

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

**Policies and Guidelines for Post-Approval Protocol Audits**

**Performance Standard:** The goal of compliance monitoring/protocol audits is to improve communications between the IACUC and the UCSD animal investigators and their staff to confirm accurate and consistent protocol description of animal use.

**Background:** A continuing program to audit approved animal use protocols is an essential component of a comprehensive Animal Care and Use program. Such a program provides an excellent method of ensuring institutional regulatory compliance, facilitating research activities, and giving investigators an opportunity to discuss concerns and or changes needed in active projects. The process also allows for a thorough inspection of individual laboratories, and all animal-related procedures performed and agents used therein. Also, this process provides the opportunity to meet with personnel actively engaged in animal-based research giving a personalized review of relevant IACUC policies, observations of techniques, and provision of specific training.

**Policy Expectations:** The goal of the post-approval audit program is to review active protocols on a regular basis.

**Selection of Protocols:**

Selection of protocols include a cross section of species and pain categories (C, D, E), with an emphasis on the following categories:

- 1) All studies classified as Pain Category E.
- 2) Studies involving USDA-covered species, especially socially sensitive species, such as dogs, cats, rabbits, and nonhuman primates.
- 3) Studies or groups that have had past compliance issues and need regular close oversight.
- 4) Studies or groups the IACUC or veterinarians designate for review.
- 5) Projects that require the use of a satellite facilities.

**Principal Investigator Notification:**

The Principal Investigator (PI) will receive notification about 1 month in advance that the protocol will be audited. In addition to the notice, they also receive a copy of the Audit of Approved Animal Care and Use Protocol checklist. This allows the PI sufficient time to gather relevant information as outlined in the checklist, review the protocol, and prepare for the meeting. A follow-up phone call is placed about one week after the notification letter to schedule the protocol audit meeting and answer any questions the PI may have. In addition to the PI, all protocol participants should attend the protocol audit meeting. The audit may take place in the PI's office, laboratory, a nearby conference room, or during a planned experiment.

**Pre-review of the Protocol**

Before the meeting, the Animal Welfare Specialist will review the animal use protocol, using the 'Audit of Approved Animal Care and Use Protocol' checklist. The Animal Welfare Specialist must read and have thorough knowledge of the animal use protocol and any approved amendments before the audit meeting. During the pre-review process, the Animal Welfare Specialist can formulate specific questions for the PI for use during the audit meeting. Areas of interest in the protocol can be highlighted for inspection or review during the meeting.

**Process of monitoring:**

2. The Animal Welfare Specialist shall send the PI on the Protocol a standard notification letter advising the PI of the necessity for protocol post approval compliance monitoring. This letter shall include the name of the Animal Welfare Specialist who will officiate the audit, cite regulatory requirements, and be signed by the IACUC chair. A copy of the current monitoring checklist is attached for PI edification.

3. The Animal Welfare Specialist will then contact the PI by phone setting up a mutually agreeable meeting date to commence within 30 (thirty days). Note: Occasionally circumstances may require a longer period due to holidays, vacations, experimental planning, etc. These will be approved on a case by case basis.
4. The Animal Welfare Specialist shall use the IACUC approved "Audit of Approved Animal Care and Use Protocol" checklist for the activity review (attached). Prior to the scheduled audit, the protocol is reviewed by the Animal Welfare Specialist, and specific notes for discussion with the PI are compiled. Any conditions or special requirements of the IACUC are also gathered.
5. During each monitoring session, the Animal Welfare Specialist will compare procedures conducted in the laboratory with those listed in the approved protocol. Documented discrepancies (See Below between the procedures performed in the lab and those listed in the protocol will be brought to the attention of the PI. Such discrepancies may include:
  - a. Personnel performing procedures are not listed in the approved protocol.
  - b. Procedures performed in the lab are not listed in the approved protocol.
  - c. Anesthetics, analgesics, tranquilizers, antibiotics, or other medications used in the lab are not noted in the protocol, are different from those listed in the protocol, or are not used in accordance with the protocol.
  - d. Procedures listed in the protocol to promote animal welfare (e.g. post-op monitoring procedures) are not being performed, or documented, as approved in the protocol.
  - e. Survival surgery is not performed aseptically.
  - f. Euthanasia procedures that differ from those listed in the protocol and/or a method for ensuring death (e.g. after CO2 exposure) are not employed.
  - g. Lab personnel appear to lack the necessary training to appropriately perform procedures listed in the protocol.
  - h. Supporting documentation for animal care, post-op care, or other study procedures is incomplete or unavailable.
  - i. Conditions are not safe for humans and/or animals.
  - j. Outdated materials (drugs, experimental agents, suture, sterile supplies, etc.) are used.
  - k. Equipment (e.g. anesthetic vaporizers) in use is not calibrated.
6. Animal misuse, mistreatment or neglect or willful disregard for appropriate animal care will be immediately reported to the IACUC Chair, the Attending Veterinarian and the Director of the Animal Welfare Program. The AWP Director will gather information to present to the IACUC for further investigation and review. Corrective action will be determined by the IACUC.

