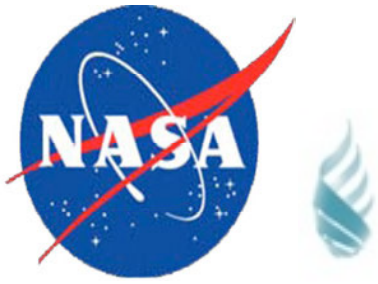

NASA ARC – LifeSource Biomedical Services LLC

Program Description of Institutional Animal Care and Use Program

MS 261-1, Building 261

Moffett Field, CA 94035

AAALAC International

5283 Corporate Drive Suite 203

Frederick, MD 21703-2879

December 1, 2018

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Appendices

Program Description

Instructions for Completing and Submitting the Program Description for the Institutional Animal Care and Use Program

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 National Aeronautics and Space Administration Ames Research Center (NASA ARC) Animal Care and Use Program (AAALAC file # 000587). All animal research at the site, including research conducted by NASA and LifeSource Biomedical Services, LLC (LifeSource), is included in this program unit.

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.

Ames was founded in 1939 as an aircraft research laboratory and was part of the National Advisory Committee on Aeronautics. In 1958, Ames became part of the National Aeronautics and Space Administration (NASA) and has continued to perform research geared toward creating new knowledge and new technologies in support of space flights, the health of our planet, and other aspects of astronomical and planetary scientific endeavors. Specifically, the major types of research include basic science studies related to the physiological effects encountered by humans during the microgravity of space flight. In addition, flight projects require the development and testing of hardware and restraint systems for animal-based comparative research focusing on this research. LifeSource is a contract research organization and provides husbandry and research support services and housing space to NASA and to private companies wishing to perform preclinical research projects using laboratory animals. NASA maintains the administrative authority for the Animal Care and Use Program, with the Center Director for the Ames Research Center appointing the Institutional Official, who is also a NASA employee, and members of the IACUC, including representatives from LifeSource and NASA. Animal facilities are the responsibility of LifeSource with regards to access control, operations, and maintenance. Clients are currently private research and development companies who either do not have their own Animal Care and Use Programs/ Facilities or who require additional services and/or space that can be provided by LifeSource. The mission of the NASA Animal Care and Use Program is to support research programs for NASA and commercial clients of LifeSource engaged in preclinical research and development.

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 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.

The NASA ARC Animal Care and Use Program follows guidelines from the Animal Welfare Act, Guide for the Care and Use of Laboratory Animals (Guide) 8th Edition, Public Health Service Policy; Office of Laboratory Animal Welfare, the Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide), and the AVMA Panel on Euthanasia 2013.

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 publicly available, provide the titles and names; for individuals whose information is not publicly 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.

Dr. Eugene Tu is the Center Director for the NASA Ames Research Center. The Center Director appoints the Institutional Official and the members of the Institutional Animal Care and Use Committee (IACUC), who include both NASA and LifeSource representatives. Reporting directly to Dr. Tu is (b) (6), (b) (7)(C), (b) (7)(F) who is the Director of Safety and Mission (b) (6), (b) (7)(C), (b) (7)(F) ce and is the appointed Institutional Official for the Animal Care and Use Program. s responsible for planning, directing and coordinating the Center's management operations necessary to support aeronautics, information technology, science, and space research programs. Reporting directly to (b) (6), (b) (7)(C), (b) (7)(F) on behalf of the Animal Care and Use Program is (b) (6), (b) (7)(C), (b) (7)(F) IACUC Chair a ct Manager of the Space Synthetic Biology

Program. [redacted] is the Attending Veterinarian and also reports directly to [redacted] represents LifeSource as CEO/President and IACUC Administrator. [redacted] RVT, RLATG, is the Director of Operations for LifeSource Biomedical Services, LLC. [redacted] is an IACUC member and oversees LifeSource staff providing organization admin [redacted] usbandry care for all species, technical support, facilities/maintenance operations for the Animal Care and Use Program, assists with veterinary medical care for the research animals, and also assists with technical research support services. Six full time husbandry staff (1 supervisor and 5 technicians and 2 part-time staff) reporting to [redacted] provide day-to-day care for the animals.

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.

Eugene Tu, PhD; Center Director

[redacted] BS; Director of Safety and Mission Assurance; Institutional Official

[redacted] BS; Project Manager of Space Synthetic Biology Program; IACUC Chair

[redacted] DVM; Attending Veterinarian; President, LifeSource Biomedical Services, LLC

[redacted] RVT, RLATG; Director of Operations for LifeSource Biomedical Services, LLC

*Members of the IACUC

ACF Staff

[redacted] Environmental Health and Safety Consultant, ISO 14001 Lead Auditor Certified, OHSAS 18001 Lead Auditor Certified

(*Individuals expected to participate in the AAALAC site visit)

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 type of research conducted by NASA scientists is basic and applied research addressing the effects of spaceflight, or simulated spaceflight conditions, on living systems. Projects include evaluation of the effects of gravity on gene expression, bone/mineral densities,

regeneration of cells/tissues, development of musculoskeletal abnormalities, vestibular function and other tissues/organ functions, as well as the effects of exposure to space-related hazards like radiation. Major projects conducted for and/or by LifeSource contract clientele include tissue harvest protocols, pharmacokinetic/ pharmacodynamic evaluations of novel compounds, new therapeutic approaches for macular degeneration and other ocular disorders, potency and local effects of botulinum toxin and derivatives, neuronal function, organ preservation, antibody generation, cholesterolemia therapeutics, and generation of xenograft mouse models. There are 34 active protocols and 22 principal investigators.

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

NASA funding comes from the federal government and from funding agencies. At this time, LifeSource clients fund research projects with their own private, internal monies, venture capital or NIH grants.

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.

Not applicable

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 relevant contractor's 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.

NASA ARC and LifeSource do not own any other animals at any other sites. Clients of LifeSource may maintain their own Vivarium; however, those animals and facilities are the responsibility of those individual companies. The institution does not contract for animal care facilities or services.

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

There is no additional relevant background at this time.

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.

The Attending Veterinarian, LifeSource Director of Operations, and IACUC Chair attend the IACUC meetings during which any issues that come up regarding the animal research program are addressed. The IACUC Administrator provides a summary of IACUC minutes and these minutes provide a format for discussion at future meetings. The Attending Veterinarian also informs the IACUC Chair directly of any issues of concern and these concerns would be shared with the IACUC and IO. In addition, the Attending Veterinarian and the IACUC Chair regularly discuss all ongoing research within the ACF. Any issues/ concerns would be discussed at that time. The LifeSource Director of Operations also communicates directly with the Attending Veterinarian and IACUC chair regarding any concerns relative to the animal research program. A direct line of communication to the IO is available to all IACUC members.

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.

(b) (6), (b) (7)(C), (b) (7)(F), (b) (4)	DVM- Attending Veterinarian	(b) (6), (b) (7)(C), (b) (7)(F), (b) (4)
(b) (6), (b) (7)(C), (b) (7)(F), (b) (4)		

(b) (6), (b) (7)(C), (b) (7)(F), (b) (4)

The Attending Veterinarian or designated appointee is authorized to:
1) Enter any place within the jurisdiction of the animal care and use program to conduct on-site inspections of animal facilities and animals, to ensure that animal husbandry, sanitation practices and animal health and research techniques are compliant with all relevant federal, state, local and institutional requirements. This includes, but is not limited to:
a) Advising the IACUC on matters relating to the animal care and use program, facilities and personnel.
Stopping any experiment and, if necessary, euthanizing animals if, in his/her judgment, the animals are experiencing unnecessary distress;
b) Examining and testing any animals for disease or disease processes detrimental to humans, or to the same or other animal species; Conducting necropsy examinations; providing/ordering adequate veterinary medical care for sick /injured animals; conducting, prescribing and monitoring pre-and post-surgical care.
2) Assures enrollment in the occupational health program of all ACF personnel and others supervised by LifeSource staff that are involved in the primary care or husbandry of animals.
3) Approves the purchase and acquisition of all animals by the ACF, including:
a) Animals purchased from commercial suppliers of laboratory research animals (including selection of the sources of animals for the purpose of decreasing the risk of disease in the ACF's animal colonies).
b) Animals purchased or received from other biomedical institutions.
4) Examining and, where necessary, placing newly acquired animals into quarantine.
5) Requiring vaccination when indicated, treatment, testing of all newly acquired animals as necessary.
6) Recommending and approving all purchases and use of feed, bedding and animal housing, and all other materials pertaining to animal care.

7) Recommending and approving all vermin control programs within the ACF or affected areas where laboratory animals are housed, transported or utilized.
8) Overseeing animal space utilization on a day-to day basis, and reviewing and approving plans for alterations in all institutional and animal facilities.
9) Serving as a voting member of the IACUC.
10) Serving as a liaison in matters of animal care between the IACUC and staff of the ACF.
11) Providing guidance to, and consultation with, the investigators in matters of anesthesia, techniques to minimize pain and distress, euthanasia, and animal models.
12) Reviewing animal protocols prior to their review by the IACUC, with particular concern for the use of anesthetics, analgesics, tranquilizers, methods of euthanasia, and availability of proper housing.
13) Treating outbreaks of disease in the animal colonies in a manner that is compatible with the research being conducted.
14) Assuring that all animals are observed daily by trained animal care staff;
15) Providing and monitoring the animal care and use training program for all investigators, research technicians and ACF staff.
16) Assisting investigators in surgery and post-surgical care.
17) Overseeing animal records.

The Attending Veterinarian oversees all animal care and use matters and is responsible for the animal care and use program (which includes the veterinary care and animal husbandry program). Certain aspects of this responsibility are delegated to the LifeSource Director of Operations and Husbandry Supervisor, who in turn are responsible for all animal housing and support facilities, and the training and supervision of the animal care technicians. The Attending Veterinarian is also directly responsible for the preventive medicine program and the various diagnostic services required for monitoring animal health. All of the daily health observations and most of the animal treatment and post-op care are carried out by either the Attending Veterinarian, LifeSource Director of Operations, Husbandry Supervisor or experienced animal caretakers under the supervision of the Attending Veterinarian. In some cases, investigators will carry out treatments or provide post op care. All research personnel who carry out treatments or post-op care are trained by the LifeSource Director of Operations, Attending Veterinarian, or an approved designee, and ACF staff provides general supervision of their activities.

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.

Only LifeSource staff members provide primary care to the research animals

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.

There are no offsite collaborations at this time.

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.

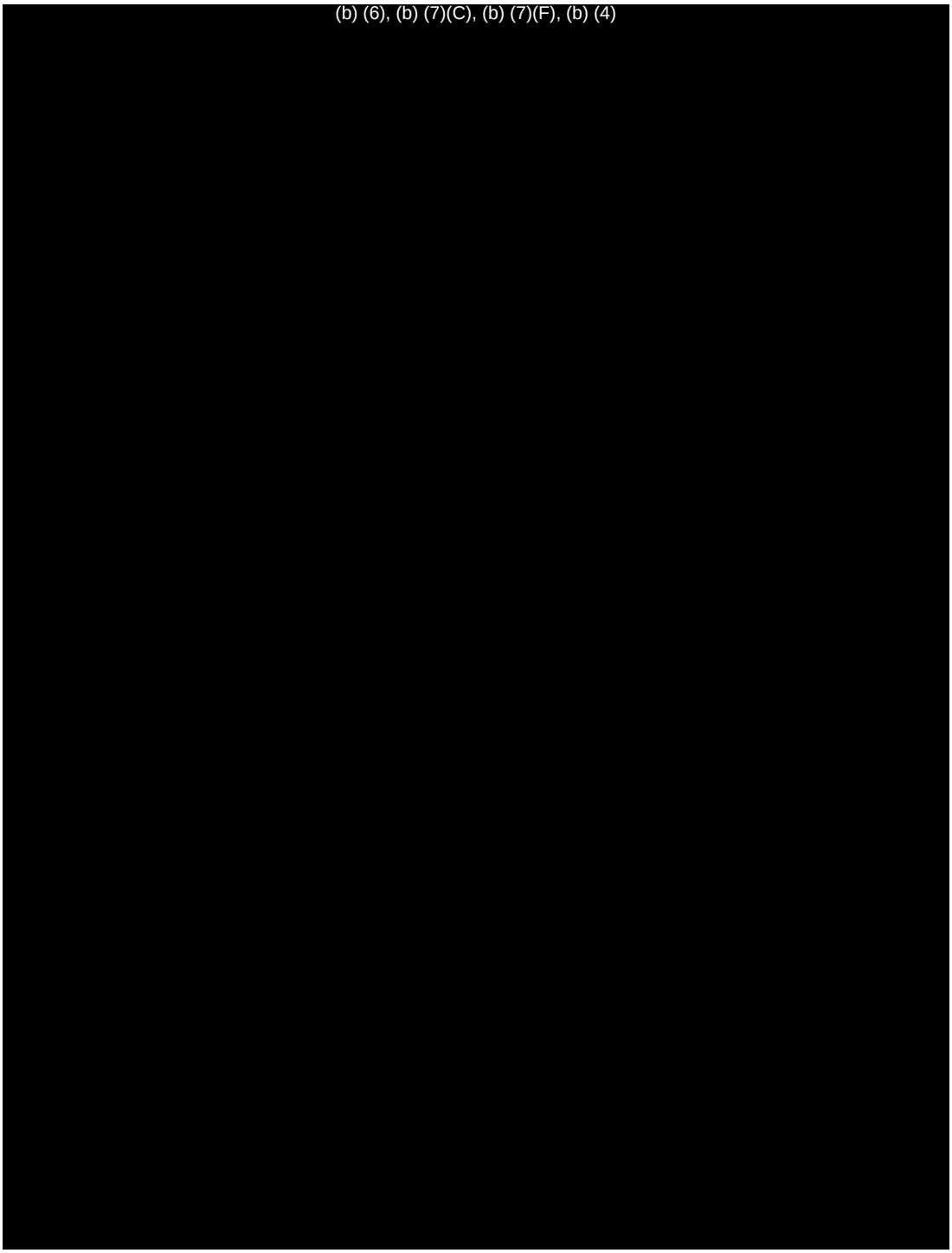
The IACUC provides guidance and oversight to all aspects of the training program for all animal users. Investigators and research personnel are not approved for entrance into the ACF until they have been added to an approved animal protocol. Completion of all requirements of the Animal Exposure Program is required for any individuals who will be exposed to animals or their tissues/ fluids. Four hours of mandated online training covers species-specific information, animal welfare issues, euthanasia, anesthesia, regulations, and related topics. A resource library of text and audiovisual material, as well as access to the AALAS On-line Learning Library is available for use by all animal users to meet instructional needs. Additionally, LifeSource staff members are required to complete an additional minimum of eight hours of relevant training per year to maintain their Animal Exposure Program participation. Successful completion of the training modules is required and documented. Training on specific research procedures may be provided by LifeSource staff when indicated, requested, or required. Topics include humane restraint and handling, blood collection techniques, etc. Training for more advanced surgical procedures and/ or manipulations can be required by the IACUC, identified during an observation by LifeSource staff, or requested by the investigator.
All on-line training and additional hands-on training is documented and tracked by the IACUC Administrator and placed in the individual's electronic training file.
The effectiveness of the training program is evaluated during post-approval monitoring (PAM) and on a continuous basis by LifeSource staff while providing oversight/supervision for all of the activities occurring in the ACF.

