Program Description
Animal Care and Use Program

Unit 000954

Upstate Medical University
State University of New York

750 East Adams St.
Syracuse, NY 13210

March 31, 2020

For

AAALAC International

Table of Contents

Appendices

Section 1. Introduction

A. State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

The name of the program unit is the Department of Laboratory Animal Resources (DLAR) at the State University of New York (SUNY) Upstate Medical University. The parent organization is the State University of New York at Albany. The Syracuse Veterans Administration Medical Center (VAMC) and Syracuse University are affiliated with SUNY Upstate and are in the same geographic location. There are shared faculty appointments between the three institutions. Both the Syracuse VAMC and Syracuse University are independently AAALAC accredited. Crouse-Irving Hospital is also affiliated with SUNY Upstate and there are shared faculty appointments between the two institutions. There are no animal resource facilities or programs at Crouse-Irving Hospital.

The clinical campus, a branch campus of the College of Medicine, is located in Binghamton, New York, approximately 80 miles south of Syracuse. The Binghamton program offers clinical education programs for 3rd and 4th year medical students and is independently AAALAC accredited.

B. Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

SUNY Upstate Medical University is a tertiary care center for professional education, patient care and biomedical research. One of four medical universities in the SUNY system, the facility serves the fifteen-county Central New York region.

Central to the patient care of the SUNY Upstate Medical University is University Hospital, built in 1964 Special patient care services and features include: the Golisano Children's Hospital, Central New York Burn Treatment Unit, the Joslin Center for Diabetes, the Autologous Bone Marrow Transplant Program, the Gamma Knife Center, the Upstate Cancer Center, the Comprehensive Epilepsy Center, cardiovascular surgery, organ transplantation service, magnetic resonance imaging and same-day surgery.

The University's education programs cover the spectrum of health care. Enrollment is approximately 1,500 including all students and residents in programs in the College of Medicine, the College of Health Professions, the College of Graduate Studies, and the College of Nursing.

The Upstate Medical University traces its roots to the Geneva Medical College established in 1834. In 1849, the school gave the distinction of awarding an M.D. degree to Elizabeth Blackwell, the first woman to become a physician in the United States. She later organized the New York Infirmary for Women and Children and helped to form the nursing corps for the Union Army during the Civil War. The College became part of Syracuse University in 1872 and was transferred to the

State University of New York in 1950 as the Upstate Medical Center. The name changed a couple times since then, but in 1999 it was changed to SUNY Upstate Medical University to re-establish familiarity with the community served by the institution as the name “Upstate” has remained in common usage.
The Department of Laboratory Animal Resources provides services to a wide-ranging program of research and teaching. Research endeavors are highly encouraged and supported in all facets of the university, therefore leading to a variety of basic and clinical research projects using a diverse population of animal species.

C. Note that AAALAC International’s three primary standards are *the Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC, 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations (pertinent local and national regulations) and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

Upstate Medical University uses the PHS policy, the Guide, and the AWA regulations to determine standards of care and use. These regulations are applied to all species used in research, teaching and testing with the exception of lower invertebrates (fruit flies, ticks, etc.).

D. Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note:* For individuals whose information is publically available, provide the titles and names; for individuals whose information is not publically available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care

programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

Organizational chart is attached as **Appendix 4.**

The Chancellor of the State University of New York system is Dr. Kristina Johnson. Dr. Mantosh Dewan serves as Interim President of SUNY Upstate Medical University and Dr. Lawrence Chin is the Dean of the College of Medicine. Dr. David Amberg is the Vice President for Research and the Institutional Official. Dr. Robert Quinn is the Director of the Department of Laboratory Animal Resources (DLAR).

Mrs. Kathleen Reinhard is the Associate Director for Facilities Management. Mrs. Reinhard is in charge of all aspects of the husbandry program and has 43 years of experience. There are two facility supervisors, John Gersch and John (Jay) Satalin, and 13 animal care technicians.

Dr. Pradeep Dumpala is the Associate Director for Clinical Services. He has more than 10 years of experience in laboratory animal medicine. Mrs. Jennifer Kieffer functions as the Senior Veterinary Technician. She has more than 28 years of experience in laboratory animal medicine and coordinates both the surgical research and animal health programs. She is assisted by Mrs. Nicolle Comstock, who has 12 years of laboratory animal experience and 15 years of small animal private practice experience.

Mrs. Julie Ritchie serves as the IACUC administrator. Mrs. Janet Jackson is the administrative assistant for DLAR and coordinates purchases and receipt of animals between the Purchasing Department, the IACUC, the vendors, and the principal investigators.

E. Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

The key institutional representatives that will most likely participate in the AAALAC site visit are:

Dr. David Amberg	V.P. for Research and Institutional Official
Dr. Robert Quinn	Assoc. V.P. for Research Integrity and DLAR Director
Dr. Michael Lyon	IACUC Chair
Julie Ritchie	IACUC Administrator
Kathleen Reinhard	Associate Director for Facility Managment, DLAR
Dr. Pradeep Dumpala	Associate Director for Clinical Services, DLAR
Dr. Jarrod Bagatell	Director of Employee/Student Health Services
Robert Andrus	Director of Environmental Health & Safety

F. Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete **Appendix 5** (Animal Usage) or provide the information requested in a similar format as an Appendix.

The animal usage form is provided as **Appendix 5.**

The types of projects involving animals are related to the mission statement of the SUNY Upstate Medical University, which is as follows:

The mission of SUNY Upstate Medical University is to improve the health of the communities we serve through education, biomedical research and patient care.

The types of research and teaching are quite varied with approximately 115 protocols from nearly 60 principal investigators representing the following departments: Biochemistry & Molecular Biology, Cell & Developmental Biology, Laboratory Animal Resources, Medicine, Microbiology & Immunology, Neurology, Neuroscience & Physiology, Neurosurgery, Ophthalmology, Orthopedics, Otolaryngology, Pediatrics, Pharmacology, Psychiatry, Surgery, and Urology.

G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

The annual budget for the SUNY Upstate Medical University is approximately $1.8 billion with research funding from external sources accounting for approximately $40 million annually. Research funding for projects involving animals comes from a variety of external sources (PHS, NSF, Private Associations such as AHA, Pharmaceutical Industry) and internal sources (Departmental Funds, Hendrick's Foundation, Dean's Fund).

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.
Note: Questions regarding this section should be forwarded to the AAALAC Office.

N/A

I. Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the contractor's relevant programs and facilities must be

provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

We do not contract for services. The only time SUNY Upstate Medical University animals leave the institution is for purposes of collaboration with other institutions, which is always covered under an inter-institutional agreement and only occurs with other PHS-assured institutions.

J. Note other relevant background that will assist reviewers of this report.

There have been a number of significant personnel changes since our last AAALAC site visit. These have all been reported previously, but summarized here to be complete:

Dr. Mantosh Dewan assumed the role of Upstate Medical University's Interim President in December 2019. The position was previously held by Dr. Danielle Laraque-Arena.

Dr. David Amberg has recently resumed his role as V.P. for Research and Institutional Official. Dr. Amberg took a 2-year leave of absence to serve as Interim President of SUNY Environmental Science and Forestry. During his absence, the interim position was held by Dr. Mark Schmitt.

There have been a number of personnel changes on the IACUC. The current roster is included as **Appendix 8.**

We are in the process of renovation and commissioning a new BSL-3 facility which will have a small vivarium included. This facility will not be completed prior to the site visit, so it has not been included in the program description yet.

Section 2. Description

I. Animal Care and Use Program

A. Program Management

1. Program Management Responsibility [*Guide*, pp. 13-15]

a. The Institutional Official [*Guide* pp. 13-14]
Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

Dr. Quinn reports to Dr. Amberg, the Institutional Official, and has direct access to him to relay any immediate and pressing needs of the program.

In addition, the IACUC reports to Dr. Amberg on all of its activities. Dr. Amberg receives copies of all meeting minutes, semiannual program reviews, semiannual facility inspections, and is usually the signatory on all reportable actions.

b. Role of the Attending Veterinarian [*Guide*, p. 14]

i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:

- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.
  Note: If preferred, this information may be provided in a Table or additional Appendix.

Dr. Robert Quinn is the Attending Veterinarian. He is ACLAM-boarded and devotes 100% of his time to Upstate Medical University. He maintains overall responsibility for the animal health and animal care programs. He is also a member of the Institutional Biosafety Committee (IBC) and serves as the institutional Research Integrity Officer (RIO).

Dr. Pradeep Dumpala is the Associate Director for Clinical Services. His responsibilities include (but are not limited to) developing, monitoring, and/or performing all of the following:

Disease prevention, surveillance, diagnosis, and treatment
Anesthesia, analgesia and euthanasia
Surgery and postsurgical care
Enrichment and the psychological well-being of animals
Surgical training of staff, students and investigators
Member of the IACUC

Drs. Quinn and Dumpala are supported by a contract with the Center for Animal Resources and Education (CARE) at Cornell University. CARE laboratory animal veterinarians provide backup emergency veterinary services in the absence of both veterinarians, although both are available for consultation via cell phone 24/7.

ii. List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a *direct role in the provision of veterinary care* and describe their responsibilities. The Organizational Chart(s) provided in **Appendix 4** must depict the reporting relationship between these individuals and the Attending Veterinarian.
Note: If preferred, this information may be provided in a Table or additional Appendix.

DLAR also employs two veterinary technicians, both with 100% effort within the department [see **Appendix 4**]. They share responsibilities for initial veterinary examination, surgical support, health monitoring, veterinary treatments, and consultation with the DLAR veterinarians.

All animal care staff (as well as investigators, research staff, and students) are involved in the health monitoring program. All staff are trained in the recognition of disease signs in the species with which they work and help serve DLAR as the “front-line” of our veterinary health program.

c. Interinstitutional Collaborations [*Guide*, p. 15]
Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

Collaborations currently only occur with other PHS-assured institutions. An inter-institutional agreement is completed [see **Appendix 6**], which normally assigns responsibility for oversight of the research and animal care to the IACUC at the site where the work will be conducted. If a project were to be approved where research or housing were to be conducted at a non-PHS-assured institution, either that institution would need to negotiate an assurance or the SUNY Upstate Medical University IACUC would provide the oversight.

2. Personnel Management

a. Training, Education, and Continuing Educational Opportunities

Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe how training is documented.

Note: Do not include details about the training program, which should be described in the following sections.

All training is documented through the IACUC office on the Training Summary maintained for each individual. This Training Summary corresponds to the Personnel Information Sheet that is included in the protocol form [See **Appendix 10**] and must be completed for all personnel who will work on that protocol. The IACUC Administrator can then make direct comparisons between the Personnel Information Sheet and the Training Summary to ensure that all required training has been completed before that individual is approved to work on the protocol.

Effectiveness of training is assessed both during the semiannual laboratory inspections (which also serve as the program of post-approval monitoring) and by daily interaction of DLAR staff with investigative staff. DLAR staff immediately report unusual or insufficient procedures or techniques to the veterinarians who then report to the IACUC as necessary to ensure that all staff are appropriately trained and conducting procedures according to approved protocols and with proper techniques.

i. Veterinary and Other Professional Staff [*Guide*, pp. 15-16]

For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.

Note: Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

Robert Quinn, D.V.M., DACLAM – Dr. Quinn has been involved with laboratory animal medicine for 33 years. He received his DVM from Colorado State University in 1991 and completed a post-doctoral fellowship in laboratory animal medicine at the University of Michigan in 1994. He became a diplomate of the American College of Laboratory Animal Medicine in 1995. He began serving as an ad hoc specialist for AAALAC in 2006 and has been on Council since 2011. Dr. Quinn has remained very active in ACLAM, AALAS, and ASLAP throughout his career and is currently the national AALAS District I Trustee, Chair of the AALAS QUAD Symposium Committee and is the ACLAM representative to

the AVMA Veterinary Specialties Oversight Committee. He attends multiple national continuing education meetings each year.

Pradeep Dumpala, DVM, PhD, DACLAM – Dr. Dumpala has been involved with laboratory animal medicine for last 10 years. He received his DVM from Acharya N. G. Ranga Agricultural University, India in 2004, completed PhD in veterinary medical sciences at Mississippi State University in 2010, and residency in laboratory animal medicine at the Pennsylvania State University, Hershey in 2012. He became a diplomate of the American College of Laboratory Animal Medicine in 2014. Dr. Dumpala is a member and remained active in ACLAM, AALAS, APV, and ASLAP throughout his career and served in various committees. He attends multiple national and regional continuing education meetings each year.

Backup Veterinary Services: Cornell's Center for Animal Resources and Education (CARE) provides emergency veterinary services in Dr. Quinn's absence. CARE is composed of multiple laboratory animal veterinarians and residents with a wide range of laboratory animal medicine experience. Their primary responsibility is to provide laboratory animal veterinary services to Cornell's vast comparative medicine program. Services to Upstate would only be provided by the veterinarian on call for Cornell during the absence of both veterinarians. Although residents may be responsible for emergency call services, they are always supported by ACLAM-boarded veterinarians.

Jennifer Kieffer, B.B.A, CMAR, ILAM, RLATG – Mrs. Kieffer joined the staff in 1998 after 9 years of experience at a medical device company. She earned her Bachelor's degree in veterinary technology management in 2015. She earned her CMAR certification in 2006. She actively pursues continuing education through AALAS meetings at the local, regional and national levels.

Nicolle Comstock, L.V.T. – Mrs. Comstock has an Associate's Degree in Applied Science from the State University of New York at Canton. She joined the staff in 2007 and has 15 years of prior experience in a private practice clinic. Her continuing education consists primarily of attending local and district AALAS meetings.

ii. Animal Care Personnel [*Guide*, p. 16]

1) Indicate the number of animal care personnel.

13

2) Summarize their training, certification level and type, experience, and continuing education opportunities provided.
Note: If preferred, this information may be provided in a Table or additional Appendix.

Our animal care technicians have laboratory animal experience from between 3 to 22 years.

1 has a bachelor's degree
4 have associate's degrees
3 are licensed veterinary technicians (LVT)
3 are certified laboratory animal technicians (LAT)
5 are certified assistant laboratory animal technicians (ALAT)

All animal care technicians are supported to attend all local AALAS meetings and regional or national meetings on a rotating basis.

iii. The Research Team [*Guide*, pp. 16-17; 115-116; 122; 124]

1) Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

Any personnel involved in an IACUC protocol must complete the CITI training module entitled "Investigators, Staff and Students" as well as any of the species-specific modules that are applicable to the animals with which they will be working. In addition, they must provide documentation of training or experience in the procedures that they will be performing. If such documentation is unavailable or is inadequate, someone at the institution who is proficient in that procedure must train the individual. This training must then be documented to the IACUC by the trainer. All documentation of training is maintained in the Training Summary for each individual and this information is compared to the procedures that the person will be conducting on the protocol to ensure that there is congruency. Documentation of proficiency is not included in their Training Summary until the trainer is comfortable that they can perform the task without supervision.

a) Briefly describe the content of any required training.

CITI training includes applicable laws and regulations, principles of animal welfare, the 3 R's, and IACUC requirements and function. The species-specific modules include handling, restraint, behavior, signs of disease, and some technical procedures. All investigators performing surgery must complete the aseptic surgery module as

well and view a video on [redacted] surgery. Hands-on training content is individualized to the specific research procedures being conducted by the laboratory. In addition, all research faculty and students must complete the CITI Responsible Conduct of Research modules which also include information concerning the use of animals in research, teaching and testing.

b) Describe the timing of training requirements relative to the commencement of work.

All training must be completed prior to being able to work independently on a research project involving animals. Personnel may work with animals under direct supervision prior to this strictly for the purpose of training. It is only after documentation of training proficiency that the procedure is added to their Training Summary and they are approved to perform that procedure on the protocol without supervision.

c) Describe continuing education opportunities offered.

When a protocol is up for triennial renewal, the IACUC requires that all personnel on the protocol have current certification in "Responsible Conduct of Research" – either the basic or refresher course. Repeating other courses or training is currently not required, but all CITI courses have a three-year reminder to encourage staff to refresh this knowledge base. They are also encouraged to seek refresher training in hands-on techniques at any time and especially after a period of inactivity. Training is offered free of charge through DLAR for handling and treatment of all species on an as needed basis and investigative staff often take advantage of this service.

2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:

- who determines that personnel are qualified and trained for surgical procedures
- the roles that the Attending Veterinarian and IACUC/OB have in this determination [*Guide*, pp. 115-116]

For [redacted] surgery, investigators must provide documentation of experience or proficiency with the surgical model to be used or have training documented by someone proficient in the model at Upstate. In addition, if they do not have previous [redacted] surgical experience they must take the aseptic surgery module through CITI and view a video on aseptic [redacted] surgery.

For survival surgery on [redacted] species, these are always conducted within the DLAR surgical suite with DLAR staff providing anesthesia, prep and surgical support. The surgeon must provide documentation of experience or proficiency with the surgical model to be used or have training documented by someone proficient in the model at Upstate. Surgical procedures are under the constant supervision of DLAR veterinary staff to ensure proper surgical technique and sterility maintenance.

Non-survival surgeries on [redacted] species may be conducted in laboratory settings, but only with the same documentation of surgical experience or training as noted above.

Proficiency in surgical methods is reviewed during post approval monitoring visits to each laboratory every 6 months.

3) Describe the training and experience required to perform anesthesia. [*Guide*, p. 122]

Training documentation for anesthesia in [redacted] is similar to training requirements for all research with [redacted]. The CITI [redacted] modules discuss some aspects of anesthesia, but experience or training in the actual conduct of anesthesia in the specific species with the specific anesthetic agent must be provided prior to personnel being allowed to conduct anesthesia unsupervised.

For [redacted] species, the vast majority of anesthesia is performed by trained DLAR staff. For non-survival procedures outside of DLAR, research staff must provide documentation of experience or training in the actual conduct of anesthesia in the specific species with the specific anesthetic agent. In the few cases where this occurs most personnel have been trained by DLAR veterinary staff or very experienced investigators.

Proficiency with methods of anesthesia is reviewed during post approval monitoring visits to each laboratory every 6 months.

4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [*Guide*, p. 124]

Training documentation for euthanasia in [redacted] is similar to training requirements for all research with [redacted]. The CITI [redacted] modules discuss some aspects of euthanasia, but experience or training in the actual conduct of euthanasia in the specific species with the specific method must be provided prior to personnel being allowed to conduct euthanasia unsupervised.

For [redacted] species, the vast majority of euthanasia is performed by trained DLAR staff. For non-survival procedures outside of DLAR, research staff must provide documentation of experience or training in the actual conduct of euthanasia in the specific species with the specific method. In the few cases where this occurs most personnel have been trained by DLAR veterinary staff or very experienced investigators.

Proficiency with methods of euthanasia is reviewed during post approval monitoring visits to each laboratory every 6 months.

b. Occupational Health and Safety of Personnel [*Guide*, pp. 17-23]

i. Institutional Oversight [*Guide*, pp. 17-19]

1) List the institutional entities (units, departments, personnel, *etc*.) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists, Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.
- If contracted services are used, also include their location (e.g.,remote offices to which personnel must report).

The occupational health and safety program is a combined effort between SUNY Upstate Medical University's Employee/Student Health Services, the Environmental Health and Safety Office (EH&S), the Institutional Biosafety Committee (IBC), and the Radiation Safety Office.

Employee/Student Health Services is run by an occupational health physician with extensive experience assisted by numerous nursing and technical staff with many years devoted to occupational health.

Environmental safety is managed by an occupational safety specialist with more than 20 years of experience who also sits on the IACUC. They manage all chemical and general laboratory hazard assessment.

2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to,

researchers, veterinarians, husbandry staff, cage washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including nonaffiliated members), contractors, visitors, etc. [*Guide*, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

The responsibility for risk identification in research involving animals is shared among the groups identified above as well as the IACUC.

Biological Hazards: Dr. Robert Quinn is a member of the IBC and reviews every IACUC protocol. In addition, Mr. Rob Andrus, Director of Environmental Health & Safety, is a member of the IBC and serves on the IACUC as well. The IACUC protocol also asks for identification of biological hazards by the principle investigator. Once a hazard is identified, the PI is required to submit a description of how personnel will be protected from the hazard and must submit approval from the IBC prior to approval of the IACUC protocol. All procedures for protecting all personnel from biological hazards are reviewed and approved by the IBC.

Chemical Hazards: Mr. Rob Andrus, Director of Environmental Health and Safety, serves on the IACUC and therefore can assist the IACUC in identifying chemical hazards within protocols. The handling procedures for all hazardous chemicals identified on protocols must receive approval from the EH&S office prior to IACUC protocol approval.

Radiation Hazards: Mr. Thomas LaVoy is the institution's Radiation Safety Officer. Although Mr. LaVoy does not serve on the IACUC, he reviews all use of radioactivity and approves all use of radiation-generating equipment at the institution. The safe handling plan for the use of any radioactive agents in animals would require prior approval by the Radiation Safety Office prior to IACUC approval. Specific approval for the use of radiation-generating equipment (i.e. irradiators,C-arm) is not required prior to IACUC approval, but the Radiation Safety Office maintains approval and training records for all personnel using this type of equipment.

3) Describe methods and frequency of reassessing work-related hazards.

There are several mechanisms in place for reassessing hazards:

Any workplace accidents, spills, hazardous exposures or other safety incidents must be reported though our OSHA-compliant accident reporting system. All such reports are reviewed for safety practice considerations which may result in more extensive re-review of safety procedures.

All spaces where animal use occurs are inspected every 6 months. During this inspection process, procedures in use are reviewed, including any safety procedures involving hazards.

IACUC protocols involving hazards (like all IACUC protocols) undergo *de novo* review every 3 years. All hazards involved with the protocol would be re-reviewed at that time and appropriate approvals would be ensured.

IBC approval must be renewed every 5 years. The IBC would review the agents and practices in use at that time to ensure they are still appropriate for the safety of personnel involved along with a lab inspection to assess compliance with the practices approved.

Radiation-producing equipment is evaluated annually by Radiation Safety to ensure all protective aspects are functioning properly. Any radioactive agent use in animals would be reviewed by the Radiation Safety Committee annually.

4) Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [*Guide*, pp. 18-19]

Regardless of the type of hazard exposure or injury, all personnel are instructed to report to Employee/Student Health Services or the University Hospital Emergency Room. If it is not an emergent situation, chemical, biological, or radiation exposures may be reported to the corresponding oversight office or body first, but if there is any potential risk to the exposed personnel they will be directed to report to Employee/Student Health Services immediately.

All hazard exposures would be reviewed immediately to assess whether proper procedures were followed or if additional protective measures need to be implemented.

ii. Standard Working Conditions and Baseline Precautions

The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in ***subsection iii*** below.

1) Medical Evaluation and Preventive Medicine for Personnel [*Guide*, pp. 22-23] *Note:* Include blank forms used for individual health assessment as **Appendix 7.**

a) Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are ***not*** included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

All personnel at Upstate receive a baseline medical evaluation at employment. Non-Upstate personnel (such as the non-affiliated IACUC members) who may have significant exposure are offered medical evaluation if they are not included in an appropriate program externally.

External contractors who may only have incidental or very limited exposure are informed of the potential for allergies or other potential animal facility related hazards prior to entry.

b) Describe provisions for allowing an individual (following completion of individual health and job related risk assessments) to decline participation in all or part(s) of subsequently available medical and preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.
Note: Do not include names of the personnel

Upstate Medical University does not allow employees to decline the pre-employment physical. It is a requirement for obtaining a position in the institution.

For others, the assessment would be made on an individual basis. We have never had anyone decline participation, but if they did the risk would be assessed for that individual and involvement either tailored to prevent or minimize exposure or the individual would not be allowed to participate.

c) Describe provisions for assuring confidentiality of medical information.

Occupational health forms are sent directly from the individual to the Employee/Student Health Office. After review, the Health Office

provides written approval to the IACUC Administrator of their adequacy to work in the facilities and/or any restrictions required.

d) Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open laboratories).

Most of the contractors who must actually enter the animal facilities routinely work within the industry and are well-aware of the hazards involved. For those who may not routinely work in animal facilities, the animals would normally be removed from any spaces where they would need to work. In addition, all external personnel entering the facilities would be warned of potential hazards (such as allergen exposure) they are most likely to encounter by the DLAR personnel accompanying them.

For animal work in spaces outside of DLAR, exposure to non-involved personnel is minimized to the greatest extent possible. In nearly all cases, animal procedures are conducted within individual rooms with the doors closed or in remote areas of larger labs away from standard work areas. Any incidentally-exposed personnel who developed symptoms or concerns related to animal exposure would be immediately directed to Employee Health for assessment. If it were determined that the incidental exposure were problematic for any personnel, the animal procedure would be relocated to another area.

e) Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:

- pre-employment/pre-assignment health evaluation,
- medical evaluations (including periodicity),
- diagnostic tests (e.g., for tuberculosis),
- precautions for working with potentially hazardous species (e.g., [redacted], [redacted], venomous species)
- immunization programs, and
- procedures for communicating health related issues.

All Upstate employees and students are monitored through Employee/Student Health Services. This includes pre-employment physicals, annual checkups, and tetanus vaccinations. Tetanus vaccinations are updated every 10 years or after a high exposure incident. Occupational health risks for all personnel working with animals in research are reassessed annually. A copy of the medical evaluation form is included as **Appendix 7.**

All employees with patient contact or that work with [redacted] are screened with annual tuberculin skin tests. This includes all physical plant or other staff needing to enter nonhuman primate areas. If personnel without known tuberculin skin-test status must work in these areas, the animals would be removed and the room sanitized before work begins.

Employee/Student Health Services maintains records on employee occupational animal exposure and information on zoonotic health hazards. They serve as a referral center and can alert the care physician as to potential zoonotic or animal-related risks to consider.

Employees are instructed to report any changes in health status to Employee Health immediately. Employee Health would then assess whether the condition warranted changes in the risk assessment for their position and notify their supervisor if changes in procedure were necessary.

f) Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

Most issues would be handled through the Employee Health Office who are well-versed in zoonotic and other concerns related to the use of animals in research.

Severe illness or accidents would be directed to our emergency room. If the condition was associated with an occupational health exposure (such as a [redacted] bite), information concerning the hazard would be sent with the patient and/or the patient would be directed to have the emergency room personnel contact the Director of DLAR (or other appropriate personnel) for additional information.

2) Personnel Training Regarding Occupational Health and Safety
[*Guide*, p. 20]

Describe general educational program(s) to inform personnel about:

- allergies,
- zoonoses,
- personal hygiene,
- physical injuries in animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., [redacted], agricultural animals),

- other considerations regarding occupational health and safety.

Include in the description a summary of the topics covered, including:

- Entities responsible for providing the training
- Frequency of training or refresher training

Note: Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

Zoonotic training (including allergies) involves handouts summarizing the major risks associated with each species and where to find additional information. Each person using animals must sign off on a training summary sheet that they have received the information applicable to the species(s) they utilize. This information is also available through Employee/Student Health Services and online. Information on zoonotic disease is also included in the online modules through CITI that must be completed prior to working with animals. Some information concerning occupational health is included in the CITI RCR course that must be completed every 3 years.

All new employees attend a day-long orientation session where the topics of chemical hazards, biological hazards, and personal hygiene are discussed.

The QUAD AALAS meeting, Upstate Branch AALAS meetings, and the AALAS District I Training Seminar often include presentations on occupational health and safety. DLAR personnel routinely attend these meetings.

3) Personal Hygiene [*Guide*, p. 20; *Ag Guide* pp. 4-5]

a) List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

Personal protective equipment available for animal care personnel include dedicated scrubs, steel-toed shoes, rubber boots, face shields, hearing protection and disposable attire as needed.

Technical staff are expected to wear a clean lab coat or disposable gown and gloves when working with animals. Dedicated shoes or shoe covers are not required for working with [redacted] since all are handled within either BSCs or ventilated change stations and the floor is sanitized daily, so the risk of floor contamination is minimal.

Additional PPE is required for specialized areas (SCID, quarantine, biohazard, NHP), which includes disposable gowns, gloves, shoe covers, hair bonnets, face masks, +/- eye protection.

b) Describe arrangements for laundering work clothing.

Scrubs are laundered by a commercial uniform service, ALSCO Linen and Uniform Rental in Rochester, NY. DLAR personnel don clean scrubs daily. Clean scrubs are delivered and soiled scrubs are picked up weekly.

c) Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

Sinks for hand washing are provided in all animal rooms and support areas and DLAR staff wash their hands between rooms or tasks. Locker rooms with showers are provided in each building where DLAR staff can change into clean scrubs in the morning prior to starting work. If DLAR personnel leave Upstate during the day, they change out of their uniforms and into personal clothing. They do not need to change if just moving from one vivarium to another, although they must put a clean lab coat or jacket over their scrubs.

d) Describe policies regarding eating, drinking, and smoking in animal facilities.

SUNY Upstate Medical University is a smoke-free institution.

No eating or drinking is permitted in the animal facility, except in the designated employee break rooms [redacted] These rooms are equipped with refrigerators and cooking equipment that are only used for human food preparation.

4) Standard Personnel Protection [*Guide*, pp. 21-22]

a) Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., [redacted], agricultural animals).

