Semiannual Program Review[1]

Use this checklist and the *Guide for the Care and Use of Laboratory Animals*, (1996 edition) to review the program of animal care and use. This document is intended to aid Animal Care and Use Committees (ACUCs) during the semiannual program review process. It can be used as a whole or in parts to focus the discussion and intensify the detail of the review.

Name of Reviewed Unit:

This review covers the period from:

Reviewers:

INSTRUCTIONS:

Indicate your response by circling the appropriate symbol. Make comments in the margin on the right side or use the back of the page. Comments will become a part of the official program review. Answer to the best of your knowledge. Forms do not need to be typed, but please write or print legibly.

Y = Yes
N = No (Any "No" should be accompanied by a clarifying comment or explanation.)
? = Unable to determine
X = Not Applicable

[1] This checklist is intended to aid ACUCs during semiannual program review. It is not meant as a replacement for the "Semiannual Program Review Checklist" and is not to be submitted with the semiannual report. It is meant as a guide to assist ACUCs to ensure that all aspects of the program are reviewed.

INSTITUTIONAL POLICY

General Requirements

YN?X Does the institution devote sufficient resources to conduct the animal care and use program?
YN?X Is there a functioning animal care and use committee? (See ARAC Guidelines for ACUC Membership and Deliberative Processes)
YN?X Is there at least one trained and experienced veterinarian associated with the program and is he authorized by formal agreement to guide the program of animal care and use?

Are appropriate records maintained?
YN?X for each protocol with a record of the committee's action and date of expiration?
YN?X for each committee meeting?
YN?X for each facility and program review?
YN?X of any outside evaluations?
YN?X regarding any complaints?
YN?X for all other pertinent information?

Monitoring the Care and Use of Animals

Institutional Animal Care and Use Committee
YN?X Is membership in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals and the Animal Welfare Regulations? (See ARAC Guidelines for ACUC Membership and Deliberative Processes)
YN?X Veterinarian
YN?X One practicing scientist experienced in research involving animals
YN?X One public member not an animal user or affiliated with the institution
YN?X One non-scientist
YN?X One Division of Occupational Health and Safety member (See NIH Policy Appointment of Safety & Health Specialists to Animal Care & Use Committees)
YN?X At least one additional member
YN?X Are the members of the IACUC appointed in writing by the Institutional Official (IO)?
YN?X Does the committee have access to the appropriate resources including administrative support sufficient to conduct the duties as required?

Are procedures and policies in place to conduct the following activities of the IACUC:
YN?X Does the committee meet at least once every six months as required?
YN?X Are minutes of these meeting written and filed for future review?
YN?X Are facilities inspected at least once every six months?
YN?X Is the program for the care and use of animals evaluated at least once every six months?
YN?X Are the ARAC Guidelines on Classifying Deficiencies Identified During Semiannual Reviews followed during semiannual program review?
YN?X Is the ARAC IC Collaborations involving Animal Activities Performed inside NIH Core Facilities or Special Procedure Laboratories being practiced?
YN?X Is the ARAC Guidelines for ACUC Oversight of Animal Activities in Shared and Central Facilities being practiced?

Are reports submitted as required:
YN?X To the Institutional Official; Is a written report, signed by a majority of the IACUC members, sent to the IO every six months?
YN?X To USDA (Annually) (See ARAC Guidelines for Preparing USDA Annual Reports)
YN?X To OLAW; at least every 12 months through the IO
YN?X To AAALAC (Annually)
YN?X In these reports are deficiencies listed as either minor or major and is a plan and timeline for correction set forth? (See Guidelines on Classifying Deficiencies Identified During Semiannual

INSTITUTIONAL POLICY

Reviews)

YN?X Are procedures in place to receive and deal with complaints regarding animal care and use?

YN?X Do procedures for dealing with complaints meet ARAC Procedures for Response to Animal Care and Use Complaints from Outside the NIH and Dr. Gottesman's memo concerning communicating animal care and use concerns within the NIH IRP?

Animal Care and Use Protocols

YN?X Has an animal study proposal (ASP) form been developed which asks the appropriate questions for the review process? (See Page 10 of Guide).