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.

(b) (6), (b) (7)(C), (b) (7)(F), (b) (4)



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

1) Indicate the number of animal care personnel.

5 full time, 2 part time personnel (weekends only)

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.

LifeSource animal caretakers are trained to perform their husbandry responsibilities following standard guidelines and have extensive husbandry experience. Their years of experience range from 1 - over 20 years in the field of laboratory animal medicine and husbandry both in government and industry. Animal care staff are required to complete written and hands-on training for the individual animal species as well as Working with the IACUC. Animal care staff are encouraged to attend local and regional AALAS and other organizational meetings and are involved in frequent in-house training. The LifeSource Director of Operations meets with the animal care staff at least twice a month and those meetings include any updates on changes in guidelines or requirements in the laboratory animal field, as well as principles of animal care and use, personal hygiene, facility safety, and security. All animal care staff have access to the AALAS Learning Library and are encouraged to complete all trainings that are available within this resource. The Attending Veterinarian provides applicable training in the areas of care and use of laboratory animals, as well as review of current protocols, and the LifeSource library maintains current materials available to all animal users.

Training files are maintained in the LifeSource offices or electronically.

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.

The IACUC Administrator and the LifeSource Director of Operations review the background of all personnel prior to approving their addition to an animal protocol. Qualifications of personnel are reviewed as part of the IACUC protocol approval process. Research personnel are not allowed to work with animals until they have been added to an approved protocol and completed the Animal Exposure Program. The training program is on-line and/ or in person, depending upon the procedures that are going to be carried out under the approved IACUC protocol. All new personnel are required to complete an orientation of the animal facility that includes a review of all of the regulatory requirements, participation in the occupational health program, proper use of the animal facility and safety and proper restraint and humane handling of animals. All personnel are required to complete AALAS training modules that include principles of working with the IACUC as well as species-specific modules. LifeSource staff will provide hands-on training when observed to be necessary, dictated by the IACUC during protocol review, and /or when requested by the investigator. All procedures including survival surgeries are carried out in the ACF so that the veterinary staff maintains oversight. When dictated by the IACUC or Attending Veterinarian, LifeSource staff will monitor procedures to assure competency with all animal work that is being conducted. The LifeSource Director of Operations works closely with research personnel to verify they are proficient in the research procedures they are approved to perform.

a) Briefly describe the content of any required training.

All LifeSource personnel and NASA and LifeSource research personnel are required to complete on-line AALAS training, as well as any necessary hands-on training specific to the species they are working with. The on-line resource provides training on IACUC function, investigator responsibility in research, regulatory requirements and specific methods for working with individual species in a humane and ethical manner. The training is renewed every year and personnel are required to successfully complete associated testing. Personnel are required to complete the trainings that specifically relate to the research that is being carried out, i.e.: mice investigators are required to complete the mouse module successfully. LifeSource personnel are required to complete training on all species housed within the ACF.

All new animal users complete an orientation training provided by the LifeSource Director of Operations. Topics include humane restraint and handling of animals, use of anesthetics and analgesics, proper use of PPE, clean and dirty concepts in an animal facility and zoonoses along with other applicable topics. There is also a discussion about safety and the use of hazardous agents and responding to a disaster etc. New investigators are provided a tour of the animal facility during which the requirement to follow facility standard guidelines and safety policies are emphasized.

The LifeSource Director of Operations and/ or Attending Veterinarian also provide individualized training to personnel in proper euthanasia techniques, bleeding and injecting of rodents, proper anesthetic techniques for each species and training in any approved research procedure that lab personnel may request or require. These trainings are documented in the individual's training file.

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

Work cannot commence until research personnel are added to an approved protocol, have completed requirements of the Animal Exposure Program, and have been adequately trained to carry out approved procedures and their training is documented and placed in their training file.

c) Describe continuing education opportunities offered.

Continuing education opportunities are provided for LifeSource staff through the AALAS Learning Library, attendance at local AALAS trainings, and any other training that may be offered by related professional organizations. LifeSource staff is provided ongoing training during staff meetings and all staff are encouraged and supported to become certified by AALAS. The LifeSource Director of Operations and Attending Veterinarian identify any valuable on-line or hands-on training and encourage their completion by LifeSource staff. The Attending Veterinarian and LifeSource Director of Operations attend at least one professional meeting annually.

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]

Surgical and related procedures are provided oversight through the process of veterinary consult, review and approval of the IACUC of the research proposals and the supervision of research activities by the Attending Veterinarian and LifeSource veterinary care staff. During the veterinary consult and the IACUC review of the protocol, the qualifications and training of personnel is reviewed and considered. If it is determined that a researcher needs additional training prior to initiating a study, the IACUC will require that additional training is provided and documented. The majority of animal procedures are carried out in the ACF, including all survival surgeries, where veterinary staff can provide oversight. The LifeSource Director of Operations provides anesthetic and surgical support when required and/ or requested. In the event that personnel are not adequately trained to carry out a procedure, they will not be allowed to carry out the procedure until such time that they complete additional training and their competency is reviewed and documented by the LifeSource Director of Operations or Attending Veterinarian. When dictated by the IACUC or the Attending Veterinarian, the LifeSource Director of Operations will review investigator competency regarding any proposed research procedures.

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

The training and experience requirements to independently perform anesthesia are determined on an individual basis. Researchers are required to confer with the Attending Veterinarian and/ or LifeSource Director of Operations prior to the submission of a new animal protocol. During the veterinary consult, all issues that impact animal welfare are reviewed and discussed with the Attending Veterinarian including issues of anesthesia and analgesia and the Attending Veterinarian will make recommendations to the researcher. The Attending Veterinarian will also discuss experience and training of all personnel who will be approved to carry out procedures in the proposed protocol including experience in the use of any anesthetic agents in the species that will be used. During the protocol review process, the IACUC reviews the details of the experimental procedures and the qualifications of all personnel including training and experience in the use of anesthetics. If the IACUC determines that personnel require additional training, then additional training will be a requirement for approval of the protocol. Depending on the nature of the proposed work and the species involved, the IACUC could require that LifeSource staff provide anesthetic support in lieu of research personnel anesthetizing the animals. In general, experienced LifeSource staff provide all anesthesia for non-rodent species- any investigator wishing to provide anesthesia in these species would be considered on an individual basis. In the event that research personnel require training in proper anesthetic techniques, the LifeSource Director of Operations and/ or Attending Veterinarian will provide the required training and lab personnel will also have access to

resources that are available in the on-line or in the LifeSource Library. Individual training is provided, and proficiency confirmed by the LifeSource Director of Operations, Attending Veterinarian, or designee, and is documented in the individual's training records.

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

The training and experience requirements to independently perform anesthesia are determined on an individual basis. Researchers are required to confer with the Attending Veterinarian and/ or LifeSource Director of Operations prior to the submission of a new animal protocol. During the veterinary consult, all issues that impact animal welfare are reviewed and discussed with the Attending Veterinarian including issues of anesthesia and analgesia and the Attending Veterinarian will make recommendations to the researcher. The Attending Veterinarian will also discuss experience and training of all personnel who will be approved to carry out procedures in the proposed protocol including experience in the use of any anesthetic agents in the species that will be used. During the protocol review process, the IACUC reviews the details of the experimental procedures and the qualifications of all personnel including training and experience in the use of anesthetics. If the IACUC determines that personnel require additional training, then additional training will be a requirement for approval of the protocol. Depending on the nature of the proposed work and the species involved, the IACUC could require that LifeSource staff provide anesthetic support in lieu of research personnel anesthetizing the animals. In general, experienced LifeSource staff provide all anesthesia for non-rodent species- any investigator wishing to provide anesthesia in these species would be considered on an individual basis. In the event that research personnel require training in proper anesthetic techniques, the LifeSource Director of Operations and/ or Attending Veterinarian will provide the required training and lab personnel will also have access to resources that are available in the on-line or in the LifeSource Library. Individual training is provided, and proficiency confirmed by the LifeSource Director of Operations, Attending Veterinarian, or designee, and is documented in the individual's training records.

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).

LifeSource has developed, implemented, and maintains an occupational health and safety program. All LifeSource personnel receive a detailed health questionnaire and health exam by US HealthWorks, an offsite provider that performs health and risk assessments. All NASA personnel receive a detailed health questionnaire and health exam by the NASA Health Unit. The LifeSource Director of Operations, with the assistance of the Environmental Health and Safety consultant, reviews any issues identified during the health assessment and is responsible for ensuring compliance with all applicable rules and regulations pertaining to occupational health and safety.

LifeSource contracts with US Healthworks as their occupational health provider. They provide all non-emergency occupational health needs, such as injury treatment and management, vaccines/TB tests etc.

LifeSource contracts with (b) (6), (b) (7)(C), (b) (7)(F), (b) (4) as their Environmental Health and Safety representative. (b) (6), (b) (7)(C), (b) (7)(F), (b) (4) conducting all hazard identification and risk assessments.

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 non-affiliated 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 EH&S Consultant and the Director of Operations work together to identify hazards. Job Hazard Analysis are completed by job function and at least one walk through inspection of the animal facility is conducted per year. If any hazards or deficiencies are noted, they are documented and resolved in an appropriate timeframe. Additionally, the EH&S Consultant reviews animal care and use protocols involving hazardous agents or safety concerns and provides expertise on any necessary special precautions or practices. It is the responsibility of the Attending Veterinarian and/or the Director of Operations to establish that personnel involved in animal studies have adequate training to deal with the specific hazardous materials to be used, that appropriate

safeguards are or will be in place prior to beginning any hazardous procedures, and that adequate monitoring will be conducted, if required.

Biohazards and sharps are reviewed periodically to ensure current practices and controls are adequate.

A Job Exposure Descriptor (JED) is provided to every individual working within the animal facility. This questionnaire, along with completion of the Use of Hazardous Agents or Biological Materials section of the protocol, defines any exposures to which an individual will be exposed, and appropriate training is then provided.

All personnel working in the animal facility receive Bloodborne Pathogens training from the EH&S Consultant. This training minimally covers the hazards associated with blood and tissues, routes of exposure, personal protective equipment, universal precautions, safe handling and disposal of sharps, safe disposal of biohazardous materials, and reporting requirements and processes for accidental exposures.

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

The Director of Operations periodically conducts walk throughs and identifies hazards. The Director of Operations also conducts walk throughs with the EH&S Consultant a minimum of once a year. Job Exposure Descriptors (JED) are reviewed annually. EH&S reviews all protocols utilizing hazardous agents or biological materials. If any significant work-related changes occur, the Director of Operations consults with the EH&S Consultant and precautions are taken, JHAs are modified, and training is provided accordingly. The IACUC also conducts safety inspections during the semi-annual review process.

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]

An Injury Illness and Prevention Program (IIPP) exists. Inspections are conducted at minimum annually to identify workplace hazards and employees are trained on hazards, accident and injury prevention, response, and corrective action. Meetings are also conducted to communicate potential hazards. If an unsafe condition arises, employees are to immediately report the condition to their Supervisor and the Injury and Illness Prevention Program Officer for correction. Furthermore, the Occupational Injury and/or Illness Investigation Form is completed, and corrective and preventative actions are determined and implemented accordingly.

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 6.**

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.

LifeSource has developed, implemented, and maintains a medical evaluation and preventative medicine program. All animal users are required to complete a laboratory animal medical surveillance questionnaire. The LifeSource Director of Operations, with the assistance of the Environmental Health and Safety consultant, is responsible for assuring compliance with all applicable rules and regulations pertaining to occupational health and safety. The IACUC reviews the Animal Exposure Program during the IACUC Semi-Annual Facility Inspection and Program Review.

All individuals, regardless of category, who will have contact with research animals are included in the Occupational Health Program. These personnel include all ACF staff, lab/research personnel who are planning to work with animals, members of the IACUC, and any other personnel who anticipate coming in contact with animals. Visitors are allowed to tour the animal facility but are not allowed to have contact with the animals and must sign a waiver from the Animal Exposure Program. Any personnel who are actively participating in research projects involving animals must be on an approved protocol and are required to participate in the Animal Exposure Program.