Equipment that is utilized to reduce the potential for physical injury include hearing protectors, steel-toed shoes, rubber boots, masks,

PAPRs, protective gloves, and lifts. Training is provided in the handling of animals, equipment and supplies to minimize the exposure to injury. Initial university orientation training includes the proper handling of sharps. Additionally, the size and weight of items is limited when personnel are required to lift or manipulate the items (e.g., caging, bags of feed and bedding are kept at less than 50 lbs.). All bulk chemicals are kept on spill pallets and eye protection must be worn when dispensing any reactive chemicals. Ergonomic considerations are always evaluated prior to the introduction of new equipment or procedures.

b) Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

[redacted] and [redacted] are the most likely sources of significant allergen exposure within our facilities.

[redacted] [redacted] and [redacted] are the most common species used. Nearly all [redacted] are housed in [redacted] with HEPA-filtered exhaust capture. On rare occasions [redacted] are housed in [redacted] or [redacted] depending on specific experimental requirements. All cages are manipulated within change stations or biosafety cabinets which help reduce direct exposure to personnel. All soiled caging is dumped in HEPA-filtered dump stations by personnel wearing disposable PPE.

[redacted] are housed in [redacted]. HEPA-filtered vacuums are available for collecting loose hair. Disposable PPE and respiratory protection is available for personnel with sensitivity to [redacted] allergens.

c) Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

The potential for zoonosis exposure is very minimal at Upstate. All animals received are purpose-bred and specific-pathogen-free. The [redacted] are B-virus negative (although always treated as if they are positive). The most likely source of zoonosis would be the farm [redacted] which we generally use acutely. Although they are SPF, they are raised in a standard farm environment and therefore may be exposed to unknown agents. The most likely route of exposure would be fecal-oral. Personnel working with the [redacted] always wear

gloves and additional protective clothing when performing sanitation.

d) Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

The vast majority of equipment for personnel protection is disposable or is replaced as it wears. No maintenance is performed except for large equipment (such as cage washers) that have their own safety features and receive maintenance service at least annually per a service contract. HEPA filters on racks, change stations, biosafety cabinets and dump stations are certified annually. PAPRs are maintained according to manufacturer's specifications, Lead gloves and aprons are x-rayed annually to ensure integrity.

e) Respiratory Protection

i) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

Specific respiratory protection is not required for any specific procedures at Upstate. Employee health may require specific personnel to wear respiratory protection based on their personal risk assessment. Dust masks, N95 masks and PAPRs are available for any procedures likely to generate large amounts of aerosol. Cages are dumped in HEPA-filtered dump stations and personnel wear dust masks to decrease exposure to any allergens on bedding dust that may escape the dump station vacuum.

ii) Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

For any personnel mandated to don respiratory protective equipment to safely conduct procedures, Employee Health conducts annual training and fit testing.

iii) Describe how such respiratory protective equipment is selected and its function periodically assessed.

The proper respiratory protective equipment for an individual would be determined jointly by the Environmental Safety and Employee Health Offices. Annual training and fit testing (if appropriate) would be conducted by Employee Health.

f) Heavy Equipment and Motorized Vehicles

i) Provide a general list of the types of cage processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 19** (Facilities and Equipment for Sanitizing Materials).

The only hazardous large equipment personnel work with are cage washers, rack washers and autoclaves. All personnel are trained on safe usage and the safety mechanisms inherent to each machine. Signage is located on rack washers.

ii) List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: If preferred, this information may be provided in a Table or additional Appendix.

na

iii) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal and passenger transport.

DLAR uses [redacted] for transporting materials the short distance between animal facilities. Although there is only a perforated panel to protect the driver from materials in the storage compartment, most animal transport is in the filtered shipping containers from the suppliers or in microisolator caging. Very occasionally a [redacted] or [redacted] may be transported within a transport cage that is placed within a secondary container for the very short trip between facilities. For [redacted], personnel would wear appropriate PPE during this transport.

g) Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

Anesthetic gases are scavenged [redacted] Animals are [redacted] scavenging system. [redacted]

CO2 is used primarily in open spaces with high ventilation rates. All CO2 is dispensed through flow regulators that limit the flow rate such that buildup within the open environment is impossible without catastrophic failure of the system.

iii. Animal Experimentation Involving Hazards [*Guide*, pp. 20-21]

1) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. *Note:* If preferred, this information may be provided in a Table or additional Appendix.

a) Biological agents, *noting hazard level* (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

Biological Agents	Biohazard Level
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

b) Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

[redacted]	Irritant
[redacted]	Cytotoxin
[redacted]	Irritant
[redacted]	Irritant
[redacted]	Irritant
[redacted]	Toxin
[redacted]	Cytotoxin
[redacted]	Toxin, Mutagen
[redacted]	Cytotoxin
[redacted]	Cytotoxin
[redacted]	Irritant
[redacted]	Cytotoxin
[redacted]	Cytotoxin
[redacted]	Cytotoxin, Irritant
[redacted]	Cytotoxin
[redacted]	Cytotoxin
[redacted]	Irritant
[redacted]	Carcinogen, Cytotoxin

[redacted]	Cytotoxin
[redacted]	Immunosuppressant
[redacted]	Toxin, Carcinogen
[redacted]	Toxin
[redacted]	Cytotoxin
[redacted]	Cytotoxin
[redacted]	Toxin, Mutagen
[redacted]	Irritant
[redacted]	Cytotoxin
[redacted]	Cytotoxin
[redacted]	Irritant
[redacted]	Irritant
[redacted]	Cytotoxin, Irritant
[redacted]	Toxin
[redacted]	Irritant
[redacted]	Cytotoxin, Irritant
[redacted]	Irritant
[redacted]	Toxin
[redacted]	Carcinogen, Cytotoxin
[redacted]	Cytotoxin, Irritant
[redacted]	Carcinogen, Teratogen, Irritant
[redacted]	Teratogen
[redacted]	Carcinogen, Irritant
[redacted]	Carcinogen, Irritant
[redacted]	Irritant
[redacted]	Mutagen, Teratogen
[redacted]	Cytotoxin
[redacted]	Irritant
[redacted]	Irritant
[redacted]	Toxin, Mutagen, Teratogen, Carcinogen
[redacted]	Carcinogen, Teratogen
[redacted]	Cytotoxin
[redacted]	Toxin
[redacted]	Cytotoxin
[redacted]	Carcinogen
[redacted]	Teratogen, Irritant
[redacted]	Cytotoxin
[redacted]	Cytotoxin

c) Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

^{14}C
X-ray Irradiation
UV light

2) Experiment-Related Hazard Use [*Guide*, pp. 18-19; See also Chapters 2 and 3 in *Occupational Health and Safety in the Care and Use of Research Animals*, NRC 1997].
Note: Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents should be available during the site visit.

a) Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

The responsibility for risk identification in research involving animals is shared among the groups identified above as well as the IACUC.

Biological Hazards: Dr. Robert Quinn is a member of the IBC and reviews every IACUC protocol. In addition, Mr. Rob Andrus, Director of Environmental Health & Safety, is a member of the IBC and serves on the IACUC as well. The IACUC protocol also asks for identification of biological hazards by the principle investigator. Once a hazard is identified, the PI is required to submit a description of how personnel will be protected from the hazard and must submit approval from the IBC prior to approval of the IACUC protocol. All procedures for protecting all personnel from biological hazards are reviewed and approved by the IBC.

Chemical Hazards: Mr. Rob Andrus, Director of Environmental Health and Safety, serves on the IACUC and therefore can assist the IACUC in identifying chemical hazards within protocols. The handling procedures for all hazardous chemicals identified on protocols must receive approval from the EH&S office prior to IACUC protocol approval.

Radiation Hazards: Mr. Thomas LaVoy is the institution's Radiation Safety Officer. Although Mr. LaVoy does not serve on the IACUC, he reviews all use of radioactivity and approves all use of radiation-generating equipment at the institution. The safe handling plan for the use of any radioactive agents in animals would require prior approval by the Radiation Safety Office prior to IACUC approval. Specific

approval for the use of radiation-generating equipment (i.e. irradiators, C-arm) is not required prior to IACUC approval, but the Radiation Safety Office maintains approval and training records for all personnel using this type of equipment.

b) Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies) responsible for reviewing and implementing appropriate safety or containment procedures.

The same individuals and groups described in section a would assess the risks associated with the identified hazards and develop the methods used to mitigate those risks. They would all be part of the approval process by the appropriate group/individual.

c) Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

Hazardous wastes are handled according to protocols approved by the Institutional Biosafety Committee or the Institutional Radiation Safety office on an individual project basis. In most cases, bedding or carcasses exposed to biological hazards are treated as regulated medical waste. Sharps are disposed of in red sharps disposal boxes which are located in all procedure areas. The institution has a needle box recycling program through Stericycle.

d) Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous agents.

Medical evaluation would be specific for the agent being used. Chemical hazard use is monitored independently through Environmental Safety. Biological hazards are monitored through the IBC. In either case, personnel are instructed to report to Employee Health if they have had an exposure to a hazardous agent. If necessary, Employee Health would contact the appropriate approval group/individual to obtain additional information in relation to the exposure. If vaccines are required to work with a specific biologic agent, Employee Health either provides the vaccine, arranges vaccination elsewhere, or collects samples for titer confirmation. Although pre-exposure serum may be collected for specific high-risk studies, baseline serum collection is not routinely done for all employees working with hazards.

3) Hazardous Agent Training for Personnel [*Guide*, p. 20]
Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

Prior to beginning a project involving hazardous agents in animals, the investigator, their research staff, DLAR staff and the appropriate safety representative meet to discuss all aspects of hazard containment, protection and animal husbandry. Procedures and responsible personnel are assigned and agreed upon by all parties involved. The approval process through each of the safety committees also requires documentation of training procedures and participation in such training. IACUC proposals involving hazardous
materials are not approved prior to approval confirmation from the appropriate safety committee or office. All personnel working with radiation are required to complete annual training in radiation safety. Approval through the biosafety committee requires that all personnel document training of the approved laboratory safety manual (which also includes the handling of environmental hazards.)

4) Facilities, Equipment and Monitoring [*Guide*, pp. 19-20]

a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and containment levels (if appropriate*).*
Note: If preferred, information may be provided in a Table or additional Appendix.

There are no special facilities for the handling of hazardous agents. [redacted] rooms [redacted]) have been designated for the housing of animals exposed to biosafety level 2 agents. These rooms are maintained under negative pressure and have increased PPE requirements relative to other housing rooms. All cages from these rooms are autoclaved prior to dumping and washing.

Biosafety level 1 agents may be used in any housing room, but cages are identified and autoclaved prior to dumping.

Chemical hazards may be used in any animal housing room. The process for handling the caging would depend on the agent.

b) Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard containment.

None is specific containment facilities. See section a above.

c) Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

No special equipment is used beyond biosafety cabinets and/or fume hoods. All hoods are certified annually.

d) Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

PPE (head cover, mask, gown, shoe covers) is required when manipulating biohazard level 2 caging in all areas. No specific PPE is required for BSL-1 handling beyond normal provisions. No chemicals currently used in animals require additional PPE beyond normal provisions. Most chemical use hazards are related to the mixing of the chemical for administration which is done within a fume hood within the investigator's laboratory before being brought to the animal facility for administration.

e) Incidental Animal Contact and Patient Areas

i) List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

N/A

ii) Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

Some [redacted] are transported to laboratories through public corridors. Personnel are required to transport [redacted] [redacted]

[redacted] (which also helps to minimize public exposure to allergens). Concerted effort is made to provide procedure space within the animal facilities to minimize the need for public transport. When this transport is necessary, pathways are selected to minimize transport time and public exposure.

B. Program Oversight

1. The Role of the IACUC/OB [*Guide*, pp. 24-40]

a. IACUC/OB Composition and Function [*Guide*, pp. 17; 24-25]
Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 8**.

i. Describe Committee membership appointment procedures.

Dr. David Amberg, Vice President for Research, has been officially designated by the President of SUNY Upstate as the Institutional Official with delegated authority to appoint IACUC members. New members can self-nominate for membership consideration or recommendations for new members can be made through any IACUC member and are discussed at a convened IACUC meeting. The IACUC forwards all recommendations for committee appointment to the Institutional Official for final consideration and appointment.

ii. Describe frequency of Committee meetings. Note that **Appendix 9** should contain the last two IACUC/OB meeting minutes.

The IACUC usually meets monthly.

iii. Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [*Guide*, p. 17]

All new members participate in an orientation session with the Attending Veterinarian and the IACUC Administrator to provide a broad-based, comprehensive approach to the duties of an IACUC member. All members are required to maintain CITI certification in animal welfare laws and regulations. Regular IACUC meetings often include a training session covering a wide variety of IACUC/DLAR related issues. The University supports members' participation in continuing education conferences, webinars and workshops sponsored by AAALAC, AALAS, OLAW, PRIM&R,

USDA and other local, state, and federal agencies/professional organizations.

b. Protocol Review [*Guide*, pp. 25-27]
A blank copy of your institution's protocol review form should be provided as **Appendix 10**. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

i. Describe the process for reviewing and approving animal use. Include descriptions of how:

- the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),
- protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
- veterinary input is provided, and
- the use of animals and experimental group sizes are justified.

Note: Make sure you address each of the items above.

All teaching, training and research involving the use of live vertebrate animals conducted at SUNY Upstate must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) in compliance with state and federal regulations. The Principal Investigator must submit an animal use protocol to the IACUC for approval.

In the protocol submission, the Principal Investigator must describe the potential adverse effects of the study on the animals and the potential benefits of the study on human and/or animal health or welfare. These are specific questions on the protocol form and the IACUC uses this information to make the "harm-benefit analysis."

Specifically addressing pain and distress issues, investigators must consult the DLAR veterinarian regarding proposed studies for guidance on the anesthesia and/or analgesia appropriate for the species involved in the study. All protocols in USDA pain categories D or E must include a search for alternatives and a description of how the 3Rs have been addressed or why they could not be implemented. Monitoring of projects involving pain or distress is multifaceted. All anesthesia and analgesia administration must be recorded in the animal's (or group's) record, which is maintained by both the investigative staff and/or DLAR personnel. These records are reviewed by the IACUC during semiannual laboratory inspections. DLAR personnel directly monitor all animals in the facilities on a daily basis and

therefore are very likely to identify animals that are experiencing unrelieved pain or distress.

The total number of animals and the experimental group sizes are justified within the protocol. Aside from pilot projects, the IACUC requires that this determination be based on a statistical evaluation and/or previous experience as to the number required for statistical significance.

Protocol submissions are due from investigators on or about the 15th of each month for review at the following month's convened IACUC meeting. Protocols are assigned a primary reviewer and secondary reviewer (usually the Attending Veterinarian). Electronic versions of protocols are emailed to the primary and secondary reviewers within a week of the submission deadline.

Approximately 5 days prior to the IACUC meeting date, all protocols (and reviews if available) are emailed to all IACUC members. At the convened IACUC meeting, each protocol is presented by the primary reviewer and all concerns are discussed. Each protocol is voted on by the quorum attending the meeting. Potential actions include:

1) Approval as written,

2) Modification required to secure approval,

3) Tabled for major revisions or

4) Rejected.

The IACUC vote and all minority views are recorded in the official meeting minutes.

When protocol modifications are requested in order to secure approval, a revised protocol must be submitted with a line-by-line cover memo that addresses all concerns of the IACUC. All changes made to the protocol must be indicated by highlighted text. To meet the requirements of Public Health Service Policy (PHS Policy IV.C.2) for DMR subsequent to FCR, all IACUC members have agreed in advance and in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modifications are required to secure approval and that any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

If a protocol is tabled at a convened meeting, the principal investigator will be given until the Friday two weeks prior to the next scheduled meeting to submit a revised protocol. This will allow the primary reviewers adequate time to re-review the protocol. If a revised protocol is not received by the stated deadline, the protocol will need to be submitted by the deadline for

the month of the meeting at which it is being considered (for example, March 15th for consideration at the April meeting.)

In all cases, the Principal Investigator will be provided with an electronic version of the Committee's review, which s/he must use to format his/her line-by-line response cover memo to the Committee.

In addition, any modification requested must be submitted within six months of the meeting date in order to be considered for approval. If no response is received to the request for modifications, a reminder email will be sent to the principal investigator one month before this deadline. After six months have elapsed, the protocol will be considered withdrawn and no further action can be taken. A new protocol would then need to be submitted for consideration.

ii. Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description/definition of "major" vs. "minor" amendments.
Note: If preferred, this information may be provided in a Table or additional Appendix.

Before any significant changes to animal use in existing protocols can be performed, a protocol addendum form must be completed by the principal investigator and approved by the IACUC. (see **Appendix 11** for addendum form)

Significant changes that would require the submission of an addendum and IACUC review include, but are not limited to: changes in animal numbers, addition or deletion of new anesthetics or drug, the addition or deletion of a new phase of the study or principal investigator change.

A new protocol form may be required if there is a change in the research objectives being investigated or if there are many significant changes in the procedures to be used.

Administrative changes to an existing protocol (i.e. new personnel, title change, room number change, strain change, change in sex - depending on species and how the change may affect the research) do not require the submission of an addendum. These changes are handled administratively through the IACUC Office.

The IACUC administrator will route the addendum form to the Attending Veterinarian (AV) to determine whether the addendum meets the criteria for Veterinary Verification and Consultation (VVC), [IACUC Policy: Protocol Review & Facility Assessment, Item 5 – Veterinary Verification and

Consultation (VVC)]. Significant changes within the following categories CANNOT be approved by VVC:

1. from non-survival to survival surgery;
2. resulting in greater pain, distress or degree of invasiveness;
3. in housing or use of animals in locations not overseen by the IACUC;
4. in species;
5. in study objectives;
6. in Principal Investigator (PI) and;
7. that impact personnel safety.

If the AV determines that the proposed change meets the criteria for VVC, the addendum will be processed for review as follows:

The AV will interact directly with the PI (or through the IACUC Administrator) to resolve any questions or concerns. When all questions/concerns have been resolved, the AV will route the approved addendum to the IACUC administrator for final processing. The IACUC administrator will verify personnel training for any added procedures. The IACUC administrator will notify the PI of approval.
If the AV determines that a proposed change does not meet the criteria for VVC, the addendum will be processed for review as follows:

The addendum will be sent to the designated reviewers (usually the primary reviewer of the original protocol and the AV) and to all other members to provide comments and/or call for full committee review. All members will be given 7 days to review the document and respond back to the designated reviewers or the IACUC Office with comments, questions or call for full committee review.

If full committee review is requested, the addendum will be discussed at the next scheduled IACUC meeting.

If full committee review is not requested, the designated reviewers will review the addendum and decide on one of the following actions:

1) approve as written, or

2) require modifications to secure approval

If modifications are required to secure approval, the principal investigator should address them in a revised addendum. However, an email response from the principal investigator may be accepted at the reviewers' discretion.

When all questions/concerns have been resolved, the reviewers will confirm approval with the IACUC administrator. The IACUC administrator will verify personnel training for any added procedures. The IACUC administrator will notify the PI of approval.

Approval of an addendum must occur within six months of submission date or the addendum will be withdrawn from further consideration.

c. Special Considerations for IACUC/OB Review [*Guide*, pp. 5; 27-33]

i. Experimental and Humane Endpoints [*Guide*, pp. 27-28]

1) Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

Determination of humane endpoints begins when the PI consults with the AV concerning the project. The AV advises on relief of pain and distress, including selection of humane endpoints.

These endpoints must then be detailed in the IACUC protocol (which includes a discussion of the 3 Rs) which is reviewed and discussed again during the IACUC meeting. In reverence to the 3Rs principle of refinement, the IACUC reviews all protocols with the intent of minimizing pain or distress that animals may experience.

Although there is not a specific question on the IACUC form addressing criteria for removal or euthanasia of animals used in painful or stressful procedures, this subject must always be addressed in the protocol. Any project that involves progressive disease or increasing potential for pain and distress must include clearly-defined endpoint criteria and/or a statement of understanding that the veterinarians have authority to determine when an animal should be removed from a study and/or euthanized.

In addition to this general approach for all protocols, there are specific, detailed guidelines set forth by the IACUC for specific types of animal use:

1) Guidelines for the Use of Paralytic Agents During Anesthesia

2) Guidelines on Death as an Endpoint

3) Guidelines for the Production of Monoclonal and Polyclonal Antibodies in [redacted] and [redacted]

4) Guidelines for Utilization of Animals in Experimental Neoplasia and Ascites Production

5) Guidelines on Tail Biopsy of [redacted]

2) For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., pilot studies, special monitoring, other alternatives).

Once a study is approved and animals are utilized, DLAR and investigative staff monitor daily (or more often) to ensure that the approved endpoints are not exceeded. If, prior to reaching the approved endpoint, animals appear to be in more pain or distress than anticipated during the protocol review, the IACUC will request that the PI re-evaluate the endpoint in consultation with the AV to determine if an alternative endpoint can be used or if other interventions can be utilized to relieve the pain or distress. This alternative endpoint or intervention would then be submitted as a protocol addendum.

If humane endpoints cannot be anticipated (such as with newly-created transgenic animals) or if the approved endpoint is expected to coincide with pain or distress, the IACUC will require increased frequencies of animal observation commensurate with the intensity of the anticipated pain or distress.

3) Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

All staff involved in the animal use program are responsible for reporting indications of pain or distress. The training program for all personnel includes species-specific indications of pain or distress.

DLAR staff monitor all animals daily. Several staff members are licensed veterinary technicians with extensive experience monitoring for pain and distress in a clinical setting.

ii. Unexpected Outcomes that Affect Animal Well-being [*Guide*, pp. 28-29]
Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-modified animals) are identified, interpreted, and reported to the IACUC/OB.

If there is an unexpected event resulting in morbidity or mortality, the DLAR staff would identify and the AV would be notified immediately. Animals would be treated or euthanized as necessary and the AV would work with

the PI to identify the cause of the iatrogenic disease or problem. If the same problem could not be avoided in the future, a plan will be developed for monitoring, treatment, and/or alternative endpoint and this would be submitted to the IACUC as an amendment.

In addition, PIs are required to report any unanticipated animal deaths on the annual review form for each protocol. If the number of deaths were higher than would be expected normally, the IACUC may request that the PI meet with the AV to resolve potential complications in the future.

iii. Physical Restraint [*Guide*, pp. 29-30]

Note: This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

1) Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

Physical restraint is defined as the use of manual or mechanical means to limit some or all of an animal's normal movements for the purpose of examination, collection of samples, drug administration, therapy, or experimental manipulation. Routine restraint involves confinement for short periods of time (up to 15 minutes) either manually or in a restraint device. Restraint of this type does not require detailed description within the protocol, as long as such restraint is not expected to cause significant distress or discomfort to the animal.

Non-routine restraint is defined as animal restraint for longer than 15 minutes or confinement for any period of time in a restraining device not typically used for that species. Additionally, any restraint that causes substantial changes in the animal's behavior or physiologic parameters (suggesting that the animal is experiencing distress or discomfort) will be considered non-routine. Restraint that involves adverse physiological responses or is likely to induce significant physical or psychological distress to the animal will require an E classification on the protocol regardless of the restraint duration or technique. Non-routine restraint must be fully described and scientifically justified within the procedures section of the protocol form.

Non-routine restraint should be avoided unless it is essential for achieving the research objectives. When non-routine restraint devices are used, they should be specifically designed to accomplish research goals that are impossible or impractical to accomplish by other means.

The following are important guidelines for non-routine restraint:

-Restraint devices should not be considered a normal method of housing.
-Restraint duration should be the minimum needed to accomplish the research objectives.
-Animals should be adapted to the restraint device.
-Animals should be observed frequently while in the restraint device.

2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe

- the duration of confinement
- acclimation procedures
- monitoring procedures
- criteria for removing animals that do not adapt or acclimate, and
- provision of veterinary care for animals with adverse clinical consequences.

Note: If preferred, this information may be provided in a Table or additional Appendix.

Species:			and
Duration of confinement	1		
Acclimation procedures			
Monitoring procedures			
Criteria for removing animals that do not adapt or acclimate			
Provision for veterinary care			

for animals with adverse clinical consequences	[redacted]	[redacted]	[redacted]

iv. Multiple Survival Surgical Procedures [*Guide*, p. 30]

Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

Major surgery penetrates and exposes a body cavity, involves orthopedic surgery, or produces substantial impairment of physical or physiological function. Multiple major survival surgical procedures on a single animal are discouraged, but may be approved by the IACUC if scientifically justified. It is considered preferable to utilize more animals, if possible, to reduce the amount of pain or distress that any individual animal may experience. Multiple major survival surgeries can be justified if they are related components of a research project, conserve scarce animal resources, or if required for clinical treatment. Cost savings alone is not an adequate reason for performing multiple major survival surgeries.

A major survival operative procedure must not be performed a second time on an animal in a separate proposal. In order to comply with the intent of the Animal Welfare Act (AWA), animals surviving a major operative procedure must be identified (written documentation) to prevent their use in a second major survival operative procedure. However, an animal that has an emergency major operative procedure as part of proper veterinary care may still be used in a proposal that requires a major survival operative procedure.

If multiple survival surgery is approved, the IACUC will pay particular attention to animal well-being through continuing evaluation of outcomes. Additional survival surgeries will not be allowed on any animal that has not returned to normal physiologic function since its last surgery and is deemed unfit by a veterinarian to undergo additional surgery.

2) Summarize the types of protocols currently approved that involve multiple major survival surgical procedures.

Note: If preferred, this information may be provided in a Table or additional Appendix.

IACUC #	Procedure(s)	Species	Time interval between surgeries
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

v. Food and Fluid Regulation [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)
- methods of ensuring adequate nutrition and hydration during the regulated period

Note: If preferred, this information may be provided in a Table or additional Appendix.

IACUC	**Title of Experiment & Justification**	Species	Length
[redacted]	[redacted]	[redacted]	[redacted]

	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances [*Guide*, p. 31]

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

The administration of NPG compounds to live animals will only be permitted following review and approval by the Institutional Animal Care and Use Committee (IACUC). The use of NPG compounds as described in the protocol must address the following:

- What is the justification for the use of the NPG compound?
- How is the compound prepared?
- How will the sterility be assured? (N/A for gavage or topical)
- How will the compound be stored?
- How long will the compound remain safe and effective?

The primary acceptable justifications for using NPG compounds include scientific necessity and non-availability. Generally, cost savings alone is not an adequate justification.

vii. Field Investigations [*Guide*, p. 32]

Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

N/A

viii. Animal Reuse [*Guide*, p. 5]

1) Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

The reuse of animals is encouraged when the research or teaching activity does not involve invasive procedures. Currently, we do not have any protocols where animals used experimentally on one protocol are transferred to another protocol. We do transfer extraneous breeding animals from various protocols to the training protocol for use in training investigative staff on various procedures.

2) Briefly describe the types of activities currently approved that involve the reuse of individual animals.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

N/A

3) Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

On very rare occasions, animals that are no longer needed for experiments and either have not had any invasive procedures ([redacted] or have recovered from all procedures ([redacted]) are adopted out. New York state legally requires adoption of all research [redacted] and [redacted] that are deemed appropriate for adoption. All adoptions have been to either DLAR staff or research staff well-trained in the care of the species.

2. Post-Approval Monitoring [*Guide*, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

All approved protocols are reviewed on an annual basis via an Annual Review Form (see **Appendix 12**). The Annual Review Form is reviewed via designated member review usually by the primary reviewer of the original protocol and the AV.

All protocols (regardless of funding) undergo a de novo IACUC review every 3 years according to the process for a new submission described previously. A Triennial Review Form (see **Appendix 13**) accompanies the updated protocol with information concerning the previous year.

b. Describe the process and frequency with which the IACUC/OB reviews the program of animal care and use.

The IACUC uses the OLAW program review checklist as a basis for conducting the program review. The review is divided into sections with one section reviewed at the monthly IACUC meetings, but each section is reviewed at least once every 6 months.

The last semiannual facility inspection and program review is included as **Appendix 14**.

c. Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.

- Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
- If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.

Note: A copy of the last report of these reviews should be included as **Appendix 14**.

The IACUC conducts DLAR facility inspections every 6 months using the OLAW facility inspection check list as a guide.

All laboratories with designated areas for use of live animals are inspected every 6 months regardless of the procedures performed there. Completed inspection reports will be available for review during the site visit.

The last semiannual facility inspection and program review is included as **Appendix 14**.

d. If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies. *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.

N/A

e. Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

The primary mechanism for conducting post-approval monitoring is the semiannual laboratory inspection. During this process, PIs are asked to describe how animals are utilized in the laboratory, including methods of anesthesia, analgesia, surgery, euthanasia, behavioral assessments, or any other procedures involving animals. These procedures are then compared to the approved protocol to ensure compliance. Updates on personnel training are also reviewed with the PI and staff during semiannual laboratory inspections.

Monitoring of animals and procedures happen on a daily basis by DLAR staff. DLAR staff have access to the IACUC protocols and are familiar with the procedures associated with each protocol. If they witness any unfamiliar procedures, unexpected surgeries, or strange animal behavior or clinical state, they immediately report to the DLAR Director for investigation and reporting to the IACUC (as necessary).

3. Investigating and Reporting Animal Welfare Concerns [*Guide*, pp. 23-24]
Describe institutional methods for reporting and investigating animal welfare concerns.

Concerns or complaints regarding the care or use of laboratory animals at SUNY Upstate are reported via phone (anonymously if desired), email or in person to the Director of Laboratory Animal Resources (DLAR), the Chair of the Institutional Animal Care and Use Committee (IACUC), the Institutional Official or the Institutional Compliance Hotline. Questions, complaints or concerns will be brought to the attention of the IACUC and investigated and reported (as appropriate) to regulatory agencies through the Institutional Official.