#### **Process of Sharing Information Concerning the Review:**

7. When possible, the Animal Welfare Specialist shall discuss the audit results with the Principal Investigator and other lab personnel before leaving the laboratory.
8. Any animal welfare concerns raised during the audit will be referred to the appropriate individual within the ACP or AWP for resolution.
9. The Animal Welfare Specialist shall send a final written report of the monitoring results to the Principal Investigator, Lab Manager, and IACUC File. A formal report of all protocol audits is presented to the IACUC Executive Subcommittee by the Animal Welfare Specialists on a monthly basis.

#### **Process of Follow-up:**

10. The Animal Welfare Specialist will follow up on any issues raised during a protocol audit that requires protocol modifications, orientation of new personnel, or additional training. The Animal Welfare Specialist will support the laboratory corrective action by providing required training, or insuring that training is conducted by the ACP Training Coordinator, EH&S Vivarium Safety Officer, Controlled Substances Officer, or other appropriate trainer.
11. If Protocol modification is required, the Animal Welfare Specialist will follow up to insure that a Protocol Amendment is submitted in time for the next IACUC meeting and will be available to respond if the PI has questions on the Amendment submission process.
12. On occasion, additional monitoring sessions may be part of the follow-up to assist with proper corrective actions. These will be scheduled as appropriate for the situation.
13. In most cases, issues raised during the audit shall be addressed by:
  - a. Amending an existing protocol, or
  - b. Reverting to the procedures which are already listed in the approved protocol.

#### **Process for PI Appeal:**

14. Investigators who disagree with the audit results and/or recommendations may appeal to the IACUC. This can be done by following the steps below:
  - a. Send an e-mail to [iacuc@uscd.edu](mailto:iacuc@uscd.edu). The information will be passed on to the IACUC Executive Subcommittee for review. This may result in one of the following:
    - 1) A response from the Subcommittee either upholding the audit report or recommending modification of the original findings.
    - 2) A request for the PI to appear at a meeting with the IACUC Executive Subcommittee to present their case or
    - 3) A request to for the PI to appear before the convened IACUC at the next meeting to present their case.

**Recordkeeping:**

15. A copy of the final electronic compliance monitoring report shall be kept in the online audit file located at f:/compliance/audits/audit year folder.
16. A hard copy shall be maintained in the audit folder located in the compliance file cabinet.
17. All audit files shall be maintained for 10 years.

UCSD Institutional Animal Care and Use Committee  
**Audit of Approved Animal Care and Use Protocol**

Principal Investigator: \_\_\_\_\_  
 Protocol # \_\_\_\_\_ Species: \_\_\_\_\_ Effective Dates: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date of Protocol Audit: \_\_\_\_\_ Audited by: \_\_\_\_\_  
 Number of animals approved: \_\_\_\_\_ Number ordered to date: \_\_\_\_\_ Breeding colony? \_\_\_\_\_

				<b>Protocol and Personnel</b>
1.	Y	N	n/a	Do the PI and personnel all have access to the most recent version of this protocol and (any) amendments?
2.	Y	N	n/a	Do the PI and personnel have accurate knowledge of the protocol?
3.	Y	N	n/a	Are all personnel who handle animals listed on the protocol?
4.	Y	N	n/a	Have all personnel completed the Risk Assessment Questionnaire and enrolled in the Occupational Health Medical Surveillance program as necessary?
5.	Y	N	n/a	Are all Personnel Qualifications forms up to date, training completed and courses completed?
6.	Y	N	n/a	If this protocol has USDA-covered animals, is the Policy 12 narrative adequate?
7.	Y	N	n/a	Is each room where animals are taken listed on the Animal Use Protocol?
				<b>Study Procedures</b>
8.	Y	N	n/a	If the protocol has a condition, has it been met?
9.	Y	N	n/a	Are the procedures used the same as those described in the protocol?
10.	Y	N	n/a	Are the species, strain, ages, and numbers of animals consistent with those in the approved protocol?
11.	Y	N	n/a	Have amendments been submitted for any changes in procedure?
				<b>Anesthesia &amp; Analgesia</b>
12.	Y	N	n/a	Are the methods of anesthesia in compliance with what is written in the protocol?
13.	Y	N	n/a	Are pharmaceutical grade compounds being used for anesthesia (unless otherwise approved in the protocol)?
14.	Y	N	n/a	Are anesthetized animals being monitored according to what is written in the protocol?
15.	Y	N	n/a	Is animal's body temperature maintained adequately throughout surgery and recovery with approved devices?
16.	Y	N	n/a	If inhalant anesthetics are used, are they scavenged properly?
17.	Y	N	n/a	Is analgesic used for painful procedures and/or surgeries (or is there a scientific justification for not using analgesia)?
18.	Y	N	n/a	Are analgesic dosages, frequency, and routes of administration accurately recorded?
				<b>Rodent Surgery</b>
19.	Y	N	n/a	Is there a clean uncluttered dedicated area for surgeries?
20.	Y	N	n/a	Is the surgeon properly trained in anesthetic, surgical, and post-operative monitoring techniques?
21.	Y	N	n/a	Do the surgeon(s) wear clean gloves during surgery?
22.	Y	N	n/a	Is the operative field shaved (or is there an IACUC-approved exception)?
23.	Y	N	n/a	Is an antiseptic solution such as povidone iodine applied to the surgical site?
24.	Y	N	n/a	Are disinfected instruments being used (glass bead sterilizer or bacteriocidal solution)?
25.	Y	N	n/a	Are implanted devices sterilized before use?
26.	Y	N	n/a	Is there an appropriate recovery area for this species?
				<b>Survival Large Animal (Non-Rodent Mammalian) Surgery</b>
27.	Y	N	n/a	Are surgical procedures being performed in a surgical suite approved by the IACUC?
28.	Y	N	n/a	Are all personnel familiar with UCSD Policies and Guidelines for Surgery?