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

Any individual that does not wish to participate in the Animal Exposure Program must sign a waiver indicating their declination. There are no personnel that are not participating in the program.

c) Describe provisions for assuring confidentiality of medical information.

Confidential medical information is shared only between US Healthworks or the NASA Health Unit and the individual.

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

Individuals with incidental exposure, such as contractors (eg: facilities, maintenance) are given an orientation by the Director of Operations prior to entering the animal facility. This orientation includes information on the humane care and use of animals, reporting welfare concerns, no photography policy, limited access, personal protective equipment, potential exposure to allergens, and a tour of areas with allowed access. LifeSource personnel monitor all contractors while in the animal care facility and ensure that any required personal protective equipment is used. All animal room and most procedure room doors are locked and require an escort if access is required. In these cases, a contractor would be required to have LifeSource personnel present at all times.

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., nonhuman primates, sheep, venomous species)
- immunization programs, and
- procedures for communicating health related issues.

All personnel or contract clientele coming in contact with animals, animal tissues, or animal waste products are provided with a Job Exposure Descriptor (JED) that requests information on the frequency and types of exposure to animals and/or animal tissues and any health-related concerns. The JED evaluation includes information on current immunization status with regards to tetanus and Hepatitis B, TB testing, and measles history. This information is updated yearly.

If immunizations/vaccines are needed, LifeSource personnel are sent to US Healthworks to complete.

All personnel are instructed to inform their personal physicians that they are working with animals. NASA personnel are instructed to inform the Ames Health Unit. Further, if the individual or their physician suspects that an illness or allergy may be animal related, the LifeSource Director of Operations is to be notified immediately.

At this time, [redacted] and [redacted] are maintained in the ACF. Annual TB testing and a measles titer or proof of vaccination is a requirement of all personnel working with [redacted] or their equipment. As a part of training, animal care and research staff working with nonhuman primates are advised on zoonotic diseases that can be transmitted to and/or from the animals, including Herpes B, TB, and bacterial dysenteries such as Shigellosis. In addition, instructions on washing hands after handling animals or their equipment, use of personal protective equipment that is disposed of as biohazardous waste prior to exiting designated areas, and seeking immediate medical attention for any illness/injury—including always informing the physician of exposure to nonhuman primates, is included in the training.

Injuries and/or illnesses are reported to the LifeSource Director of Operations immediately, and personnel would be required to go to the designated LifeSource health care provider (US HealthWorks or El Camino Hospital) for treatment. The Case Management Procedure for Old World Nonhuman Primates Exposures is found in all Primate Exposure Kits and should be followed in the event of an exposure.

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.

No entities other than US Healthworks, the NASA Ames Health Unit, or El Camino Hospital are currently involved in providing medical services. If a life-threating emergency occurs, the Ames on-site fire department can respond and provide immediate assistance.

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 (b) (4)],
- 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.

The EH&S consultant conducts annual training for LifeSource staff. This includes Bloodborne Pathogens, laboratory animal allergies, personal protective equipment and safety, reporting injuries/illnesses, handling hazardous chemicals, chemical spills and other related topics.

Training on proper chemical handling, waste, and zoonotic diseases (including personal protective equipment and issues related to specific biohazardous agents) is provided by the EH&S consultant, a consulting Occupational Health Physician through US Healthworks, the Attending Veterinarian, the NASA safety office, and/ or the LifeSource Director of Operations. Use of the cesium irradiator is restricted to NASA personnel who have been trained and are monitored by the NASA Radiation Safety Officer.

All new personnel who work in the ACF are required to receive training by the LifeSource Director of Operations or designee. Personnel required to work with equipment located inside the animal facility receive hands-on training by the LifeSource Director of Operations or designee until competent with the equipment, as verified by the LifeSource Director of Operations. Personnel are trained in the use of all safety equipment such as ear plugs, safety glasses, safety shields, high heat gloves, PPE, steel toed rubber boots, etc. Training with regards to proper lifting technique is also provided.

At this time, [redacted (b) (4)] and [redacted (b) (4)] [redacted (b) (4)] are maintained in the ACF. Annual TB testing and a measles titer or proof of vaccination is a requirement of all personnel working with [redacted (b) (4)] [redacted (b) (4)] or their equipment. As a part of training, animal care and research staff working with [redacted (b) (4)] are advised on zoonotic diseases that can be transmitted to and/or from the animals, including Herpes B, TB, and bacterial

dysenteries such as Shigellosis. In addition, instructions on washing hands after handling animals or their equipment, use of personal protective equipment that is disposed of as biohazardous waste prior to exiting designated areas, and seeking immediate medical attention for any illness/injury—including always informing the physician of exposure to [redacted] is included in the training.

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.

Animal care personnel are provided with coveralls or scrub suits, shoes and disposable shoe covers, lab coats, facemasks, hair bonnets, safety glasses and gloves. Dedicated coveralls and footwear are required personal protective equipment for husbandry staff. When working with hazardous agents or in [redacted] rooms, personnel are required to wear disposable lab coats or coveralls, hair bonnets, shoe covers, or footwear dedicated to the room, gloves, facemasks, and full-face shields. Hearing protection is offered, but not required. Research staff, IACUC members, and others touring the ACF are offered disposable shoe covers, disposable lab coats, face masks, hair bonnets and gloves and are required to follow any specific posted PPE requirements.

b) Describe arrangements for laundering work clothing.

Coveralls and scrub suits are placed in a dedicated dirty laundry bin in the locker rooms and laundered on site by LifeSource staff a minimum of once 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.

[redacted] has separate locker rooms for men and women [redacted] each with shower facilities. Sinks for hand washing are located either in animal housing rooms and/or procedure rooms. Individuals working with animals and equipment are encouraged to wash their hands frequently. Hand sanitizer is provided at each exit from the facility.

Coveralls may be worn when transporting animals and/or equipment between areas of the facility.

Disposable PPE must be removed when leaving the facility. Scrubs/coveralls/lab coats may not be worn outside the ACF (e.g.: in the office area.

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

LifeSource maintains a non-smoking work environment. Smoking is permitted in outside areas only. In addition, no eating, drinking, or applying of cosmetics is allowed in the ACF. Eating and drinking is allowed in the office areas or employee break room located in (b) (7)(F), (b) (7)(E)

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., (b) (4) (b) (4).

All new personnel who work in the Vivarium are required to receive training by either the LifeSource Director of Operations or designee.

Personnel are trained in the use of all safety equipment such as ear plugs, safety glasses, safety shields, high heat gloves, PPE, steel toed rubber boots, etc. Training with regards to proper lifting technique is also provided.

Hearing protection is available, but all potential noisy areas have been evaluated and are below 85 decibels.

At this time, (b) (4) and (b) (4) (b) (4) are maintained in the ACF. Annual TB testing and a measles titer or proof of vaccination is a requirement of all personnel working with (b) (4) or their equipment. As a part of training, animal care and research staff working with nonhuman primates are advised on zoonotic diseases that can be transmitted to and/or from the animals, including Herpes B, TB, and bacterial dysenteries such as Shigellosis. In addition, instructions on washing hands after handling animals or their equipment, use of personal protective equipment that is disposed of as biohazardous waste prior to exiting designated areas, and seeking immediate medical attention for any illness/injury—including always informing the physician of exposure to (b) (4) is included in the training.

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

Animals and animal caging/bedding/equipment are the main sources of allergens in the facility. The facility is supplied with 100% outside air, the air is not recirculated. All rooms have a minimum of 12 air changes per hour (ACH). Animals are housed in ventilated cages. Soiled cages are kept covered when transporting to the dirty side of cage wash. Personnel wear PPE, scrubs/coveralls, gloves, disposable lab coats, dedicated shoes or shoe covers when working with animals/animal equipment. A bedding dump station is provided for LifeSource personnel on the dirty side of cage wash to reduce bedding dust exposure. Air sampling in the dirty side of cage wash is done periodically. There is a large roll up door that allows fresh air into the area.

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

While the likelihood of zoonoses is relatively small, the most likely source would be from animal bites or handling of tissues or blood, either directly or via contaminated caging or equipment, obtained from (b) (4) (b) (4)

Caging is sanitized in the rack washer that is guaranteed to 180°F and some caging is autoclaved. Equipment is sanitized after each use.

Personnel are trained on proper procedures for animal bites/ scratches in general and personnel working with (b) (4) are trained on how to use the (b) (4) Exposure Kit in the event of an exposure by the Attending Veterinarian or designee. This kit includes Case Management Procedures for (b) (4) Exposures and all supplies associated with those instructions, laboratory submission forms, directions to US Healthworks and El Camino Hospital, and general information.

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

All personal protective equipment (PPE) provided to personnel in the animal facility is disposable.

Eyewash stations and safety showers are tested monthly. Fire extinguishers are evaluated monthly.

Ventilated racks, biosafety cabinets are on annual maintenance contract. Cage/rack washer and autoclave are on quarterly maintenance contract. Anesthesia machines are calibrated/tested annually and charcoal canisters are disposed of following a 50 gram increase from initial weight.

The HVAC system is on a quarterly maintenance schedule, balancing/calibration, room pressures are done yearly.

All caging equipment is sanitized and autoclaved, with monitors to ensure adequate temperature and steam penetration.

e) Respiratory Protection

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

All animal care staff and research personnel are required to wear a disposable surgical mask when working with animals and/ or animal equipment and while on the dirty side of cage wash in the animal facility.

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

Any individual required to wear certain respiratory protective devices (e.g.: an N95 mask) would be required to have an evaluation and training by either their personal physician or an occupational health physician (e.g.: US Healthworks) and undergo an annual qualitative fit test.

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

Respiratory equipment is selected based on the recommendation from an individual's personal physician and /or an occupational health physician (eg: US Healthworks) and any recommendations based on their annual assessment would be followed.

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 15** (Facilities and Equipment for Sanitizing Materials).

Double door cage/rack washer
Double door autoclave

Employees are trained in the use and safety features of all equipment prior to use, including emergency exit from the rack washer. There are signs posted on the interior door of the washer to indicate where to push and exit in an emergency. There is also signage on the side walls of the washer indicating where to pull emergency cord to stop the machine. Proficiency is evaluated by the Director of Operations or their designee prior to working with this equipment.

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.

Not Applicable

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.

Not Applicable

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

All inhalant anesthetics are scavenged using portable charcoal canisters, e.g.: F/AIR® or Vaporguard®. All anesthetic machines are calibrated and serviced annually. These canisters are weighed prior to initial use and discarded prior to or when they reach 50 grams over the initial starting weight. There are also VetEquip active scavenging units in use, scavenging cube with vented induction chamber

Medical grade CO2 and O2 canisters are used in the facility and are transported from an outside holding area to inside the facility using hand

carts. Once inside the facility, canisters are secured to the wall via double chain or restraint. There is also an OxyVet O^2 concentrator used in the LifeSource D1 surgery suite.

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.

(b) (4)

[redacted]

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

(b) (4)

[redacted]

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

There is a cesium irradiator in the ACF that is maintained and used only by NASA.

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.

Protocols which require the use of hazardous substances must be reviewed by the LifeSource EH&S consultant and/ or the NASA Radiation Safety Officer (for NASA investigators utilizing the irradiator only), whichever is applicable. Personnel are required to receive appropriate training on biohazards and bloodborne pathogens, as needed. Those studies that propose the use of hazardous agents are submitted to the EH&S Consultant and appropriate safety committee prior to being reviewed and approved by the IACUC. Guidance is provided in the management and use of these agents while working with animals.

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.

Radiation Hazards: There is a (b) (7)(E), (b) (7)(F) in the ACF that is maintained and used only by NASA. The NASA Radiation Safety Officer is responsible for the management of the irradiator and the training of personnel. Proof of current certification of any NASA personnel intending to use the irradiator in their animal work prior to initiation of work is required during the protocol review process.

The Director of Operations and the EH&S consultant, are responsible for performing ongoing evaluations of the animal facility to identify and address any known or suspected safety issues for employees.

Chemical and General Safety Hazards: All chemical use is governed by the LifeSource EH&S consultant. LifeSource personnel are trained on the proper use and storage of hazardous chemicals and agents. All biosafety cabinets and laminar flow hoods are certified on an annual basis. ACF safety inspections

occur during the IACUC semi-annual review process as well as during regular routine inspections by LifeSource staff as part of facility maintenance.

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.

LifeSource contracts with a licensed hazardous and medical waste transporter. Biohazardous waste (red bags, sharps containers) and animal carcasses are picked up on a weekly basis or more frequently as needed. The carcasses are stored in freezers that are located on the outside loading dock. Once a week they are placed in containers for pick up. Red biohazard bags and sharps containers are placed in biohazard containers, also located on the outside loading dock, for weekly pick up. Bedding is disposed of in regular trash, unless indicated/ described as biohazard waste in the protocol, in which case it would be disposed of as biohazardous waste as described above.

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

Radiation Hazards: There is a (b) (7)(E), (b) (7)(F) in the ACF that is maintained and used only by NASA. The NASA Radiation Safety Officer is responsible for the management of the irradiator and the training of personnel.

Infectious Disease Hazards: For standard work performed in the ACF, no special precautions are required. Standard procedure requires that disposable gowns, caps, facemasks, and shoe covers be used when handling all animals. Animal care staff observes the animals daily and perform routine husbandry procedures. For BSL-2 work performed in the ACF, the Biosafety Level 2 Protocol is followed.

Chemical and General Safety Hazards: All chemical use is governed by the LifeSource EH&S consultant. LifeSource personnel are trained on the proper use and storage of hazardous chemicals and agents. All biosafety cabinets and laminar flow hoods are certified on an annual basis. ACF safety inspections occur during the IACUC semi-annual review process as well as during routine inspections by LifeSource staff.