The University does not tolerate retaliation toward or harassment of individuals who report actual or possible concerns of noncompliance or misuse of the care and use of animals in research or research misconduct. All reasonable efforts will be made to protect the anonymity of complainants and to protect the rights and interests of all parties involved.

4. **Disaster Planning and Emergency Preparedness** [*Guide* p. 35]
Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:
- Identify those institutional components and personnel which would participate in the response.
- Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

Note: A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

Emergency response in DLAR is integrated into the emergency response program for the entire institution. The Director of DLAR fills a position on the Incident Command Team to integrate animal welfare concerns into the overall response of the institution. The primary concerns we would generally have to deal with are facilities issues or staffing issues. With multiple facilities, the general plan for emergencies of sufficient severity or duration would be relocation if feasible. Staffing concerns would be handled through a pool of research faculty, technicians and students with backup from neighboring facilities if feasible.

The institutional emergency response plan will be available for review during the site visit.

II. Animal Environment, Housing and Management

Note: Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, cephalopods (whose use may be described in Appendix 18 in lieu of each section of the Program Description), etc.

A. Animal Environment

Note: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 15**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 15.**

1. **Temperature and Humidity** [*Guide*, pp. 43-45]

a. Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.
Note: If preferred, this information may be provided in a Table or additional Appendix.

Continuous performance monitoring of the HVAC system is provided by the Office of Physical Plant at their control panel, which is staffed 24-hours a day and located in room [redacted]. Some rooms have an individual room

monitoring system while some areas are monitored at the level of the HVAC unit. If a room deviates significantly from set temperature or humidity parameters or an HVAC unit malfunctions, an alarm is activated, the cause of the problem is identified and corrective action initiated immediately. Physical Plant personnel contact DLAR management to apprise them of the situation and to initiate emergency procedures in the event that the health and safety of animals might be compromised prior to resolution of the problem.

Temperature and humidity of individual rooms are also monitored by the DLAR staff. Each room contains a maximum/minimum thermometer and humidity monitor and daily readings are recorded on log sheets in the room. The monthly logs are filed for future reference. Abnormalities from the established reference ranges are immediately reported to DLAR management for resolution with Physical Plant personnel.

b. List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity.
Note: If preferred, this information may be provided in a Table or additional Appendix. [*Guide*, pp. 44 and 139-140]

See **Appendix 15**.

c. Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [*Guide*, p. 43]

Generally, this is not applicable with the exception of [redacted]

2. Ventilation and Air Quality [*Guide*, pp. 45-47]

a. Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).
Note: If preferred, this information may be provided in a Table or additional Appendix.

As noted above, continuous performance monitoring of the HVAC system is provided by the Office of Physical Plant at their control panel, which is staffed

24-hours a day and located in room [redacted] If an HVAC unit malfunctions, an alarm is activated and the cause of the problem identified and corrective action initiated. Physical Plant personnel contact DLAR management to apprise them of the situation and to initiate emergency procedures in the event that the health and safety of animals might be compromised prior to resolution of the problem.

The animal room ventilation rates and pressure gradients are checked triennially by HVAC personnel or by commercial HVAC consultants. Air pressure differential indicators are located on all doors in the [redacted] SCID facility. All ventilation is 100% fresh air supply with no recirculation.

See **Appendix 15** for the most recent assessment of the HVAC system.

b. Describe ventilation aspects of any special primary enclosures using forced ventilation.

The only forced ventilation equipment in service is [redacted]

c. If any supply air used in a room or primary enclosure is recycled, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

N/A

3. Life Support Systems for Aquatic Species [*Guide*, pp. 84-87]

a. Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

Aquatic housing systems must be suitable for the species, provide the ability to adequately maintain the animal's health and well-being while ensuring the safety of personnel, provide adequate space to meet the maximum housing density requirements, and ensure appropriate water quality standards.

b. Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.
Note: Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 16** (Aquatic Systems Summary).

Upstate houses both [redacted] and [redacted]. [redacted]

[redacted]

Water treatment and quality assurances are provided in **Appendix 16**.

The flow-through systems include mechanical, charcoal, and biological filters. Water quality parameters are continuously monitored and adjusted [redacted]

The Z-Mod recirculating aquatic systems also house [redacted] and consist of individual units with mechanical, biological and charcoal filtration as well as UV water sterilization. [redacted]

[redacted] are also housed in static tanks of variable configuration [redacted]

4. **Noise and Vibration** [*Guide*, pp. 49-50]
Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

Methods used to control or reduce excessive noise in the animal facility include performing noise-generating activities away from the animal rooms whenever and wherever possible, utilizing methods that do not generate excessive noise, or temporarily relocating the animals when excessive noise will be generated within the room. Nearly all facilities are constructed with CMU walls to diminish noise transfer between areas. Wash facilities are located as far from animal holding areas as is practical.

B. Animal Housing (all terrestrial, flighted, and aquatic species)

1. **Primary Enclosures**
Note: A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) should be included in **Appendix 17**.

a. Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, cephalopods, and wildlife when reviewing biomedical, field and agricultural research studies.

All housing sizes are based upon the Guide and USDA regulations. Caging equipment is listed in **Appendix 17.**

b. Describe space exceptions to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

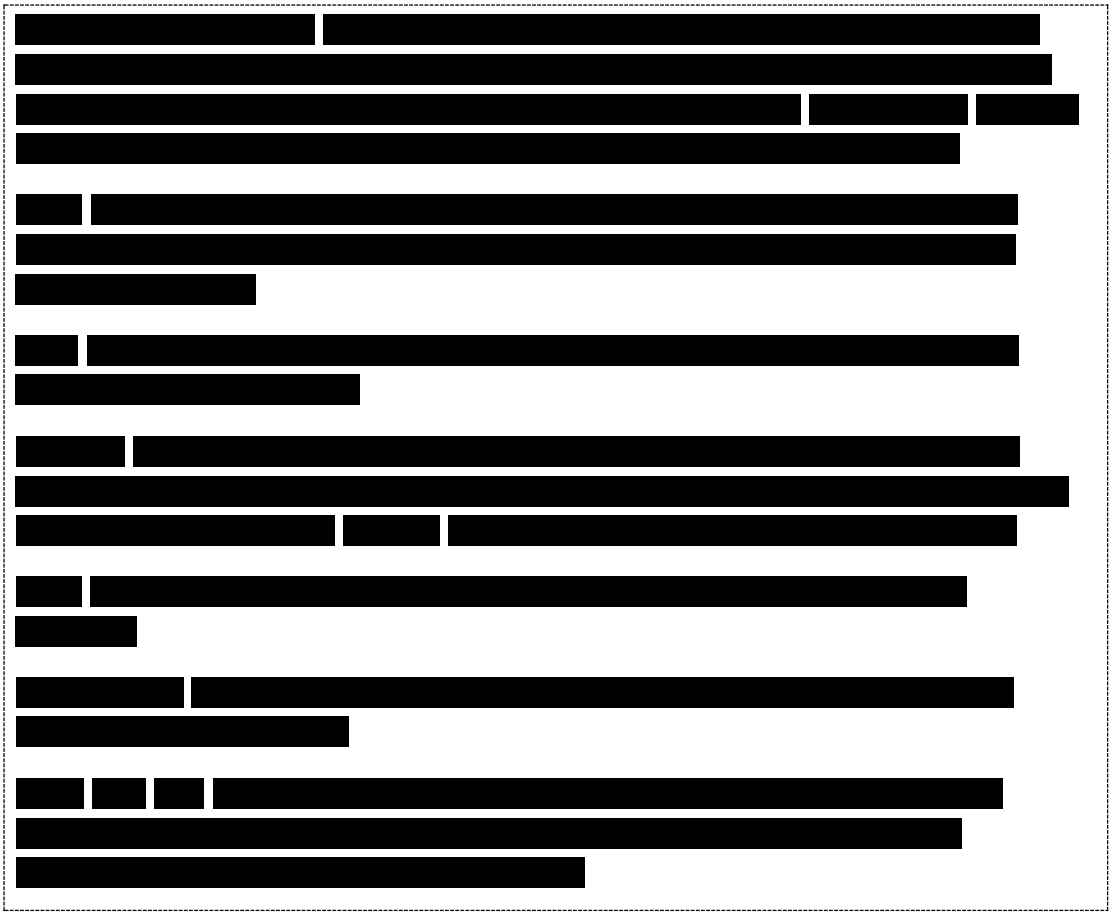
N/A

2. **Environmental Enrichment, Social, and Behavioral Management** [*Guide*, pp. 52-55; 63-65: *Ag Guide*, Chapter 4]

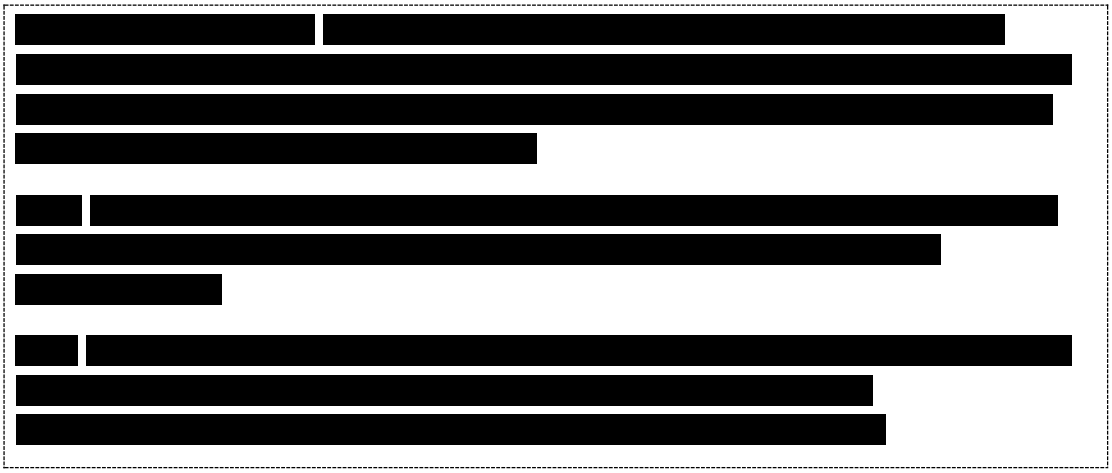
a. **Environmental Enrichment**

i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards,

privacy areas, shelves/perches, swings, hammocks).



ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).



[redacted]

b. Social Environment [*Guide*, p. 64]

i. Describe institutional expectations or strategies for social housing of animals.

Group housing of social species is the standard at Upstate. Animals are group-housed whenever possible unless specifically justified by the IACUC, as required for health-related purposes, or under the circumstances described below.

ii. Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for housing animals individually.

There are occasional situations where social species may be individually housed for limited periods of time:

Breeding [redacted] – [redacted]

Experimental animals – [redacted]

[redacted]

Post-surgery/procedure – [redacted]

iii. Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans, environmental enrichment, etc.).

[redacted]

c. Enrichment, Social and Behavioral Management Program Review [*Guide*, pp. 58, 69]
Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

Exemptions from social housing and/or enrichment related to research protocols are reviewed by the IACUC triennially when the protocol is resubmitted or at any time if staff were to identify animal welfare concerns resulting from these exemptions.

Veterinary exemptions are generally of short duration, but if not, they would be reviewed by the veterinary staff at least once every 30 days.

Social housing exemptions for reasons identified above in section b.ii are reviewed by the IACUC every 6 months during the program review.

d. Procedural Habituation and Training of Animals [*Guide*, pp. 64-65]
Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

[redacted]

e. Sheltered or Outdoor Housing [*Guide*, pp. 54-55]

i. Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

N/A

ii. Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

N/A

iii. Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

N/A

f. Naturalistic Environments [*Guide*, p. 55]

i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from predation).

N/A

ii. Describe how food, water, and shelter are provided.

N/A

iii. Describe how animals are captured.

N/A

C. Animal Facility Management

1. Husbandry

a. **Food** [*Guide*, pp. 65-67]

i. List type and source of food stuffs.

Species	Feed Type	Source	Supplier
[redacted]	[redacted]	PMI Feeds, Inc.	Scott's Distributing
[redacted]	[redacted]	PMI Feeds, Inc.	Scott's Distributing
[redacted]	[redacted]	PMI Feeds, Inc.	Scott's Distributing
[redacted]	[redacted]	PMI Feeds, Inc. ZuPreem Clear H2O	Scott's Distributing Scott's Distributing Clear H2O
[redacted]	[redacted]	PMI Feeds, Inc.	Scott's Distributing
[redacted]	[redacted]	PMI Feeds, Inc.	Scott's Distributing
[redacted]	[redacted]	PMI Feeds, Inc.	Scott's Distributing
[redacted]	[redacted]	[redacted] Express [redacted] Express Frontier	[redacted] Express [redacted] Express

		Frontier [redacted] Express	[redacted]Express
[redacted]	[redacted]	Skretting	Skretting

Supplemental Feed Stuffs

Species	Feed Type	Source	Supplier
[redacted]	[redacted] [redacted] [redacted]	Retail Stores Bio-Serv, Inc.	Walmart Price Rite Tops Scott's Distributing
[redacted]	[redacted] [redacted]	Bio-Serv, Inc. Retail	Scott's Distributing Walmart Price Rite Tops
Various	Ensure®, Boost® [redacted]	Bio-Serv, Inc.	Upstate Central Stores Scott's Distributing

ii. Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:

- vendors (if more than one source, describe each)
- centralized or bulk food storage facilities if applicable

- animal facility or vivarium feed storage rooms
- storage containers within animal holding rooms

ScottPharma is a Certified Labdiet® Dealer and is inspected and audited annually by Purina Animal Nutrition. [redacted]

[redacted]

iii. Describe special food preparation areas, such as feed mills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline Precautions above).

[redacted]

iv. Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

Species	Food Type	Feeder Type	Amount	Frequency
[redacted]				

	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

v. Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

Quality control procedures include [redacted]

b. Drinking Water [*Guide*, pp. 67-68]

i. Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams).

Water is obtained through the City of Syracuse municipal water system, which originates from Skaneateles Lake and is occasionally supplemented with Lake Ontario water. Municipal water supplied is chlorinated and fluoridated. Water is tested by the City of Syracuse for pesticides, trihalomethanes (thm's), volatile organic compounds (voc's), PCB's, Giardia, Cryptosporidium, phytoplankton, radionucleotides and for bacterial contamination.

Water in the [redacted] and [redacted] facilities is passed through a 25-micron filter and provided to animals either through [redacted]

SCID Facility [redacted] are provided with RO water that has an automatic chlorinator system and is monitored by Physical Plant personnel. [redacted]

Water in the [redacted] facility is acidified RO distributed through [redacted]

Species	Method to Provide Water
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

ii. Describe methods of quality control, including monitoring for contaminants.

As the city water is monitored by the water department and in compliance with New York State regulations, no additional quality control monitoring of the Syracuse tap water is performed. If a project were to be identified that had requirements for a specific contaminant-free water supply, samples would be sent out to an independent laboratory for testing or a certified contaminant-free water source would be utilized. RO systems are maintained by Physical Plant personnel or outside contractors which do periodic testing to ensure integrity of the RO membrane and purity of the water produced. The SCID facility water is monitored for appropriate chlorine levels and the [redacted]

[redacted] is monitored for pH, conductivity, temperature and UV function by DLAR staff at least weekly. Water samples were last tested in 2019.

iii. If automatic water delivery systems are used, describe how they are maintained and sanitized.

Species	Automatic watering system maintenance and sanitation.
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

c. Bedding and Nesting Materials [*Guide*, pp. 68-69]

i. Describe type(s) and how used for various species.

Species	Bedding Type	Material
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

ii. Describe bulk bedding storage facilities, if applicable, including vermin control measures.

Bulk bedding is [redacted]

iii. Describe quality control procedures, including monitoring for contaminants.

Bags containing bedding material are closely inspected [redacted]

d. Miscellaneous Animal Care and Use Equipment

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

Transportation of animals and equipment between the main facilities and the [redacted] is accomplished with [redacted] dedicated for DLAR use. The cargo compartment is contiguous with the passenger compartment (separated by a metal grate), therefore the climate controls function to heat/cool the entire vehicle. During temperature extremes, [redacted] to equilibrate throughout the entire cargo area prior to loading animals.

ii. Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

There are several HEPA-filtered vacuum cleaners, floor-buffing machines and walk-behind floor scrubbers used to clean floors within the animal facilities. A vaporized hydrogen peroxide generator is used for room decontamination.

e. Sanitation [*Guide*, pp. 69-73]

i. Bedding/Substrate Change

1) Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

Species	Cage / Bedding Type	Change Frequency
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

2) Describe any IACUC/OB approved exceptions to frequencies recommended in the *Guide* or applicable regulations and the criteria used to justify those exceptions.

Although the IACUC no longer considers this an exception to the Guide, it is mentioned here for the purpose of full disclosure:

[redacted] in [redacted]

[redacted]

3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

[redacted]): Soiled cages are removed to room [redacted] where they are emptied into a HEPA-filtered dump station. Whenever cages are being dumped, the room door must be closed. Clean cages are filled in the clean cage storage room [redacted]).

[redacted] Soiled cages are dumped on the dirty side of the cage wash facility (room [redacted]) into a HEPA-filtered dump station. Clean cages are filled in the clean bedding room ([redacted]).

[redacted]): Soiled cages are dumped on the dirty side of the cage wash facility (room [redacted]) into a HEPA-filtered dump station. Clean cages are filled on the clean side of the cage wash ([redacted]).

ii. Cleaning and Disinfection of the Micro- and Macro-Environments
Note: A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 18** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 19** (Facilities and Equipment for Sanitizing Materials).

1) Describe any IACUC/OB approved exceptions to the *Guide* (or applicable regulations) recommended sanitation intervals.

[redacted]

[redacted]

2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

a) Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

[redacted]

Washers are serviced at least annually through an outside contract to assess temperature, chemical distribution, and cycle function to ensure adequate sanitation.

[redacted]

b) Describe preventive maintenance programs for mechanical washers.

Preventive maintenance programs are in place for all mechanical washers according to the specifications of the manufacturer.

f. Conventional Waste Disposal [*Guide*, pp. 73-74]
Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

i. Soiled bedding and refuse.

[redacted]

[redacted] The dumpsters are emptied weekdays by Environmental Services personnel. The trash is incinerated by OCCRA

ii. Animal carcasses.

[redacted]

g. **Pest Control** [*Guide*, p. 74]

i. Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:

- monitoring devices and the frequency with which devices are checked
- control agent(s) used and where applied, and
- who oversees the program, monitors devices, and/or applies the agent(s).

[redacted]

[redacted]

ii. Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

n/a

iii. Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

As stated above, investigators would be contacted (by telephone/email) prior to treatment with any insecticides. Animals would always be relocated prior to application of any insecticides

h. Weekend and Holiday Animal Care [*Guide*, pp. 74-75]

i. Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

[redacted]

ii. Indicate qualifications of weekend/holiday staff if not regular staff.

n/a

iii. Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

The mechanical systems have built-in fault alarms monitored by the HVAC staff 24 hours a day. In the event of an emergency or disruption, protocols are in place for contacting the appropriate DLAR personnel (Director and/or

Associate Director). Emergency contact information is also available on the weekend check sheets and is posted within the facilities.

2. Population Management [*Guide*, pp. 75-77]

a. Identification

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

Species	Individual ID	Cage ID
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	Marking Ink	[redacted]

Cage cards contain the following information (as a minimum): Investigator, Department, IACUC #, Number of animals, Sex, Date of birth and/or date received, and DLAR cage #.

b. Breeding, Genetics, and Nomenclature

i. Describe the program for advising investigators on the selection of animals based on genetic characteristics.

As new proposals are submitted to the IACUC, the attending veterinarian reviews the application and provides guidance or recommendations to the P.I. as necessary to ensure that the animal model is appropriate for the research. For existing research projects, refinements to the animal model are made at the time of annual renewal, or when situations arise that indicate the model should be reevaluated.

The DLAR Director must sign off on any grant submission that includes the use of animals. This ensures that the project is brought to DLAR's attention. If it is a new project, details are discussed with the P.I. concerning animal model selection. Often, prior to grant or IACUC submission, the investigator will initiate contact with the Director to discuss various aspects of the project, including model selection. As a last possible interaction, the Director or Clinical Veterinarian must review every protocol and model selection may be discussed at this juncture as well.

ii. Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and substrain or the genetic background of all animals used in a study.

Nomenclature can, and often is, discussed during the initial consultations about a project (see #1 above). Aside from this, the topic is most often discussed when animals are ordered. All animal orders must be approved through the DLAR office. Often the order information will contain "shorthand" designations for strains which are then investigated to ensure that the entire, correct designation is used. As this is investigated, it provides the opportunity to re-emphasize the importance of complete nomenclature disclosure in any published materials resulting from the project.

iii. Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including recordkeeping practices (*Guide*, pp. 75-76).

Breeding is limited to [redacted]

iv. For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, “Unexpected Outcomes that Affect Animal Well-Being.”

[redacted]

[redacted]

III. Veterinary Care [*Guide*, pp. 105-132]

Note: Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Procurement and Transportation [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

Sources for laboratory animals are divided into approved and non-approved vendors. Vendors on the approved list have historically been able to provide quality animals on a timely basis utilizing dedicated delivery vehicles. Additionally, the health reports from these vendors are continually monitored and shown to be negative for pathogenic, opportunistic or latent organisms of concern. Animals from approved vendors are received directly into existing colonies.

Animals from non-approved vendors are ordered and received only if the appropriate animal model is not available from an approved vendor. The health status of the animals from non-approved vendors is scrutinized to the fullest extent possible prior to receipt of the animals. Once the health status is determined and is acceptable, the animals are received into quarantine. Sentinel animals are acquired with the shipment or added during the quarantine period and evaluated prior to movement of any animals to established colonies. A site visit may be performed if a new vendor is considered for ongoing supply of animals. This would only occur if an approved vendor can no longer supply the necessary animals or a new model will be utilized that is not supplied from an approved vendor.

2. Transportation of Animals

Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

For transport of animals to SUNY Upstate Medical University, dedicated vendor trucks are used whenever available. When dedicated vehicles are not available, alternate arrangements are made to ensure appropriate environmental

conditions. In most cases this would be arranged through a commercial transport company (usually World Courier).

Animal shipments are received at the [redacted]

Transport within the facility is [redacted] The following table provides a summary of the approved vendors and their shipping arrangements:

Species	Vendor	Transport Method	Origin
[redacted]	[redacted]1 [redacted] Express	Commercial Carrier	Ann Arbor, MI Homosassa, FL
[redacted]	Liberty Research Inc.	Commercial Carrier	Waverly, NY
[redacted]	Keystone Mills	Dedicated Truck	Romulus, NY
[redacted]	LABS Covance	Air	Yemassee, SC Alice, TX
[redacted]	New Iberia [redacted] Center Sierra Biomedical	Dedicated Truck	New Iberia, LA Sparks, NV
[redacted]	Three Springs	Direct Services	Perkasie, PA
[redacted]	Worldwide [redacted], Inc.	Air	Miami, FL
[redacted]	Bristol-Myer Squibb	Air	Plainsboro, NJ
[redacted]	Harlan Sprague-Dawley	Dedicated Truck	Indianapolis, IN
[redacted]	Taconic Farms Harlan Sprague-Dawley Charles River	Dedicated Truck	Germantown, PA Indianapolis, IN Raleigh, NC
[redacted]	Jackson Laboratories	Direct Services	Bar Harbor, ME

B. Preventive Medicine

1. Animal Biosecurity [*Guide*, pp. 109-110]

a. Describe methods used to monitor for known or unknown infectious agents. Note that if sentinel animals are used, specific information regarding that program is to be provided below.

[redacted]:
All [redacted] are housed in [redacted] Our [redacted] health monitoring program relies on 2 primary monitoring methods, [redacted] and screening of Exhaust Air Dust (EAD®).

[redacted]

Screening of Exhaust Air Dust (EAD®): [redacted] Sentinel™ EAD® capture unit is placed in the exhaust plenum of all [redacted] racks. Sentinel™ EAD® automatically captures exhaust air dust samples as the air flows over its filter media. Semi-annually integrated collection media is collected and sent to Charles River for testing. Samples are submitted for FELASA Complete and FELASA basic panels, alternatively.

[redacted]:
[redacted] found in the system sumps and/or aged colony animals are submitted [redacted] to Charles River for testing. Semi-annually, pooled [redacted] are submitted for Modified Surveillance Plus PCR Panel.

Although there is no specific monitoring program for other species, such as [redacted], [redacted] ([redacted] and [redacted]), and [redacted], a diagnostic work-up is done in the event of a clinical outbreak or significant alteration in expected research results. [redacted] are TB tested twice a year.

b. Describe methods used to control, contain, or eliminate infectious agents.

The primary means of controlling infectious agents is exclusion. It starts with obtaining [redacted] from approved commercial vendors with known colony health status. Animals received from non-approved vendors must meet minimal health standards and veterinarian approval prior to being allowed into the facility and must go through a rigorous quarantine procedure with sentinel and/or direct animal testing. [redacted]

If an excluded agent is identified in existing colonies, the colony is isolated and a plan is developed with the investigator/s to eliminate the agent or colony as soon as practically possible. Access to the infected colony is limited to the minimum necessary. Animals with treatable diseases, such as internal or external parasites, are treated accordingly.

Methods of containment of infectious agents include [redacted]

2. **Quarantine and Stabilization** [*Guide*, pp. 110-111]

a. Describe the initial animal evaluation procedures for each species.

[redacted]

b. Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals, random-source animals, or both.

Our designated [redacted] quarantine room is [redacted]. This room [redacted]. Quarantine room is maintained [redacted]

[redacted] from preferred commercial vendors (The Jackson Laboratories, Charles River, Taconic Biosciences, Envigo, NCI, MMRRC-Jackson, and Simonsen Laboratories), [redacted] (Charles River), and [redacted] (NASCO, Charles Sullivan, [redacted] I, [redacted] Express) are received to either [redacted] loading dock of [redacted]) colony housing) or receiving bay of [redacted] [redacted]) and [redacted]

Purpose-bred [redacted] from non-approved vendors are received [redacted]

All [redacted] undergo a 60-day quarantine (regardless of source). NY state law requires filovirus testing prior to shipping and during the first 45 days after shipping. Animals are also B-virus tested at this time. Animals are tuberculin tested at least 3 times during quarantine.

Every effort is made to maintain separation between groups of animals from different non-approved vendors for the duration of the projects.

[redacted] received from preferred commercial vendors are housed directly in respective holding rooms in [redacted]. [redacted] received from non-approved vendors

are housed in [redacted]. During that time, their health status is observed daily by veterinary and animal care staff. [redacted]

[redacted] colonies at Upstate are well established and perpetual through in-house breeding. Very rarely when new strains are brought in, [redacted]

[redacted] are the only animals received that are not raised specifically for research. These animals are received, quarantined and housed in [redacted] purpose. The vast majority of [redacted] are [redacted]

c. Describe the required/recommended stabilization period for each species.

Species	Acclimation Period (Days)	Comments
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]	[redacted]	

3. Separation by Health Status and Species [*Guide*, pp. 111-112]

a. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

Animals of different species are separated by room. [redacted]

[redacted]

b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

All animals are separated by species with one exception of [redacted]

c. Describe isolation procedures and related facilities for animals.

There are no facilities specifically designed for isolation of animals. If infections are identified, [redacted]

C. Clinical Care and Management [*Guide*, pp. 112-115]

1. Surveillance, Diagnosis, Treatment and Control of Disease [*Guide*, pp. 112-113]

a. Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:

- the observers' training for this responsibility
- method(s) for reporting observations (written or verbal)
- method(s) for ensuring that reported cases are appropriately managed in a timely manner.

All animals are observed daily by DLAR technical staff. [redacted]

[redacted]

b. Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

[redacted] communication between the care staff, veterinary staff, and research staff may be either in person, telephone, text or email depending on the severity of the situation.

c. Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

The preventative medicine program focuses on exclusion of infectious agents and elimination or isolation of animals with questionable health status, as opposed to routine preventative therapeutics.

[redacted]

[redacted]

2. **Emergency Care** [*Guide*, p. 114]

   a. Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

DLAR staff is on site every day of the year during regular working hours [redacted]

DLAR veterinarians are always available by cell phone 24 hours a day. [redacted]

   b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

SUNY Upstate Medical University and the IACUC have given the AV the authority to intervene on behalf of the animal in all cases. The decision of the AV or his designee supersedes all others, but the AV/designee makes every effort to work with the investigator to agree on an outcome that is both good for the animal and for the research (if possible).

3. **Clinical Record Keeping** [*Guide*, p. 115]

   a. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

[redacted] Information to be added

to this record would include all laboratory results, historical information, treatments, observations and final resolutions.

[redacted]

b. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including the IACUC/OB has access to the records.

The primary responsibility for medical record maintenance falls with the veterinary technicians.

[redacted] medical records are maintained [redacted] Animal records are maintained for 3 years.

Upon request IACUC, regulatory personnel, and PI's has access to the medical records.

c. Describe the role of the Attending Veterinarian in recordkeeping.

The AV or his designee, veterinary technicians, and (occasionally) PI staff may make notations of observations, treatments provided, etc. as necessary.