29.	Y	N	n/a	Is surgery done using aseptic technique as described in UCSD Policies and Guidelines for Surgery?
30.	Y	N	n/a	Are all drugs, fluids, suture, etc within the expiration dates?
31.	Y	N	n/a	Are scheduled drugs stored under double lock and key and with appropriate records?
32.	Y	N	n/a	Do surgeon(s) wear mask, shoe covers, cap, sterile gloves and gown?
33.	Y	N	n/a	Is surgical scrub/hand wash performed?
34.	Y	N	n/a	Are sterile drapes used?
34.	Y	N	n/a	Are all instruments sterilized? (autoclave, ethylene oxide)?
36.	Y	N	n/a	Is there only one major surgery performed on each animal (unless prior approval by IACUC)?
				<b>Post-Surgical Care</b>
37.	Y	N	n/a	Is post-surgical care in compliance with UCSD Policies and Guidelines for Surgery, UCSD Post-Anesthetic Monitoring Guidelines & with the protocol?
38.	Y	N	n/a	Is it indicated where animals are recovered?
39.	Y	N	n/a	Is the frequency of monitoring adequate? Are animals monitored until conscious and sternal?
40.	Y	N	n/a	Are the criteria for cessation of monitoring indicated and clear?
41.	Y	N	n/a	Is the analgesia used consistent with that described in the protocol?
42.	Y	N	n/a	Is the post-surgical care adequately documented?
43.	Y	N	n/a	Are surgical sutures or staples removed at appropriate interval, no later than 14 days?
44.	Y	N	n/a	Are post-operative problems reported to the ACP veterinary staff?
				<b>Euthanasia</b>
45.	Y	N	n/a	Does the method of euthanasia correspond with what is written in the protocol?
46.	Y	N	n/a	Are animal carcasses disposed of promptly and correctly?
47.	Y	N	n/a	Is the final disposition of the animal recorded?
				<b>Breeding Colony</b>
48.	Y	N	n/a	Are animals weaned at appropriate time?
49.	Y	N	n/a	Are animals separated into appropriate size cages in a timely manner?
50.	Y	N	n/a	Are all mating, birth and weaning records kept up to date according to UCSD Policy on Breeding Colonies?
51.	Y	N	n/a	Is the Monthly Breeding Colony Report turned into AWP in a timely manner?
				<b>General Record-Keeping</b>
52.	Y	N	n/a	Are animals identified by protocol number and individual ID number?
53.	Y	N	n/a	Are medical/observational/treatment notes complete and adequate?
54.	Y	N	n/a	Are treatments such as antibiotics recorded (dosages, frequency, route, date, time, initials)?
55.	Y	N	n/a	Is there a surgical log? Is it up to date?
56.	Y	N	n/a	Is there an up to date inventory of the number of animals used in each pain category on the protocol?
57.	Y	N	n/a	Are injections, blood/tissue/fluid collections recorded (amount, date, initials)?
				<b>Satellite Facilities</b>
58.	Y	N	n/a	Is there an IACUC-approved exception to the 12 hour limit on animals in laboratories?
59.	Y	N	n/a	Do animals removed from the vivarium always have a removal date, time and initials?
60.	Y	N	n/a	Are daily observations recorded in a husbandry log?
61.	Y	N	n/a	Are animals monitored daily including weekends and holidays?
62.	Y	N	n/a	Are daily health observations recorded?
63.	Y	N	n/a	Are sick animals reported to the veterinary staff according to SOPs and approved Animal Use Protocol?
64.	Y	N	n/a	Is food dated and stored in vermin-proof container as required?

Attach extra pages to explain the details of any questions answered "No"