YN?X If an IC-specific form is developed, are all elements of the NIH ASP form, including the "Instructions for Emergency Animal Treatment and Care Form", incorporated into the form? (See Attachment 1, Manual 3040-2: Animal Care and Use in the Intramural Program)

YN?X Is the ARAC Guideline Regarding Significant Changes to Animal Study Proposals practiced?

Has special consideration and careful review and justification been made for the following?

YN?X Prolonged restraint.

YN?X Multiple major survival surgeries.

YN?X Food or fluid restriction. (See Page 12 of Guide and ARAC Guidelines for Diet Control in Animal Studies)

YN?X Use of wire bottom caging in rodents.

YN?X Use of inflammatory agents - Complete Freund's Adjuvant (See ARAC Guidelines for the Research Use of Adjuvants)

YN?X LD50 testing (See IRAC Recommendation on LD_{50} Testing)

YN?X Oocyte harvesting in *Xenopus laevis* (See ARAC Guidelines for Egg and Oocyte Harvesting in *Xenopus laevis)*

YN?X Toe clipping of animals (See ARAC Guidelines for Toe Clipping of Rodents)

YN?X Ascites production in Mice (See ARAC Guidelines for Ascites Production in Mice)

YN?X Alleviation of pain and distress (See ARAC Guidelines for Pain and Distress in Laboratory Animals: Responsibilities, Recognition and Alleviation)

YN?X Endpoints in animal studies (See ARAC Guidelines for Endpoints in Animal Study Proposals)

YN?X Survival bleeding in of mice and rats (See ARAC Guidelines for Survival Bleeding of Mice and Rats)

YN?X Genotyping of rodents (See ARAC Guidelines for the Genotyping of Mice and Rats)

Veterinary Care (see separate section)

YN?X Is there an attending veterinarian that has been given direct or delegated authority to ensure that humane needs are met and are compatible with scientific requirements?

YN?X Is there adequate staffing to ensure timely provision of veterinary care?

YN?X Is there timely assessment and resolution of animal welfare issues in accordance with Dr. Gottesman's memo dated May 26, 2005? [See Policy Memo Timely Assessment and Resolution of Animal Issues involving Pain and Distress]

Personnel Qualifications and Training

YN?X Is the animal care staff trained?

YN?X Is the research staff trained?

YN?X Does the ACUC have a process to track training and maintain records of training of animal care staff?

YN?X Does the ACUC have a process to track training and maintain records of training of research staff?

OCCUPATIONAL HEALTH AND SAFETY PROGRAM (OHSaP)

Hazard Identification and Risk Assessment

YN?X Are inherent dangers identified and evaluated? Bites, chemical cleaning agents, allergens, zoonotic diseases, etc.

Is the extent and level of participation in the program based on:
YN?X The type of hazard present?
YN?X Exposure intensity, duration , and frequency?
YN?X Susceptibility of the individual?
YN?X History of problems in the work place?

Personnel Training (OHSaP)

YN?X Is there an appropriate training program?
YN?X Are there clear and defined procedures for conducting the duties of the animal care and use program?

Personal Hygiene

Is personal hygiene encouraged by:
YN?X Providing protective clothing such as uniforms and lab coats?
YN?X Emphasis on hand washing?
YN?X Prohibiting eating, drinking, using tobacco, or applying cosmetics in the vivarium?

YN?X Is a sign in place instructing personnel of this prohibition?
YN?X Is a place provided for doing prohibited activities (break room).
YN?X Are hand washing facilities available?

Facilities, Procedures, and Monitoring

YN?X Are there appropriate facilities, procedures, and monitoring programs in place for the OHSaP?
YN?X Is safety equipment properly maintained and routinely calibrated?

Animal Experimentation Involving Hazards

YN?X Are procedures in place to identify and manage animal experiments that involve the use of hazardous agents such as biological agents, chemicals, carcinogens, and volatile anesthetics?

Personal Protection

YN?X Is the appropriate personal protective equipment provided to employees?
YN?X Is use of this equipment mandatory?
YN?X Is the ARAC Guidelines for Personnel Protection and Minimum Requirements for Protective Clothing in Animal Facilities being practiced as applicable?