4. Diagnostic Resources. Describe available diagnostic methods used in the program including:

a. In-house diagnostic laboratory capabilities.

The diagnostic labs are located in [redacted] and [redacted]. These areas include [redacted] Capabilities include [redacted] and preparation of samples for submission to external laboratories. These areas are used primarily for in-house diagnostic work up [redacted]

[redacted] and for sample preparation for submission to external laboratories.

b. Commercially provided diagnostic laboratory services.

Diagnostic services provided by commercial laboratories include serology, environmental PCR testing, histopathology, bacteriology, hematology, and clinical chemistries. Samples are sent by overnight mail service, picked up by UPS at drop off location available within the building. Samples are routinely sent to Charles River and Antech laboratories.

c. Necropsy facilities and histopathology capabilities.

The necropsy facilities are located in [redacted] and [redacted]. [redacted]

d. Radiology and other imaging capabilities.

Currently, the only imaging capabilities within DLAR consist of a fluoroscopy unit ([redacted]), portable ultrasound unit, and [redacted] preclinical ultrasound imaging system. MicroCT imaging is available through the Radiology Dept. (unit temporarily housed within DLAR in [redacted]). The Department of Orthopedics also has high-definition small animal radiography equipment [redacted]) at the disposal of DLAR. Radiographic use is very low for diagnostic purposes. [redacted] is owned by an investigator from [redacted] Department, housed within the DLAR ([redacted]), and is available for DLAR and other researchers' usage. Veterinary staff routinely perform ultrasound examination of female [redacted] for pregnancy determination.

5. Drug Storage and Control

a. Describe the purchase and storage of controlled and non-controlled drugs.

All controlled substances are purchased under Dr. Quinn's DEA license and maintained by approved DLAR veterinary staff. [redacted]

[redacted]

b. Describe record keeping procedures for controlled substances.

Records maintained for controlled substances [redacted]

D. Surgery [*Guide*, pp. 115-123]

1. Pre-Surgical Planning [*Guide*, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

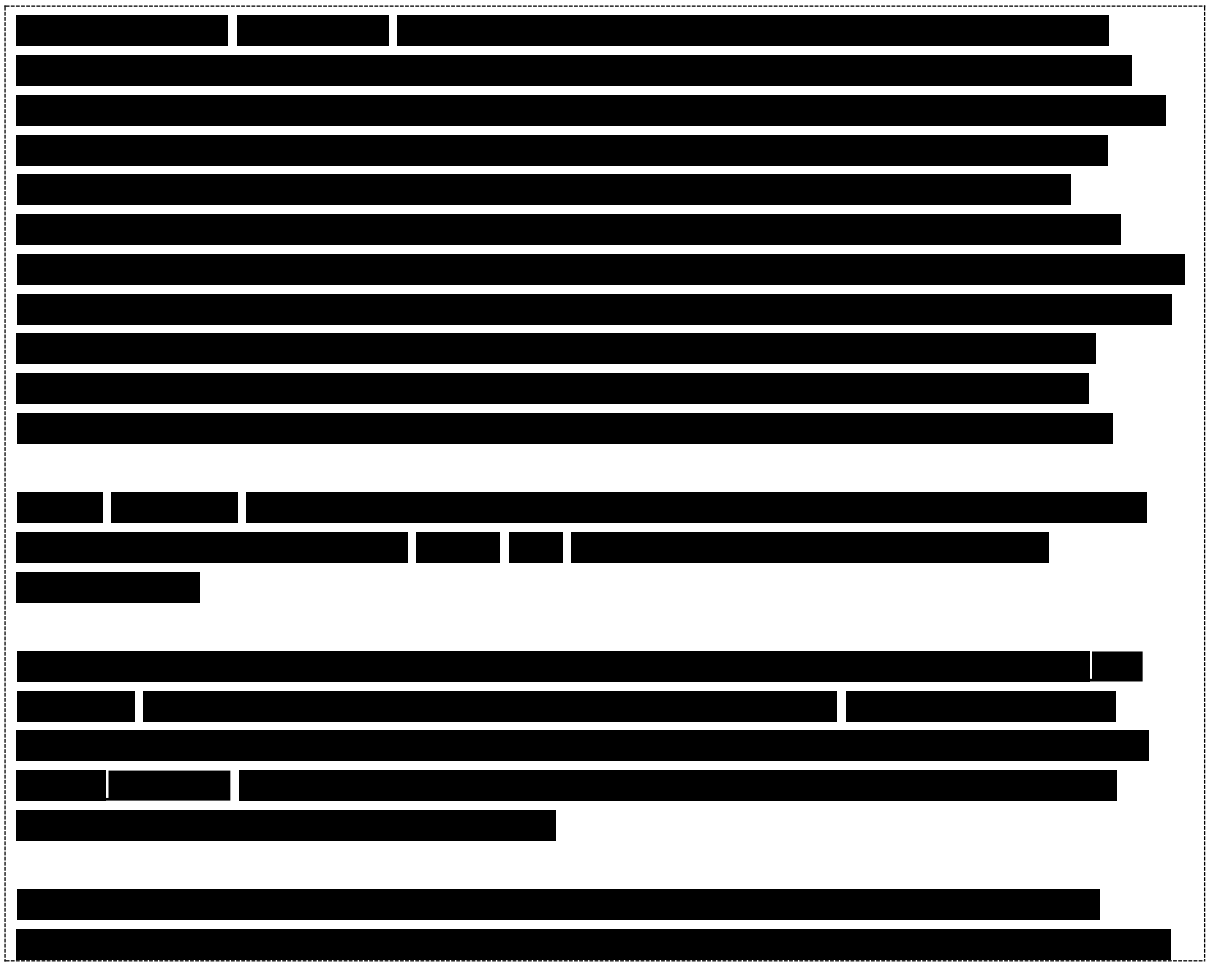
All protocols that involve surgical manipulation must have a completed "Surgical Intervention Form" attached. Information required on this form includes species, surgical procedures, personnel performing the procedure, pre-anesthesia and anesthetics, location of operative procedure, and post-operative procedures. This form also indicates who will be responsible for each aspect.

If the protocol indicates special equipment or expertise needs, the ability of the P.I. to fulfill these requirements is determined prior to approval. Usually the details on responsibilities and equipment are determined during the meeting for veterinary pre-approval of protocols concerning pain and distress issues and peri-operative care.

2. **Surgical Facilities** [*Guide*, pp. 116-117, 144-145]
List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:

- the type of species (including rodents, fish, agricultural species, etc.)
- nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
- the amount of use [heavy (daily), moderate (weekly), or light]
- major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
- facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery
- construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

Note: If preferred, the information requested in this section may be provided in Table.



[redacted]

3. **Surgical Procedures** [*Guide*, pp. 117-118]

   a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

Major surgery is defined as any procedure which exposes a body cavity, orthopedic surgery or surgery that results in permanent physical or physiological impairment. This also includes procedures that invade a body cavity such as laparoscopy or intracranial access.

Minor surgery is defined as all invasive procedures that do not fit the definition of major surgery such as subcutaneous vascular access or osmotic pump placement.

   b. How is non-survival surgery defined?

[redacted]

4. Aseptic Technique [*Guide*, pp. 118-119]

   a. Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

Procedures within DLAR ([redacted]):

[redacted]

[redacted]

Procedures outside of DLAR ([redacted]):
All procedures must follow the IACUC Guidelines on Aseptic Surgery which includes (as a minimum): [redacted]

b. Describe methods used to sterilize instruments and protective clothing, including a description of approved liquid sterilants and instrument exposure time(s) required for each, if applicable.

The primary method used to sterilize instruments is steam autoclaving. Autoclaves are located in the DLAR areas. [redacted]

[redacted]

All linens, gowns and gloves are disposable and pre-sterilized.

c. Describe methods for instrument re-sterilization between serial surgeries.

[redacted]

d. Indicate how effectiveness of sterilization is monitored.

Autoclave tape and steam sterilization integrator are placed in each load of autoclave. [redacted]

e. Describe surgical support functions provided by the program to investigators.

[redacted] Training on [redacted] surgery, anesthesia, etc. is always available and free upon request.

5. Intraoperative Monitoring [*Guide*, p. 119]
Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

[redacted] **surgeries**: [redacted]

[redacted]

surgeries: [redacted]

6. **Postoperative Care** [*Guide*, pp. 119-120]
   Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

animals: [redacted]

[redacted]

E. Pain and Distress [*Guide*, pp. 120-121]

1. Describe how and by whom pain and distress are assessed.

The level and type of pain or distress that may be associated with each procedure is assessed by the attending veterinarian and the IACUC by reading the description of the proposed procedures in the protocol submission. The principal investigator can make the initial categorization; however, the IACUC has the final authority on category placement. If the IACUC determines that additional expertise is needed to determine levels of pain and distress, consultation with qualified individuals may occur. Additionally, the category may be changed if it is determined that the initial assessment was incorrect, or if new information is presented or published.

The categories that are used are:

Category	Description
C	Procedures not expected to cause more than momentary or slight pain/distress.
D	Procedures that may cause more than momentary pain or distress but that are alleviated with medication.
E	Procedures that cause more than momentary pain or distress but are NOT alleviated due to scientific requirements.

Once the study actually begins, animals are monitored on a daily basis by DLAR staff and P.I. staff. Any animal in apparent discomfort or distress is reported through the normal health reporting mechanism and is then examined by one of the veterinarians. The veterinarian makes the final decision as to the course of action (change/increase analgesia, euthanasia, etc.) in consultation with the P.I. If there is conflicting opinion between the veterinarian and the P.I., the decision of the veterinarian will stand.

Many studies utilize pain/distress scoring paradigms to make assessments more objective and to minimize pain or distress that may occur from an errant subjective assessment.

2. Describe training programs for personnel responsible for monitoring animal well-being, including species-specific behavioral manifestations as indicators of pain and distress.

All personnel working with a given species must take the appropriate species-specific CITI training course which includes information on the assessment of pain or distress in that species. In addition, the training on laws and regulations includes discussion of the need to minimize pain and distress in animals. Indications of pain or distress specific to a given procedure is included in the training provided either by DLAR or the investigator for that procedure.

F. Anesthesia and Analgesia [*Guide*, pp. 121-123]

1. List the agents used for each species.
Note: If preferred, this information may be provided in Table or additional Appendix.

Use	Agent(s)	Specie(s)	Route	Dosage(s)
Sedation				
Anesthesia				
Analgesia				

	[redacted]	[redacted]	[redacted]	[redacted]

Note: Other combinations/drugs may be used for specialized projects with justification and approval by the IACUC.

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

Guidance and advice by the veterinarian concerning the choice and use of drugs is done when the IACUC proposal is being drafted. The PI may (and often does) meet with the AV to discuss the proposal prior to submission to the IACUC. If such a meeting cannot occur prior to submission, the AV reviews all protocols and would require revision if the anesthesia or analgesia proposed was not appropriate. Preemptive analgesia is always encouraged if compatible with the study design.

Even after the IACUC approves the project and work begins, if problems or concerns are brought to the attention of the veterinarians or animal health staff, the agent and dose may need to be altered after discussing the situation with the investigator. Such changes would then be incorporated into the IACUC protocol via an addendum.

3. Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to diminish pain and distress.

The use of anesthetics and analgesics is monitored [redacted]

Non-pharmacologic means of diminishing pain or distress are project-specific. [redacted]

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

Any protocol that proposes the use of neuromuscular blocking agents must follow the IACUC "Guidelines for the Use of Paralytic Agents During Anesthesia." This describes the additional monitoring that must take place (at a minimum including blood pressure) as well as testing and weaning procedures that must be followed. Scientific justification must be provided in the IACUC protocol for the use of neuromuscular blocking agents and their use must be the minimum necessary to achieve the scientific goals. Neuromuscular blocking agents may not be used solely to prevent the inconvenience of muscle activity during surgery.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

All [redacted] vaporizers must be tested and calibrated annually by a professional maintenance service. [redacted]

G. Euthanasia [*Guide*, pp. 123-124]

1. Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent AAALAC Reference Resources). Include:
   - consideration of species, age, condition (e.g., gestational period, or neonatal) and
   - location(s) for the conduct of the procedure.

   Note: If preferred, this information may be provided in Table or additional Appendix.

Specie(s)	Method(s)	Justification if conditionally acceptable
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Note: [redacted]

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

[redacted]

3. Describe the methods used to confirm death of an animal.

All euthanasia methods must include [redacted]

IV. Physical Plant [*Guide*, pp. 133-155]

A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

[redacted]**:** The animal facility encompasses [redacted] of [redacted]. This facility is centrally managed by DLAR.

[redacted]: The animal facility encompasses [redacted]. This facility is centrally managed by DLAR.

[redacted]: The animal facility encompasses [redacted] This facility is centrally managed by DLAR.

B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however, common features among locations or facilities may be indicated as such and do not need to be repeated.

1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
2. Physical relationship of the animal facilities to the research laboratories where animals may be used.
3. Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
4. Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).
5. Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
6. Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas incorporating fewer or additional security features than the general features described.
7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.
8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage washing chemicals, pesticides, fuel).

1. [redacted] Generally, the animal housing areas, storage areas and support areas are located [redacted]

The facility is operated as a [redacted]

[redacted]: The animal housing areas, storage areas and support areas are located [redacted]

[redacted]: Generally, the animal housing areas, storage areas and support areas are located [redacted]

2. [redacted]: [redacted]

[redacted]: Laboratories supported by this facility are located [redacted]

3. There are several specialized housing areas within DLAR facilities:

[redacted]:
"SCID" Facility: [redacted]

[redacted] Biocontainment ([redacted]): [redacted]

[redacted] housing ([redacted]): [redacted]

[redacted] Quarantine [redacted]): [redacted]

[redacted]:
[redacted] Quarantine ([redacted]): [redacted]
facility.

Reverse light cycle housing ([redacted]

[redacted] housing [redacted]): [redacted]

[redacted] housing [redacted]): [redacted]

[redacted] housing ([redacted]): [redacted]

4. [redacted]: [redacted]

[redacted]: [redacted]

[redacted]: [redacted]

5. [redacted]

6. [redacted]

7. [redacted]

8. [redacted]

C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 15**) and Lighting Systems (**Appendix 20**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 21)**, “Satellite Animal Housing Areas.”

1. Describe the criteria used to determine/define a “Satellite Animal Housing Area,” which may include remote housing facilities or laboratories temporarily or consistently housing animals.

[redacted]

2. Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

Scientific justification for the establishment of a satellite housing area must be included in the IACUC protocol and approved prior to use. [redacted]

D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 15**) and Lighting Summary (**Appendix 20**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

1. **Power** [*Guide*, p. 141]
   For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:
   - Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
   - History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

Emergency power for lights, certain outlets, and HVAC equipment is available in all facilities supplied by redundant transformers and circuitry. [redacted]

[redacted]

2. **Other System Malfunctions.** If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

[redacted]

E. Other Facilities [*Guide*, pp. 144, 150]

1. **Other Animal Use Facilities** [*Guide*, pp. 146-150]
Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

[redacted]

2. **Other Animal Program Support Facilities**
Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

n/a

Appendices

Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.

Abbreviation/Acronym	Definition
DLAR	Department of Laboratory Animal Resources
EAD®	Exhaust Air Duct
[redacted]	[redacted] (satellite housing)
[redacted]	[redacted]
SCID (facility)	Barrier for immunocompromised [redacted]
SUNY	State University of New York
[redacted]	[redacted]
[redacted]	[redacted]

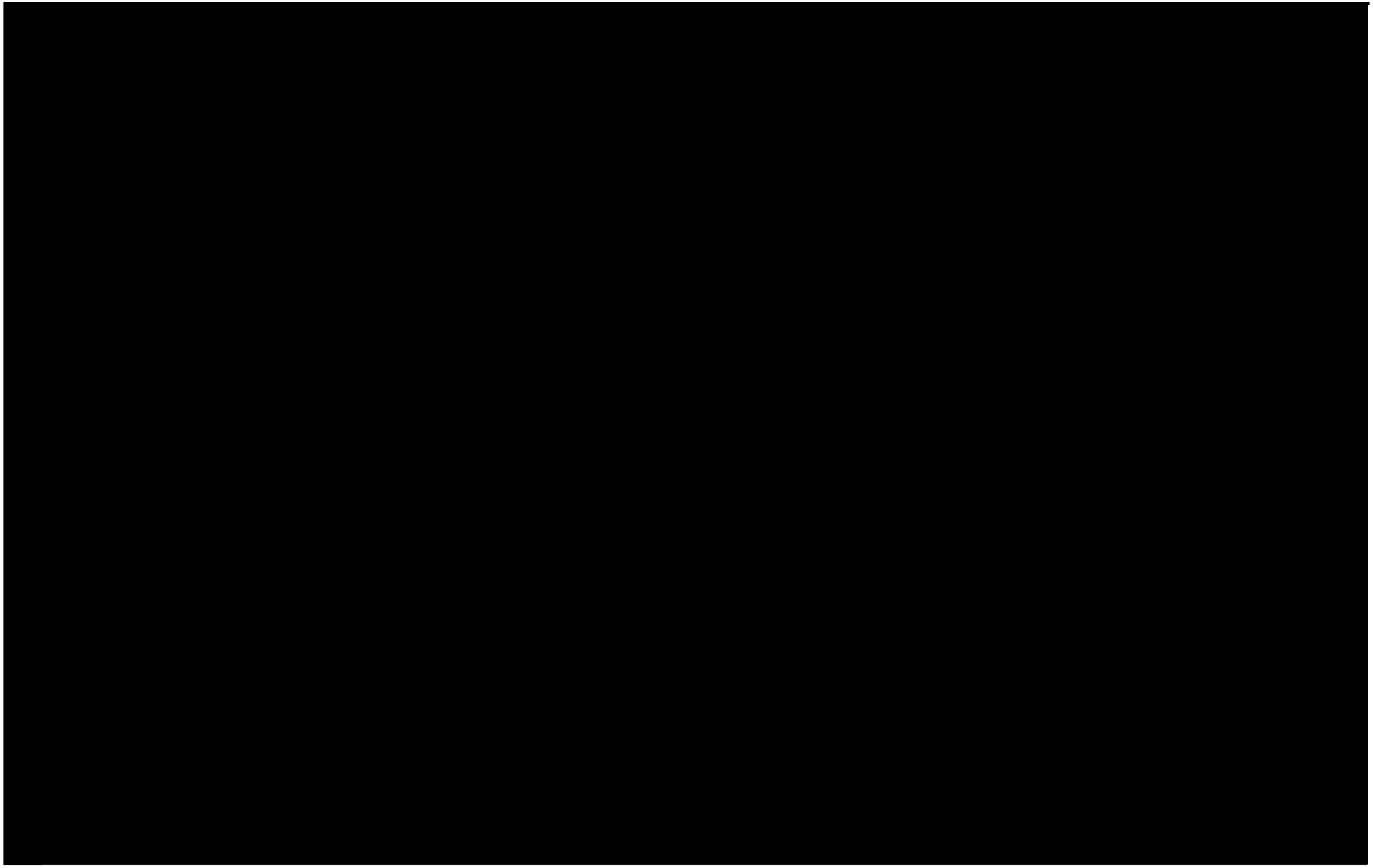
Appendix 2: Summary of Animal Housing and Support Sites

Animal Housing and Support Sites						
Location (building, site, farm name, etc.[a])	**Distance** from main facility[b]	**Animal Housing** Approx. ft^2/m^2	**Support/ Procedures** Approx. ft^2/m^2 or acreage	**Species Housed**	**Animal Census by Species** Approx. Daily	**Person in Charge of Site**
[redacted]	N/A	6, 700 sq. ft.	10,300 sq. ft.	[redacted]	[redacted]	Dr. Robert Quinn
[redacted]	N/A	2,300 sq. ft.	14,000 sq. ft.	[redacted]	[redacted]	Dr. Robert Quinn
[redacted]	[redacted]	8,300 sq. ft.	21,450 sq. ft.	[redacted]	[redacted]	Dr. Robert Quinn
Satellite Housing Facilities Total (Expand in Appendix 21)		400 sq. ft.	100 sq. ft.			

Subtotals (ft^2/m^2):	17,700 sq. ft.	45,850 sq. ft.
TOTAL Acreage:		
TOTAL Animal Housing/Support Procedures (excluding acreage)**:**	**63,550 sq. ft.**	

[a]Please state name and/or use acronyms described in **Appendix 1** for building names, if not coded for confidentiality.
[b]Campus or site map(s) may also be provided in lieu of this information.

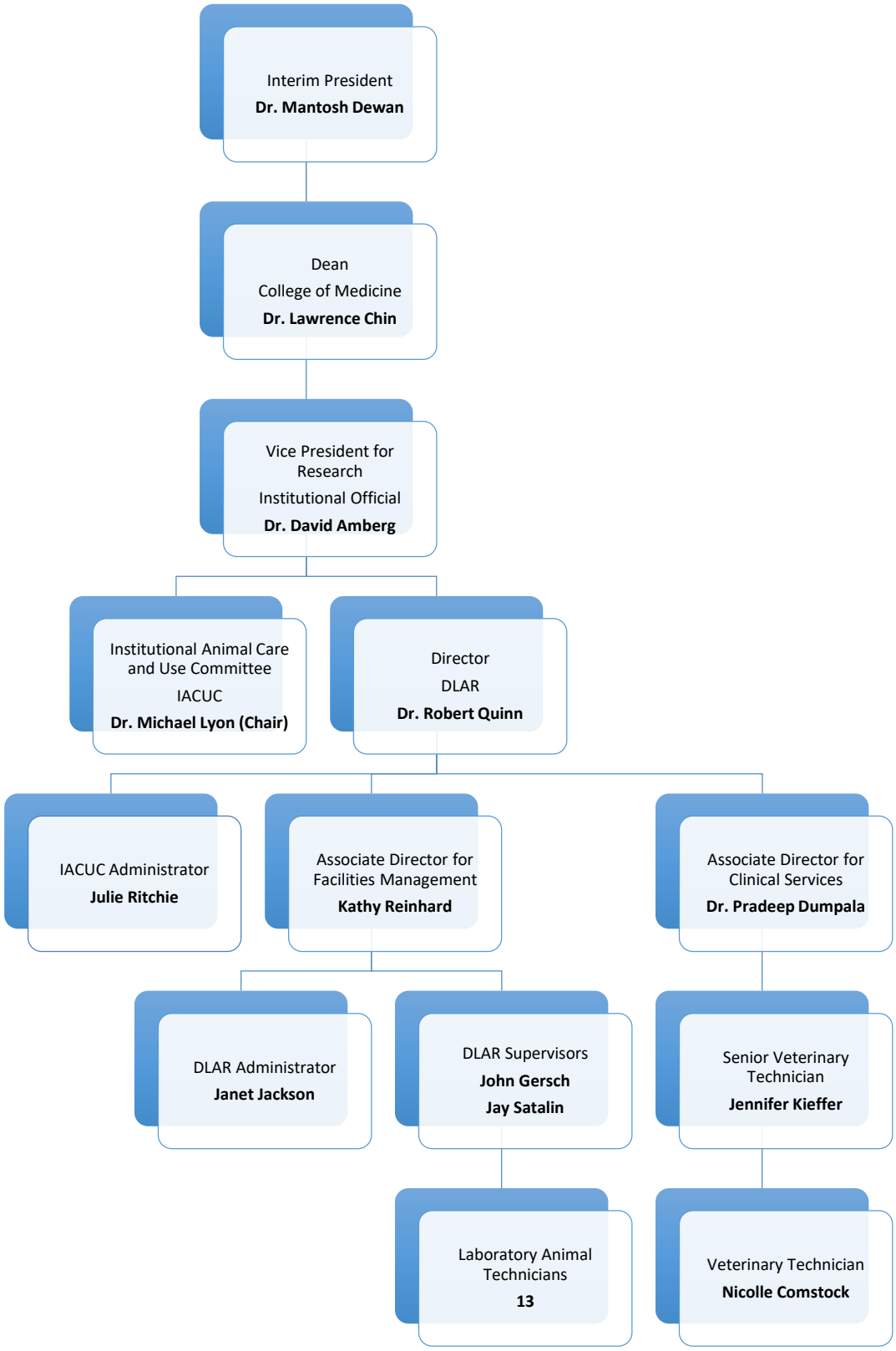
Appendix 3: Line Drawings



Appendix 3: Line Drawings

Appendix 3: Line Drawings

Appendix 4: Organizational Chart(s)



Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
					C						
					D						
					D						
					D						
					C						
					E						
					D						
					C						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C	[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
			[redacted]	[redacted]							
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
			[redacted]	[redacted]							
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
					D						
					D						
					D						
					C						
					D						
					D						
					D						
					D						
					D						
					C						
					D						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C	[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D	[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	E	[redacted]					
			[redacted]	[redacted]							
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
			[redacted]	[redacted]							
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
			[redacted]	[redacted]							
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
					C						
					C						
					D						
					D						
					D						
					D						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D	x					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	C						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	E						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
	[redacted]	[redacted]	[redacted]	[redacted]	D						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
					D						
					D						
					C						
					C						
					D						
					C						
					C						
					D						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
					D						
					D						
					D						
					D						
					D						
					E						
					D						
					D						
					D						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
					D						
					D						
					D						
					E						
					D						
					D						
					E						
					D						
					D						

Appendix 5: Animal Usage

Project/ Protocol Title	IACUC Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
[redacted]						[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	E						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
			[redacted]	[redacted]							
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	E						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	D						
			[redacted]	[redacted]							

Appendix 5: Animal Usage

(1) If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.
(2) Survival Surgery (SS)
(3) Multiple Survival Surgery (MSS)
(4) Food or Fluid Regulation (FFR)
(5) Prolonged Restraint (PR)
(6) Hazardous Agent Use (HAU)
(7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

In the Table below, provide an approximate annual usage for all species:

Animal Type or Species	Approximate Annual Use
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Appendix 6: Inter-Institutional Agreement Form

Institutional Animal Care and Use Committee

UPSTATE MEDICAL UNIVERSITY

SUNY Upstate Medical University
Institutional Animal Care and Use Committee
Inter-Institutional Agreement

This form should be completed in cases where animal work is to take place at an institution other than SUNY Upstate Medical University (SUNY Upstate) and where SUNY Upstate is funding the animal use activity (either directly or through the sub-contracting of a sponsored project). Federal animal use regulations allow institutions to develop methods to ensure the appropriate regulatory compliance without requiring duplicative review of animal care and use protocols when two or more institutions are collaborating in research, testing or teaching involving the use of live vertebrate animals. This Inter-Institutional Agreement provides assurance that the collaborative animal use has received Institutional Animal Care and Use Committee (IACUC) review.

Collaborating Institution Information

1. Name of Collaborating Institution Providing IACUC Review:

2. Collaborating Institution USDA Registration # (if applicable):

3. Collaborating Institution Animal Welfare Assurance (AWA) #:

4. AAALAC Accreditation Status:

5. The Officials signing on page 2 agree that SUNY Upstate Medical University may rely on the designated IACUC of the above-named Collaborating Institution for the review and continuing oversight of its research conducted at the Collaborating Institution involving animals funded by SUNY Upstate,

6. Completion of this document provides assurance that the review performed by the Collaborating Institution's IACUC meets animal welfare requirements prescribed in the Institution's OLAW-approved Animal Welfare Assurance.

Appendix 6: Inter-Institutional Agreement Form

7. SUNY Upstate remains responsible for ensuring compliance with its IACUC's determinations and with the Terms of its OLAW-approved Animal Welfare Assurance.

8. SUNY Upstate's IACUC requests that the collaborating institution provide:
   - A copy of the IACUC-approved protocol covering the collaborative work (*proprietary information may be redacted)*.
   - Copies of continuing IACUC approval (and triennial renewal, if applicable) of protocols covered by this agreement.
   - Notification of review and reporting of any incidents of non-compliance with PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, or any suspension of activities involving SUNY Upstate contracted work.
   - Notification of change in PHS Assurance status or AAALAC, International accreditation status.

Signature of IACUC Official for Collaborating Institution:

Name:			
Title:			
Email address:			
Signature:		Date:	

Signature of IACUC official for SUNY Upstate

Michael Lyon, PhD, IACUC Chair or
Richard Veenstra, PHD, IACUC Vice Chair
SUNY Upstate Medical University
Animal Welfare Assurance # D16-00318 (A3514-01)
USDA Registration #: 21-R-0037

Signature [redacted] Date:

PDF or hard copy of this Agreement signed by the IACUC Official for the Collaborating Institution must be submitted to:

Appendix 6: Inter-Institutional Agreement Form

Ms. Julie Ritchie, IACUC Administrator
SUNY Upstate Medical University
Department of Laboratory Animal Resources
[redacted]
Syracuse, NY 13210

Phone: 315-464-4292
Email: ritchiej@upstate.edu

Appendix 7: Personnel Medical Evaluation Form

Employee/Student Health
Jacobsen Hall, 4TH Floor
750 East Adams Street
Syracuse, New York 13210

Telephone:(315) 464-4260
Fax #: (315) 464-5471
Email: EShealth@upstate.edu

OCCUPATIONAL HEALTH ASSESSMENT FOR ANIMAL CONTACT

INSTRUCTIONS:

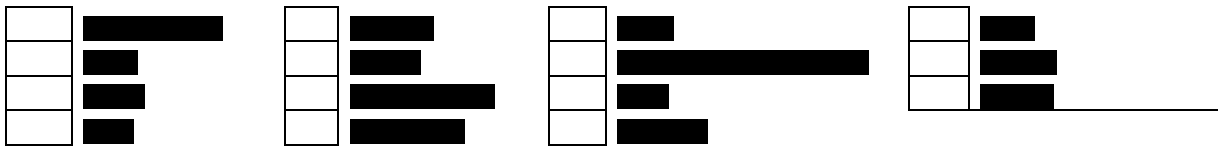
1. Complete the questionnaire below.
2. Save completed form to your computer.
3. Email the completed form to the Employee/Student Health Office: EShealth@upstate.edu

Today's Date:		SUNY ID#:		**(REQUIRED)**
Name:		Department:		
Date of Birth:		Telephone:		

1. Does or will your employment, academic or volunteer duties involve direct or indirect contact with animals or animal products (fresh or fixed tissues, body fluids, or animal bedding or waste)?