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.

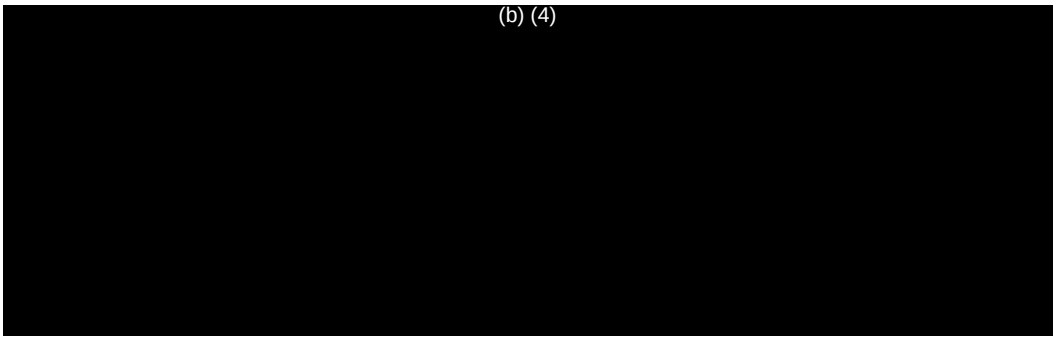
Oversight for training of staff involved in the use of hazardous agents is provide by LifeSource's EH&S consultant and consists of annual training on blood-

borne pathogens, general chemical safety and hazard communication. More specific training for staff required to work with specific agents is also provided, which covers the specific agent, including MSDS review, when applicable.

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.

(b) (4)



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.

Animals are only housed in designated holding rooms within the vivarium.

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

HVAC air handlers are under a quarterly preventative maintenance program to ensure proper function. Rooms are under either negative or positive pressure. The pressures along with air changes are evaluated annually by an outside vendor specializing in HVAC systems. Biosafety cabinets and flow hoods are maintained and certified annually by a commercial contract vendor. Inhalant anesthesia machines and related equipment are tested and calibrated annually by an outside vendor specializing in anesthesia systems. Ventilated racks are tested and certified annually. The ventilated rack pre-filters are changed weekly.

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

assignment involves hazardous agents.

The IACUC, LifeSource EH&S consultant, Attending Veterinarian, and LifeSource Director of Operations provide oversight to the activities of the animal research program. The components of institutional oversight include animal protocol review, development and implementation of guidelines and routine inspections of facilities. The Attending Veterinarian, in conjunction with LifeSource staff, has developed and implemented guidelines to assure personnel safety during the conduct of standard animal husbandry activities. All personnel are trained prior to working in any hazardous areas and are provided all required personal protective equipment. Training on the principles of occupational health and safety including the use of hazardous agents are provided to LifeSource staff and research personnel and are reviewed when necessary. Safety principles and zoonotic health hazards that could be encountered in animal research facilities are discussed during ongoing meetings/trainings.

A bedding dump station is provided for LifeSource personnel on the dirty side of cage wash to reduce bedding dust exposure.

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.

Not Applicable

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.

[redacted] are delivered to the front lobby area in filtered transport containers and are immediately received by husbandry staff who take the animals to their assigned housing room in the ACF. All animal shipments are scheduled, and a transport cart is ready in the hallway so that the animals can be transported as soon as possible. All LifeSource staff, including the front office staff, participate in the Animal Exposure Program.

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 7**.

i. Describe Committee membership appointment procedures.

All IACUC members are appointed by the Center Director for the Ames Research Center. The IACUC Committee reviews the qualifications and experience of proposed new members and the names of the recommended members are forwarded to the Center Director who officially appoints the members in writing.

ii. Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

The IACUC has a standard monthly meeting, which may be not be held if there are no business or protocols to review.

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

Committee members review training materials, including required on-line training modules covering rules, regulations and ethics of animal use, writing a protocol, and IACUC essentials. New IACUC members are required to attend "IACUC 101" conferences or their equivalent within the first year of their appointment. IACUC members also participate in training opportunities offered either during the monthly IACUC meeting or elsewhere.
Members are encouraged to attend local and national meetings that involve animal research and IACUC responsibilities (PRIM&R, AALAS, etc.).

b. Protocol Review [*Guide*, pp. 25-27]

A blank copy of your institution's protocol review form should be provided as **Appendix 9**. 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.

The IACUC review and approval process is initiated when an investigator submits a Protocol for Animal Use (protocol) to the Attending Veterinarian/ IACUC Administrator (the Attending Veterinarian also acts as the IACUC Administrator), who performs an initial review to ensure all questions are answered and sufficient information is given to allow further review and works with the investigator to resolve any incomplete information. The Attending Veterinarian/ IACUC Administrator either sends written comments to the investigator or communicates verbally with the investigator to discuss minor issues. The investigator submits a revised protocol, as needed, for review. The protocol is then distributed electronically to all members of the IACUC, with three members specified to be the primary reviewer, secondary reviewer, and ethical reviewer. Reviewers may submit questions/ concerns in writing or verbally to the investigator prior to the IACUC meeting. A fully convened meeting of the IACUC is held to discuss and vote on protocols. The primary reviewer presents a summary of the protocol to the IACUC, with a listing of concerns and/or unresolved questions. The secondary reviewer provides further review comments/concerns. The ethical reviewer evaluates whether the protocol adequately justifies the use of the requested species of animals and the number of animals, whether appropriate alternatives searches have been conducted, whether societal benefit have been addressed, and whether pain and/or distress to the animals is minimized/alleviated. The other IACUC members express any opinions or additional concerns/questions. There is a paper vote of the protocol, with the vote to approve without any required revisions, the vote to require minor changes that can be administratively reviewed, the vote to require changes with resubmission to the entire IACUC for further review, or disapproval of the protocol. The investigator is notified of the IACUC's decision and is provided a list of required revisions, as needed, or would be given an explanation for a disapproval vote. Investigators would have an opportunity to revise and resubmit any protocol that is disapproved.

A designated review process may be used for protocols and amendments that are submitted between IACUC meetings with a request to review prior to the next regularly scheduled IACUC meeting. The proposal would be sent to all IACUC members, with at least two members proposed to be designated reviewers if no member calls for review at a fully convened IACUC meeting. Designated reviewers either resolve all concerns with the PI and approve of the protocol unanimously or request that the protocol is forwarded for review at a fully convened IACUC meeting.

Once approved, specific protocols may be designated for Post-Approval Monitoring (PAM). PAM may be done on any protocol but is most often requested

for protocols with investigators that are new to the ACF, when new procedures are being performed, or when there is the potential for pain and/or distress. Any issued identified are addressed promptly with the investigator, and if necessary reported to the IACUC for further action.

All protocols and amendments, regardless of funding source, are reviewed in the same manner. During IACUC committee deliberations the justification is reviewed and as a best practice the committee will request the use of a statistical analysis to determine the animal numbers. Although the committee understands that there is value in empirical data, it is the IACUC position that the numbers of animals should also be supported by an objective analysis. If a PI wants to discuss this issue with the IACUC they are welcome to come to a meeting to address the committee.

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.

For all amendments, the PI must submit an amendment form. The amendment form requires the PI to give a brief summary of the proposed changes and then go into more detail in the appropriate section. Once the amendment is submitted, the IACUC Administrator may place it on the agenda for review at the next convened IACUC meeting or request review by DMR. Major amendments are those which request changes such as: the objectives of a study, non-survival to survival surgery, species or approximate number of animals used, a greater degree of pain/ distress or invasiveness, or the PI. Minor amendments, such as the addition of qualified personnel to an approved protocol, the addition of less than 10% of the total number of [redacted] and [redacted] may be administratively reviewed and approved. If modifications are needed to secure approval, the IACUC Administrator will send the PI the modifications required by the IACUC. To secure IACUC approval, the assigned reviewers must review and approve the modifications

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.

The IACUC establishes humane endpoints for each protocol based on standard and common references in the field, the NASA IACUC Humane Endpoints Guidelines, and the collective experience and expertise of the IACUC members

and research staff. The parameters being monitored and the frequency of monitoring must be detailed in the protocol.

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).

If novel studies are proposed or information for an alternative endpoint is not available, the use of pilot studies would be considered for identifying and defining humane endpoints. These studies would be closely monitored by the Attending Veterinarian and Director of Operations and updates provided to the IACUC.

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.

The animal care staff monitors all animals minimally twice daily and the research staff monitors animals in their individual study as described in the protocol. Any animal identified as potentially experiencing pain and/ or distress would immediately be reported to the Director of Operations, with possible escalation to the Attending Veterinarian.

All personnel are required to complete species-specific training with their initial participation in the Animal Exposure Program and continuing education and training is encouraged and provided by the Director of Operations and/ or the Attending Veterinarian or their designee. Post-Approval Monitoring is conducted to ensure proficiency of any personnel working with animals.

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.

In an effort to identify any unexpected research outcomes that are not immediately reported to the animal care staff, the protocol renewal template asks the investigator to provide the details and likelihood of any potential adverse outcomes in carrying out their research and the impact that these events may have had on animal welfare and/ or their results. The significance of any potential adverse events would be determined during the protocol review process and ACF staff are trained to recognize these potential problems. In the event that an unexpected outcome was identified by the Attending Veterinarian through an investigator self-reporting or an issue being observed by LifeSource staff, it would be reported to

the IACUC for further review. If necessary, the Attending Veterinarian would stop certain procedures until further review could be completed.

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."

Procedures that require prolonged physical restraint are considered category E procedures by the IACUC. Prolonged restraint is considered any restraint in an awake animal over 15 minutes. Category E procedures by definition require a rigorous scientific justification including alternatives and documented monitoring of the animals during the entire time they are restrained. Animals are provided training including the use of positive reinforcement when applicable. The IACUC assures that the investigator understands the purpose of the use of the restraint method and its potential impact on the welfare of the animals. All prolonged restraint methods are discussed with the Attending Veterinarian prior to submitting a protocol to the IACUC and the inherent issues of animal welfare including alternatives, are discussed at that time. These issues may include additional enrichment or supportive care as needed. The Attending Veterinarian and/ or LifeSource Director of Operations will observe the initial use of any restraint device and will report any pertinent findings to the IACUC.

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.

There are currently two NASA investigators approved to conduct hindlimb unloading studies in [redacted] which requires prolonged physical restraint. [redacted] are acclimated to the NASA-designed and built cage prior to hindlimb unloading and then tethered by means of tail suspension, with freedom of movement of forelimbs, in the cage. Any animals that do not acclimate or adapt

are removed immediately from the study. Up to 40 days of hindlimb unloading is approved.

Hindlimb unloaded animals are monitored at least twice daily by LifeSource staff, in addition to at least once daily by research staff.

Veterinary care is available at all times including weekends and holidays, and in the rare event that an animal is injured, the Attending Veterinarian or designee would be immediately contacted.

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.

The performance of multiple survival surgeries on the same animal is discouraged unless the investigator can provide sound justification in the animal care and use protocol that the surgeries are related and necessary components of the research project. Cost savings is not sufficient justification for performing multiple survival surgeries.

Any protocol requesting multiple major survival surgeries requires written scientific justification including consideration of alternatives, details of the surgical procedures and timeframe between surgeries, post-operative monitoring plans, and means of alleviating pain and/ or distress in the animals. An investigator is required to discuss the use of multiple survival procedures with the Attending Veterinarian who assures that issues of humane care and use including alternatives are addressed. The use of multiple survival surgeries must be deemed an integral component of the same project by the IACUC. This determination would occur during the deliberation aspect of the IACUC review of the protocol. Any concerns voiced by IACUC members, including the Attending Veterinarian, must be addressed prior to final review and approval of the protocol. The IACUC would approve a protocol that proposes multiple survival surgeries when the value of the study is significant, and the committee confirms that the health and welfare of the animals will be assured. This assurance can be provided by veterinary oversight, effective post-operative care, the use of additional environmental enrichment when applicable and the observance and documentation of effective humane end points.

The training of personnel who are performing surgery is reviewed by the IACUC and if deemed necessary additional training will be required or the Attending Veterinarian and/ or LifeSource Director of Operations will be directed to observe the first procedure to confirm competency. LifeSource staff

observes the animals twice daily, which is documented on the room log sheet and the IACUC approves the frequency at which the investigator is required to observe the animals. These observations are documented in the post-procedural record. The Attending Veterinarian and LifeSource Director of Operations conduct clinical rounds frequently.

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.

(b) (4)

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.

Pair-feeding in (b) (4) is approved in one protocol and is required to eliminate potential confounding variables between normal loaded (NL) and hindlimb unloaded (b) (4) particularly, as in the (b) (4) sex-hormone levels and their receptors and hence sex-organ health are affected greatly by nutrition and caloric intake during development. This technique ensures animals have access to the same caloric amount on a daily basis and may be employed during an experiment following routine procedures (Ellacott, et al, Cell Metab, 2010). For HU animals, the amount of food will be measured at delivery and daily upon removal, factoring in losses through the grating. The average consumption for all HU animals will be calculated and average mass of food provided to NL animals the following day. Longitudinal weight loss of 20% will result in immediate removal of the subject from the experiment and euthanasia. If animals are losing weight (~5%), then

additional food will be added at delivery. If animals lose 10%, then they will be removed from study and euthanized. Additionally, pair-fed NL animals will be compared to animals fed with standard volumes of chow for additional characterization of mass changes.