Medical Evaluation and Preventive Medicine for Personnel

Do personnel participate in a medical evaluation and are there appropriate preventive medical programs for:
YN?X government employees? (NIH Animal Exposure Program)
YN?X contract employees?

YN?X Are tetanus vaccinations given at appropriate intervals?
YN?X Are other vaccinations given as required?

ANIMAL ENVIRONMENT, HOUSING, AND MANAGEMENT

YN?X Is there a pre-employment physical exam or health history taken and does this aspect of the program involve a medical doctor?
YN?X Are there any periodic medical exams required? If so, are exams accomplished as scheduled?
YN?X Does the research staff participate in the medical evaluation and preventive medicine program?

Physical Environment

Microenvironment and Macroenvironment
YN?X Has consideration been given to the actual environment surrounding the animal as opposed to consideration only for the larger area such as a room?

Housing
YN?X Is housing appropriate to the species involved?
YN?X Is caging in good repair?
YN?X Where possible have wire bottom cages for rodents been eliminated?

Space Recommendations
YN?X Is the space provided for animals in accordance with the Animal Welfare Regulations and the Guide?
YN?X Do all animals have enough space to turn around and to express normal postural adjustments?
YN?X Do all animals have ready access to food and water.
YN?X Do all animals have enough clean bedded or unobstructed area to move and rest?
YN?X Are animals housed in compatible groups where appropriate?
YN?X Do cats have a raised resting surface?

Temperature and Humidity
YN?X Are temperatures maintained in accordance with the Guide, page 32?
YN?X Is humidity controlled to between 30-70% RH?
YN?X Are extremes of temperature or humidity kept to a minimum?
YN?X Are temperature and humidity monitored and is a record maintained?

Ventilation
YN?X Has the system been reviewed by a qualified mechanical engineer? (Recommended Practice)
YN?X Do animal rooms meet the general standard of 10-15 fresh-air changes per hour?
YN?X If not, what other mitigating factors have been considered which make the general standards invalid?
YN?X Have Minimal ventilation rates been established?
YN?X Have unwanted drafts been eliminated?
YN?X Have static-pressure differentials been evaluated?
YN?X Is all of the animal-area air exhausted or recirculated only to animal areas so as to avoid contamination of people areas?
YN?X Have you made any husbandry changes to control ventilation and air quality in static filter-top cages?
YN?X Are animal rooms free of excessive odors indicative of a high level of toxic gases?
YN?X Do you avoid recycled air within the animal areas of the facility?
YN?X Is recycled air returned to only the same room or area?
YN?X Is recycled air HEPA filtered?
YN?X Is recycled air treated to remove toxic gases and odors?
YN?X Are proper temperatures and humidity maintained?
YN?X Does the HVAC system have periodic maintenance and evaluation?

Illumination
Have the following factors been considered with regards to lighting?

ANIMAL ENVIRONMENT, HOUSING, AND MANAGEMENT

YN?X Length of photo period
YN?X Photo intensity
YN?X Quality of light
YN?X Distribution of light
YN?X Are light timers used to control photo periods?
YN?X Is timer performance checked periodically including an after normal hours check?
YN?X Have light levels been evaluated?
Date
Note: 12-30 ft. candles is recommended

Noise
YN?X Are species separated by noise level?
YN?X Has equipment been evaluated for the production of sound outside normal human hearing but which may effect animals?
YN?X Within your facility do you avoid noise above 85dB?
YN?X Are normal operations conducted so as to minimize noise which may affect animals?

Behavioral Management

Structural Environment
YN?X Does the environment enhance animal well-being as appropriate to the species? See Nonhuman Primate Management Plan & Enrichment Strategies for Rodents in the Laboratory)

Social Environment
YN?X Are social animals given the opportunity to interact with other members of the species?
YN?X If housed, is there an enrichment program for non-human primates? (See Nonhuman Primate Management Plan)

Activity
YN?X Do animals (especially higher animals such as dogs, pigs, cats and primates) have the opportunity to exhibit species - typical activity patterns?
YN?X Are higher animals given the opportunity to interact with humans as appropriate?
YN?X Are dogs given the opportunity for additional exercise as required by Animal Welfare Regulations?
YN?X Are other animals given the opportunity to exercise as applicable. (Pens, runs, pastures, exercise lots, etc.)?