   ☐ Yes ☐ No **If yes,** please complete the remainder of the questionnaire.

2. Which species will you have direct contact with? [Check (X) all that apply]



3. Have you ever experienced an allergic reaction to animals or animal products? **If yes,** please list and explain.

4. Have you ever consulted a physician about an allergic reaction to animals or animal products? **If yes,** provide the approximate date and describe the outcome of the consultation.

5. Have you ever been tested for allergies? **If yes**, please detail the results of this testing.

6. Do you have annual health assessments at Employee/Student Health? ☐ Yes ☐ No

Appendix 8: IACUC Membership Roster

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division).

Membership of the Institutional Animal Care and Use Committee

(Effective 1/9/2020)

Chairperson	Degree/ Credentials	Title & Contact Information	PHS Policy Membership Requirements
Michael Lyon	PhD	Associate Professor Department of Otolaryngology & Communication Sciences SUNY Upstate Medical University [redacted] Syracuse, NY 13210 315-464-7253 [phone] Email: lyonm@upstate.edu	Scientist
Members	**Degree/ Credentials**	**Position Title**	**PHS Policy Membership Requirements**
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Appendix 9: IACUC Meeting Minutes

Institutional Animal Care and Use Committee Meeting
February 10, 2020

Minutes

Attendance: [redacted]

I. APPROVAL OF MINUTES

A. ***January 13, 20920 meeting***
☑ Approved as written [redacted]

II. PREVIOUSLY TABLED SUBMISSION

A. IACUC [redacted]
☑ Modifications required to secure approval [redacted]

Clarification of Experimental Approach

1. [redacted]

2. [redacted] Please change accordingly.

3. [redacted] Please make it consistent.

Administrative Corrections

4. [redacted] will have to complete all of the actions of new personnel. Please visit the Upstate IACUC website for forms and further information:

https://www.upstate.edu/iacuc/training.php. Actions needed before protocol approval can be granted:

- Submit training summary form to IACUC office
- Complete the appropriate CITI online courses or submit proof to the IACUC office that these courses have been taken elsewhere
- File occupational health assessment (indicating animal contact) with Health office.

III. TRIENNIAL RENEWALS

A. IACUC [redacted]
☑ Modifications required to secure approval [redacted]

Animal Welfare Concerns:

1. [redacted]

2. [redacted] Describe the post-surgery recovery process.

3. [redacted] Please also describe the post-surgery recovery process.

Clarification of Experimental Approach:

4. [redacted] Please make consistent in all sections of the protocol.

5. [redacted]

b. [redacted]

c. Detail is lacking [redacted] Please provide similar information for these studies.

d. [redacted] Please make consistent.

6. [redacted]

7. [redacted]

8. [redacted]

9. [redacted] Please clarify.

10. [redacted]

11. [redacted]

[redacted]

12. [redacted]

13. [redacted] Please revise.

Administrative Corrections:

14. **General:** In many sections, the protocol is written in past tense as if the experiments had already been conducted. As IACUC protocols need to indicate approval prior to conducting of studies, it should be written as what will be done, not what has been done. Please revise where appropriate.

15. [redacted]

16. [redacted] The lay description must be written for comprehension at the high school level of education. Please define scientific words such as [redacted].

17. [redacted]

18. [redacted] A variety of potential approaches to address the 3 Rs are described here, but it is unclear if these will be incorporated or not. If they cannot be incorporated, this must be explained.

19. [redacted]

20. [redacted]

21. [redacted]

B. *IACUC* [redacted]
☑ Approve as written [redacted]

IV. NEW SUBMISSION

A. *IACUC* [redacted]
☑ Modifications required to secure approval [redacted]

Clarification of Experimental Approach

1. [redacted]

2. [redacted]

3. [redacted] Please clarify.

B. *IACUC* [redacted]
☑ Modifications required to secure approval [redacted]

Clarification of Experimental Approach

1. [redacted] Please make consistent.

2. [redacted] Please make consistent.

Administrative Corrections

3. [redacted] Please ensure that the IACUC office receives the IBC approval letter when that has been granted. IBC approval will need to be in place before final approval for this animal protocol can be granted.

4. **Personnel Information Sheets (pg. 3):** Nearly all procedures are checked off yet many of them do not appear to apply to this protocol. Please only include procedures performed on this protocol.

V. ANIMAL CARE & USE PROGRAM REVIEW

A. *Part B and related IACUC policies-* [redacted] and [redacted] recused themselves from review of this section of the program review. Checklist was reviewed with no deficiencies noted. No revisions to policies were suggested.

VI. ATTENDING VETERINARIAN'S REPORT

A. AVMA guidelines have changed regarding flow rate of CO2 for [redacted] euthanasia. Upstate policy will change accordingly. [redacted] Compliance will be checked on post-approval site visits.

VII. OPEN DISCUSSION

A. None of the members had any topics for open discussion.

Meeting was adjourned at 4:25 pm.

Respectfully submitted:

[redacted]

DR. MICHAEL J. LYON

Appendix 9: IACUC Meeting Minutes

Chair, Institutional Animal Care and Use Committee

Attachment 1: Other Actions
c: [redacted], Institutional Official

Appendix 9: IACUC Meeting Minutes

February 2020 IACUC actions

Date	Investigator	IACUC	Action
2/6/2020	[redacted]	[redacted]	Addendum approved
2/6/2020	[redacted]	[redacted]	New protocol approved
2/11/2020	[redacted]	[redacted]	Addendum approved
2/11/2020	[redacted]	[redacted]	Annual report approved
2/11/2020	[redacted]	[redacted]	Annual report approved
2/13/2020	[redacted]	[redacted]	Triennial renewal protocol approved; replaces previous version
2/20/2020	[redacted]	[redacted]	New protocol approved
2/21/2020	[redacted]	[redacted]	Addendum approved
2/26/2020	[redacted]	[redacted]	Addendum approved
2/28/2020	[redacted]	[redacted]	Addendum approved by VVC review

Appendix 9: IACUC Meeting Minutes

Institutional Animal Care and Use Committee Meeting
March 9, 2020

Minutes

Attendance: [redacted]

Guests: [redacted]

VIII. INTRODUCTION OF POSSIBLE NEW COMMITTEE MEMBER

The Committee made introductions to [redacted], and in turn [redacted] described [redacted] current position in the Department of [redacted], and his experience as the [redacted] of the [redacted] before joining Upstate a year ago. [redacted] was on the [redacted], in which their Committee met every two weeks and reviewed 10-15 applications at each meeting. [redacted] is very eager to join the Committee, to meet new people and learn the policies for when the new Vector lab is built and functioning. [redacted] welcomed [redacted] to our meeting.

IX. APPROVAL OF MINUTES

A. *February 10, 2020 meeting*

☑ Approved as written [redacted]

X. TRIENNIAL RENEWALS

A. *IACUC* [redacted]

☑ Modifications required to secure approval [redacted]

Animal Welfare Concerns:

1. [redacted]

Appendix 9: IACUC Meeting Minutes

Clarifications of Experimental Approach:

2. [redacted] Please make consistent throughout protocol.

3. [redacted]

4. [redacted]

5. [redacted]

6. [redacted]. Please be consistent.

7. [redacted] Please revise.

8. [redacted]

9. [redacted] Please clarify.

10. [redacted] Please revise.

11. [redacted] Please make consistent.

12. [redacted] Please clarify.

13. [redacted]

14. [redacted]

15. [redacted]

Administrative Corrections:

16. [redacted] Some of the terms in the lay description are not described [redacted] Please clarify. Also, there is a lot of unnecessary experimental detail that would need further explanation to be understood by a high school student. Most of this could be summarized in a few sentences without the details that need explanation. [redacted]

17. [redacted]
Please correct.

18. [redacted]
Please correct.

19. Personnel information pages: there are many procedures marked for personnel as adequately trained but this is not reflected in training summaries most recently updated in October 2019. Please verify when and how the following procedures have been acquired:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

B. IACUC [redacted]

☑ Modifications required to secure approval [redacted]

Animal Welfare Concerns:

1. [redacted] Please justify treatment parameters using reference and/or prior lab experience.

2. [redacted]

Appendix 9: IACUC Meeting Minutes

[redacted]

Clarifications of Experimental Approach:

3. [redacted] The Lay Description is brief. Please add information to support [redacted]

4. [redacted]

5. [redacted]

6. [redacted]

7. [redacted] Please add references to support such testing. [redacted]

8. [redacted] Please clarify.

9. [redacted] Please explain.

10. [redacted]

11. [redacted] Please list # animals needed for [redacted] and how the numbers were derived for statistical analysis.

12. [redacted] Please indicate how the standard error for the calculations was determined.

13. [redacted] Please explain and if necessary adjust animal numbers accordingly.

14. [redacted] Please revise.

15. [redacted] Please make consistent.

16. [redacted]

17. [redacted]

18. [redacted]

Administrative Corrections:

19. [redacted] Please revise.

C. IACUC [redacted]

☑ Modifications required to secure approval [redacted]

Clarifications of Experimental Approach:

1. [redacted]

2. [redacted]

[redacted]

3. [redacted]

Administrative Corrections:

4. All Personnel Information pages: Personnel who will be doing the IV injections will need to indicate their skill level to perform the procedure.

5. Personnel Information (p. 5): [redacted] is new personnel and will need to complete all of the actions of new personnel: submit training summary form, complete CITI training, file occupational health assessment (indicating animal contact) with Health office. Please visit the IACUC website, https://www.upstate.edu/iacuc/training.php for forms or contact the IACUC office directly.

6. [redacted]

7. [redacted] Please revise.

D. IACUC [redacted]

☑ Modifications required to secure approval [redacted]

Animal Welfare Concerns:

1. [redacted]

Clarifications of Experimental Approach:

2. [redacted]

[redacted]

3. [redacted]

4. [redacted]

Administrative Corrections:

5. [redacted]

6. [redacted]

7. [redacted] Please revise.

8. [redacted]

9. [redacted]

XI. NEW SUBMISSION

A. *IACUC* [redacted]

☑ Modifications required to secure approval [redacted]

Animal Welfare Concerns:

1. [redacted]

[redacted] Please clarify what [redacted] will be used and why.

Clarifications of Experimental Approach:

2. [redacted] Please provide justification for why the [redacted] to this model.

3. [redacted]

Administrative Corrections:

4. [redacted] Please list appropriate [redacted] to be used and make consistent throughout protocol.

XII. ANIMAL CARE & USE PROGRAM REVIEW

A. Part C and related IACUC policies- The checklist was reviewed with no deficiencies noted. No revisions to policies were suggested.

XIII. ATTENDING VETERINARIAN'S REPORT

A. [redacted] reported on the expansion of the [redacted] colony. Four new [redacted], [redacted], are due to arrive next week and will need to be in quarantine for 30 days. Current quarantine rooms are being reviewed and changes may happen, e.g moving the [redacted] colony room from the vivarium on the [redacted] of [redacted] to the [redacted] vivarium.

XIV. OPEN DISCUSSION

A. [redacted] talked about [redacted] lab shutting down and having surplus equipment available.

B. [redacted] reminded everyone that the next IAUCC meeting will be on April 13th at noon. A lunch will be provided while we conduct regular business and then the Committee will divide into three groups to conduct semi-annual facility inspections of the three DLAR vivariums.

Appendix 9: IACUC Meeting Minutes

Meeting was adjourned at 4:35 pm.

Respectfully submitted:

[redacted]

DR. MICHAEL J. LYON
Chair, Institutional Animal Care and Use Committee

Attachment 1: Other Actions

c: [redacted], Institutional Official

Appendix 9: IACUC Meeting Minutes

Date	Investigator	IACUC	Action
3/2/2020	[redacted]	[redacted]	New protocol approved
3/2/2020	[redacted]	[redacted]	Addendum approved
3/3/2020	[redacted]	[redacted]	Expired protocol, not renewed
3/3/2020	[redacted]	[redacted]	Expired protocol, renewal is pending approval
3/3/2020	[redacted]	[redacted]	Expired protocol, not renewed
3/3/2020	[redacted]	[redacted]	Expired protocol, not renewed
3/3/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/3/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/3/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/3/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/3/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/4/2020	[redacted]	[redacted]	Addendum approved
3/4/2020	[redacted]	[redacted]	Addendum approved
3/11/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/11/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/11/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/11/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/11/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/12/2020	[redacted]	[redacted]	Annual report approved
3/12/2020	[redacted]	[redacted]	Annual report approved
3/12/2020	[redacted]	[redacted]	Annual report approved
3/12/2020	[redacted]	[redacted]	Annual report approved
3/23/2020	[redacted]	[redacted]	Addendum approved by VVC review
3/27/2020	[redacted]	[redacted]	Addendum approved by VVC review

Appendix 10: Blank IACUC Protocol Form

Institutional Animal Care and Use Committee
SUNY Upstate Medical University

ANIMAL CARE AND USE PROTOCOL

Updated: AUGUST 2018

Federal and State Regulations require that the use of living vertebrate animals be reviewed for their appropriateness and approved by the Institutional Animal Care and Use Committee (IACUC) ***BEFORE*** commencement of a study.

All of the information requested in the following form is based on USDA Federal Regulations (Animal Welfare Act), PHS/NIH policy (Health Research Extension Act) and/or the New York State Department of Health Regulations.

Submission Deadline: **The 15th of each month. Protocol will be reviewed at the following month's meeting, scheduled for the 2nd working Monday of each month.**

Instructions:

1. Complete **SECTIONS A – O** of this protocol.

2. Complete the **APPENDICES** that apply to this protocol. Delete non-applicable appendices.

3. The IACUC **strongly recommends that you have another individual, who is familiar with the protocol review process, read and evaluate your protocol prior to submission**. This often identifies common errors that may delay approval of the protocol.

4. **Federal regulations require that you consult with the veterinarian in the Department of Laboratory Animal Resources (DLAR) regarding issues of pain and/or distress *before* submitting your protocol.** Dr. Quinn may be contacted via phone: 464-6563 or via email: quinnr@upstate.edu

5. The completed protocol should stand as an independent document, i.e. none of the answers should require the reviewer to refer to a grant application, scientific publication or any other external source for the requested information.

6. It is essential to use language understandable to all reviewers, particularly in the Lay Description (Section C). The remainder of the document must be understandable by a scientist OUTSIDE of your discipline.

7. Please answer all questions. Questions that are not relevant must be answered "N/A".

8. The Principal Investigator must electronically submit this protocol via his/her own email account.
   Document submission by other lab personnel **will not be accepted. DO NOT** submit a hard copy.

9. Approval of an animal use protocol is not required by PHS prior to grant review. "Just in time" policy allows for approval after the grant receives a "fundable" priority score, but prior to receipt of funds. (Note: To avoid delay in funding, protocols should be submitted at least 3 months prior to earliest possible funding date.)

Questions? Email the IACUC office or call 315-464-4292.

Appendix 10: Blank IACUC Protocol Form

IACUC Office use ONLY

IACUC #: _____

Approved: _____

Institutional Animal Care and Use Committee
SUNY Upstate Medical
University

ANIMAL CARE and USE PROTOCOL

Principal Investigator: _____
Full Name Degree Department Bldg./RM

Protocol Title: _____

Place an [X] in the appropriate column.

Yes	No	
		Does this protocol involve **surgery** (survival and/or nonsurvival surgery)? **If yes,** please complete **Appendix I**.
		Does this protocol involve **cardiac perfusion?** (The IACUC considers cardiac perfusion to be nonsurvival surgery) **If yes,** please complete **Appendix I.**
		Does this protocol involve the maintenance of a **breeding colony**? **If yes**, please complete **Appendix II**.
		Do you anticipate using any **expired materials** and or drugs on animals? (Non-survival procedures only.) **If yes,** please complete **Appendix III** and explain in **Section N**.
		Does this protocol involve the **Production of Polyclonal and Monoclonal Antibodies in** [redacted] **and** [redacted]? **If yes,** please complete **Appendix IV**. [If noncompliant with this Guideline, you must provide justification in **Section N**]
		Does this protocol involve the **Utilization of Animals in Experimental Neoplasia and Ascites Production?** **If yes,** please complete **Appendix V**. [If noncompliant with this Guideline, you must provide justification in **Section N**]
		Does this protocol involve **Death as an Endpoint? If yes,** please complete **Appendix VI** and provide justification in **Section N**.
		Does this protocol involve the **Use of Paralytic Agents during Anesthesia?** **If yes,** please complete **Appendix VII** and provide justification in **Section N**.
		Does this protocol involve **Tail Biopsy of** [redacted]**?** **If yes,** please complete **Appendix VIII.** [If noncompliant with this Guideline, you must provide justification in **Section N.**]
		Does this protocol use **animal tissues from a source other than the animals requested** on this protocol? **If yes**, please complete the **Use of Animal Products Form.** [Download from website http://www.upstate.edu/iacuc/forms.php]
		Does this protocol involve **restraint** of conscious animals for longer than 15 minutes? **If yes**, please provide justification in **Section N**.
		Does this protocol involve **food or water restriction beyond standard pre-surgical fasting?** **If yes**, please provide justification in **Section N**.
		Does this protocol involve **collaborative research** wherein any animal studies will be conducted at another institution? **If yes,** please attach the following information from the collaborating institution: (1) approval letter from the Institutional Animal Care and Use Committee (IACUC), (2) a copy of the protocol, and (3) the institution's PHS Assurance Number.
		Does this protocol involve the in **vivo use of biohazardous materials, human tissues/blood/body fluids, recombinant DNA and/or infectious agents**? **If yes,** approval from the ***Institutional Biosafety Committee*** must be obtained prior to receiving IACUC approval to conduct those specific experiments using these agents. A copy of the IBC approval letter must be supplied to the IACUC office. **IBC info:** phone 464-4317 or http://www.upstate.edu/researchadmin/ibc/basic_science.php **List Agent(s) to be used:**

Appendix 10: Blank IACUC Protocol Form

		Does this protocol involve the **in vivo use of radioactive materials**? **If yes,** approval from the ***Radiation Safety Office)*** must be obtained prior to receiving approval to conduct those specific experiments using radioactive materials. A copy of the approval letter must be supplied to the IACUC office. **Radiation Safety Info:** phone 464-6510 or http://www.upstate.edu/researchadmin/rad.php **List Material(s) to be used:**
		Does this protocol involve the **in vivo use of carcinogens, toxins or mutagens?** **If yes,** approval from ***Environmental Health & Safety*** must be obtained prior to receiving approval to conduct those specific experiments using these agents. A copy of the approval letter must be supplied to the IACUC office. **EHS Info:** phone 464-5782 or http://www.upstate.edu/ehs/ **List Agent(s) to be used:**
		Does this protocol involve animals previously used on a different project? **If yes,** provide Investigator's name:_____ and IACUC Number:_____

What is the funding source for this project?

Note: Approval of IACUC application is not required by PHS prior to grant review. "Just in time" policy allows for approval after the grant receives a "fundable" priority score, but prior to receipt of funds. (To avoid delay in funding, applications should be submitted at least 3 months prior to earliest possible funding date.)

Funding Source Place an **[X]** in the box next to all anticipated funding sources.		**Status of Funding** Place an **[X]** in the appropriate column.		
		Funded	**Under Review**	**To be submitted**
	Public Health Service (NIH) **Please specify Agency/Institute:**	**Grant #:**		
	Other Federal/State Agency **Please specify:**			
	Foundation or Industry **Please specify:**			
	Departmental, Clinical or Personal Funds **Please specify:**			

A. PERSONNEL:

At least one person listed on the protocol must be available at all times to deal with complications. (If all of the personnel will be unavailable at the same time (meetings, vacations, etc.), prior arrangements should be made with DLAR (4-6563) to handle emergency situations involving the animals on this protocol.)

Appendix 10: Blank IACUC Protocol Form

Who will serve as the **"Primary Contact?**"

Name: _____

Bldg. / RM#: _____

Work Phone: _____

Cell Phone: _____

Email: _____

* * * * * * * * * * *

Please complete the following Personnel Information section for <u>each</u> person with animal contact (principal investigators, technicians, graduate students, medical students, residents, fellows & visiting faculty). It is the responsibility of the investigator to notify the IACUC Office at 464-4292 of any changes in personnel.

Appendix 10: Blank IACUC Protocol Form

Personnel Information

(Complete a separate form for each individual working on this protocol - *Duplicate as needed)*

Name	Degree	Dept.	Work Phone	Alternate phone	Email

Has this individual has completed the mandatory CITI Lab Animal Welfare Laws & Regulations online training or provided documentation of equivalent training? Training requirements are posted on the IACUC website.	**YES**	**NO**

Instructions & Certification of Training

In the checklist below, place an [X] in the appropriate column for each procedure that this individual will perform on this protocol.

By indicating that this individual is adequately trained in the procedure(s) below, the Principal Investigator is certifying that the individual is competent to independently perform these procedures. Furthermore, the Principal Investigator understands that procedures marked "Training Required" may not be performed unsupervised by this individual until adequate documentation of training is submitted to the IACUC office.

Person responsible for training*	

***"Trainer"** must contact the IACUC office (464-4292) at the completion of training to provide documentation. DLAR can provide training on handling and basic procedures (injections, etc.) Please contact DLAR (464-6563) to arrange a training session.

List all species that will be used on this protocol →	**Species 1:**		**Species 2:**		**Species 3:**		**Species 4:**	
PROCEDURES:	**Adequately Trained**	**Training Required**	**Adequately Trained**	**Training Required**	**Adequately Trained**	**Training Required**	**Adequately Trained**	**Training Required**
Handling & Restraint								
Euthanasia:								
Cervical Dislocation								
Decapitation								
CO2								
Injectable agents								
Other – describe:								
Anesthesia:								
Injectable								
Inhalational								
Regional (local)								
Aseptic Survival Surgery [redacted]								
Sterile Survival Surgery [redacted]**)**								
Injections:								
Subcutaneous (SQ)								
Intramuscular (IM)								
Intraperitoneal (IP)								
Intravenous (IV)								
Submandibular								
Retro-orbital								
Gavage								
Other – describe:								
Other procedures – list below:								

Appendix 10: Blank IACUC Protocol Form

B. ANIMAL INFORMATION (Please provide a separate table for **each** species and/or strain.)

Species:	**Sex**:
Strain or Breed:	**Age or Weight**:
Preferred Source (if any):	
Total Number Requested (must equal the total for all groups in Section D(IV):	
Please describe any special environmental requirements (cages, feed, etc.):	

C. LAY DESCRIPTION

Please provide a succinct description of the proposed experiments that could be understood by an **average high-school student**. Any technical or scientific terms and all abbreviations must be defined. This description must answer all of the following questions:

(1) What are the goals of the research?

(2) Why are these goals important?

(3) What are the proposed experiments?

(4) How will the proposed experiments help achieve these goals?

D. INFORMATION IN SUPPORT OF THE EXPERIMENTAL APPROACH

I. Please describe the scientific background and the rationale for the proposed experiments.
(Answer must include citations that reference specific statements in the narrative.)

II. What value or potential contributions to biology or medicine may come from this work?

III. Please give specific reasons why the chosen species should be used. (Answer must take into consideration the use of species lower on the phylogenetic scale. Animals higher on the phylogenetic scale should also be considered if they represent a more suitable model. Cost savings alone is not an adequate justification.)

Appendix 10: Blank IACUC Protocol Form

IV. Table of Animals Required for Each Proposed Experiment
(Insert rows as needed to list all proposed experiments. The total of all groups listed here **must** match the total requested in **Section B**.)

Experiment	Species	Strain(s)	Group Size (n)	TOTAL # of animals required

V. Please provide a description of how the number of animals for each group (n) was determined. (It is preferable that this determination be based on a power analysis and/or previous experience as to the number required for statistical significance. Do not include animals used solely for breeding purposes unless integral to the scientific aims of the study.)

VI. Please describe the proposed experiments.

E. PROCEDURES

I. Flow Diagram. For each different type of experiment, provide a flow diagram or sequential list of procedures to help the Committee understand what happens experimentally to each animal from initiation of experiment to euthanasia.

II. Describe ALL experimental procedures involving animals. Every potential manipulation of an animal must be described in detail. Details on surgical procedures may be deferred to Appendix I – Surgical Intervention Form. Please duplicate the table below for each experimental procedure.

Procedure:	**Bldg/Room#**:
Description:	

F. USE OF PHARMACEUTICAL GRADE COMPOUNDS: Principal investigators are required to use pharmaceutical grade compounds for all experiments involving the use of live animals. The administration of non-pharmaceutical grade compounds (NPG) to live animals will only be permitted following review and approval by the IACUC.

- NPG compounds are defined as any compound not specifically formulated and approved by the FDA for administration into humans or animals. Any chemical purchased from a chemical supply company (e.g.: Sigma-Aldrich) and mixed in the lab is considered NPG by definition.

- Justifications for using NPG compounds can include the following:

  a. No pharmaceutical grade veterinary or human drug is available or consistently available.
  b. Although a pharmaceutical grade drug is available, a greater concentration, different formulation, or route of administration is required.
  c. Although a pharmaceutical grade drug is available, it contains preservatives or inactive ingredients that confound the research goals of the study.
  d. Although a pharmaceutical grade drug is available, the NPG drug is required to replicate methods from previous studies.
  e. Although a pharmaceutical grade drug is available, the exorbitant cost has made it logistically unavailable (generally, cost savings alone is not adequate justification).
  f. Other (provide justification in table below).

Will this protocol only use pharmaceutical grade substances? Mark (X) appropriate response:

	YES. All chemicals and substances used in animals will be pharmaceutical grade. *(**Skip** to **Section G**.)*
	NO. Some or all chemicals and substances used in animals will be non-pharmaceutical grade. ***Complete** the table below for <u>each</u> NPG compound to be administered to live animals.*

NPG Compound Name:	
• What is the justification for the use of the NPG compound? (*See a. – f. above for guidance*)	
• How is the compound prepared?	
• How will the sterility be assured? (N/A for gavage or topical)	
• How will the compound be stored?	
• How long will the compound remain safe and effective?	

Appendix 10: Blank IACUC Protocol Form

G. EXPOSURE TO HAZARDOUS MATERIALS: Describe specific methods to protect employees from exposure to hazardous materials (biological, chemical, radiation) used in animals. **This should include methods to be used:**

1) during transport of the agent or exposed animals to and from the animal facility,
2) during the actual inoculation or exposure,
3) during animal housing post-exposure, and
4) during terminal procedures.

H. EUTHANASIA: **Describe the euthanasia method(s) to be used, including the dose and route of administration of any drugs.** All methods must comply with the *AVMA Guidelines for the Euthanasia of Animals: 2013 Edition*. If the method of euthanasia does not include a physical disruption incompatible with life (opening the thorax, decapitation, etc.), please describe how death will be assured prior to disposal of the animal.

I. RESULTS: **What are the outcome measures and how do they relate to the hypothesis being tested?** Please describe so that an outside reviewer could understand the type of data that will be collected and how that information addresses the question(s) being investigated.

J. PAIN and/or DISTRESS INFORMATION:

One of the major responsibilities of the IACUC is to determine the degree of pain and/or distress that will be imposed on the animals and what method(s) will be used to prevent, relieve or minimize that pain and/or distress. The Animal Welfare Act (as amended July 22, 1993) defines a ***Painful procedure*** as:

"any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or other minor procedures"

Significantly Painful and/or Distressful Procedures: The following are some examples. (incomplete list)

- Surgery
- Fracturing bones
- Neurophysiological preparations
- Drug or radiation toxicity
- Intracardiac or periorbital blood collection
- Moderate to severe malnutrition

- Diseases that result in tissue destruction or death
- Agents causing excessive inflammation or necrosis, e.g. Freund's complete adjuvant, Bradykinin
- Chair or stock restraint of unadapted animals or restraint of any animal for more than 12 hours
- Burning or freezing
- Electrical shocks, including shock reinforcement
- LD 50 determinations
- Intracerebral or intracardiac inoculations
- Application of noxious stimuli without escape
- Imposition of abnormal environmental conditions

Behavioral Indicators of Pain: *Note*: There is considerable interspecies and individual variability in response to pain.

