

ROGER WILLIAMS UNIVERISTY

SEMIANNUAL PROGRAM & FACILITY REVIEW CHECKLIST

INTRODUCTION

Many institutions have sought guidance on how to conduct adequate semiannual reviews of institutional programs and facilities for the care and use of animals as required by the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy). This PHS Policy requirement, found at IV.B.1 &2., states that, at least once every six months, the Institutional Animal Care and Use Committee (IACUC) will review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities. The *Guide for the Care and Use of Laboratory Animals (Guide)* contains the standards and benchmarks to be used as a basis for evaluation.

This sample checklist is a tool designed to assist IACUCs in conducting thorough semiannual reviews. The sample checklist covers the major topics of the *Guide*, and the requirements of the PHS Policy. Endnotes are included to reference specific United States Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy.

This checklist does not replace the *Guide*; it should be utilized in conjunction with the *Guide* which contains the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program.

This checklist is provided only as a suggestion. **USE OF THIS CHECKLIST IS NOT MANDATORY.** OLAW encourages institutions to try this checklist, to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist.

OLAW is interested in your comments on the usefulness of this checklist and any suggestions for revision. We consider this document to be dynamic, subject to change as institutions provide feedback on their experiences with it. Suggestions or comments about this checklist should be sent to: olaw@od.nih.gov.

INSTRUCTIONS FOR CHECKLIST

The IACUC has a mandate to review at least once every six months the institution's program for the care and use of animals using the *Guide* as a basis for evaluation. The program review section is titled Sample Semiannual Program Review Checklist. This program review section is further divided into Institutional Policies and Responsibilities that corresponds to Chapter One of the *Guide*, and Veterinary Medical Care that corresponds to Chapter Three of the *Guide*. It is recommended that the program review section be completed during an IACUC meeting.

The IACUC is also charged with inspecting at least once every six months all of the institution's animal facilities, including satellite facilities, using the *Guide* as a basis for evaluation. The second half is titled ample Semiannual Facility Inspection Checklist and corresponds to Chapters Two and Four of the *Guide*. This section is further divided into: animal housing and support areas; cagewash; aseptic surgery; and procedure areas, non-survival surgeries, laboratories, and rodent surgeries. Because these are physical aspects of a program that require visual observation to evaluate, it is recommended that this section be completed during an inspection of facilities. There is an additional page on which to record observations during the facility inspection.

A table is provided, titled Sample Semiannual Program and Facility Review Report. It is intended to suggest a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. Some IACUCs may wish to attach the table to the report to the Institutional Official.

SEMIANNUAL PROGRAM REVIEW CHECKLIST ¹ INSTITUTIONAL POLICIES AND RESPONSIBILITIES

DATE:

1. IACUC MEMBERSHIP AND FUNCTIONS			
- institution provides training and resources to assist IACUC members in understanding and evaluating issues brought before the committee			
- at least 5 members, appointed by CEO			
- members include veterinarian, scientist, non-scientist, and non-affiliated non-lab animal user ²			
- responsible for oversight and evaluation of institution's program			
- reports to Institutional Official (IO)			
- conducts semiannual evaluations of institutional animal care and use program			
- conducts semiannual inspections of institutional animal facilities			
- reviews and investigates concerns about animal care and use at institution ³			
- procedures for review, approval and suspension of animal activities ⁴			
- procedures for review & approval of significant changes to approved activities			
- policies for special procedures (e.g. restraint, multiple survival surgery, fluid restriction) ⁵			
2. IACUC RECORDS AND REPORTING REQUIREMENTS⁶			
Reports to Institutional Official (IO)			
- reports of semiannual program reviews & facility inspections are submitted to IO ⁷			
- include minority IACUC views			
- describe departures from <i>Guide</i> or PHS Policy and reasons for departure ⁸			
- distinguish significant from minor deficiencies			
- include plan and schedule for correction of each deficiency identified ⁹			
Reports to Office of Laboratory Animal Welfare (OLAW)			
- reports include any minority IACUC views			
- annual report to OLAW documents program changes & dates of IACUC semiannual review			
- promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or <i>PHS Policy</i> noncompliance			
- promptly advises OLAW of any suspension of activity by the IACUC			
Reports to United States Department of Agriculture (USDA)			
- annual report contains required information			
- reporting mechanism in place for IACUC-approved exceptions to the regulations and standards			
- reports within 15 days failure to adhere to timetable for correction of deficiencies			
- reports suspension of activity by the IACUC to USDA and any Federal funding agency			
Records			
- minutes of IACUC meetings and semiannual reports maintained for 3 years			
- IACUC review documentation maintained for 3 years after end of study			
- IACUC review of activities involving animals includes all required information ¹⁰			
3. VETERINARY CARE (See also next section - Veterinary Medical Care)			
- institutional arrangement for veterinarian with training or experience in lab animal medicine ¹¹			
- veterinary access to all animals			
- provision for backup veterinary care			
- must provide guidance on handling, immobilization, sedation, analgesia, anesthesia, euthanasia			
- must provide guidance/oversight on surgery programs and oversight of postsurgical care			
- veterinary authority to oversee all aspects of animal care and use			

*A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

SEMIANNUAL PROGRAM REVIEW CHECKLIST INSTITUTIONAL POLICIES AND RESPONSIBILITIES (cont.)