Husbandry

Food
YN?X Is food appropriate to the species?
YN?X Is food of high quality and free of contaminants?
YN?X Have the procedures and practices of the feed vendor been evaluated?
YN?X Is shelf life data available and is feed rotated to assure food does not become stale? Generally food is good for 3-6 months.
YN?X Is stored feed protected from vermin?
YN?X Is feed stored off the floor?
YN?X Are storage conditions monitored?
YN?X Are feeds stored below 70°F?
YN?X Are purified and chemically defined diets stored below 39°F?
YN?X Are special autoclavable diets used when required and is the date of autoclaving recorded so that diets are rotated and used quickly?

ANIMAL ENVIRONMENT, HOUSING, AND MANAGEMENT

YN?X Is the transfer of feed-storage containers between areas that pose different risks of contamination avoided?
YN?X Are storage containers cleaned regularly?
YN?X Is the feed of some animals restricted as appropriate? Rabbit, pigs, dogs, cats, NH primates, etc.
YN?X Are "treats" used for enrichment as appropriate?
YN?X Is care taken to assure that the balance of the diet is not altered by excessive treats?
YN?X If food is fed on the floor of a shoebox cage, is this approved in the ASP or in an SOP?
YN?X Are food treats included in an SOP?
YN?X Are food restriction studies conducted in accordance with ARAC Guidelines for Diet Control in Animal Studies?

Water
YN?X Do animals have access to potable drinking water?
YN?X Periodically do you monitor (review reports) for pH, hardness, and microbial and chemical contamination as required by the scientific studies being conducted?
YN?X Are watering devices checked daily?
YN?X Do you avoid refilling water bottles?
YN?X If bottles are refilled are they returned to the same cage?
YN?X Are water restriction studies conducted in accordance with ARAC Guidelines for Diet Control in Animal Studies?
YN?X If water is treated with acid or chlorine, are the chemical levels being monitored?

Bedding
YN?X Do you avoid softwood (pine is a softwood) bedding in those studies that may be effected by the aromatic hydrocarbons they contain?
YN?X Is cedar avoided in all cases?
YN?X Do you evaluate procedures of the bedding vendor?
YN?X Are bedding materials stored in such a way that they are protected from contamination and vermin?
YN?X If autoclaved, is bedding dried before use or storage?

Sanitation
YN?X Is bedding changed often enough to keep animals clean and dry? Usually twice a week for rodents and rabbits in standard caging is appropriate.
YN?X Are pens and runs not using bedding flushed with water at least once daily?
YN?X Are animals kept dry during cage cleaning as appropriate?
YN?X Are cages and accessories such as tops sanitized at least once every other week?
YN?X Are solid bottom cages sanitized at least once a week?
YN?X Are bottles and sipper tubes sanitized at least once a week?
YN?X Are cages treated with acid to remove urine scale as necessary?
YN?X Is the effectiveness of the method of sanitization verified by use of systems such as RODAC plates?
YN?X Are automatic watering systems flushed periodically?
YN?X Are cages autoclaved where appropriate?
YN?X Are autoclaves monitored by systems such as kilits[7]?
YN?X Are cleaning implements dedicated to areas of similar contamination risk?
YN?X Are worn cleaning implements replaced as required?
YN?X Are implements stored in a manner that will facilitate drying and minimize contamination?

Waste Disposal
YN?X Are Medical Pathological Waste boxes used as required?
YN?X Is conventional, biological, and hazardous waste removed and disposed of regularly and safely?
YN?X Are adequate numbers of properly labeled waste receptacles strategically placed throughout the facility?
YN?X Are receptacles leak proof and equipped with tight-fitting lids?
YN?X Are containers cleaned often and regularly?

ANIMAL ENVIRONMENT, HOUSING, AND MANAGEMENT

YN?X Are waste storage areas tidy and free of vermin and insects?
YN?X Are procedures in place for the safe handling of hazardous waste? See page 45 of the Guide.
YN?X Are adequate numbers of sharps containers made available and disposed of when ¾ full?
YN?X Are recapped needles found in the sharps containers?