- Biting or resistance to handling (in adapted animals)
- Guarding the painful area
- Vocalization
- Self-mutilation
- Looking at, licking, chewing, or smelling painful area
- Reluctance to bear weight, limping
- Reluctance to move or rise
- Lethargic behavior
- Abnormal breathing pattern
- Excess salivation
- Inappetence
- Shivering
- Assuming unusual positions
- Acting “anxious”

Nutritional Distress: Nutritional distress is defined as a level of malnutrition that **significantly** interferes with the normal physiology of the animal. Fasting for up to 24 hours in most animals (48 hours for [redacted]) is not considered to be significant nutritional stress, except in the case of neonates or animals with high metabolic rates (e.g.[redacted]). Nutritional distress can be imposed by either fasting or feeding a diet with one or more nutrients below recommended levels. Any planned nutritional distress must be described in **Section E and** a justification for its use provided in **Section N.**

****

K. USDA CATEGORY THAT APPLIES TO THIS PROTOCOL: (indicate more than one **only** if there are different uses of animals that would distinctly fall into different categories, i.e., some animals are only euthanized for tissue collection (“C”) while others undergo surgery (“D”) prior to euthanasia.)

Appendix 10: Blank IACUC Protocol Form

____	**Category C**	Pain and/or distress no greater than an injection.
____	**Category D**[1]	Pain and/or distress fully alleviated with analgesics and/or anesthetics.
____	**Category E**[1,2]	Pain and/or distress not fully alleviated with analgesics and/or anesthetics.

[1]For protocols in *either* **Categories D or E**, Section L **must** be completed.
[2]The Principal Investigator **must also include a written justification in Section N** as to the necessity of withholding anesthetics and/or analgesics. You may also be requested to attend a meeting to discuss the proposed research with the IACUC.

L. SEARCH FOR ALTERNATIVES: The Principal Investigator must provide a search for alternatives to painful and distressful procedures When performing the search for alternatives, please refer to: *AWIC Tips for Searching for Alternatives to Animal Research and Testing*. At the very minimum, this description must include a database search with all of the following components identified.

I. The database(s) searched:

II. The date on which the search was conducted:

III. The time period covered by the search (*e.g,1970 – present***)**:

IV. The key words and/or search strategy used:

V. Other methods utilized:

M. POTENTIAL ALTERNATIVES: Please give specific reasons why the anticipated data could not be obtained using a non-animal alternative or an alternative procedure. ALL methods or techniques that could result in the **Reduction** of animals used, **Replacement** of animals with non-animal models, and/or result in **Refinement** of experimental techniques to reduce pain and distress must be considered and an explanation provided as to why they are unsuitable.

N. JUSTIFICATIONS: If this protocol involves any of the following procedures that require specific justification, please provide below **OR** check (X) box for N/A.

I. Non-compliance with "Guidelines for Production of Polyclonal and Monoclonal Antibodies in [redacted] and [redacted]"

☐ N/A

II. Non-compliance with "Guidelines for the Utilization of Animals in Experimental Neoplasia and Ascites Production"

☐ N/A

III. Non-compliance with "Guidelines for Tail Biopsy of [redacted]"

☐ N/A

IV. Death as an Endpoint – Justification for why earlier euthanasia would invalidate study.

☐ N/A

V. Use of Paralytic Agents – Justification for why paralytic agents must be used.

☐ N/A

VI. Use of Expired Medical Materials – Description of expired materials to be used and justification for why this is necessary.

☐ N/A

VII. Restraint of Conscious Animals for Longer than 15 minutes – Explain the necessity.

☐ N/A

VIII. Food or Water Restrictions Beyond Standard Pre-Surgical Fasting – Explain the necessity.

☐ N/A

IX. USDA Category E – Justification for why anesthetics/analgesics must be withheld.

☐ N/A

X. Multiple Survival Surgery – Justification for why multiple, separate surgical procedures must be conducted on the same animal.

☐ N/A

O. PRINCIPAL INVESTIGATOR CERTIFICATION FOR ELECTRONIC SUBMISSIONS*

The Principal Investigator certifies that:

- all the information provided is accurate to the best of his/her knowledge and s/he will adhere to the procedures described;
- the animals in this study will be used in accordance with the laws and regulations of:
  - the Animal Welfare Act
  - the Public Health Service
  - the New York State Health Department
  - the SUNY Upstate Medical University Department of Laboratory Animal Resources
- the species, number of animals, and procedures to be used are the most appropriate for the proposed study;
- consideration has been given to any and all alternatives to painful and/or distressful procedures;
- pain and/or distress to animals will be limited to that which is unavoidable in the conduct of scientifically-valuable research;
- analgesic, anesthetic and tranquilizing drugs will be used where indicated to minimize pain and/or distress;
- the activities described in this study do not unnecessarily duplicate previous experiments. If activities will duplicate previous experiments, I have included a written explanation and justification for the duplicative procedures;
- all individuals listed on this protocol are trained and qualified for their specific duties involving animals under this proposal;
- all individuals listed on this protocol who lack sufficient training must be supervised while performing such tasks until adequate documentation of training is submitted to the IACUC office;
- all individuals listed on this protocol have read the protocol or will be provided access to the complete protocol approved by the committee before engaging in any animal use related to this project;

and s/he agree to:

- obtain approval from the IACUC in advance of any changes in the project;
- notify the Attending Veterinarian and/or the IACUC of any unexpected study results that impact\
  animal welfare;

- be familiar with and comply with all pertinent institutional, state, and federal rules and policies;
- be responsible for the supervision and work of my staff; and
- retain copies of this protocol and all correspondence associated with it for three years beyond the completion of the animal use.

Please certify (X) the following*:

	I certify adherence to the criteria listed above **and** that I have read and understand the information on potentially painful / distressful procedures and behavioral indicators pain provided in **Section J** of this animal use protocol.

*Electronic submission of this document by the Principal Investigator via his/her own email serves as his/her electronic signature. Document submission by other lab personnel **will not be accepted.** **DO NOT** submit a hard copy.

Appendix 10: Blank IACUC Protocol Form

Appendix I

SURGICAL INTERVENTION FORM

If more than one type of surgery is planned, please complete a separate Appendix I for each type of surgery.

Type of surgery:	☐	**Major –** Major Surgery is defined as any surgical intervention that exposes a body cavity or has the potential for producing permanent physical or physiological change.
	☐	**Minor**
	☐	Multiple Survival – Justification for multiple survival surgeries must be provided in **Section N**.
	☐	**Nonsurvival**

Name of Surgical Procedure: _____

Species: _____

1. **Detailed Description of Surgical Procedure:**

2. **Approximate length of surgical procedure:** _____

3. **Location of Surgical Procedure (DLAR or other) -** Survival surgical procedures on all [redacted]) *must* be conducted in dedicated surgical facilities. The DLAR surgical facilities must be used unless justification is provided for another location (see Survival Surgery section). Survival surgery on [redacted] does not require a dedicated facility, but [redacted] surgeries may also be performed in DLAR facilities. Contact Jennifer Kieffer @ Ext. 4-4289 to schedule surgery within the DLAR facilities.

   Building: _____ Room Number _____

4. **Personnel Performing Surgery: Please list all personnel who may be performing this surgery*.**
   *Training for this procedure must be documented on each individual's Training Summary in the IACUC office.

5. **Will animals be attended at all times during the surgical procedure?** **YES** ___ **NO*** ___
*If no, please explain:

Method of Anesthesia During Surgical Procedure

6. **Pre-anesthetic**:

Agent(s)	**Dose** (mg/kg)	**Route** (IM, IP, etc.)

7. **Anesthetic**:

Agent(s)	**Dose** (mg/kg)	**Route** (IM, IP, etc.)

Survival Surgery - Complete the following sections of Appendix I ONLY if animals will recover from anesthesia.

Survival surgery on [redacted] must be performed using standard sterile operating room procedures. Survival surgery on [redacted] must be performed using aseptic procedures, which include (as a minimum) sterile surgical gloves, mask, and sterile instruments.

8. **Will survival surgery on [redacted] species be performed in facilities other than DLAR?**

___ Yes*
___ No
___ Not applicable, using [redacted] species

***If yes, please provide justification for the location chosen (specialized equipment, etc.):**

9. **Describe the pre-operative procedures to be performed (i.e., fasting, pre-medication, preparation of surgical site, etc.):**

Appendix 10: Blank IACUC Protocol Form

10. **Describe the sterile or aseptic procedures to be followed by all personnel (gowns, gloves, masks, instruments preparation, etc.):**

11. **Immediate Post-Operative Care:**

Location of recovery: _____
Person(s) monitoring: _____
Minimum frequency of monitoring: _____
When will animal be returned to DLAR? _____

12. **Describe <u>all</u> potential post-operative complications and what procedures are planned to monitor and address these complications:**

13. **Postoperative Analgesia:**

Agent(s)	**Dose** (mg/kg)	**Route** (IV, etc.)	**Frequency**	**Duration** (days)

14. **Postoperative Treatments:**

Agent(s)	**Dose** (mg/kg)	**Route** (IV, etc.)	**Frequency**	**Duration** (days)

15. **Other postoperative procedures:** (suture removal, etc.):

Appendix 10: Blank IACUC Protocol Form

Appendix II

BREEDING COLONY INFORMATION*

***The experimental use of embryos or offspring does not necessarily constitute a breeding colony (i.e., ordering pregnant dams). It is only when you intend to breed multiple generations of offspring that it becomes a breeding colony.**

Species: _____

Specific strain of male: _____

Specific strain of female: _____

Original source of animals: _____

Purpose for establishing and/or maintaining breeding colony (special strain, etc.)**:**

Phenotypic considerations (clinical signs; special care):

Approximate number of animals to be produced (This should be the total number of animals that you expect to produce over the entire approval period which should include experimental animals, replacement breeders and all unusable animals. Any animals determined to be unusable for your experimental purposes (e.g. wrong genotype) should be transferred to DLAR for disposal, and should not appear as animals that were "used" on your "Record of Animal Usage" during annual protocol review.):

Please explain how the number to be produced was determined:

Breeding system: ____ Inbred ____ Outbred _____ Other (please explain):

Breeding method: ____ Monogamous ____ Harem Other (please explain):

Method of identification: _____

Method of genetic monitoring: _____

Personnel responsible for pedigree records: _____

Additional Information: _____

Appendix 10: Blank IACUC Protocol Form

Appendix III

GUIDELINES FOR THE USE OF EXPIRED MEDICAL MATERIALS

The Animal Care division of the United States Department of Agriculture (USDA) has developed a policy (Policy #3: Veterinary Care) concerning the use of expired medical materials for non-survival experimental procedures. In consideration of this policy, the IACUC has developed the following guidelines, which should be followed when utilizing outdated pharmaceuticals or medical devices in experimental animals:

1. Outdated materials may only be used if the item is irreplaceable or replacement would be prohibitively expensive and its use does not adversely affect the animal's well-being or compromise the validity of the study.

2. Drugs administered to relieve pain or distress and emergency drugs must not be used beyond their expiration dates.

3. The outdated items must be physically separated from other similar items and clearly labeled **"Outdated Materials – For Terminal Procedures Only"** (or similarly).

4. Expired materials should be maintained in as sterile or clean condition as possible.

5. A description of the expired materials to be used and justification for why this is necessary must be provided in **Section N** of the animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

and

☐ I have provided written justification in **Section N.**

Appendix 10: Blank IACUC Protocol Form

Appendix IV

GUIDELINES FOR THE PRODUCTION OF POLYCLONAL AND MONOCLONAL ANTIBODIES IN [redacted] AND [redacted]

I have read the **Guidelines for the Production of Polyclonal and Monoclonal Antibodies in [redacted] and [redacted]**, revised 10/17/01. I understand that the use of Freund's Complete Adjuvant (FCA) is discouraged and alternatives should be considered. I also understand that intradermal or foot pad injections require specific justification.

I understand that any deviation from these guidelines requires justification in **Section N** of animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

OR

☐ I have provided written justification for noncompliance with these guidelines.

Appendix 10: Blank IACUC Protocol Form

Appendix V

GUIDELINES FOR THE UTILIZATION OF ANIMALS IN EXPERIMENTAL NEOPLASIA AND ASCITES PRODUCTION

I have read the Guidelines for the Utilization of Animals in Experimental Neoplasia and Ascites Production, revised 10/17/01.

I understand that any deviation from these guidelines requires justification in **Section N** of animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

OR

☐ I have provided written justification for noncompliance with these guidelines.

Appendix 10: Blank IACUC Protocol Form

Appendix VI

GUIDELINES ON DEATH AS AN ENDPOINT

Death as an endpoint is defined as the experimental necessity to allow animals to die spontaneously (not euthanasia). Regulatory agency guidelines highly discourage the use of death as an endpoint for **any** experiment. Investigators **must** euthanize moribund experimental animals unless there is significant scientific support that euthanasia would invalidate experimental data collection. For the definition of moribund, please refer to the IACUC Policy on Euthanasia for Humane Purposes.

If death as an endpoint is a necessity, scientific justification must be provided in **Section N** of the animal use protocol**.** Investigators who receive approval to use death as an endpoint **must** agree to the following:

1. To use the minimum number of animals necessary to achieve statistical significance.
2. To use alternative endpoints (other than death) whenever possible.
3. To monitor animals at least twice daily (including weekends and holidays) and separate out debilitated animals to allow easy access to food and water.
4. To keep written records of all monitoring sessions which indicate the time observed, person observing, and any noteworthy observations such as clinical signs, number dead, etc. These records must be current and available to the Department of Laboratory Animal Resources and the IACUC at all times (within the housing area unless other arrangements are made with DLAR).

Investigators should note that any approved use of death as an endpoint will normally be categorized in the highest USDA pain and distress **category E.**

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

and

☐ I have provided written justification in **Section N.**

Appendix 10: Blank IACUC Protocol Form

Appendix VII

GUIDELINES FOR THE USE OF PARALYTIC AGENTS DURING ANESTHESIA

Although the use of paralytic agents is recognized as a necessary component of some experimental protocols, the use of these agents renders assessment of the level of general anesthesia much more difficult. The IACUC policy on the Use of Paralytic Agents During Anesthesia provides the following guidance for the use of paralytic agents during anesthesia:

1. Paralysis should not be induced until the animal has reached a surgical plane of anesthesia (no response to toe pinch).

2. To an extent consistent with the experimental protocol, potentially painful procedures should be minimized in paralyzed animals.

3. The planned anesthetic regimen should be sufficient to prevent the animal from experiencing significant pain or distress. This shall be determined based upon previous experience, consultation with a veterinarian, documentation, and/or trial use in non-paralyzed animals exposed to the same planned experimental procedures.

4. To the extent consistent with the experimental protocol, paralytics should be temporarily withheld periodically to reassess anesthetic depth (best accomplished by utilizing short-acting paralytics).

5. During paralysis, adequacy of anesthesia should be assessed continuously by monitoring heart rate and/or blood pressure. Temperature should also be monitored and maintained within normal parameters. If necessary, provisions for voiding urine should be provided.

6. I understand that the use of paralytic agents requires justification in **Section N** of the animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

and

☐ I have provided written justification in **Section N.**

Appendix 10: Blank IACUC Protocol Form

Appendix VIII

GUIDELINES ON TAIL BIOPSY OF [redacted]

Tail biopsy of [redacted] is often used to obtain tissue samples for genetic analysis.

For a single sample collection in an UNANESTHETIZED animal, the following criteria must be met:

a. Sample length must not exceed 0.5 cm
b. Animal must be 4 weeks of age or less
c. Excisional tool (scalpel or scissors) must be sharp
d. Bleeding must be controlled (if it exceeds 1-2 drops)

This sample collection will be considered a USDA pain or distress category "C".

ANESTHESIA is required for any repeat biopsies, sample size > 0.5 cm, and/or animals older than 4 weeks. Bleeding must be controlled. Post-procedural analgesics may also be required. This must be determined in consultation with DLAR veterinary staff **PRIOR to collecting samples.** (4-6563).

If anesthesia is required, this procedure will be considered a USDA pain or distress category "D".

The IACUC encourages investigators to consider alternatives to tail biopsy such as utilizing ear punch tissue obtained during identification or using oral swabs to obtain cells from mucous membranes (contact DLAR for specific references). These techniques have been used successfully for genetic monitoring, especially when PCR techniques are utilized that require very little tissue.

I understand that any deviation from these guidelines requires justification in **Section N** of animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

OR

☐ I have provided written justification for noncompliance with these guidelines.

Appendix 11: Blank IACUC Addendum Form

Institutional Animal Care and Use Committee
SUNY Upstate Medical University

PROTOCOL ADDENDUM FORM

For IACUC Use Only

Addendum #_____

Date Received:_____

Date Approved:_____

IACUC # _____ **Principal Investigator:** _____

INSTRUCTIONS:

Please complete this form with a **detailed** description of all changes from the original protocol and the explanation for these changes. The appropriate types of changes include (but are not limited to) any of the following: additional test substances administered, changes in anesthesia, changes in data collection, changes in species or strain, need for additional animals, etc. Complex changes in experimental procedure or multiple departures from the original protocol may require submission of an entirely new protocol. Contact the IACUC office for guidance.

As mandated by the Animal Welfare Act, 9 CFR and our Assurance with PHS: If the following **items will be altered from the original protocol**, please address each individually in the addendum regarding the proposed changes. **Any non-applicable items must be indicated by N/A.**

The Principal Investigator must electronically submit this form via his/her own email account. Document submission by other lab personnel or from an alternate email address **will not be accepted**.
DO NOT submit a hard copy.

Questions? Email the IACUC office or call 315-464-4292.

---

1. **Describe ALL proposed changes and provide an explanation of why they are necessary.** (For example, scientific background and rationale would be appropriate if requesting new experiments.) If new surgical procedures will be performed, please attach a completed Appendix I – Surgical Intervention Form.

2. **Species/strain involved**.

Appendix 11: Blank IACUC Addendum Form

3. **Number of additional animals needed for this addendum.**

4. **If additional experiments are proposed,** please provide a description of how the number of animals for each group (n) was determined. (It is preferable that this determination be based on a power analysis and/or previous experience as to the number required for statistical significance. Do not include animals used solely for breeding purposes unless integral to the scientific aims of the study.)

5. **Changes in anesthesia or other methods of minimizing pain and discomfort.**

6. **Changes in euthanasia methods**.

7. **What is this protocol's current USDA pain category?**

8. **Changes in the Administration of Compounds to Animals** – Principal investigators are required to use pharmaceutical grade compounds for all experiments involving the use of live animals. The administration of non-pharmaceutical grade compounds (NPG) to live animals will only be permitted following review and approval by the IACUC.

   - NPG compounds are defined as any compound not specifically formulated and approved by the FDA for administration into humans or animals. Any chemical purchased from a chemical supply company (e.g.: Sigma-Aldrich) and mixed in the lab is considered NPG by definition.

   - Justifications for using NPG compounds can include the following:

     a. No pharmaceutical grade veterinary or human drug is available or consistently available.
     b. Although a pharmaceutical grade drug is available, a greater concentration, different formulation, or route of administration is required.
     c. Although a pharmaceutical grade drug is available, it contains preservatives or inactive ingredients that confound the research goals of the study.
     d. Although a pharmaceutical grade drug is available, the NPG drug is required to replicate methods from previous studies.

e. Although a pharmaceutical grade drug is available, the exorbitant cost has made it logistically unavailable (generally, cost savings alone is not adequate justification).
f. Other (provide justification in table below).

Do the proposed experiments only use pharmaceutical grade substances? Mark (X) appropriate response:

	NA. No new chemicals or substances are being added. *(No additional information is required.)*
	YES. All chemicals and substances used in animals will be pharmaceutical grade. *(No additional information is required.)*
	NO. Some or all chemicals and substances used in animals will be non-pharmaceutical grade. ***Complete** the table below for <u>each</u> NPG compound to be administered to live animals.*

NPG Compound Name:	
• What is the justification for the use of the NPG compound? (*See a. – f. above for guidance)*	
• How is the compound prepared?	
• How will the sterility be assured? (N/A for gavage or topical)	
• How will the compound be stored?	
• How long will the compound remain safe and effective?	

Appendix 12: Blank IACUC Annual Report Form

Institutional Animal Care and Use Committee
SUNY Upstate Medical University

IACUC PROTOCOL - ANNUAL REVIEW REPORT

Animal Welfare Regulations require an annual review of protocols. PHS Policy requires the IACUC to conduct continuing review of each previously approved ongoing activity at appropriate intervals as determined by the IACUC. At SUNY Upstate Medical University, regardless of the species used, the IACUC requires an annual report on the status of each animal use protocol. Failure to file this report in a timely manner may result in administrative suspension of all activities involving the use of live animals covered under the approved protocol.

- **This report must be emailed to the IACUC office** by the submission deadline.
- **If you choose to terminate the protocol**, you still must file this report with IACUC office by the submission deadline.
- The Principal Investigator must electronically submit all documents via his/her own email account. Electronic submission by the Principal Investigator certifies that:
    1. s/he understands the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals, applicable USDA regulations and the University's policies governing the use of vertebrate animals for research, testing or demonstration purposes, and
    2. s/he will continue to conduct the project in full compliance with the aforementioned requirements.
- **DO NOT** submit a hard copy.
- **SUBMISSION DEADLINE: «Enter deadline date»**

Questions? Email the IACUC office or call 315-464-4292.

PROTOCOL INFORMATION:

Principal investigator:	**«PINAME»**
IACUC #:	**«IACUC»**
Title:	**«Protocol_Title»**
Expires on:	**«Date_Expires»**
USDA Pain Category:	**«Pain_Category»**
Period covered by this report:	**«Reporting_period_start_date» through the present**

Appendix 12: Blank IACUC Annual Report Form

Please answer ALL of the following questions.

1. **Report Date:** _____

2. **Protocol Status –** Check (X) one:

	Ongoing
	Terminate immediately. Protocol is no longer being used.

3. **Number of Animals Used:** In the following table, please list the species of animals covered by this protocol and indicate how many animals were **used since the date of the previous annual report or protocol approval (see page 1).** Please list only animals that were used for experimental purposes as outlined in this protocol.

   Do not include:
   a) surplus animals that were genetically unusable
   b) animals that were counted in the previous year

Species	**# of animals used per species**
«List_species»	

4. **Unexpected Deaths:** Have unexpected deaths occurred in relation to this protocol? Select (x) applicable box:

Yes*	
No	
N/A	

*If you answered YES, please provide the following information:

   a) Total number of deaths: _____
   b) Percent of Total Number Used:_____
   c) Explanation, if known:

5. **Search for Alternatives: For protocols in categories D or E,** the Principal Investigator must provide a search for alternatives to painful and distressful procedures. When performing the search for alternatives, please refer to: ***AWIC Tips for Searching for Alternatives to Animal Research and Testing*** - https://www.nal.usda.gov/awic/awic-tips-searching-alternatives-animal-research-and-testing

   At the very minimum, this description must include a database search with all of the following components identified.

   a) The database(s) searched:

   b) The date on which the search was conducted:

   c) The time period covered by the search:

   d) The key words and/or search strategy used:

   e) Other methods utilized:

6. **Potential Alternatives: Please give specific reasons why the anticipated data could not be obtained using a non-animal alternative or an alternative procedure.** ALL methods or techniques that could result in the **Reduction** of animals used, **Replacement** of animals with non-animal models, and/or result in **Refinement** of experimental techniques to reduce pain and distress must be considered and an explanation provided as to why they are unsuitable.

7. **Progress Report:** Please provide brief a description of any advances or information you have collected from your research (i.e. published articles, presentations, abstracts). If this is a teaching protocol, please provide a brief comment as to the success of the teaching exercises completed. (i.e., How many individuals participated and how was the course received by those in attendance?)

8. **Abstracts:** In the space below, please provide the **abstract** for each publication referenced in #7 above that is the result of work performed under this IACUC protocol. Please **do not** attach the full publication.

Appendix 13: Blank IACUC Triennial Report Form

Institutional Animal Care and Use Committee
SUNY Upstate Medical University

IACUC PROTOCOL – TRIENNIAL REPORT

To continue the activities covered by your expiring animal use protocol, a renewal protocol must be submitted approx. 2 months before this protocol expires. Any addenda you plan to continue should be incorporated into the text of the new protocol. The Institutional Animal Care and Use Committee (IACUC) must perform a complete review of the renewal protocol before your currently approved protocol expires.

- **This report and the renewal animal use protocol must be emailed to the IACUC office** by the submission deadline.
- **If you choose to terminate the protocol immediately or let it expire**, you still must file this report with IACUC office by the submission deadline.
- The Principal Investigator must electronically submit all documents via his/her own email account. Electronic submission by the Principal Investigator certifies that:
    3. s/he understands the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals, applicable USDA regulations and the University's policies governing the use of vertebrate animals for research, testing or demonstration purposes, and
    4. s/he will continue to conduct the project in full compliance with the aforementioned requirements.
- Document submission by other lab personnel **will not be accepted**.
- **DO NOT** submit a hard copy.

Submission Deadline: **Enter deadline date**

Questions? Email the IACUC office or call 315-464-4292.

EXPIRING PROTOCOL INFORMATION:

Principal investigator:	**«PINAME»**
IACUC #:	**«IACUC»**
Title:	**«Protocol_Title»**
Expires on:	**«Date_Expires»**
USDA Pain Category:	**«Pain_Category»**
Period covered by this report:	**«Reporting_period_start_date» through the present**

Appendix 13: Blank IACUC Triennial Report Form

Please answer ALL of the following questions.

1. **Report** [ ] **Date:**

2. **Protocol Status –** Check (X) one:

	I plan to continue these studies. A renewal protocol is attached – Must be the 8/2018 version
	I will not renew this protocol.
	Terminate immediately. Protocol is no longer being used.

3. **Number of Animals Used:** In the following table, please list the species of animals covered by this protocol and indicate how many animals were **used since the date of the previous annual report (see page 1).** Please list only animals that were used for experimental purposes as outlined in this protocol.

   Do not include:
   a) surplus animals that were genetically unusable
   b) animals that were counted in the previous year

Species	**# of animals used per species**
«List_species»	

4. **PROGRESS REPORT:** Please provide brief a description of any advances or information you have collected from your research (i.e. published articles, presentations, abstracts). If this is a teaching protocol, please provide a brief comment as to the success of the teaching exercises completed. (i.e., How many individuals participated and how was the course received by those in attendance?)