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 IACUC reviews the use of all test substances and drugs administered to animals during the protocol review process. If indicated, the IACUC will inquire as to the grade classification of the drug that is being used. If the drug is not pharmaceutical grade, then the investigator is required to provide scientific justification as to its proper use in animals and if animal welfare would be impacted. Processes to ensure the safety and efficacy of the drug may be required. The approval of any proposed use would be determined on an individual basis.

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.

Not Applicable

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

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

Under the Method of Euthanasia or Disposition of Animals section of the NASA IACUC Protocol Template, there is a choice for "excess/ deselected animals may be transferred per approved process to another protocol, if applicable". These animals are typically extra or unused animals, and this allows them to be transferred to another protocol for use or training. Additionally, animals held under the Master Holding Protocol are often transferred to the Master Training Protocol as needed for staff training.

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.

Under the master training protocol, excess animals may be utilized to train LifeSource husbandry staff and investigators and their staff in various procedures, e.g. handling, injections, routine dosing, blood collection etc.

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.

Not Applicable

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 animal protocols must be submitted yearly to the IACUC for review. During the renewal process, PI's are required to provide an update of the project on the protocol form. All renewal protocols are reviewed and approved by the IACUC as previously described. In addition, during post-approval monitoring (PAM), a series of standard questions regarding many aspects of the management of the protocol and the animals are asked. Follow up of the post- approval monitoring (PAM) process addresses any needed additional protocol updates such as personnel training etc. and all of the findings and resolutions are presented to the IACUC

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

The program of animal care and use is reviewed every 6 months.

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 10**.

The IACUC conducts a facility inspection and program review every 6 months during which the entire animal facility is inspected. This inspection includes areas where animals are housed, areas where animals are euthanized, procedure rooms, clean and dirty cage wash, drug storage, and feed and bedding storage.

The IACUC inspection of the ACF concentrates on the appropriate care and use of the animals as well as any facility issues that can impact animal welfare such as temperature and ventilation problems. The committee also reviews any safety issues, disposal of biohazardous waste, appropriate signage etc. and the general safety of personnel.

The results of the Semi-Annual Facility Inspection and Program Review are submitted to the IO.

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.

NASA animal facilities are not routinely inspected by the USDA. The animal research program is reviewed semi-annually during the Semi-Annual Facility Inspection and Program Review and any deficiencies that are noted are documented and tracked until they are corrected. All Semi-Annual Facility Inspection and Program Review reports are submitted to the IO and kept on file in the Vivarium Office for 3 years.

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

The post approval monitoring process (PAM) is conducted as requested by the IACUC, the Attending Veterinarian, and/ or the LifeSource Director of Operations. Since the majority of animal procedures are carried out in the ACF, oversight is automatically provided to all activities by LifeSource staff. All animal care staff and the Attending Veterinarian, LifeSource Director of Operations and the Husbandry Supervisor are located in the animal facility and interact directly with research staff on a daily basis. LifeSource animal care staff are required to be familiar with protocol(s) of the animals for which they provide care and are encouraged to develop effective communication with the research staff. They are then in a better position to provide monitoring of the animals. LifeSource animal care staff receive training on approved protocols, both new and renewal. In the event that the animal care staff has any concerns they will inform the Attending Veterinarian directly.

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

All personnel are encouraged to report any animal welfare concerns. Concerns or questions can be shared with LifeSource management, the Attending Veterinarian, IACUC Chair or any IACUC member, or LifeSource staff, either anonymously or not. Once anyone is informed of a concern, it would be reported to the IACUC Chair and would be discussed at

a convened IACUC meeting. The IACUC would conduct an investigation of the reported concern and determine the next step. The IACUC would also decide if the event is reportable to regulatory agencies. If the animal welfare concern is emergent and requires immediate action, the Attending Veterinarian would be contacted immediately and would intervene to assure the welfare of the animal. When possible, the findings of the review would be communicated to the individual reporting the concern. A posted sign, Reporting Concerns Involving the Care and Use of Laboratory Animals is located at multiple sites within the ACF and readily visible to all staff. The sign includes multiple points of contact and compliance with applicable whistleblower protection act.

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.

Vivarium Management is responsible for directing emergency procedures within the animal facility in collaboration with the EH&S representative and has the authority to make decisions regarding animal care during emergencies. Vivarium Management will work with the EH&S representative to determine the appropriate course of action based on specific emergency situations.

There is a written disaster plan for the animals that categorizes various emergency situations and actions to be followed for each situation. The Vivarium maintains enough food, water/gel packs and clean cages on site for at least one week. Cages may not be sanitized or may be hand sanitized depending on the nature and duration of the disaster. In addition, dirty cages may have dirty bedding removed and clean bedding added in order to maintain the animals in a dry environment.

Enough euthanasia solution and carbon dioxide are available at all times to euthanize all animals if necessary.

In the event of a power outage, back-up diesel generators provide emergency power the HVAC and emergency outlets in the Vivarium. These generators are checked monthly by NASA.

II. Animal Environment, Housing and Management

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

A. Animal Environment

Note: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 11.**

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.

Digital minimum-maximum thermometers or hygrometers with humidity readings are read twice daily by husbandry staff and recorded on the daily room check sheets located on a clipboard in every occupied room.

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]

(b) (4) are maintained at a set point of 72 ± 2°F (hindlimb unloaded rodents are maintained at 75°F) (b) (4) are maintained at a set point of 68 ± 2°F. (b) (4) are maintained at a set point of 72 ± 2°F, (b) (4) (b) (4) are maintained at a set point of 75 ± 2°F, (b) (4) are maintained at a set point of 72°F. LifeSource monitors the set points and alarms. If a temperature falls out of range an alarm is sent to the Director of Operations and the contracted HVAC vendor. Humidity is monitored to ensure that the acceptable range of 30-70% is met but not controlled in any rooms.

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]

Animals are provided with a variety of cage enhancements to aid in thermoregulation. (b) (4) are group housed. (b) (4) are provided with plastic huts/tubes. Additionally, (b) (4) are given Enviro-dri® or Bed-r'Nest® nesting material. Individual housing/exemptions from enrichment would be specified and justified in the protocol, reviewed and approved by the IACUC.

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.

The Director of Operations, in conjunction with the HVAC engineer, discuss any changes in air changes or pressure gradient changes that maybe needed quarterly or as needed. The HVAC engineer keeps records of all room air changes and room pressures.

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

Ventilated racks for (b) (4) are currently in use. They provide individually ventilated HEPA filtered air with defined air exchange rates. The rates of air exchange are reviewed on a daily basis by animal care staff to assure that they are maintaining the established number of air changes per hour recommended by the Attending Veterinarian and or the manufacturer. HEPA filters are changed at intervals recommended by the manufacturer, pre-filters are changed and cleaned weekly. The ventilated racks are maintained on a preventive maintenance agreement.

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.

There is no recycled air in the ACF, 100% fresh outside air.

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).

Not Applicable

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 12** (Aquatic Systems Summary).

Not Applicable

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.

The animal facility is located on the ground floor, separate from direct contact with administrative areas and offices. There are no audible fire alarms in any animal holding rooms, notification is provided by flashing lights. There is no intercom system in the facility. (b) (4) and (b) (4) ousing areas are separated from (b) (4) and (b) (4) (b) (4) housing and support areas. The cage wash areas do not share walls with animal housing or procedure rooms and noise is monitored by the EH&S consultant and exposure is no more than the allowable 8-hour time weighted average (TWA) of 85 decibels. Earplugs are available for personnel when working in the cage wash areas and for other personnel upon request. Offices and break areas are in a separate building from the ACF. All animal holding room and procedure room doors are kept shut at all times.

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 13**.

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, and wildlife when reviewing biomedical, field and agricultural research studies.

The adequacy of space for all animals housed in the ACF is assessed as part of the daily observation of the animals. If animals exhibit abnormal behavior or present signs of stress or clinical disease, the environment of the animal is reviewed, and the review includes, among many factors, the primary cage environment. The IACUC reviews animal housing during the semiannual inspection and if any concerns develop regarding caging of any species, they would be addressed at an IACUC meeting. The IACUC requires investigators to address housing of animals in their protocol and to justify the use of non-standard housing arrangements. The 8th Edition of the Guide for the Care and Use of Laboratory Animals is used to determine the adequacy of animal housing arrangements.

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]

Hindlimb Unloading Cages: the dimensions of the hindlimb unloading cage for mice are 7.6" X 11" X 12".

Animals must be inspected daily by the Attending Veterinarian and/ or the Veterinary Care Staff to ensure the health of the animals. In addition, animals are inspected carefully twice a day by the investigator or his/her staff to ensure that any animal slipping out of the traction tape (and, thus, weight-bearing) is discovered as soon as possible so that it can be hindlimb unloaded if desired, with a minimal exposure to re-loading, or removed from the experiment. Criteria for removing an animal from the study are documented in the IACUC protocol; criteria include, but are not limited to, tail status, weight, appearance, and inability to remain attached to the unloading device. A weight loss of more than 20% in any animal over the entire experimental period would be considered excessive and the animal will be removed from the study and euthanized. Any abnormalities are immediately brought to the attention of the Veterinary Care Staff and/ or Attending Veterinarian. All experiments involving hindlimb unloading are considered Category E in this program.

Description of the hardware or techniques can be found in the following references: Harper JS, Mulenburg GM, Evans J, Navidi M, Wolinsky I, and Arnaud SB. Metabolic cages for a space flight model in the rat. *Lab Anim Sci* 44: 645-647, 1994.

Park E and Schultz E. A simple hindlimb unloading apparatus. *Aviat Space Environ Med* 64: 401-404 1993.

Wronski TJ and Morey-Holton ER. Skeletal response to simulated weightlessness: a comparison of suspension techniques. *Aviat Space Environ Med* 58: 63-68, 1987.

Morey-Holton ER and Globus RK. The hindlimb unloading rodent model: a technical review. *J. Appl. Physiol.*, 92:1367-1377, 2002, and Morey-Holton, E.R., R.K. Globus, G. Durnova, and A. Kaplansky.

G. Sonnenfeld (Ed.), Elsevier Science, pp. 7-40, 2005. NASA Institutional Animal Care and Use Procedure for Mice and Rat Hindlimb Unloading.

Metabolic Cages- the dimensions of metabolic cages for (b) (4) are 14"X11"X19".

For long-term studies, animals may be housed in a metabolic cage for no more than 4 days during any consecutive seven days except for the last week on the study when animals may be held in metabolic cages for seven consecutive days. For shorter term studies, animals may be housed in metabolic cages for 14 consecutive days on a one-time basis.

Criteria for removing an animal from the study are documented in the IACUC protocol; animals will be weighed weekly, increasing to daily if 15% weight loss compared to age match controls is observed. Animals will be removed from the study

if they are moribund or if weight loss is 20% as compared to age match controls or as compared to the initial weight at the start of the study.

Ding, S. Y. et al. Pioglitazone can ameliorate insulin resistance in low dose streptozotocin and high sucrose-fat diet induced obese rats. Acta Pharmacol Sin 2005, 26(5): 575-80.

Watkins, SM. et al. Lipid metabolome-wide effect of the PPAR-gamma agonist rosiglitazone. J Lipid Res 2002, 43(11):1809-17.

Shatara, RK. et al. Fenofibrate lowers blood pressure in two genetic models of hypertension. Can J Physiol Pharmacol 2000, 78(5):367-71.

Grond, et al. Animal models in chronic renal failure. Contributions Nephrol 1988, 60:83-93.

Eiam-ong, S. et al. Studies on the mechanism of trimethoprim-induced hyperkalemia. Kidney International 1996, 49:1372-1378.

Néstor H. et al. Hyperkalemia, renal failure, and converting-enzyme inhibition. Hypertention 2001, 38: 639-644.

Borok Z. A rat model for hyperkalemia. Proc Soc Exp Biol Med 1987, 185(1):39-40.

Kawai, et al. Behavioral and biochemical characterization of rats treated chronically with thioacetamide: proposal of an animal model for hepatic encephalopathy associated with cirrhosis. The Journal of Toxicological Sciences 2012, 37(6):1165-1175.

Rat CCl_4-induced cirrhosis plus total portal vein ligation: a new model for the study of hyperammonaemia and brain oedema. Liver International 2010, 979-987.

Morris, G.P., Beck, P.L., Herridge, M.S., Depew, W.T., Szewczuk, M.R., Wallace, J.L. Hapten-induced model of chronic inflammation and ulceration in the rat colon. Gastroenterology, 96: p.795-803, 1989.

Animal Enclosure Models (AEMs)- housing floor space in the Habitat (~11.9 in^2 per mouse). These housing dimensions have been well-tolerated in previous ground-based testing and Rodent Research missions.

	Length (in)	Width (in)	Surface area (in^2)	Surface area per mouse (in^2/mouse)
AEM	14.3	8.4	119	11.9
Standard Mouse cage	11.5	7.5	86	17.2

https://www.nasa.gov/sites/default/files/atoms/files/np-2015-03-016-jsc_rodent-iss-mini-book-508.pdf

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).

[redacted] are provided with resting boards, swings, and perches, as well as access to outdoor runs via a guillotine door. [redacted] are provided with access to outdoor runs and a larger outdoor common area via guillotine doors. [redacted] may be provided with houses/tunnels/wheels. [redacted] are housed in solid bottom cages on contact bedding (usually corn cob direct bedding) that allows for natural burrowing activities. Cages allow visual contact between adjacent cages as well as visual contact with room activities.

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).

Enrichments include, but are not limited to, foraging devices, juice and/or food treats weekly, nesting materials, climbing and perching devices, low volume music, group housing, and access to runs, pens or larger cages when available. Enrichment will be provided that is appropriate for each species, and each animal's current condition and/or stage of life (e.g., dams with litters). The program of enrichment is part of the animal care program overseen by the Attending Veterinarian.