Pest Control
YN?X Is there a regularly scheduled and documented program of pest control and monitoring?
YN?X Have steps been taken to eliminate harborage (places bugs like to live such as cracks, dark and dirty spaces, and areas of trash and debris) and prevent entry?
YN?X Are the use of chemical pesticides limited and controlled?
YN?X If pesticides are used, is it done in consultation with investigators and its use documented?
YN?X If traps are used, are they checked frequently to assure humane euthanasia after capture?

Emergency, Weekend, and Holiday Care
YN?X Are animals cared for by qualified personnel each and every day?
YN?X Is emergency veterinary care available each and every day?
YN?X Do police and fire agencies have telephone numbers of key personnel?
YN?X Is there a disaster plan and are key personnel included as official responders to emergencies that involve animals?
YN?X Is there adequate staffing of animal husbandry personnel to ensure daily care of all animals?

Population Management

Identification and Records
YN?X Are all animals identified in some manner?

Does identification, including cage cards and animal records associated with the animal's ID, include the following:
YN?X Source of animals
YN?X Strain of stock
YN?X Name and location of responsible P.I.
YN?X Pertinent dates
YN?X Protocol number
YN?X Number of animals
YN?X Age or weight
YN?X Sex
YN?X Are clinical records for individual animals (chronic dogs, cats, pigs, rabbits, NH primates) available as required?
YN?X Are clinical records available near the animals for which they apply?

Genetics and Nomenclature
YN?X Are founding populations of in-house outbred breeding colonies large enough to ensure the long-term heterogeneity of the colony or are other steps taken to ensure heterogeneity?
YN?X Are in-house inbred breeding programs monitored to ensure continued homozygosity?
YN?X Are steps taken to prevent and/or identify contamination resulting from mutation and/or mismating?
YN?X Are transgenic animals managed using standard genetic-management procedures, including the maintenance of detailed records and genetic monitoring to verify the presence and zygosity of transgenes?

VETERINARY CARE

General requirements for adequate veterinary care

YN?X Is there a program of preventive medicine?
YN?X Is there a program for the surveillance, diagnosis, treatment, and control of natural diseases or conditions?
YN?X Is there a program to manage diseases or conditions induced by experimental conditions?
YN?X Is the veterinarian involved in the selection and use of anesthetics and analgesics?
YN?X Is there a program for the management of surgery and post operative care?
YN?X Is there a program for the assessment of animal well-being including daily observation of all animals?
YN?X Is there a program to provide for the humane euthanasia of all animals? (See AVMA Guidelines on Euthanasia)
YN?X Is there frequent communication between the veterinarian and lay personnel regarding the condition of animals and aspects of care and treatment?

Does the veterinarian provide guidance as follows:
YN?X To scientific investigators regarding the use of animals?
YN?X To other persons involved in the care and use of animals?
YN?X With respect to the surgical and post operative care program?

Animal Procurement and Transportation

YN?X Are all animals obtained lawfully?
YN?X If dogs or cats are used and obtained from a Class B dealer, are steps taken to assure that animals are not pets or stolen?
YN?X Are steps taken to minimize the use of endangered species?
YN?X Are vendors evaluated for quality of the animals they supply?
YN?X Is transportation consistent with ARAC Guidelines for NIH Rodent Transportation, ARAC Guidelines for NIH Non-Rodent Transportation and the Clinical Center Transportation Policy?
YN?X Are transportation vehicles clean and does transportation minimize the spread of disease and stress of the animals?
YN?X Are animal shipments inspected for compliance with procurement specifications and signs of clinical disease?
YN?X Are rodents imported and exported according to ARAC Guidelines and NIH Manual 3043-1: Introduction of Rodents and Rodent Products?
YN?X Is there an appropriate quarantine program for animals that are not from a known specific-pathogen-free facility?
YN?X Are animals stabilized prior to use in research projects?
YN?X Is the Central Animal Procurement System used for animal ordering?
YN?X Is ordering and receiving of animals coordinated with the appropriate animal care personnel to assure that appropriate facilities are available for housing?