5. **ABSTRACTS:** In the space below, please provide the **abstract** for each publication referenced in #4 above that is the result of work performed under this IACUC protocol. Please **do not** attach the full publication.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

SUNY Upstate Medical University

Institutional Animal Care and Use Committee

Semiannual Report to the Institutional Official

October 2019

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

Contents

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

I. Semiannual Program Review
Part A - Institutional Policies and Responsibilities

Key:

A = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable
[must] = indicates actions that the Committee for the Update of the *Guide* considers imperative and mandatory duty or requirement for providing human animal care and use (*Guide,* p 8)

1. Animal Care and Use Program	A	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (*Guide*, p 1) *[must]*	X				
• IO has authority to allocate needed resources (*Guide*, p 13)	X				
• Resources necessary to manage program of veterinary care are provided (*Guide*, p 14) *[must]*	X				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the *Guide* (*Guide*, pp. 11, 15)	X				
• Program needs are regularly communicated to IO by AV and/or IACUC (*Guide,* p 13)	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 (*Guide*, p 14) *[must]*					X
• Inter-institutional collaborations are described in formal written agreements (*Guide*, p 15)	X				
• Written agreements address responsibilities, animal ownership, and IACUC oversight (*Guide*, p 15)	X				
2. Investigating & Reporting Animal Welfare Concerns	**A**	**M**	**S**	**C**	**NA**
• Methods for investigating and reporting animal welfare concerns are established (*Guide*, p 23) *[must]*	X				
• Reported concerns and corrective actions are documented (*Guide*, p 24)	X				
• Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (*Guide*, p 24)	X				
○ Includes multiple contacts (*Guide*, p 24)	X				
○ Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (*Guide*, p 24)	X				
3. Disaster Planning and Emergency Preparedness	**A**	**M**	**S**	**C**	**NA**
• Disaster plans for each facility to include satellite locations are in place (*Guide*, p 35, p 75) *[must]*	X				
• Plans include provisions for euthanasia (*Guide*, p 35) *[must]*	X				
• Plans include triage plans to meet institutional and investigators' needs (*Guide*, p 35)	X				
• Plans define actions to prevent animal injury or death due to HVAC or other failures (*Guide*, p 35)	X				
• Plans describe preservation of critical or irreplaceable animals (*Guide*, p 35)	X				
• Plans include essential personnel and their training (*Guide*, p 35)	X				
• Animal facility plans are approved by the institution and incorporated into overall response plan (*Guide*, p 35)	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

•	Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (*Guide*, p 35)	X				
4.	**IACUC**	**A**	**M**	**S**	**C**	**NA**
•	Meets as necessary to fulfill responsibilities (*Guide*, p 25) *[must]*	X				
•	IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (*Guide*, p 26) *[must]*	X				
•	Continuing IACUC oversight after initial protocol approval is in place (*Guide*, p 33)	X				
•	IACUC evaluates the effectiveness of training programs (*Guide*, p 15)	X				
5.	**IACUC Protocol Review - Special Considerations**	**A**	**M**	**S**	**C**	**NA**
•	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 (*Guide*, p 27)	X				
•	For pilot studies, a system to communicate with the IACUC is in place (*Guide*, p 28)	X				
•	For genetically modified animals, enhanced monitoring and reporting is in place (*Guide*, p 28)	X				
•	Restraint devices, when necessary, are justified in the animal use protocols (*Guide*, p 29) *[must]*	X				
•	Alternatives to physical restraint are considered (*Guide*, p 29)	X				
•	Period of restraint is the minimum to meet scientific objectives (*Guide*, p 29)	X				
•	Training of animals to adapt to restraint is provided (*Guide*, p 29)	X				
•	Animals that fail to adapt are removed from study (*Guide*, p 29)	X				
•	Appropriate observation intervals of restrained animals are provided (*Guide*, p 29)	X				
•	Veterinary care is provided if lesions or illness result from restraint (*Guide*, p 30) *[must]*	X				
•	Explanations of purpose and duration of restraint are provided to study personnel (*Guide*, p 30)	X				
•	Multiple surgical procedures on a single animal are justified and outcomes evaluated (*Guide*, p 30)	X				
•	Major versus minor surgical procedures are evaluated on a case-by-case basis (*Guide*, p 30)	X				
•	Multiple survival procedure justifications in non-regulated species conform to regulated species standards (*Guide*, p 30)	X				
•	Animals on food/fluid restriction are monitored to ensure nutritional needs are met (*Guide*, p 31)	X				
•	Body weights for food/fluid restricted animals are recorded at least weekly (*Guide*, p 31)	X				
•	Daily written records are maintained for food/fluid restricted animals (*Guide*, p 31)	X				
•	Pharmaceutical grade chemicals are used, when available, for animal-related procedures (*Guide*, p 31)	X				
•	Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (*Guide*, p 31)	X				
•	Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (*Guide*, p 32)					X

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

• Disposition plans are considered for species removed from the wild (*Guide*, p 32)					X
• Toe-clipping only used when no alternative, performed aseptically and with pain relief (*Guide*, p 75)	X				
6. IACUC Membership and Functions	**A**	**M**	**S**	**C**	**NA**
• IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.)	X				
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (*Guide*, p 24)	X				
• IACUC authority and resources for oversight and evaluation of institution's program are provided (*Guide*, p 14)	X				
• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.)	X				
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.)	X				
• IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)	X				
• Methods for reporting and investigating animal welfare concerns are in place (*Guide*, p 23) *[must]*	X				
• Reviews and investigates concerns about animal care and use at institution (PHS Policy, IV.B.)	X				
• Procedures are in place for review, approval, and suspension of animal activities (PHS Policy, IV.B.)	X				
• Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.)	X				
• Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (*Guide*, p 27-32)	X				
• Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS (*Guide*, p 32) *[must]*					X
7. IACUC Records and Reporting Requirements	**A**	**M**	**S**	**C**	**NA**
• Semiannual report to the IO (PHS Policy, IV.B.)					
○ Submitted to IO every 6 months	X				
○ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	X				
○ Includes minority IACUC views	X				
○ Describes IACUC-approved departures from the *Guide* or PHS Policy and the reasons for each departure	X				
○ Distinguishes significant from minor deficiencies	X				
○ Includes a plan and schedule for correction for each deficiency identified		X			
• Reports to OLAW (PHS Policy, IV.F.)					
○ Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views	X				
○ Promptly advises OLAW of serious/ongoing *Guide* deviations or PHS Policy noncompliance (NOT-OD-05-034)	X				
○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)	X				
• Reports to U.S. Department of Agriculture (USDA) or Federal funding agency					
○ Annual report to USDA contains required information including all exceptions/exemptions	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

○ Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards	X					
○ Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies	X					
○ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency	X					
• Records (PHS Policy, IV.E.)						
○ IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	X					
○ Records of IACUC reviews of animal activities include all required information	X					
○ Records of IACUC reviews are maintained for 3 years after the completion of the study.	X					

I. Semiannual Program Review
Part B - Veterinary Care

A = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable
[must] = indicates actions that the Committee for the Update of the *Guide* considers imperative and mandatory duty or requirement for providing human animal care and use (*Guide,* p 8)

1. Veterinary Care	**A**	**M**	**S**	**C**	**NA**
• An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care	X				
• Veterinary access to all animals is provided (*Guide*, p 14) *[must]*	X				
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (*Guide*, p 14) *[must]*	X				
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (*Guide*, p 5) *[must]*	X				
• Veterinarian provides consultation when interventional control is not possible (*Guide*, p 5) *[must]*	X				
• If part-time/consulting veterinarian, visits meet programmatic needs (*Guide*, p 14)					X
• Regular communication occurs between veterinarian and IACUC (*Guide*, p 14)	X				
• Veterinarian(s) have experience and training in species used (*Guide*, p 15) *[must]*	X				
• Veterinarian(s) have experience in facility administration/management (*Guide*, p 15)	X				
2. Clinical Care and Management	**A**	**M**	**S**	**C**	**NA**
• Veterinary program offers high quality of care and ethical standards (*Guide*, p 105) *[must]*	X				
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (*Guide*, p 106)	X				
• Veterinarian provides oversight to surgery and perioperative care (*Guide*, p 106)	X				
• Veterinary care program is appropriate for program requirements (*Guide*, pp. 113-114)	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

•	Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (*Guide*, p 114)	X				
•	Procedures to triage and prioritize incident reports are in place (*Guide*, p 114)	X				
•	Procedures are in place to address:					
	○ Problems with experiments to determine course of treatment in consultation with investigator (*Guide*, p 114)	X				
	○ Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (*Guide*, p 114)	X				
	○ Veterinary review and oversight of medical and animal use records (*Guide*, p 115)	X				
•	Procedures established for timely reporting of animal injury, illness, or disease (*Guide*, p 114) *[must]*	X				
•	Procedures established for veterinary assessment, treatment, or euthanasia (*Guide*, p 114) *[must]*	X				
•	Veterinarian is authorized to treat, relieve pain, and/or euthanize (*Guide*, p 114 *[must]*	X				
3.	**Animal Procurement and Transportation/Preventive Medicine**	**A**	**M**	**S**	**C**	**NA**
•	Procedures for lawful animal procurement are in place (*Guide*, p 106) *[must]*	X				
•	Sufficient facilities and expertise are confirmed prior to procurement (*Guide*, p 106)	X				
•	Procurement is linked to IACUC review and approval (*Guide*, p 106)	X				
•	Random source dogs and cats are inspected for identification (*Guide*, p 106)					X
•	Population status of wildlife species is considered prior to procurement (*Guide*, p 106)					X
•	Appropriate records are maintained on animal acquisition (*Guide*, p 106)	X				
•	Animal vendors are evaluated to meet program needs and quality (*Guide*, p 106)	X				
•	Breeding colonies are based on need and managed to minimize numbers (*Guide*, p 107)	X				
•	Procedures for compliance with animal transportation regulations, including international requirements, are in place (*Guide*, p 107) *[must]*	X				
•	Transportation is planned to ensure safety, security and minimize risk (*Guide*, p 107)	X				
•	Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (*Guide*, pp. 107- 108)	X				
•	Appropriate loading and unloading facilities are available (*Guide*, p 109)	X				
•	Environment at receiving site is appropriate (*Guide*, p 109)	X				
•	Policies in place on separation by species, source, and health status (*Guide*, pp. 109, 111-112)	X				
•	Procedures in place for quarantine to include zoonoses prevention (*Guide*, p 110)	X				
•	Quarantined animals from different shipments are handled separately or physically separated (*Guide*, p 110)	X				
•	Procedures in place for stabilization/acclimation (*Guide*, pp. 110-111)	X				
•	Policies in place for isolation of sick animals (*Guide*, p 112)	X				
•	Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (*Guide*, p 112)	X				
•	Diagnostic resources are available for preventive health program (*Guide*, p 112)	X				
4.	**Surgery**	**A**	**M**	**S**	**C**	**NA**

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

• Surgical outcomes are assessed and corrective changes instituted (*Guide*, p 115)	X					
• Researchers have appropriate training to ensure good technique (*Guide*, p 115) *[must]*	X					
• Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (*Guide*, p 116)	X					
• Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (*Guide*, p 116)	X					
• Surgical procedures including laparoscopic procedures are categorized as major or minor (*Guide*, pp. 117-118)	X					
• For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (*Guide*, p 118)	X					
• Aseptic technique is followed for survival surgical procedures (*Guide*, pp. 118-119)	X					
• Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (*Guide*, p 119)	X					
• Procedures for monitoring surgical anesthesia and analgesia are in place (*Guide*, p 119)	X					
• For aquatic species, skin surfaces are kept moist during surgical procedures (*Guide*, p 119)	X					
• Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (*Guide*, pp. 119-120)	X					
5. Pain, Distress, Anesthesia and Analgesia	**A**	**M**	**S**	**C**	**NA**	
• Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (*Guide*, p 121)	X					
• Selection of analgesics and anesthetics is based on professional veterinary judgment (*Guide*, p 121)	X					
• Painful procedures are monitored to ensure appropriate analgesic management (*Guide*, p 122)	X					
• Nonpharmacologic control of pain is considered as an element of post-procedural care (*Guide*, p 122)	X					
• Procedures are in place to assure antinoception before surgery begins (*Guide*, p 122) *[must]*	X					
• Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (*Guide*, p 122)	X					
• Special precautions for the use of paralytics are in place to ensure anesthesia (*Guide*, p 123)	X					
6. Euthanasia	**A**	**M**	**S**	**C**	**NA**	
• Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (*Guide*, p 123)	X					
• Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (*Guide*, pp. 123-124)	X					
• Training is provided on appropriate methods for each species and considers psychological stress to personnel (*Guide*, p 124)	X					
• Procedures and training are in place to ensure death is confirmed (*Guide*, p 124) *[must]*	X					
7. Drug Storage and Control	**A**	**M**	**S**	**C**	**NA**	

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

• Program complies with federal regulations for human and veterinary drugs (*Guide*, p 115) *[must]*	X				
• Drug records and storage procedures are reviewed during facility inspections (*Guide*, p 115)	X				
• Procedures are in place to ensure analgesics and anesthetics are used within expiration date (*Guide*, p 122) *[must]*	X				
• Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (*Guide*, p 122)	X				

I. Semiannual Program Review
Part C – Personnel Training and Occupational Health & Safety

Key:

A = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

[must] = indicates actions that the Committee for the Update of the *Guide* considers imperative and mandatory duty or requirement for providing human animal care and use (*Guide,* p 8)

1. IACUC Training	**A**	**M**	**S**	**C**	**NA**
• All IACUC members should receive:					
○ Formal orientation to institution's program (*Guide*, p 17)	X				
○ Training on legislation, regulations, guidelines, and policies (*Guide*, p 17)	X				
○ Training on how to inspect facilities and labs where animal use or housing occurs (*Guide*, p 17)	X				
○ Training on how to review protocols as well as evaluate the program (*Guide*, p 17)	X				
○ Ongoing training/education (*Guide*, p 17)	X				
2. Personnel Qualifications and Training	**A**	**M**	**S**	**C**	**NA**
• All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included *[must]*:					
○ Veterinary/other professional staff (*Guide*, p 15-16)	X				
○ IACUC members (*Guide*, p 17)	X				
○ Animal care personnel (*Guide*, p 16)	X				
○ Research investigators, instructors, technicians, trainees, and students (*Guide*, pp. 16-17)	X				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training (*Guide*, pp. 16-17)	X				
• Training is available prior to starting animal activity (*Guide*, p 17)	X				
• Training is documented (*Guide*, p 15)	X				
• Training program content includes: (*Guide*, p 17)					
○ Methods for reporting concerns (*Guide*, p 17)	X				
○ Humane practices of animal care (e.g., housing, husbandry, handling)	X				
○ Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (*Guide*, p 17)	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

	○ Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)	X				
	○ Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)	X				
	○ Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (*Guide*, p 20)	X				
	○ Animal care and use legislation (*Guide*, p 17)	X				
	○ IACUC function (*Guide*, p 17)	X				
	○ Ethics of animal use and Three R's (*Guide*, p 17)	X				
3.	**Occupational Health and Safety of Personnel**		**M**	**S**	**C**	**NA**
	• Program is in place and is consistent with federal, state, and local regulations (*Guide*, p 17) *[must]*	X				
	• Program covers *all* personnel who work in laboratory animal facilities (*Guide*, p 18)	X				
	• Changing, washing, and showering facilities are available as appropriate (*Guide*, p 19)	X				
	• Hazardous facilities are separated from other areas and identified as limited access (*Guide*, p 19)	X				
	• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (*Guide*, p 20)	X				
	• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (*Guide*, p 20)	X				
	• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (*Guide*, p 21)	X				
	• Personal Protective Equipment for the work area is appropriate and available (*Guide*, p 21)	X				
	• Program for medical evaluation and preventive medicine for personnel includes:					
	○ Pre-employment evaluation including health history (*Guide*, p 22)	X				
	○ Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (*Guide*, p 22)	X				
	○ Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (*Guide*, p 23)	X				
	○ Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (*Guide*, p 23)	X				
	○ Promotes early diagnosis of allergies including preexisting conditions (*Guide*, p 22)	X				
	○ Considers confidentiality and other legal factors as required by federal, state and local regulations (*Guide*, p 22) *[must]*	X				
	○ If serum samples are collected, the purpose is consistent with federal and state laws (*Guide*, p 22) *[must]*					X
	• Waste anesthetic gases are scavenged (*Guide*, p 21)	X				
	• Hearing protection is provided in high noise areas (*Guide*, p 22)	X				
	• Respiratory protection is available when performing airborne particulate work (*Guide*, p 22)	X				
	• Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
	○ Tuberculosis screening provided for all exposed personnel (*Guide*, p 23)	X				
	○ Training and implementation of procedures for bites, scratches, or injuries associated with macaques (*Guide*, p 23)	X				
	○ PPE is provided including gloves, arm protection, face masks, face shields, or goggles (*Guide*, p 21)	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

○ Injuries associated with macaques are carefully evaluated and treatment implemented (*Guide*, p 23)	X				
• Occupational safety and health of field studies is reviewed by OSH committee or office (*Guide*, p 32)					X
4. Personnel Security	**A**	**M**	**S**	**C**	**NA**
• Preventive measures in place include pre-employment screening, and physical and IT security (*Guide*, p 23)	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

II. Semiannual Facility Inspection
Guidance for Inspectors: What constitutes a thorough IACUC inspection?

Terrestrial Animal Housing and Support Areas

- **Location:**
  - animal areas separate from personnel areas (*Guide*, p 134)
  - separation of species (*Guide*, p 111)
  - separation by disease status (*Guide*, p 111)
  - security and access control (*Guide*, p 151)

- **Construction:**
  - corridors (*Guide*, p 136)
  - animal room doors (*Guide*, p 137)
  - exterior windows (*Guide*, p 137)
  - floors (*Guide*, p 137)
  - drainage (*Guide*, p 138)
  - walls and ceilings (*Guide*, p 138)
  - heating ventilation and air conditioning (*Guide*, p 139)
  - power and lighting (*Guide*, p 141)
  - noise control (*Guide*, p 142)
  - vibration control (*Guide*, p 142)
  - environmental monitoring (*Guide*, p 143)

- **Room/Cage:**
  - temperature and humidity (*Guide*, p 43)
  - ventilation and air quality (*Guide*, p 45)
  - illumination (*Guide*, p 47)
  - noise and vibration (*Guide*, p 49)

- **Primary Enclosure:**
  - space meets physiologic, behavioral , and social needs (*Guide*, pp 51, 55-63)
  - secure environment provided (*Guide*, p 51)
  - durable, nontoxic materials in good repair and no risk of injury (*Guide*, p 51)
  - flooring is safe and appropriate for species (*Guide*, p 51)
  - adequate bedding and structures for resting, sleeping, breeding (*Guide*, p 52)
  - objective assessments of housing and management are made (*Guide*, p 52)
  - procedures for routine husbandry are documented (*Guide*, p 52)
  - socially housed animals can escape or hide to avoid aggression (*Guide*, p 55)
  - cage height provides adequate clearance (*Guide*, p 56)
  - animals express natural postures, can turn around, access food and water, and rest away from urine and feces (*Guide*, p 56)
  - rationale for *Guide*/USDA space exceptions approved by IACUC and based on performance indices (*Guide*, p 56)
  - dogs and cats allowed to exercise and provided human interaction (*Guide*, p 58)
  - nonhuman primates are socially housed except for scientific, veterinary or behavior reasons (*Guide*, pp 58-59)
  - single housing of nonhuman primates is for shortest duration possible (*Guide*, p 60)
  - opportunities for release into larger enclosures is considered for single caged nonhuman primates (*Guide*, p 60)
  - agricultural animals are housed socially (*Guide*, p 60)
  - food troughs and water devices for agricultural animals allow access for all animals (*Guide*, p 60)

- **Environmental Enrichment, Behavioral and Social Management:**
  - structures and resources promote species typical behavior (*Guide*, pp 52-54)
  - novelty of enrichment is considered (*Guide*, p 53)
  - species specific plans for housing including enrichment, behavior and activity are developed and reviewed regularly by IACUC, researchers and veterinarian (*Guide*, pp 53, 58, 60, 63)
  - animal care personnel receive training to identify abnormal animal behaviors (*Guide*, p 53)

- stability of pairs or groups is monitored for incompatibility (*Guide*, p 64)
- single housing is justified for social species (*Guide*, p 64)
- single housing is limited to the minimum period necessary (*Guide*, p 64)
- additional enrichment for single housed animals is provided (*Guide*, p 64)
- single housing is reviewed regularly by IACUC and veterinarian (*Guide*, p 64)
- habituation to routine procedures is part of enrichment program (*Guide*, p 64)

- **Sheltered or Outdoor Housing:** (e.g., barns, corrals, pastures, islands)
  - weather protection and opportunity for retreat (*Guide*, p 54)
  - appropriate size (*Guide*, p 54)
  - ventilation and sanitation of shelter (no waste/moisture build-up) (*Guide*, p 54)
  - animal acclimation (*Guide*, p 55)
  - social compatibility (*Guide*, p 55)
  - roundup/restraint procedures (*Guide*, p 55)
  - appropriate security (*Guide*, p 55)

- **Naturalistic Environments:**
  - animals added /removed with consideration of effect on group (*Guide*, p 55)
  - adequate food, fresh water, and shelter ensured (*Guide*, p 55)

- **Food:**
  - feeding schedule and procedures including caloric intake management (*Guide*, pp 65-67)
  - contamination prevention (*Guide*, p 65)
  - vendor quality control (*Guide*, p 66)
  - storage in sealed containers (*Guide*, p 66)
  - expiration date labeling (*Guide*, p 66)
  - vermin control (*Guide*, p 66)
  - rotation of stocks (*Guide*, p 66)

- **Water:**
  - ad libitum unless justified (*Guide*, pp 67-68)
  - QC procedures (*Guide*, pp 67-68)

- **Bedding and Nesting Materials:**
  - species appropriate (*Guide*, pp 68-69)
  - keeps animals dry (*Guide*, pp 68-69)
  - QC procedures (*Guide*, pp 68-69)
  - minimizes scientific variables (*Guide*, pp 68-69)

- **Sanitation:**
  - frequency of bedding/substrate change (*Guide*, p 70)
  - cleaning and disinfection of microenvironment (*Guide*, pp 70-71)
  - cleaning and disinfection of macroenvironment (*Guide*, p 72)
  - assessing effectiveness (*Guide*, p 73)

- **Waste Disposal:**
  - procedures for collection (*Guide*, pp 73-74)
  - procedures for storage and disposal (*Guide*, pp 73-74)
  - hazardous wastes are rendered safe before removal from facility (*Guide*, pp 73-74)
  - animal carcasses (*Guide*, pp 73-74)

- **Pest Control:**
  - regularly scheduled (*Guide*, p 74)
  - documented program including control of rodent pests and insecticide use (*Guide*, p 74)

- **Emergency, Weekend, and Holiday Animal Care:**
  - care provided by qualified personnel every day (*Guide*, p 74)
  - provision for accessible contact information (*Guide*, p 74)
  - monitoring of backup systems (*Guide*, p 143)

- veterinary care available after hours, weekends, and holidays (*Guide*, pp 74, 114)
- a disaster plan that takes into account both personnel and animals (*Guide*, p 75)

- **Identification:**
  - cage/rack cards contain required information (*Guide*, p 75)
  - genotype information included and standardized nomenclature used when applicable (*Guide*, p 75)

- **Recordkeeping:**
  - clinical records accessible and contain appropriate information (*Guide*, pp 75-76)
  - records are provided when animals are transferred between institutions (*Guide*, p 75)

- **Breeding Genetics and Nomenclature:**
  - appropriate genetic records, management and monitoring procedures (*Guide*, p 76)
  - phenotypes that affect wellbeing are reported to IACUC and effectively managed (*Guide*, p 77)

- **Storage:**
  - adequate space for equipment, supplies, food, bedding and refuse (*Guide*, p 141)
  - bedding in vermin-free area and protected from contamination(*Guide*, p 141)
  - food in vermin-free, temperature and humidity controlled area and protected from contamination (*Guide*, p 141)
  - refuse storage is separate (*Guide*, p 141)
  - carcass and animal tissue storage is separate, refrigerated below 7ºC and cleanable (*Guide*, p 141)

- **Personnel:**
  - adequate space for locker rooms, administration and training (*Guide*, p 135)

Aquatic Animal Housing and Support Areas

- **Location:**
  - animal areas separate from personnel areas (*Guide*, p 134)
  - separation of species (*Guide*, p 111)
  - separation by disease status (*Guide*, p 111)
  - security and access control (*Guide*, p 151)

- **Construction:**
  - corridors (*Guide*, p 136)
  - animal room doors (*Guide*, pp 137, 150)
  - exterior windows (*Guide*, p 137)
  - floors (*Guide*, pp 137, 150)
  - drainage (*Guide*, pp 138, 150)
  - walls and ceilings (*Guide*, pp 138, 150)
  - heating ventilation and air conditioning (*Guide*, pp 139, 150-151)
  - power and lighting (*Guide*, pp 141, 150)
  - noise control (*Guide*, p 142)
  - vibration control (*Guide*, p 142)
  - environmental monitoring (*Guide*, p 143)

- **Water Quality:**
  - standards for acceptable quality are established (*Guide*, p 78)
  - chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use in aquatic systems
    (*Guide*, pp78, 86)

- **Life Support System:**
  - water source is based on appropriate controls and research requirements (*Guide*, p 79)
  - biofilter is of sufficient size to process bioload (*Guide*, p 80)

- **Temperature, Humidity and Ventilation/Illumination/Noise and Vibration:**
  - temperature and humidity (*Guide*, pp 43, 80-81)
  - ventilation and air quality (*Guide*, pp 45, 81)

- illumination (*Guide*, pp 47, 81)
- noise and vibration (*Guide*, pp 49, 81)

- **Primary Enclosure:**
  - allows for normal physiological and behavioral needs (*Guide*, p 82)
  - allows social interaction for social species (*Guide*, p 82)
  - provides a balanced, stable environment (*Guide*, p 82)
  - provides appropriate water quality and monitoring (*Guide*, p 82)
  - allows access to food and waste removal (*Guide*, p 82)
  - restricts escape and entrapment (*Guide*, p 82)
  - allows undisturbed observation (*Guide*, p 82)
  - constructed of nontoxic materials (*Guide*, p 82)
  - prevents electrical hazards (*Guide*, p 82)
  - space needs of species are evaluated by IACUC during program evaluations and facility inspections (*Guide*, p 83)

- **Environmental Enrichment, Social Housing, Behavioral and Social Management:**
  - enrichment elicits appropriate behaviors and is safe (*Guide*, p 83)
  - semi-aquatic reptiles are provided terrestrial areas (*Guide*, p 83)
  - handling is kept to a minimum and appropriate techniques are in place at facility or protocol level (*Guide*, p 84)
  - nets are cleaned, disinfected and managed to avoid contamination of systems (*Guide*, p 84)

- **Food:**
  - storage to prevent contamination, preserve nutrients and prevent pests (*Guide*, p 84)
  - delivery ensures access to all , minimizing aggression and nutrient loss (*Guide*, p 84)
  - storage times are based on manufacturer recommendations or accepted practice (*Guide*, p 84)
  - a nutritionally complete diet is provided (*Guide*, p 84)

- **Substrate:**
  - amount, type and presentation of substrate is appropriate for the system and the species (*Guide*, p 85)

- **Sanitation, Cleaning and Disinfection**
  - frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring (*Guide*, p 86)
  - cleaning and disinfection of macroenvironment (*Guide*, p 86)

- **Waste Disposal:**
  - procedures for collection (*Guide*, pp 73-74)
  - hazardous wastes are rendered safe before removal from facility (*Guide*, pp 73-74)
  - animal carcasses (*Guide*, pp 73-74)

- **Pest Control:**
  - regularly scheduled (*Guide*, p 74)
  - documented program including control of pests and insecticide use (*Guide*, p 74)

- **Emergency, Weekend, and Holiday Animal Care:**
  - care provided by qualified personnel every day (*Guide*, pp 74, 87)
  - provision for accessible contact information (*Guide*, pp 74, 87)
  - emergency response plans in place to address major system failures (*Guide*, 87)
  - veterinary care available after hours, weekends, and holidays (*Guide*, pp 74, 114)

- **Identification:**
  - cage/tank cards contain required information (*Guide*, pp 75, 87)
  - genotype information included and standardized nomenclature used when applicable (*Guide*, pp 75, 87)

- **Recordkeeping:**
  - water quality parameters and frequency of testing recorded (*Guide*, p 88)
  - records kept on feeding, nonexpired food supplies, live cultures (*Guide*, p 88)

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

- **Storage:**
  - adequate space for equipment, supplies, food, substrate and refuse (*Guide*, p 141)
  - substrate protected from contamination (*Guide*, p 141)
  - food in vermin-free, temperature and humidity controlled area and protected from contamination (*Guide*, p 141)
  - refuse storage is separate (*Guide*, p 141)
  - carcass and animal tissue storage is separate, refrigerated below 7ºC and cleanable (*Guide*, p 141)

- **Personnel:**
  - adequate space for locker rooms, administration and training (*Guide*, p 135)

Cagewash

- **Construction and Operation:**
  - dedicated central area for sanitizing cages and equipment is provided (Guide, p 143)
  - cage-washing equipment meets need (Guide, p 143)
  - doors, windows, floors, drainage, walls, ceilings (Guide, pp 136-138)
  - convenient to animal areas/waste disposal (Guide, p 143)
  - ease of access (including door size) facilitates use (Guide, p 143)
  - sufficient space for staging and maneuvering (Guide, p 143)
  - safety precautions/clothing/equipment used for waste disposal/prewash/acid wash (Guide, p 143)
  - traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (Guide, p 143)
  - insulation and/or sound attenuation present as needed (Guide, p 143)
  - utilities are appropriate (Guide, p 143)
  - ventilation meets heat and humidity load (Guide, p 143)
  - safety features (e.g., SOPs, warning signs, eyewash stations) are in use (Guide, p 143)
  - functioning safety devices to prevent entrapment in washer/sterilizers (Guide, p 143)
  - cage wash temperatures are monitored and records are available (Guide, p 73)
  - appropriate clean cage storage (Guide, p 141

Special Facilities: Aseptic Surgery

- **General Considerations:**
  - location minimizes traffic/contamination (Guide, p 144)
  - functional components (surgical support, animal preparation, surgeon scrub, operating room, postoperative recovery) are designed and separated (physically or otherwise) (Guide, p 144)
  - appropriate drug storage, control, expiration date monitoring (Guide, pp 115, 122)
  - safe sharps disposal system (Guide, p 74)
  - adequate records of anesthesia and perioperative care (Guide, p 122)
  - aseptic procedures in use for all survival surgery (Guide, pp 118-119)

- **Operating Room:**
  - effective contamination control procedures (Guide, p 144)
  - effective cleaning procedures/dedicated tools (Guide, p 145)
  - interior surfaces smooth and impervious to moisture (Guide, p 145)
  - HVAC system meets Guide requirements (Guide, p 145)
  - lighting safe and appropriate (Guide, p 145)
  - outlets safe and appropriate (Guide, p 145)
  - scavenging of anesthetic gases implemented (Guide, p 145)

- **Surgical Support:**
  - facility for washing, sterilizing, storing instruments and supplies (Guide, p 145)
  - autoclave monitoring procedures are implemented (Guide, pp 119, 145)
  - storage of autoclaved materials maintains sterility (Guide, p 145)
  - cold sterilization procedures are appropriate (Guide, p 119)

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

- **Animal Preparation**
  - Contains large sink to facilitate cleaning of animal and operative site (Guide, p 145)

- **Surgeon Scrub**
  - outside operating room, non-hand-operated sink (Guide, p 145**)**

- **Postoperative Recovery**
  - allows adequate observation, easily cleaned, supports physiologic functions, minimizes risk of injury (Guide, p 145**)**

- **Dressing Area**
  - place for personnel to change (Guide, p 145)

Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies

- **General Considerations:**
  - labs used to house animals only when scientifically required and limited to minimum period necessary (*Guide*, p 134)
  - drug storage, control, and expiration dates (*Guide*, pp 115, 122)
  - sharps disposal (*Guide*, p 74)
  - anesthetic monitoring (*Guide*, p 120)
  - scavenging of anesthetic gases (*Guide*, p 21)
  - safety features (e.g., SOPs, safety signs, eyewash stations, secure gas cylinders) are in place (*Guide*, p 19)
  - carcass disposal (*Guide*, pp 73-74)