Enrichment for [redacted]

In addition to the normal bedding material, nesting material should be provided to [redacted] other than [redacted]

Enrichment devices including rodent igloos/shelters/ huts, tunnels, perches, exercise devices, manipulanda or items to chew will be provided, as appropriate for the species and/or stage in life.

[redacted] that are housed in suspension cages or metabolic cages are given items to chew on and at least one Nestlet or other nesting material to rest on.

Some [redacted] may be given food treats such as alfalfa cubes, timothy hay, yogurt drops, fresh fruit or vegetables, or other food items approved by the Attending Veterinarian or designee on a periodic basis.

At least one enrichment device selected from approved devices is placed in cage at a time, depending on rotational schedule of each caretaker's room. A clean enrichment device of any type named will be present in cage at all times.

Enrichment for [redacted]

[redacted] are given food treats such as alfalfa cubes, timothy hay, yogurt drops, fresh fruit or vegetables, or other food items approved by the Attending Veterinarian or designee on a periodic basis.

Manipulanda, including but not limited to jingle balls, dumbbells, large nylabones and small pieces of PVC pipe are provided on day of cage change and remain in the cage for the duration of the week. Manipulanda are rotated among animals to maintain novelty. Cages should be arranged so that all animals are able to view and/ or interact with other animals.

Music played at a low volume may be present.

Enrichment for Farm Animals

Animals are provided with toys, both hanging and ground-based (such as balls), and/ or are given food treats such as fresh fruit or vegetables, or other food items approved by the Attending Veterinarian or designee on a daily basis.

Animals are provided access to a covered/ protected outside run area daily and interact with animal care staff during training, acclimation, provision of feed/ treats, and pen cleaning.

[redacted]

Manipulatable objects and alternate caging include veterinary approved devices that are sturdy enough to allow non-injurious behavior and provide tactile sensory stimulation. These may be any of the following:

- Cardboard boxes or tubes
- Plastic toys, balls, or chew toys
- Paper tubes
- Magazine perfume inserts, spices or extracts for olfactory enrichment
- Plastic denture cups
- Foraging devices (e.g., forage boards, whiffle ball feeders or similar items)
- Fleece boards and/or paint rollers for grooming
- Branches (allow for gnawing and/or perching), plastic chain, and/or ropes for perching, swings, resting boards.
- PVC pipe sections and /or caps.

All [redacted] receive daily audio and video enrichment in the form of music and/ or videos/ DVDs.

All [redacted] receive human socialization at least once per day by animal care, research, and/ or veterinary staff. Approved food treats may be fed to animals to provide an opportunity for close observation of individuals.

A variety of food treats for all primates provide gustatory and olfactory sensory stimuli and may include any of the following or any other veterinary approved food item, alone or mixed with a foraging substrate (e.g., wood chips or straw):

Dried or fresh seasonal fruits and vegetables
Seeds and nuts, shelled or unshelled
Grain-based cereals
Commercially available primate treats
Wax/meal worms
Ice cubes with or without fruit, vegetables, and/or juice
Peanut or other nut butter
Honey or fruit jam
Popcorn
Hard-boiled eggs

For all species, efforts are made to house isolated animals in a manner that allows visual, auditory, and/or olfactory interactions with con-specific species. In these instances, the husbandry technician would be made aware of the animal and additional steps would be taken to provide increased favorable environmental stimuli and human attention (if applicable). Additional forage devices and/or toys may be provided.

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

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

The IACUC requires social housing for all species unless single housing is scientifically justified and approved by the IACUC. It is assumed that all animals will be housed socially unless compelling reasons exist that preclude it. Exceptions to social housing are approved by the IACUC and Attending Veterinarian and documented in the protocol or individual animal record. LifeSource staff are familiar with the normal behavior of all species housed in the facility and are trained to identify any abnormal behaviors while interacting with the animals in the performance of daily husbandry duties. Any concerns regarding the social needs of the animals would be brought to the attention of the Attending Veterinarian and/ or the LifeSource Director of Operations.

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.

Exceptions to these expectations might include: research requirements (e.g. surgically manipulated animals, post-operative recovery, hindlimb unloaded animals, monitoring of food/water intake or fecal/urine output), the rare instance where all other members of an experimental group have been utilized, or incompatibility/aggressive behavior.

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

Animals that are housed singly are provided standard environmental enrichment, which may be supplemented if deemed appropriate, e.g.: additional food treats, toys, etc. Animal care staff provides maximum interaction with the animals during routine husbandry tasks daily and the veterinary care staff often provides additional daily interaction, especially with larger nonrodent species.

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.

We have no approved protocols where environmental enrichment cannot be provided to the animals for scientific reasons, therefore all animals are provided enrichment materials, toys, and/ or treats and provided social interaction with other animals or animal care and research staff as described above. The environmental enrichment program is continuously reviewed by the Attending Veterinarian and LifeSource Director of Operations to include all species housed within the ACF. The guidelines for environmental enrichment of nonhuman primates and all other species housed in the facility are reviewed yearly by the IACUC.

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.

All animals are given a minimum of a 72-hour acclimation period prior to being placed in any study. The only exception might be an animal that is scheduled to be euthanized immediately upon arrival for tissue harvest, arrives with an indwelling catheter placed by the vendor, or an animal that is delivered to the animal facility within 24 hours of its

scheduled use and undergoes a terminal procedure. During the acclimation period, animals are given an opportunity to explore their new surroundings, identify and acclimate to new sources of food and water, and develop interactions with their cage mates. The animals are also given an opportunity to become familiar with the animal caretakers and research personnel that will be interacting with them. If an animal is required to participate in a research study where they are expected to perform or interact in a unique environment the IACUC may require a more extensive period of acclimation before any studies are initiated.

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).

The facility is equipped with indoor/outdoor runs that can be used by (b) (4) (b) (4) and (b) (4) animals, which provide sheltered outdoor space to allow daily exercise and both indirect and direct contact with other animals, as appropriate.

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.).

The outdoor portion of the runs are the same basic construct as the indoor runs; however, a roof of corrugated plastic provides sheltered cover for the (b) (4) and a roof or corrugated metal provides sheltered cover for the (b) (4) All outdoor areas are secured by locked fencing. There are guillotine doors to allow animals to have access to both the inside and outside areas to give them control over their environment.

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.

The guillotine doors allow animals access to both sides of the runs, which allows constant access to food, water, and enrichment. Outdoor enrichment is provided for all animals, in the form of swings and toys for the (b) (4) and hanging or ground toys for the (b) (4) The same efforts to socially house animals are made in the outdoor runs and the guillotine doors would allow the animals an opportunity to escape the other side of the run, if desired.

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).

Not Applicable

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

Not Applicable

iii. Describe how animals are captured.

Not Applicable

C. Animal Facility Management

1. Husbandry

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

i. List type and source of food stuffs.

Most feed is manufactured by Purina and obtained from Newco Inc. in Hayward, CA, and/ or Envigo in Hayward, CA. (b) (4) are fed one of the following: Purina Lab Diet 5001, Lab Diet Picolab 5053, Teklad Global Diet 2016, Teklad Global Diet 2018, (b) (4) are fed Purina (b) (4) Diet 5025 and various fruits and vegetables (b) (4) are fed Lab Diet 5070 and Lab Diet 5326, Purina Alfalfa Cubes 5920 and various fruits and vegetables. (b) (4) (b) (4) are fed Lab Diet 5047, (b) (4) are fed Lab Diet 5040, Zupreem and various fruit, vegetables, and other treats. (b) (4) are fed Teklad 8753 and various fruits and vegetables. Animals on protocols involving use of the Animal Enclosure Module (AEM) hardware similar to that used for space flights receive a special food bar created by NASA scientists. When required animals may be fed specialized diets to achieve scientific objectives. These diets are identified in the IACUC protocol.

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

Envigo- the seams of the main storage facility are sealed to prevent the entrance of vermin and to eliminate pest harborage. All floors are sealed and there is an 18-inch wide white sanitation border that allows for more accurate visual inspection of the

storage facility, which occurs on a daily basis. The facility is climate controlled and the temperature does not exceed 70°F and humidity does not exceed 55%. Temperature and humidity are monitored daily. Glue boards are located every 10 to 15 feet throughout each warehouse and management performs daily inspection. An independent pest control vendor performs bi-monthly inspections.

Newco- the main facility is a cement building with a 24-foot ceiling. All lab diets are stored in a temperature-monitored room equipped with a thermometer that monitors temperature and humidity. The room is cooled by an industrial air conditioning unit. All product is kept off the floor on pallets or pallet racks and is rotated weekly. Strict sanitation methods are followed, and damaged product is removed immediately. Glue traps and tin cat mouse traps are used though out the facility. A commercial pest control vendor is used to maintain a pest-free environment.

Animal Facility- The storage facility for feed is located in building (b) (7)(F), (b) (7)(E) and is dedicated to feed and bedding storage. All feed and bedding materials are stored on pallets or racks. Feed is stored with the manufacture date visible. Temperature is maintained at 59-63°F. Temperature and humidity are recorded minimally three times per week. The food preparation (b) (7)(E), (b) (7)(F) is adjacent to the feed/bedding storage room in building (b) (7)(F), (b) (7)(E) it includes one refrigerator and one refrigerator/freezer. The primary purpose if for storage of perishable food items for (b) (4) Humane rodent traps are located in both the feed/bedding room and food preparation room.

Holding rooms- In the animal rooms, food is stored in plastic containers set on casters, feed carts with plastic bins or large rat cages with a lid. These containers are lined with plastic bags and have tight fitting lids to seal the container securely. Autoclavable scoops or measuring cups are kept inside the feed containers to scoop up the feed. The feed containers are labeled with the type of food, milling date, and expiration date. When the feed is consumed or expires, the feedbag and plastic liners are discarded, and the container and scoop/ cup are sanitized before a new bag of feed is placed inside. Standard sanitization occurs once a month.

iii. Describe special food preparation areas, such as feedmills 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).

The Food Preparation room is a limited access room located in (b) (7)(E), (b) (7)(F) Room 135, and is utilized for (b) (4) feed/supplement preparation. Inside the room is an approximately 10-foot counter that is attached to the wall, has a Formica top and contains 2 stainless steel sinks with hot and cold-water faucets. The room also includes a utility cabinet for storing

dry feed goods, one refrigerator/freezer and one refrigerator for storing perishable items and a dishwasher for washing feeding containers/utensils. The refrigerator/freezer and refrigerator are only for storing food items consumed by animals.

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

(b) (4) wire grill lids; *ad libitum.*

Mice on hindlimb unloading protocols: food is provided in small feeder cups attached to the inside of the cage or food pellets are provided on the cage floor.

Mice on study in the AEM: food bar mounted to the inside of the module to mimic spaceflight, and their controls may be fed food bar provided in the wire grill lid and/ or on the floor of the vivarium cage; *ad libitum.*

(b) (4) J-feeders; once daily.

(b) (4) stainless steel feeders or hand feeding by technical staff; twice daily.

(b) (4) Stainless steel bowls or hand feeding by technical staff; twice daily.

(b) (4) feeders in the runs; twice daily.

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

Bags of food are inspected on delivery and, if damaged or contaminated, are either not accepted or are discarded. The milling date of the food is checked to ensure that it can be used within the acceptable time for that species. All feed is rotated to ensure freshness. The feed with the earliest milling date is placed on top of the feed stack and used first. Food is used within 6-months of milling. Food stock is used on a rotating basis, oldest being used first. Husbandry staff visually inspects the food bags and expiration dates when food bags are removed from the food storage room. Food is visually inspected when it is removed from the bags. Any abnormality would be brought to the attention of the LifeSource Director of Operations.

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 supplied to the ACF from the Hetch Hetchy Reservoir. The water meets all federal and state criteria for treatment, biological quality, and operational standards. The water is chloraminated and pH-adjusted before it reaches the facility. The main water supplied to the facility is then run through Aqua Pure water filters prior to being consumed by the animals. [redacted] bottles with sipper tubes; filtered, potable water. Immunocompromised mice: bottles with sipper tubes; filtered, autoclaved water. Nonhuman primates automatic watering system or bottles with sipper tubes; filtered potable water; [redacted] automatic watering system or water buckets; filtered, potable water.

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

Annual water quality reports are available through San Francisco Public Utilities. NASA Environmental Services assays incoming water on a monthly basis for coliform counts, on a quarterly basis for chemical analysis, and periodically (currently every 6 months) for lead and copper analysis. In house, water filters are checked monthly and changed on an as-needed basis. A Diack monitor for verification of sterilization is utilized each time water is autoclaved for immunocompromised mice.

Microbial cultures for aerobic and anaerobic bacteria are taken at least once a year from sanitized sipper tubes and water bottles to ensure adequate disinfection has occurred.

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

The automatic watering system is checked weekly while in use to make sure it is running correctly. The lixit portion of the system is cleaned during normal run/ cage sanitation.

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

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

Most [redacted] are maintained in polycarbonate caging using Bed-o' Cobs (1/8" corn cob bedding) as direct contact bedding. Immunocompromised [redacted] receive autoclaved Bed-o' Cobs. [redacted] on the hindlimb suspension protocol are maintained in a cage with a grill over indirect bedding. The indirect bedding is a Poly Pad. [redacted] are maintained in caging with floor grates using Poly Pads as indirect bedding.

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

The storage facility for feed is located in (b) (7)(F), (b) (7)(E) and is dedicated to feed and bedding storage. All feed and bedding materials are stored on pallets or racks. Feed is stored with the manufacture date visible. There is pest monitoring station, Tin Cat®, located within the feed/bedding storage room.

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

When receiving bedding, bags are visually inspected by husbandry staff prior to accepting the shipment. Damaged or torn bags are rejected. The contents of bedding bags are examined when bags are opened. Any abnormalities are brought to the immediate attention of the LifeSource Director of Operations.