Preventive Medicine

Quarantine, Stabilization, and Separation
YN?X Does the veterinarian or delegated person evaluate the health and pathogen status of newly received animals.
YN?X If non-human primates are used are they quarantined? (See NIH Manual 3044-1: Nonhuman Primate Quarantine)
YN?X Are steps taken to separate species with a different microbiological profile?
YN?X Are animals given a period of stabilization before being used? (2 days)
YN?X Are animals separated by species?
YN?X Is the ARAC Guidelines for Housing Multiple Species of Large Laboratory Animals being practiced as applicable?

VETERINARY CARE

Surveillance, Diagnosis, Treatment, and Control of Disease

YN?X Are all animals observed daily (weekends and holidays) by trained personnel to identify disease or injury?
YN?X Are methods in place for disease surveillance and diagnosis?
YN?X Are the ARAC Guidelines for the Prevention and Control of Tuberculosis in Nonhuman Primates being practiced as applicable?
YN?X Is there a program in place for the reporting of unexpected deaths, signs of illness, or other deviations from normal?
YN?X Is timely care or euthanasia provided to diseased or injured animals?
YN?X Are facilities available for the diagnosis of disease?
YN?X Is there a program in place to monitor for sub-clinical diseases especially in rodents?
YN?X Are transplantable tumors, hybridomas, cell lines, and other biological materials screened for disease agents?

Surgery

YN?X Is a program in place for aseptic surgery where applicable? SOP's, etc.
YN?X Is the ARAC Guidelines for Survival Rodent Surgery followed as applicable?
YN?X Is there a program for the continuing and thorough assessment of surgical outcomes? Is corrective action taken as appropriate?
YN?X Is the ability of the surgical team assessed by the ACUC? Is training provided as needed?
YN?X Are antibiotics appropriately used?
YN?X For nonsurvival surgery, does the surgeon clip the hair around the surgical site, wear gloves, and use clean instruments?

For survival surgery, are the following practices followed except as exempted:

YN?X Routine preparation of patient?
YN?X Routine preparation of surgeon?
YN?X Routine use of surgical attire as appropriate?
YN?X Use of sterile gloves?
YN?X Sterilization of instruments and implants, etc.? (Not just alcohol!!)
YN?X Aseptic operative techniques?
YN?X Is the effectiveness of sterilization monitored by indicators or other methods?
YN?X Is nonrodent survival surgery conducted in an authorized location dedicated to the use and are the appropriate number of dedicated rooms available for different aspects of surgery?
YN?X Is the surgical area kept clean or thoroughly cleaned prior to surgical use?
YN?X Is a record of surgery and postoperative care maintained?

Pain, Analgesia, and Anesthesia

YN?X Is the use of analgesics and anesthetics considered by the IACUC and the veterinarian?
YN?X If neuromuscular blocking (NMB) agents are used are they specifically justified by the investigator and approved by the IACUC?

Euthanasia

YN?X Are methods consistent with the AVMA Guidelines on Euthanasia and appropriate to the species?
YN?X If the scientific protocol causes a disease or condition, does the protocol have specific criteria for intervention by euthanasia before the condition leads to death?
YN?X If death is an unavoidable end point, is it justified on scientific grounds?
YN?X Are individuals trained in the method of euthanasia to be used?
YN?X Is CO2 administered from a compressed gas cylinder or house supply with the use of a flow meter?
YN?X Are flow rates posted for each system?
YN?X Are the ARAC Guidelines for the Euthanasia of Rodent Feti and Neonates being practiced?

VETERINARY CARE

YN?X Are the ARAC Guidelines for Euthanasia of Rodents Using Carbon Dioxide being practiced?

SPECIAL NOTES TO BE PROVIDED BY THE FACILITIES MANAGEMENT

Name of Animal Facility:

Please indicate or attach information on the following items for the six month period covered by this review (see instructions for covered period):

1. In-service training you have conducted since the last review.

   Total staff including supervisory: _____ Total hours of instruction:

   Total number of classes given: _____ Average attendance:

2. Outside continuing education classes attended by members of your staff. (List or attach sheet.)

3. Indicate any change(s) in personnel and list certification/registration level of new individuals of new individuals.

   Persons no longer employed:

   New hires during the reporting period: Certification/Registration Level:

4. Indicate any change(s) in the certification and registration of other members of your staff.

5. Indicate any additional information that may be helpful or interesting regarding your facility and its operation.