- **Additional Concerns for Survival Surgery:** (rodent and minor procedures only)
  - rodent survival surgery clean and uncluttered, not used for anything else during surgery (*Guide*, p 144)
  - records of peri-operative care (*Guide*, p 120)
  - aseptic procedures (*Guide*, pp 118-119)
  - autoclave monitoring procedures (*Guide*, pp 119, 145)
  - storage of autoclaved materials (*Guide*, p 145)
  - cold sterilization procedures are appropriate (*Guide*, p 119)

- **Imaging/Whole Body Irradiation:**
  - location of resource limits contamination risk (*Guide*, p 147)
  - appropriate transportation methods are in place (*Guide*, p 147)
  - gas anesthesia provision, scavenging and monitoring are appropriate (*Guide*, p 147)
  - appropriate sensors and ventilation are provided for cryogen gases (*Guide*, p 147)
  - imaging console is located away from radiation source (*Guide*, p 147)

- **Hazardous Agent Containment:**
  - facility adheres to APHIS, USDA and CDC Select Agent Regulations and other federal, state and local regulations including security measures (*Guide*, p 148)

- **Behavioral Studies:**
  - facility minimizes airborne transmission of noise and ground-borne transmission of vibration (*Guide*, p 149)
  - floor coverings reduce sound transmission (*Guide*, p 149)
  - testing equipment allows for surface disinfection (*Guide*, p 150)
  - components that cannot be cleaned are not in ready contact with animals and kept covered when not in use (*Guide*, p 150)
  - housing areas are contiguous with testing areas when appropriate (*Guide*, p 150)

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

II. Semiannual Facility Inspection

Part A - [redacted] Animal Facility

Key:

A = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO & annual report to OLAW)
NA = not applicable

Individuals participating in this inspection:

[redacted]

Animal Housing & Support Areas						
Room #	**Describe Use**	**A**	**M**	**S**	**C**	**NA**
[redacted]	Supplies/equipment storage	X				
[redacted]	Waste material storage & Mister Unit	X				
[redacted]	Refrigerated Waste Holding	X				
[redacted]	Surgery (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	Dirty cage wash	X				
[redacted]	Chemical storage: locked; did not enter					X
[redacted]	Cylinder gas system: locked; did not enter					X
[redacted]	Water supply		X			
[redacted]	Necropsy		X			
[redacted]	Equipment storage room	X				
[redacted]	Bedding storage	X				
[redacted]	Clean cage wash	X				
[redacted]	Food storage		X			
[redacted]	Clean cage storage	X				
[redacted]	[redacted] housing		X			
[redacted]	[redacted] pump room	X				
[redacted]	Fluorescent screening room ([redacted]) *Covered under PAM program for individual labs*					
[redacted]	[redacted] housing		X			
[redacted]	[redacted] lab (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	[redacted] warm housing (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	Clinical lab/technician office	X				
[redacted]	Procedure room		X			
[redacted]	[redacted] housing: Did not enter, currently pinworm positive					X
[redacted]	[redacted] housing	X				
[redacted]	[redacted] housing		X			
[redacted]	[redacted] housing ([redacted]) *Covered under PAM program for individual labs*					
[redacted]	[redacted] housing	X				
[redacted]	[redacted] housing	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

Animal Housing & Support Areas						
Room #	**Describe Use**	**A**	**M**	**S**	**C**	**NA**
[redacted]	Procedure room		X			
[redacted]	Behavior test room (multiple users) *Covered under PAM program for individual labs*					
[redacted]	Behavior test room ([redacted]) *Covered under PAM program for individual labs*					
[redacted]	Behavior test room ([redacted] *Covered under PAM program for individual labs*					
[redacted]	Behavior test room (multiple users) *Covered under PAM program for individual labs*					
[redacted]	RCL vestibule	X				
[redacted]	RCL housing	X				
[redacted]	Storage (future use: [redacted])	X				
[redacted]	RCL housing	X				
[redacted]	RCL procedure room:		X			
[redacted]	Transgenic gown-in – temporary storage of behavioral testing equipment	X				
[redacted]	Behavior test room (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	Behavior test room (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	Behavior test room (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	Behavior test room (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	PI-assigned procedure room ([redacted]) *Covered under PAM program for individual labs*					
[redacted]	PI-assigned procedure room [redacted]) *Covered under PAM program for individual labs*					
[redacted]	Storage	X				
[redacted]	[redacted] housing:	X				
[redacted]	[redacted] housing	X				
[redacted]	[redacted] housing	X				
[redacted]	PI-assigned procedure room (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	PI-assigned imaging area (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	Procedure area		X			
[redacted]	PI-assigned imaging area (Multiple users) *Covered under PAM program for individual labs*					
[redacted]	Procedure room	X				
[redacted]	Equipment Storage	X				
[redacted]	PI-assigned procedure room ([redacted] *Covered under PAM program for individual labs*					
[redacted]	PI-assigned procedure room ([redacted] *Covered under PAM program for individual labs*					
[redacted]	RCL Housing: currently empty	X				
[redacted]	Housing: Did not enter, currently pinworm positive					X
[redacted]	Housing	X				
[redacted]	Procedure room		X			
[redacted]	[redacted] Procedure room		X			
[redacted]	Storage	X				
[redacted]	[redacted]Housing	X				
[redacted]	Empty	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

II. Semiannual Facility Inspection

Part B - [redacted] Animal Facility

Key:

A = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO & in annual report to OLAW)
NA = not applicable

Individuals participating in this inspection:

[redacted]

SCID Facility
Animal Housing & Support Areas

Room #	Describe Use	A	M	S	C	NA
[redacted]	Non-sterile entrance/gowning area	X				
[redacted]	Spray lock	X				
[redacted]	Shared equipment/procedure room	X				
[redacted]	Clean procedure room		X			
[redacted]	Biocontainment [redacted] housing	X				
[redacted]	Staging/dirty side of autoclave	X				
[redacted]	Clean storage/clean side of autoclave	X				
[redacted]	[redacted] housing	X				
[redacted]	[redacted] housing		X			
[redacted]	BSL procedure room	X				

[redacted]
Animal Housing & Support Areas

Room #	Describe Use	A	M	S	C	NA
[redacted]	Cage wash	X				
[redacted]	Out of service	X				
[redacted]	Clean storage	X				
[redacted]	Food storage	X				
[redacted]	Bedding storage	X				
[redacted]	Out of service	X				
[redacted]	Bottle fill & clean storage	X				
[redacted]	Out of service	X				
[redacted]	Out of service	X				
[redacted]	Out of service	X				
[redacted]	Out of service	X				
[redacted]	Micro CT procedure room *Covered under PAM program for individual labs*					
[redacted]	Laundry	X				
[redacted]	Out of service	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted] Animal Housing & Support Areas						
Room #	**Describe Use**	**A**	**M**	**S**	**C**	**NA**
[redacted]	[redacted] housing	X				
[redacted]	Procedure room	X				
[redacted]	Procedure room	X				
[redacted]	[redacted] Quarantine	X				
[redacted]	[redacted] housing	X				
[redacted]	[redacted] housing		X			
[redacted]	[redacted] housing	X				
[redacted]	Procedure room		X			
[redacted]	Procedure room	X				
[redacted]	[redacted] housing	X				
[redacted]	[redacted] housing		X			

[redacted] Animal Housing & Support Areas						
Room #	**Describe Use**	**A**	**M**	**S**	**C**	**NA**
[redacted]	Dead Animal Storage	X				
[redacted]	Sharps Container Storage		X			
[redacted]	Trash room		X			
[redacted]	Bulk chemical storage	X				
[redacted]	Autoclave – currently inoperable	X				
[redacted]	Euthanasia room	X				
[redacted]	[redacted] Quarantine	X				
[redacted]	Storage	X				
[redacted]	Storage		X			
[redacted]	Storage		X			
[redacted]	Storage	X				
[redacted]	[redacted] housing	X				
[redacted]	[redacted] lab		X			
[redacted]	[redacted] mechanical	X				

II. Semiannual Facility Inspection

Part C - [redacted] Animal Facility

Key:
A = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO & in annual report to OLAW)
NA = not applicable

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

Individuals participating in this inspection:

[redacted]

Surgical & Support Areas						
Room #	**Describe Use**	**A**	**M**	**S**	**C**	**NA**
[redacted]	[redacted] prep room *Covered under PAM program for individual labs*					
[redacted]	[redacted]lab *Covered under PAM program for individual labs*					
[redacted]	OR 4 [redacted] *Covered under PAM program for individual labs*					
[redacted]	OR 1 - storage	X				
[redacted]	OR prep/lobby	X				
[redacted]	Storage	X				
[redacted]	OR SCRUB	X				
[redacted]	OR 3	X				
[redacted]	OR storage / laundry		X			

Animal Housing & Support Areas						
Room #	**Describe Use**	**A**	**M**	**S**	**C**	**NA**
[redacted]	Cage wash – clean side		X			
[redacted]	Cage wash – dirty side	X				
[redacted]	Equipment storage/supplies	X				
[redacted]	[redacted] Housing	X				
[redacted]	Procedure room	X				
[redacted]	[redacted] animal housing	X				
[redacted]	Dead animal cooler	X				
[redacted]	Chemical storage	X				
[redacted]	Ante area	X				
[redacted]	Food cooler		X			
[redacted]	Bedding	X				
[redacted]	Isolation / Biohazard [redacted] housing	X				
[redacted]	Procedure room	X				
[redacted]	[redacted] housing	X				
[redacted]	[redacted] housing	X				
[redacted]	Procedure room	X				
[redacted]	[redacted]housing	X				
[redacted]	Necropsy		X			
[redacted]	Storage – out of service					X
Other	Hallways near [redacted] and vivarium entrance	X				
	[redacted] loading dock	X				

II. Semiannual Facility Inspection

Part D – DLAR [redacted]

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

Key:
A = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

Individuals participating in this inspection:

[redacted]

DLAR [redacted]					
	A	**M**	**S**	**C**	**NA**
DLAR [redacted]	X				

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

III. Report of Deficiencies and Corrective Action Schedule

Key:

A = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO & in annual report to OLAW)
NA = not applicable

Deficiency Category*	Room/Area	Deficiency	Corrective action	Responsible Party	Correction Deadline	Date Completed
M	[redacted]	Certificates of Radiation Safety registration expired	Contact PI and RS office for current certificates	IACUC	12/21/19	11/22/19
M	[redacted]	Expired saline and PBS found	Confiscated	IACUC	10/21/19	10/21/19
M	[redacted]	Fume hood expired	DLAR will schedule certification	DLAR/[redacted]	12/21/19	11/14/19
M	[redacted]	Rusted perfusion equipment found in fume hood	IACUC will contact PI	IACUC	11/21/19	11/13/19
M	[redacted]	2 open boxes of Kellogg's "Froot Loops" cereal found	Confiscated	IACUC	10/21/19	10/21/19
M	[redacted]	3 boxes of expired povidone-iodine swabs found	Confiscated	IACUC	10/21/19	10/21/19
M	[redacted]	Expired [redacted] food and expired "love mash" found	Disposed	DLAR/[redacted]	10/21/19	10/21/19
M	[redacted]	1) Label on containers of [redacted] water reads last cleaned on 3/9/17. 2) Large blue tub with no label. 3) Expired pH standards.	1) IACUC will contact PI 2) IACUC will contact PI 3) Confiscated	IACUC	11/21/19	11/11/19
M	[redacted]	Algae growth on tanks	Clean tanks	DLAR[redacted]	10/22/19	10/22/19
M	[redacted]	Expired Puralube (eye ointment) found	Confiscated	IACUC	10/21/19	10/21/19
M	[redacted]	Room dimly light, 1 side of lights out	Lights not out, just on lower intensity as designed for animal room. No correction required.	N/A		
M	[redacted]	Missing sprinkler cover, rusty sprinkler	Submitted work order for repair	DLAR/[redacted]	12/31/19	10/27/19
M	[redacted]	Chipped paint found in corner	Removed	DLAR/[redacted]	10/21/19	10/21/19
M	[redacted]	Paint cracks, chips in wall	Submitted work order for repair	DLAR/[redacted]	12/31/19	10/25/19
M	[redacted]	Cracked ceiling paint	Submitted work order for repair	DLAR/[redacted]	12/31/19	10/25/19
M	[redacted]	Remove door for extension cord	Submitted work order for repair	DLAR/[redacted]	12/31/19	10/23/19
M	[redacted]	Cracked paint on duct and floor paint	Submitted work order for repair	DLAR[redacted]	12/31/19	***
M	[redacted]	Ceiling paint cracked	Submitted work order for repair	DLAR/[redacted]	12/31/19	10/26/19

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

M	[redacted]	Ceiling paint peeling	Submitted work order for repair	DLAR/[redacted]	12/31/19	10/26/19
M	[redacted]	Expired chemicals	Confiscated	DLAR/[redacted]	10/21/19	10/21/19
M	[redacted]	Laundry check list not completed since Feb	Removed list, not currently relevant	DLAR/[redacted]	11/21/19	11/11/19
M	[redacted]	1) Active leak in ceiling panel 2) Wooden crates for live animals	1) Submitted work order for ceiling leak 2) Removed wooden crates	DLAR/[redacted]	12/31/19	12/4/19
M	[redacted]	Pallets too close to wall	Moved pallets away from wall	DLAR/[redacted]	10/21/19	10/21/19
M	[redacted]	Unlabeled specimen preservative	Removed	DLAR/[redacted]	11/21/19	11/11/19

***Because this room is used infrequently, fix will be held off until renovation of the [redacted] slated for spring 2020.

IV. Minority Comments

No minority opinions were expressed during the program review and facilities inspections.

V. Individual inspections/ Post-approval monitoring

Investigator	Date	Building	Room	IACUC #	Species	Use	Comments
[redacted]	10/22/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	10/22/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	10/22/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	10/16/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Space appropriate for intended use. Procedures described were consistent with the protocols. Most work is on hold due to development of [redacted] specific lines of animals and personnel turnover.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Space appropriate for intended use. Procedures described were consistent with the protocols.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. Log for feeding/cleaning was

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

							put in this room for [redacted] use.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No animals [redacted] at time of site visit.
[redacted]	5/13/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. Lab hood was congested but not currently working with animals.
[redacted]	5/13/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	5/13/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	5/13/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	9/4/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No [redacted] ongoing, none planned for next 6 months.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No [redacted] ongoing, none planned for next 6 months.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Has not performed in past six months. No plans to resume in next 6 months.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended. Hood in need of inspection. Contacted EHS for completion
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No plans to perform these procedures in the next six months. Did not visit.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No plans to perform these procedures in the next six months. Did not visit.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No plans to perform these procedures in the next six months. Did not visit.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No plans to perform these procedures in the next six months. Did not visit.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No plans to perform these procedures in the next six months. Did not visit.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No plans to perform these procedures in the next six months. Did not visit.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. Hood in need of inspection. Contacted EHS for completion.
[redacted]	6/6/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Project is in its initial stages and these procedures have not yet begun; location(s) to be determined.in consultation with Attending/Clinical Vet(s).
[redacted]	10/22/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	10/22/2019	NRB	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. See [redacted] lab site visit.
[redacted]	10/22/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] tests are inactive.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	10/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No recent training sessions. Perhaps in next 6 months. Space is appropriate for use. Space appropriate for intended use.
[redacted]	6/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. See [redacted] lab site visit.
[redacted]	6/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Space is covered under [redacted] lab site visit.
[redacted]	10/22/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Protocol currently inactive. Space is appropriate for use when surgeries start up again; possibly in next 6 months.
[redacted]	10/22/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] facility - multi-user. See [redacted] lab site visit.
[redacted]	5/17/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] facility - multi-user. See [redacted] lab site visit.
[redacted]	5/17/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	5/17/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	5/17/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. Hood in need of inspection by EHS. Hood certified by EHS on 5/28/19
[redacted]	8/7/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	This space is covered under the [redacted] lab inspection. These experiments have not yet begun.
[redacted]	8/7/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	8/7/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Vaporizer recertification was due in April 2019. Will get [redacted] 2 vaporizers on schedule to be recertified on next round (Oct 2019) Found expired surgical gloves and saline; removed by lab staff.
[redacted]	8/7/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Space covered under [redacted] lab inspection. These experiments have not yet begun.
[redacted]	8/7/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No work is being done with [redacted]

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	8/13/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Fume hood in need of re-certification. [redacted] emailed [redacted] to get hood checked. Expired [redacted] found and confiscated. Expired drug had not been adminstered to [redacted]. PI was questioned about surgery on IACUC [redacted], a new protocol pending approval. PI was not well aware of surgical procedures so he was given a list of supplies to acquire and methods to be employed by surgeon on pending protocol.
[redacted]	6/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] facility - multi-user. See [redacted] lab site visit.
[redacted]	6/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] surgeries are not being performed in [redacted] nor [redacted] at this time. This surgery may be performed in [redacted] shared procedure room). [redacted] is not being used at this time. No plans to use in the near future.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	6/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. **A bottle of expired [redacted] was found. [redacted] took it immediately to DLAR for disposal. Logs indicated that it was used, once, 2 months past expiration. Lab was retrained by [redacted]. [redacted] and [redacted] on proper handling of controlled substance usage.**
[redacted]	6/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] surgeries are not being performed in [redacted] nor [redacted] at this time.
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	7/10/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Have not performed in past six months. This room is new location due to equipment change.
[redacted]	7/10/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocols. Space appropriate for intended use.
[redacted]	10/22/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	10/22/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	10/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	10/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No work is being done with [redacted].
[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	6/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	7/16/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Space appropriate for intended use.
[redacted]	7/16/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	7/16/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocols. Space appropriate for intended use.
[redacted]	7/16/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocols. Space appropriate for intended use.
[redacted]	9/23/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Animal surgery area is not ready at the time of inspection. Drug cabinet needs to be mounted to wall. Lab does not have any animals at this time.
[redacted]	8/20/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. Unfortunately, [redacted] machine is broken;

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

							unknown when it may be fixed.
[redacted]	8/20/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. Hoods need re-certification: [redacted]
[redacted]	5/17/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. [redacted] not being conducted in this space at this time.Space appropriate for intended use.
[redacted]	5/17/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. Hood in need of inspection by EHS. Hood checked by EHS on 5/28/19
[redacted]	2/4/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	2/4/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. See [redacted] lab site visit.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

							appropriate for intended use.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. Drug cabinet was unlocked at time of inspection; was corrected
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/26/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	7/9/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Space appropriate for intended use.

[redacted]	10/1/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use. [redacted] infestations have only been happening in DLAR facility.
[redacted]	5/15/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	5/15/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	5/15/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	5/15/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	5/15/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	10/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] have started yet. PI will need to acquire a lockable drug cabinet and get it mounted to the wall. PI will speak to [redacted] about sharing [redacted] locked drug cabinet if PI's cabinet is not mounted in time for first surgery.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	10/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Not in use at this time by PI. Room [redacted] is covered under [redacted] inspection 10/22/2019
[redacted]	7/8/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	7/8/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Currently not being performed at this time.
[redacted]	7/16/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	All ok. [redacted] has not started yet.
[redacted]	7/16/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	All ok.
[redacted]	7/16/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	No use of controlled substances during the past six months; no plans for next six months.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] performed within the past six months. Space covered under [redacted] lab.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/4/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Protocol currently inactive.
[redacted]	9/4/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	7/10/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] was re-trained on proper [redacted] Hallway [redacted] was being used to store animal transport box. [redacted] was instructed to keep storage box in [redacted] or return to DLAR immediately. No animals were in [redacted] during inspection.
[redacted]	7/10/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] claims that no [redacted] testing is happening

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	7/10/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] claims that no [redacted] testing is happening
[redacted]	7/10/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted] surgeries have not started. Space appropriate for intended use. [redacted] A new drug cabinet was obtained for this room.
[redacted]	7/10/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedure(s) have not started.
[redacted]	7/10/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted].	Procedure(s) have not started.
[redacted]	7/10/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedure(s) have not started.
[redacted]	5/21/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Performed under supervision of [redacted] Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	5/21/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	5/21/2019	IHP	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	5/21/2019	NRB	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

[redacted]	5/21/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.
[redacted]	9/11/2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Procedures described were consistent with protocol. Space appropriate for intended use.

Endnotes

[1] The 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.

[1] Part 2 Subpart C - Research Facilities

Appendix 14: IACUC Periodic Program Review and Facility Inspection Report

- 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]

[1] 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]

[1] 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]

[1] 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]

[1] 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]

[1] 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]

[1] 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*]

[1] 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]

[1] 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..."

[1] 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]

[1] 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."

[1] 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."

[1] 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].

[1] 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..."

[1] 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."

[1] 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.

Appendix 15: Heating, Ventilation and Air Conditioning (HVAC) System Summary

To be submitted at a later date when completed.

Appendix 16: Aquatic Systems Summary – Part I & II

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, cephalopod housing systems, and enclosures. The following key will assist you in completing the form:

(1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number. Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
(2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
(3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
(4) Indicate water type*,* e.g.*,* fresh, brackish, or marine.
(5) Indicate water pre-treatment, e.g.*,* dechlorination, rough filters.
(6) Indicate water circulation, e.g.*,* static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
(7) Provide a key word for filtration employed, e.g.*,* biological, chemical, mechanical, and type (e.g.*,* mechanical-bead filter). A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

Part I

Location (1)	Species (2)	System Design					
		Group / Individual (3)	Water Type (4)	Pre-treatment (5)	Circulation (6)	Filtration (7)	Disinfection (e.g., UV, ozone)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Note: Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, *etc*.) should be available for review.

Appendix 16: Aquatic Systems Summary – Part I & II

The following key will assist you in completing this form:

(1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).

(2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine.

Part II

Monitoring ***Indicate in the boxes below the frequency of monitoring and method of control for the following parameters. (1)***									
Location (from Part I)	**Temperature**	**Salinity**	**pH**	**NH_4**	**NO_2**	**NO_3**	**Dissolved O_2**	**Total Dissolved Gases**	**Other. Please List (2):**

Note: This information may be provided in another format, provided that all requested data is included.

Appendix 17: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., *Guide*, Ag *Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies. Refer to AAALAC International's Position Statement [“Cage or Pen Space”]() for additional guidance.

Species	**Dimensions of Enclosure** (cage, pen, tank*, corral, paddock, etc.)	**Maximum Number Animals / Enclosure**	**Guiding Document Used to determine the Institution's Space Standards** (*Guide*, Ag *Guide*, ETS 123, Other)	**Enclosure Composition & Description****
[redacted]	[redacted]	[redacted]	Guide	[redacted] [redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted] [redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted] [redacted] [redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted] [redacted] [redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted] [redacted] [redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted] [redacted] [redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]

Appendix 17: Primary Enclosures and Animal Space Provisions

Species	**Dimensions of Enclosure** (cage, pen, tank*, corral, paddock, etc.)	**Maximum Number Animals / Enclosure**	**Guiding Document Used to determine the Institution's Space Standards** (*Guide*, Ag *Guide*, ETS 123, Other)	**Enclosure Composition & Description****
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]

Appendix 17: Primary Enclosures and Animal Space Provisions

Species	**Dimensions of Enclosure** (cage, pen, tank*, corral, paddock, etc.)	**Maximum Number Animals / Enclosure**	**Guiding Document Used to determine the Institution's Space Standards** (*Guide*, Ag *Guide*, ETS 123, Other)	**Enclosure Composition & Description****
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]
[redacted]	[redacted]	[redacted]	Guide	[redacted]

*For aquatic species, provide tank volume.
**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

Appendix 18: Cleaning and Disinfection of the Micro- and Macro-Environment

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

Area	**Washing/Sanitizing Method** (mechanical washer, hand washing, high-pressure sprayers, etc.)	**Washing/ Sanitizing Frequency**	**Chemical(s) Used***	**Other Comments** (e.g., autoclaved)
Micro-environment				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

Appendix 18: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	**Washing/Sanitizing Method** (mechanical washer, hand washing, high-pressure sprayers, etc.)	**Washing/ Sanitizing Frequency**	**Chemical(s) Used***	**Other Comments** (e.g., autoclaved)
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	

Appendix 18: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	**Washing/Sanitizing Method** (mechanical washer, hand washing, high-pressure sprayers, etc.)	**Washing/ Sanitizing Frequency**	**Chemical(s) Used***	**Other Comments** (e.g., autoclaved)
Macro-Environment				
Animal Housing Rooms:				
Floors	[redacted]	[redacted]	[redacted]	
Walls	[redacted]	[redacted]	[redacted]	
Ceilings	[redacted]	[redacted]	[redacted]	
Ducts/Pipes	[redacted]	[redacted]	[redacted]	
Fixtures	[redacted]	[redacted]	[redacted]	
Corridors:				
Floors	[redacted]	[redacted]	[redacted]	
Walls	[redacted]	[redacted]	[redacted]	
Ceilings	[redacted]			
Ducts/Pipes	[redacted]	[redacted]	[redacted]	
Fixtures	[redacted]	[redacted]	[redacted]	

Appendix 18: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	**Washing/Sanitizing Method** (mechanical washer, hand washing, high-pressure sprayers, etc.)	**Washing/ Sanitizing Frequency**	**Chemical(s) Used***	**Other Comments** (e.g., autoclaved)
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors-Procedure				
Walls-Procedure				
Ceilings-Procedure				
Ducts/Pipes-Procedure				
Fixtures-Procedure				
Floors-Surgery				
Walls- Surgery				
Ceilings- Surgery				
Ducts/Pipes- Surgery				
Fixtures- Surgery				

Appendix 18: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	**Washing/Sanitizing Method** (mechanical washer, hand washing, high-pressure sprayers, etc.)	**Washing/ Sanitizing Frequency**	**Chemical(s) Used***	**Other Comments** (e.g., autoclaved)
Implements (note whether or not shared):				
Mops				
Mop buckets				
Aquaria nets				
Other – Aquaria brushes				
Other:				
Vehicle(s)				
Other transport equipment (list):				

*Please provide chemical, not trade name.

Appendix 18: Cleaning and Disinfection of the Micro- and Macro-Environment

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand washing area, bedding dispensing unit, *etc*.). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

[*Note*: Please remove the examples provided in the Table below.]

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
[redacted]		Rack washer	[redacted]	[redacted]
[redacted]		Tunnel washer	[redacted]	[redacted]
[redacted]		Bulk autoclave	[redacted]	[redacted]
[redacted]		None-hand washing area	[redacted]	[redacted]
[redacted]		Tunnel washer	[redacted]	[redacted]
[redacted]		Bulk autoclave	[redacted]	[redacted]
[redacted]		None-hand washing area	[redacted]	[redacted]

Appendix 18: Cleaning and Disinfection of the Micro- and Macro-Environment

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
[redacted]		Bulk autoclave	[redacted]	[redacted]
[redacted]		None-hand washing area	[redacted]	[redacted]
[redacted]		Rack washer	[redacted]	[redacted]

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 19: Facilities and Equipment for Sanitizing Materials

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand washing area, bedding dispensing unit, *etc*.). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

[*Note*: Please remove the examples provided in the Table below.]

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
[redacted]		Rack washer	[redacted]	[redacted]
[redacted]		Tunnel washer	[redacted]	[redacted]
[redacted]		Bulk autoclave	[redacted]	[redacted]
[redacted]		None-hand washing area	[redacted]	[redacted]
[redacted]		Tunnel washer	[redacted]	[redacted]
[redacted]		Bulk autoclave	[redacted]	[redacted]
[redacted]		None-hand washing area	[redacted]	[redacted]

Appendix 19: Facilities and Equipment for Sanitizing Materials

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
[redacted]		Bulk autoclave	[redacted]	[redacted]
[redacted]		None-hand washing area	[redacted]	[redacted]
[redacted]		Rack washer	[redacted]	[redacted]

Appendix 20: Lighting Summary

Using the Table below, summarize the lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity (range), construction features (e.g., water resistance), photoperiod (light:dark) and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms (including alarms, if applicable).

Location:	**All facilities**

[*Note*: Please remove the examples provided in the Table below.]

Room Type[a] **(Species)**	**Light Intensity Range (Foot-candles)**	**Lighting Fixture Construction Features**[b]	**Photo-period** (hrs)[c]	**Photoperiod and Lighting Control**	**Override Mechanisms** (if applicable)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Appendix 20: Lighting Summary

Room Type[a] **(Species)**	**Light Intensity Range (Foot-candles)**	**Lighting Fixture Construction Features**[b]	**Photo-period** (hrs)[c]	**Photoperiod and Lighting Control**	**Override Mechanisms** (if applicable)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[Create additional rows by pressing TAB in the bottom-right box.]

[a] A list of each room is not needed; group or cluster rooms by species or function
[b] Include such features as water resistance, red lighting, *etc*.
[c] Note if light cycle inverted/reversed.

Appendix 21: Satellite Housing Facilities

Note: In the Program Description Section 2. IV. (Physical Plant), item C., describe the criteria used to determine a "Satellite Animal Holding Area." In the Table below, summarize these animal housing areas. Note that the total square footage for all each of these must also be included in the Summary of Animal Housing and Support Sites **(Appendix 2)**, and applicable information regarding these areas included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (**Appendix 15**) and Lighting Systems Summary (**Appendix 20**).

Building	**Room(s)**	**Person Responsible**	**Species Used**	**Approximate Area** (ft^2 or m^2) **Devoted to Housing**	**Maximum Period of Stay**	**Purpose / Rationale / Justification**	**Construction Features and Finishes**
[redacted]	[redacted]	[redacted]	[redacted]	400 sq. ft.	[redacted]	[redacted]	[redacted]