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.

Not Applicable

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.).

Floor cleaner- used for cleaning and polishing floors.

Washer and dryer- used for laundering scrubs and coveralls.

Many small in-room vacuums - used for cleaning up small amounts of loose fur and bedding.

Upright HEPA vacuum- used for cleaning up loose fur in larger areas.

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.

[redacted] in direct contact with bedding are changed minimally once a week or as needed; hind-limb suspended rodents with non-contact bedding are changed twice weekly; [redacted] being housed in a ventilated rack are changed at least every other week.

[redacted] are in direct contact with bedding and are changed three times weekly.

[redacted] have non-contact bedding and are changed three times weekly. Frequencies shown are the minimum requirement; all cages are changed more frequently as needed to keep animals clean and dry.

[redacted] ens are disinfected with a quaternary ammonium and rinsed out daily.

[redacted] cages and pens are disinfected with a quaternary ammonium and rinsed five days per week.

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

The Animal Enclosure Module (AEM) is an enclosed rodent habitat similar to that utilized on space flights that provides ventilation exceeding 15 changes per hour (at a rate of 14 cubic feet per minute), lighting, waste collection, food and water for the rodents. Change in caging and less frequent cage changes in ground-based testing of the Animal Enclosure Modules (AEMs) are approved to simulate the conditions used to house rodents during space flight while on ISS.

[redacted] dams that have recently given birth may have their cage changes delayed, but in no instance would cage changes go longer than once a week. In addition, sentinel [redacted] for the health monitoring program receive a clean cage and clean bedding as regularly scheduled; however, the clean bedding is supplemented with approximately one-half teaspoon of dirty bedding from all experimental cages being monitored.

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

Soiled bedding is removed from cages on the dirty side of the cage wash area. Clean bedding is placed into clean cages on the clean side of the cage wash area.

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 14** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

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

There is one exception to the applicable regulations regarding recommended sanitation intervals– the Animal Enclosure Module (AEM) is utilized during space flight ground verification tests and does not follow the recommended sanitation intervals. The specific interval to be followed will mimic the current spaceflight schedule and will be described and approved in the applicable protocol.

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).

The cage washer has a digital panel read out that verifies the final rinse has reached 180°F. The husbandry staff conducts testing of the water temperature using indicator strips on the first and last load. They are recorded on a daily log sheet. When the desired temperature is not reached the LifeSource Director of Operations is notified and a service call for the machine is placed. Cages and bottles are visually inspected by husbandry staff for cleanliness after each load. The item will be re-washed if it does not appear clean or if the cage washer or temperature indicator strips indicate that 180°F was not reached. Cages are swabbed at least twice a year and the swabs are submitted for microbiological assays.

b) Describe preventive maintenance programs for mechanical washers.

The cage/ rack washer and autoclave are serviced by an outside vendor. Standard preventive maintenance occurs on a quarterly basis and the LifeSource Director of Operations is provided a quarterly report that describes the performance of the equipment. The vendor is available at all times and can provide emergency services when needed.

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.

Trash is placed in plastic bags and taken from procedure and animal holding rooms daily. Soiled bedding is also placed in plastic bags on the dirty side of the cage wash. Waste is deposited in a dumpster located on the north side of building [redacted] and is picked up by a commercial waste disposal company daily.

ii. Animal carcasses.

Animal carcasses from the main ACF are placed in plastic bags and are stored in chest freezers and upright freezers located on the loading dock just outside of the dirty cage wash area. A commercial disposal company contracted for by LifeSource picks up the carcasses weekly.

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).

The exterior of Building [redacted] and [redacted] s under contract for pest control by A-Pro Corporation. At every entrance to Building [redacted] humane rodent traps are used to monitor for pests. The traps are checked daily by husbandry staff. LifeSource oversees this program and all animal technicians are trained to check the traps and record on the appropriate check sheet.

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.

Not Applicable

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

For building [redacted] office area postings are made by A-Pro when any pesticide is used. In the e [redacted] hat treatment of pests in the ACF is needed, written notification and/or a meeting with animal users would be conducted. The LifeSource Director of Operations, Attending Veterinarian or designee, and appropriate representatives

of the animal care staff and pest control company would be consulted and/or present at the meeting to address any concerns. To date no pesticides have been used in the ACF.

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.

Holiday and weekend care is provided by regular husbandry staff. All animals are observed and all animal holding rooms (including temperature and humidity) are checked twice daily. Animals are provided with food and water and cages are changed, as needed. (b) (4) cages may be changed immediately prior to a holiday if the holiday falls on a regularly scheduled change day; otherwise, cages are changed according to the regular cage changing schedule. Contact information (including emergency numbers) for the Attending Veterinarian, and the LifeSource Director of Operations is clearly posted at the entrance to each wing, (b) (7) (F), (b) (7)(E) and in the Building (b) (7) (F), (b) (7)(E) office area.

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

Not Applicable

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

In the event of an animal health emergency, the LifeSource Director of Operations and/or Attending Veterinarian are notified immediately. The Attending Veterinarian is contacted for assessment and/or treatment of animal(s). In the event of a facility-related emergency, the LifeSource Director of Operations and facility personnel are contacted.

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).

Cage cards that state the protocol number, investigator, animal species, strain, sex, receipt date, vendor, animal birth date and/or weight identify all animals in the animal facility. (b) (4) may be identified by ear tags and/or ear tattoos. (b) (4) have numeric tattoos. (b) (4) may have identification tags or indelible markings. (b) (4) may have microchips, ear tags, ear notches or tattoos.

b. Breeding, Genetics, and Nomenclature

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

The Attending Veterinarian is available at all times for consultation on animal model development and/or selection. The Attending Veterinarian reviews all research protocols submitted by investigators and can, as a part of the review process, provide guidance to investigators if they have not already consulted with them prior to submission of the protocol. In addition, investigators collaborate with specialists in their respective fields on animal model development.

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.

The Attending Veterinarian has provided reference materials and Internet access information on the (b) (4) and (b) (4) Genome and appropriate (b) (4) nomenclature rules. There are reference materials available from LifeSource and/ or the vendor.

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

Investigators with breeding colonies do their own genetic testing and maintain the records.

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.”

The investigator is asked to describe these new genotypes and if they anticipate the development of any phenotypical changes that could negatively impact the animals. The issue of alternatives will also be addressed. In the event that these changes could develop the investigator will be asked to describe what clinical signs may occur and LifeSource staff will attach a Health Surveillance Form to any cages to enhance daily monitoring of the animals. During the daily observation of the animals, any clinical signs that could be attributable to new phenotypes would be reported to the Attending Veterinarian and/or the Director of Operations.

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.).

All animals are purchased through LifeSource on an approved protocol and following receipt of a written request or an Animal Purchase Request. Animal vendors provide health report documentation concerning the status of their animals. Incoming animals are evaluated for any clinical abnormalities at the time of their arrival at the facility. Current health reports are required to be submitted and approved by the Attending Veterinarian prior to any animals being accepted from another institution or nonapproved vendor. The Veterinary Care Staff would be notified to determine appropriate actions should any abnormalities be noted. Periodically, animals from various vendor sources supplying animals to the institution are sent to commercial diagnostic laboratories for comprehensive evaluations, including serology, parasitology, microbiology, histopathology, and/or other diagnostic assays as a means of vendor surveillance.

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).

The majority of (b) (4) transported to the NASA/ LifeSource facilities are delivered in vendor-owned, environmentally-controlled trucks from their production facilities. Some (b) (4) are delivered via air shipment and commercial delivery service from nearby San Francisco or San Jose Airports. (b) (4) are trans in filtered shipping cartons and deliveries are made directly to the main office i (b) (7)(F), (b) (7)(E) LifeSource's administrative and husbandry staff are aware of all shipment rival dates to allow adequate preparation (b) (4) were transported from the breeding facility at UC Davis or the institution of origin via a temperature-controlled transport vehicle. (b) (4) are delivered by the vendor. (b) (4) were transported from the institution of origin via a temperature-controlled transport vehicle. Animal shipping containers are transported via dedicated cart to the appropriate housing rooms, where animals are transferred to cages. Carts are used to transport animals between rooms (housing and procedure) in the ACF.

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.

LifeSource has an approved vendor list. The Attending Veterinarian approves all animal orders from commercial vendors and does not approve animals that come from sources that are positive for agents that we work to exclude from the ACF. The preventive medicine program for [redacted] s based on the use of approved vendors, rodent health surveillance, quarantine procedures, effective husbandry practices and continuous medical surveillance. [redacted] undergo annual physical exams, which may include hematology, serology, dental cleaning and TB testing. In addition, monthly body weights are obtained from [redacted] and every 3 months for the [redacted] and noted in the individual medical charts.

All animals within the ACF are monitored twice daily by LifeSource staff and weekly during clinical rounds by the LifeSource Director of Operations and/ or the Attending Veterinarian. Any animal exhibiting clinical signs of illness are brought immediately to the attention of the Attending Veterinarian and the Director of Operations.
Sentinel animals are maintained in all long-term [redacted]. Sentinel samples are sent in once a quarter to an approved diagnostic laboratory for serological analysis for murine viruses performed by outside diagnostic laboratories. They are also screened for endo/ecto parasites. At least once a year, live sentinel animals may be sent for comprehensive necropsy and evaluation, including microbiology, serology, parasitology and histopathology. Health reports are maintained by the Director of Operations.

Animal serum or EZ blood spots®, feces and fur swabs are tested for the following:

[redacted]
MNV, MHV, [redacted] parvo virus (MVM/MPV), EDIM, TMEV/GDVII, SEND, PVM, REO, MPUL, Fur mites (Myobi, Myocoptes, Radfordia), Pinworms (Aspicularis, Syphacia).

[redacted]
SEND, PVM, SDAV, KRV, H-1, RPV, RMV, NS-1, REO, RTV, MPUL, RRV, Fur mites (Myobi, Myocoptes, Radfordia), Pinworms (Aspicularis, Syphacia).

All of these programmatic elements support the monitoring of known and unknown infectious agents.

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

In the event of an outbreak the methods used are determined by the agent, how contagious it may be, how widespread it is and the status of the animals that are impacted. If an agent is detected that can be treated, the animals will be isolated, and the Attending Veterinarian will discuss treatment options with the principal investigator prior to proceeding with treatment. In the event of a viral outbreak, the animals will be isolated, the investigator will be contacted and depending upon the circumstances we may proceed with additional testing of experimental animals to confirm our results especially if positive animals may face euthanasia. In all cases we work closely with the principal investigator to determine the best actions to take and inform all users of the ACF, while emphasizing the importance of biosecurity and the importance of the adherence to ACF policies and procedures. During an active outbreak we would handle the impacted animals and their caging last including the management of the impacted cages in the cage washer. Autoclaving materials prior to washing as a control measure may occur when indicated. In all cases, isolation of the impacted animals is instituted, limited access is allowed in the affected area, ACF staff and research personnel are informed, PPE requirements may be enhanced, and access to the ACF may be limited.

(b) (4) preventive medicine programs consist of vendor surveillance and a sentinel animal health monitoring program. Animals from vendors may be sent directly to outside diagnostic laboratories for comprehensive diagnostic evaluation appropriate to the species. The sentinel animal health program for (b) (4) involves exposure of sentinel (b) (4) directly or indirectly (via dirty bedding) to experimental animals. Samples (serum, feces, fur swabs) are sent in once a quarter for analysis. Whole live sentinel animals may be also sent to diagnostic laboratories for analysis. In addition, any (b) (4) experiencing unexpected clinical abnormalities may have samples or the entire animal sent for diagnostic evaluation or may have a necropsy, with tissue/sample acquisition by the Attending. (b) (4) are examined on delivery and periodically thereafter by animal husbandry staff and the LifeSource Director of Operations for clinical abnormalities, including sore hocks, malocclusion, length of toenails, etc. (b) (4) are examined on delivery and periodically thereafter by animal husbandry staff and the LifeSource Director of Operations for clinical abnormalities, including diarrhea, malocclusion, length of hooves, etc. (b) (4) body weights are taken regularly and recorded in individual medical records, with notification of the LifeSource Director of Operations or Attending Veterinarian for a medical evaluation if any abnormalities are noted on the daily observations or if the body weight decreases by 10 percent. A complete physical examination, including TB testing, blood work for complete blood count and serum chemistry, rectal cultures, and routine dentistry will be performed a minimum of once a year.

Necropsy and collection of diagnostic samples would be attempted in the event of any unexpected illness or death.

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

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

(b) (4) All (b) (4) must be shipped in filtered crates to reduce the possibility of cross-contamination in transit. If the filter is damaged the animals are not allowed into (b) (4) housing areas. If the container is accepted it is transferred to a pre-assigned room into micro-isolator caging. At the time the animals are transferred, they are visually inspected, and they will be moved from the room if they exhibit signs of poor health or are the incorrect sex or weight. Animals that do not meet specified requirements are euthanized and the vendor is notified to supply replacements. Standardized cage cards are prepared and placed on each cage. An acclimation period of a minimum of 72 hours is required prior to any experimental manipulations, unless justified an approved in the IACUC protocol. The majority of (b) (4) are acquired from commercial vendors. The health status of all animals is reviewed and approved by the Attending Veterinarian or LifeSource Director of Operations. Animals from commercial vendors with an undesirable health status are not housed in the ACF. Requests for (b) (4) from non-commercial sources are approved by the Attending Veterinarian. (b) (4) from non-commercial sources are held in quarantine until they are released into the general housing area. The Attending Veterinarian approves all releases from quarantine. Health surveillance reports for the last year and within 30 days of transport are required from non-commercial vendors as well as additional testing when required. All health information is reviewed by the Attending Veterinarian before a shipment of animals is approved.