DATE:

*A M S

4. PERSONNEL QUALIFICATIONS AND TRAINING			
- institution has established and implemented an effective training program			
- includes professional/management/supervisory personnel			
- includes animal care personnel			
- includes research investigators, instructors, technicians, trainees, students			
Training program content – Animal Users and IACUC members			
- humane practices of animal care (e.g. housing, husbandry, handling) ¹²			
- humane practices of animal use (e.g. research procedures, use of anesthesia, pre- & post-operative care) ¹³			
- research/testing methods that minimize numbers necessary to obtain valid results			
- research/testing methods that minimize animal pain or distress			
- use of hazardous agents, including access to OSHA chemical hazard notices where applicable			
5. OCCUPATIONAL HEALTH AND SAFETY OF PERSONNEL			
Institutional program for a safe and healthy workplace			
- program is established and implemented			
- covers <i>all</i> personnel who work in laboratory animal facilities			
- based on hazard identification and risk assessment			
- personnel training (e.g. zoonoses, hazards, pregnancy/illness/immunosuppression precautions)			
- personal hygiene procedures (e.g., work clothing, eating/drinking/smoking policies)			
- procedures for use, storage & disposal of hazardous biologic, chemical, and physical agents			
- specific procedures for personnel protection (e.g., shower/change facilities, injury prevention)			
Program for medical evaluation and preventive medicine for personnel			
- pre-employment evaluation including health history			
- immunizations as appropriate (e.g. rabies, tetanus) & tests			
- zoonosis surveillance as appropriate (e.g. Q-fever, tularemia, Hantavirus, plague)			
- procedures for reporting and treating injuries, including bites etc.			
6. GRANT CONGRUITY			
7. EMERGENCY MANAGEMENT AND DISASTER PLANNING			
8. POST APPROVAL MONITORING			
Notes:			

*A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

SEMIANNUAL PROGRAM REVIEW CHECKLIST VETERINARY MEDICAL CARE

DATE:

*A M S

1. PREVENTIVE MEDICINE/ANIMAL PROCUREMENT & TRANSPORTATION			
- evaluation of animal vendors or suppliers			
- procedures for lawful animal procurement, evaluation of animals, & transport			
- procedures for quarantine, stabilization			
- policies on separation by species, source, health status			
- policies for isolation of sick animals			
- program of surveillance, diagnosis, treatment and control of disease			
- availability of diagnostic resources for preventive health program			
- provision for emergency, weekend and holiday veterinary care			
2. SURGERY			
- procedures for monitoring surgical anesthesia and analgesia			
- pre-surgical plan (e.g. identify space, supplies, conduct pre-op exam, define post-op care)			
- appropriate training or experience of personnel in surgery & anesthesia			
- major procedures distinguished from minor			
- use of effective aseptic procedures for survival surgery			
- implemented procedures for use of surgical facility			
- implemented procedures for using/scavenging volatile anesthetics			
- effective procedures for sterilizing instruments & monitoring expiration dates on sterile packs			
- documentation of post-operative monitoring and care			
3. PAIN, DISTRESS, ANALGESIA, AND ANESTHESIA			
- guidelines for assessment and categorization of pain			
- IACUC guidelines for avoiding unnecessary pain and distress			
- appropriate anesthetics, analgesics, tranquilizers used for each species			
- special precautions for the use of paralytics ¹⁴			
- veterinary input in the choice of drugs			
4. EUTHANASIA			
- compliance with current AVMA Panel on Euthanasia unless approved by the IACUC			
- guidance provided on appropriate methods for each species			
- training available for personnel in humane methods of euthanasia			
5. DRUG STORAGE AND CONTROL			
- safe, secure, storage arrangement			
- record keeping meets regulations			
- procedures exist for ensuring drugs are within expiration date			
Notes:			

*A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

SAMPLE SEMIANNUAL PROGRAM & FACILITY REVIEW REPORT

DATE:

MEMBERS IN ATTENDANCE:

Deficiency Category (S or M)	*	Location	Deficiency & Plan for Correction	Responsible Party	Correction Schedule & Interim Status	Date Complete

S = significant deficiency, **M** = minor deficiency (a significant deficiency is or may be a threat to animal health or safety)

*Check if repeat deficiency

Endnotes - Selected USDA Regulatory Requirements that Differ from the PHS Policy

¹The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

²Part 2 Subpart C- Research Facilities

- 2.31(b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

³ 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

⁴ 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

⁵ 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

⁶ 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

⁷ 2.31(c)(3) - "...The reports shall be reviewed and signed by a majority of committee members..."[USDA requirement additional]

⁸ 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

⁹ 2.31 (c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the Guide]

¹⁰ [In addition to PHS requirements for IACUC review/application for funding, USDA regulations require]:

2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

2.31(d)(1)(iii) - "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

2.31(d)(1)(iv) - "Procedures that may cause more than momentary or slight pain or distress to the animals will:
- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;"

2.31(d)(1)(x) - "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."

¹¹ 2.33(a)(1) - "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]

¹² 2.32(c) - "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."

¹³ 2.32(c) - additional specifications include:

- “ proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility”
- “ methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility...”
- “ utilization of services (e.g. National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act.” [USDA training specifications are more detailed than PHS Policy].

¹⁴ 2.31(d)(iv)(C) - “ Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia.”

¹⁵ Part 3 Subpart A 3.6(c)(1) - “Each dog housed in a primary enclosure must be provided with a minimum amount of floor space, calculated as follows:
(length of dog in inches + 6)² /144 = required floor space in square feet).

- Part 3 Subpart D 3.80 (b) “Primary enclosures [for nonhuman primates] must meet the minimum space requirements provided in this subpart.”

- In situations where the USDA regulations and the Guide differ with respect to space requirements, the larger of the two must be followed.

¹⁶ Part 3 Subpart A 3.8 - “ ...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition the plan must be approved by the attending veterinarian. The plan must provide written standard procedures...”

¹⁷ Part 3 Subpart D 3.81 - “ ...research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates.”