaces are kept moist during surgical procedures ( <i>Guide</i> , <a href="#">p 119</a> )

NA	A	M	S	C	<u>Pain, Distress, Analgesia, And Anesthesia</u>
	X				Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training ( <i>Guide</i> , <a href="#">p 121</a> )
	X				Guidelines for avoiding unnecessary pain and distress, including monitoring painful procedures to ensure appropriate analgesic management ( <i>Guide</i> , <a href="#">p 122</a> ) and procedures to assure antinoception before surgery begins ( <i>Guide</i> , <a href="#">p 122</a> ) [must]. Nonpharmacologic control of pain is considered as an element of postprocedural care ( <i>Guide</i> , <a href="#">p 122</a> )
	X				Appropriate anesthetics, analgesics, tranquilizers used for each species
	X				Special precautions for the use of paralytics are in place to ensure anesthesia ( <i>Guide</i> , <a href="#">p 123</a> )
	X				Selection of analgesics and anesthetics is based on professional veterinary judgment ( <i>Guide</i> , <a href="#">p 121</a> ). Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated ( <i>Guide</i> , <a href="#">p 122</a> )
NA	A	M	S	C	<u>Euthanasia</u>
	X				Compliance with current AVMA Panel on Euthanasia unless approved by the IACUC ( <i>Guide</i> , <a href="#">p 123</a> )
	X				Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species ( <i>Guide</i> , <a href="#">pp 123-124</a> )
	X				Training available for personnel in humane methods of euthanasia and considers psychological stress to personnel ( <i>Guide</i> , <a href="#">p 124</a> ), and includes methods and procedures to ensure death is confirmed ( <i>Guide</i> , <a href="#">p 124</a> ) [must]
NA	A	M	S	C	<u>Drug Storage And Control</u>
	X				Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely ( <i>Guide</i> , <a href="#">p 122</a> )
	X				Program complies with federal regulations for human and veterinary drugs( <i>Guide</i> , <a href="#">p 115</a> ) [must]
	X				Drug records and storage procedures are reviewed during facility inspections ( <i>Guide</i> , <a href="#">p 115</a> )
	X				Procedures are in place to ensure drugs, including analgesics and anesthetics are used within expiration date ( <i>Guide</i> , <a href="#">p 122</a> ) [must]

Identify Approved Departures and State the Reasons	
Explanation of Deficiencies	
Describe the location and nature of any <u>minor</u> deficiencies. Where deficiencies are noted, indicate the date by which the deficiency must be remedied, and the person responsible for remediation.	
Describe the location and nature of any <u>significant</u> deficiencies. Where deficiencies are noted, indicate the date by which the deficiency must be remedied, and the person responsible for remediation.	

Participants in Inspection: M. Bray, D. Van Etton, J. Jancovich

IACUC Chair signature: 

Date of Inspection: 6/10/2021