(b) (4) are received by a designated animal caretaker(s), their health is assessed, they are weighed, and their ear tags are checked against the numbers listed on the shipping form. An acclimation period of a minimum of 5-days is required prior to any experimental manipulations. During the acclimation period the rabbits are observed for any signs of stress or disease.

When animals enter the animal facility and are placed in their cages they are examined by the animal care staff. If the animal appears to have a clinical problem it is immediately reported to the veterinary staff, who will determine the next step. Since the health status of the animals is documented prior to their shipping to the animal facility it is very unlikely that animals are not healthy when they arrive at the ACF.

(b) (4) are brought in their shipping crates or by wheeled transport cart to the wing where they will be housed. The animal is led to its run and observed and examined by trained animal care staff or veterinary staff. If there are any concerns, then the Attending Veterinarian and/or the Director of Operations is immediately contacted. The animal is supplied with fresh water and feed. A medical record and cage card is initiated.

(b) (4) are brought in their shipping crates directly to the room where they will be quarantined or stabilized. The animal is released into its cage/ run and is observed and examined by trained animal care staff or veterinary staff. If there are any concerns, then the Attending Veterinarian is immediately contacted. The animal is supplied with fresh water and food. A medical record and cage card is initiated. After 30 days and 2 negative TB tests, released by the Attending Veterinarian, the animal(s) would be placed into the general population.

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.

Not Applicable

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

(b) (4) obtained from an in-state source, with complete medical records, would be acclimated for 30-days prior to release for research.

(b) (4) from approved, routine sources are usually acclimated for a minimum of 72 hours prior to release for research use unless justified and approved in the IACUC protocol. (b) (4) hat have undergone surgery at the vendors (e.g., vascular cannulas) are allowed to be manipulated prior to completion of the routine acclimation period in order to optimize cannula or catheter maintenance.

(b) (4) are delivered directly to their normal holding rooms and are usually acclimated for 5 days prior to experimental manipulation (unless otherwise approved in the protocol).

(b) (4) are delivered directly to their normal holding runs and are acclimated for at least 5 days prior to experimental manipulation (unless otherwise approved in the protocol). Animals are observed at least twice daily by animal husbandry staff for general appearance, appetite, fecal/urine output and any abnormalities.

The only procedures performed during acclimation are routine husbandry, with daily observations to ensure that animals are eating, drinking, and behaving normally. Any abnormalities noted during acclimation would be brought to the attention of the LifeSource Director of Operations, who would evaluate the animal(s) and notify the Attending Veterinarian of any findings or the need for further evaluation.

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 are housed according to species, principal investigator, and/ or health status. In certain cases, [redacted] may be housed in the same room on separate racks in order to allow a client to maintain one room for their research.

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

[redacted] may be housed in the same room on separate racks in order to allow a client to maintain one room.

c. Describe isolation procedures and related facilities for animals.

[redacted] are isolated in filtered rodent cages within the normal housing rooms. In those cases where there is suspicion of a highly infectious disease agent, animals would be either immediately euthanatized or they would be quarantined in the room, flagging their cage and requiring them to be changed last and gloves changed after handling. Ill or injured animals are reported to the LifeSource Director of Operations, who would initially evaluate the animals and coordinate any further diagnostic evaluation or actions with the Attending Veterinarian, as needed.

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.

The husbandry staff is responsible for twice daily (including weekends and holidays) observation of all animals for illness or abnormal behavior. Any health or behavior issues are recorded on a Health Surveillance Form. The completed form is brought to the attention of the LifeSource Director of Operations or Attending Veterinarian for follow up or, in a non-emergency case, the completed form may be left in a designated box at the end of D wing for pick up at the end of the day and delivery to the Veterinary Care Staff. Verbal/text notification may also be used to request health evaluation of an animal, especially if the animal needs immediate attention.

Investigators are encouraged to inform the veterinary staff of any concerns that they may have so that the concern may be documented on an Health Surveillance Form. These forms allow the veterinary staff to track not only individual animal issues, but also patterns of health issues that may be present. The veterinary care staff performs rounds routinely. The room check sheet is updated daily and the staff is required to document that the animals have been observed and that required husbandry tasks are completed. In the event an ill animal is reported during normal working hours or on weekends and holidays, the Attending Veterinarian/designee, veterinary care staff or trained husbandry staff will examine the animal and contact the investigator by email or phone.

Treatments would be carried out under the supervision of the Attending Veterinarian or designee. Entries are placed in the individual animal records in case of (b) (4) (b) (4) or on the cage card or post-operative observation record for (b) (4) if appropriate.

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

If an animal is found dead, the staff will place a "found dead" notice on the cage and the researcher is notified by phone, in person or text. If an animal is found in need of attention, a health check is written, and a copy placed on the cage of concern and it is immediately brought to the attention of the LifeSource Director of Operations and or the Attending Veterinarian either verbally or by text for the initial evaluation. The researcher is notified of all evaluations and recommendations for treatment or euthanasia.

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 specie

(b) (4) preventive medicine programs consist of vendor surveillance and predominantly of a sentinel animal health monitoring program. Animals from vendors may be sent directly to outside diagnostic laboratories for comprehensive diagnostic evaluation appropriate to the species. The sentinel animal health program for (b) (4) involves exposure of sentinel (b) (4) directly or indirectly (via dirty bedding) to experimental animals. Samples are sent once quarterly. In addition, any (b) (4) experiencing unexpected clinical abnormalities may have samples or the entire animal sent for diagnostic evaluation or may have a necropsy, with tissue/sample acquisition by the Attending Veterinarian.

(b) (4) are examined on delivery and periodically thereafter by animal husbandry staff and the LifeSource Director of Operations for clinical abnormalities, including sore hocks, malocclusion, length of toenails, etc. (b) (4) are examined on delivery and periodically thereafter by animal husbandry staff and the LifeSource Director of

Operations for clinical abnormalities, including diarrhea, malocclusion, length of hooves, etc.

(b) (4) body weights are taken regularly and recorded in the individual medical records. The LifeSource Director of Operations or Attending Veterinarian are notified for a medical evaluation if any abnormalities are noted on the daily observations or if the body weight decreases by 10 percent. Room check sheets are maintained in the (b) (4) holding rooms. A complete physical examination, including TB testing, blood work for complete blood count and serum chemistry, rectal cultures, and routine dentistry are performed at least yearly.

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.

The Attending Veterinarian and LifeSource Director of Operations are available twenty-four hours a day, seven days a week for emergency advice or on-site animal care. In the event the Attending Veterinarian or the LifeSource Director of Operations is not available back up personnel is provided. The ACF staff are present every day of the week including weekends and holidays. The animals are observed twice daily and required husbandry care is provided.

The ACF has 24 hours HVAC temperature monitoring and alarm system. Any temperature fluctuations that occur outside of the acceptable range will generate an alarm and the LifeSource Director of Operations will be notified. In the event of major temperature fluctuations, airflow problems, power failure or other facility issues the LifeSource Director of Operations will be immediately notified. The Attending Veterinarian will be contacted in all cases where the welfare of the animals may be affected. The Attending Veterinarian and the LifeSource Director of Operations participate in the ARC emergency call back cascade that establishes communication with all personnel in the event of a natural disaster. A written Disaster Plan is in place.

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

The Attending Veterinarian or her designee has full authority to treat all animals in the program.

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.

Individual health records are routinely maintained on [redacted] and individual animals under veterinary care. Observations of abnormalities, records of health monitoring exams, diagnostic test results and other relevant information are documented in the record. The [redacted] are maintained in a file cabinet outside their respective holding rooms. [redacted] records are maintained in the room until the end of the study.

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.

These records are maintained by the Veterinary Care Staff. Principal investigators are responsible for the maintenance of research records that include the dates and types of experimental manipulations. In an instance where illness or injury is found on an animal where individual records are not kept (eg: a [redacted] a health surveillance report will be filled out.

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

The Attending Veterinarian provides oversight on the maintenance of all records as indicated. The Attending Veterinarian provides written reports and/ or recommendations as needed, which are maintained as described above. The Attending Veterinarian has full access to all records.

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

a. In-house diagnostic laboratory capabilities.

Not Applicable

b. Commercially provided diagnostic laboratory services.

Commercial laboratories provide routine diagnostic analysis. Analyses include serology, histopathology, microbiology, and parasitology. Pick-up services are arranged by the laboratory. Commercial laboratories are used for sentinel rodents.

c. Necropsy facilities and histopathology capabilities.

In-house necropsies can be performed in the Necropsy Room, [redacted] by the Veterinary Care Staff, LifeSource clients, NASA researchers or on [redacted] in procedure rooms by research staff upon completion of the study. Live animals may be

shipped to commercial diagnostic laboratories for comprehensive evaluation. All histopathology is conducted off site by commercial laboratories.

d. Radiology and other imaging capabilities.

Not Applicable

5. Drug Storage and Control

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

Controlled substances must be ordered through the LifeSource Director of Operations. Controlled substances are stored in a safe in a controlled access area of Building (b) (7)(F), (b) (7)(E) (b) (7)(F), (b) (7)(E) Access to this room is limited to the LifeSource Director of Operations, the Attending Veterinarian, and Business Administrator. Non-controlled substances are stored in the Pharmacy or in the procedure rooms.

b. Describe record keeping procedures for controlled substances.

All controlled substances are maintained within a restricted access safe and are checked out to research staff on an as-needed basis by the LifeSource Director of Operations or designee. A log is kept with controlled substance name, manufacturer name, lot number, expiration date, amount/concentration, date of receipt, and identification number. Entries are recorded for each use, with the date, amount used and initials of authorized user. An investigator must request controlled substances in a written request to the LifeSource Director of Operations. All staff handling controlled substances must undergo training on proper recordkeeping procedures. Records are checked by the LifeSource Director of Operations and, during semiannual evaluations, by the IACUC. A yearly inventory is done by the Director of Operations as required by the DEA.

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.

Details of surgery, including the identity and qualifications of personnel performing surgical manipulations, location where surgeries will be performed, and pre- and post-operative care, and details of anesthetics/analgesics used must be provided in the IACUC approved protocol. The Principal Investigator is responsible for ensuring that the surgical plan is followed. Research staff is encouraged to consult with the Attending Veterinarian

regarding proposed surgical procedures prior to submission of a protocol involving surgery. All animal surgeries must conform to the NASA IACUC Guidelines on Aseptic Surgery for Rodents or the NASA IACUC Guidelines on Surgery in USDA-Regulated Animals.

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.

There is a surgical suite (b) (7)(F), (b) (7)(E) which is used for survival and non-survival, major, minor, and emergency surgery in USDA-regulated species. In addition, there is a dedicated procedure room (b) (7)(F), (b) (7)(E) for minor and emergency survival and non-survival surgery in nonhuman primates. Use of the surgical suite is light to moderate and must be scheduled through the LifeSource Director of Operations. The LifeSource Director of Operations and Attending Veterinarian provide one-on-one training for all users.

Survival and non-survival, major, minor, and emergency surgery in rodents are performed in the procedure rooms in (b) (7)(F), (b) (7)(E) Use of these rooms is moderate to heavy.

Ceiling mounted surgical lights, heated stainless steel surgical tables, gas anesthetic machines, OxyVet O_2 concentrator, large animal ventilator, pulse oximeter, suction machine, hot bead sterilizer and circulating water blankets are the major equipment available for use in the surgery suites. Gas anesthetic machines, pulse oximeter, and circulating water blankets are the major equipment available for use in the (b) (4) (b) (4) procedure room. Gas anesthetic machines and circulating water blankets are the major equipment available for use in the rodent procedure rooms.

The surgery suite and procedure rooms are supplied by prefilter/HEPA filtered air.

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 procedures are defined as procedures that penetrate or expose a body cavity or produce a substantial impairment of physical or physiologic functions. Minor procedures do not expose a body cavity and cause little or no physical impairment, such as placement of a jugular catheter. Survival procedures are defined as the animal recovering from anesthesia.

b. How is non-survival surgery defined?

A non-survival surgery is one in which the animal is humanely euthanized at the end of the procedure without recovery from anesthesia.

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

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

The NASA IACUC has adopted written guidelines covering the use of aseptic technique for survival surgery in [redacted] and USDA-covered species. Research staff are advised as part of the protocol review process to adhere to the procedures enumerated in these documents or are requested to justify any proposed deviations.

Guidelines for [redacted] survival surgery are as follows:

Animal Preparation
Do not withhold food in [redacted] before surgery unless specifically mandated by the protocol or surgical procedure. Water must NOT be withheld unless required by the protocol.

Animals must be prepared for surgery in a site that is separated from the surgical area. Animals are placed under general anesthesia and a drop of lubricating ophthalmic ointment (such as Lacrilube® or Puralube®) must be placed in animal's eyes to prevent drying, unless an eye procedure prevents its use and is justified in the approved protocol.

Prior to taking the animals to the surgery area, remove all hair for at least a centimeter on either side of the surgical site (do not remove too large an area of hair, as this can interfere with the animal's ability to thermoregulate). Hair can be removed by clipping with an appropriate-sized clipper blade, shaving with a razor, plucking a small area (in anesthetized mice or similar-sized rodents), or by using a depilatory cream followed by a saline rinse. Then vacuum or otherwise remove loose hair.

Clean and aseptically prepare the surgical site. Use an effective antiseptic surgical scrub solution (Nolvasan surgical scrub, etc.). Carefully scrub the area with a new clean surgical sponge or sterile cotton swab. Scrub in a gradually enlarging circular pattern from the center of the proposed incision to the periphery. The sponge or swab should not be brought back from the contaminated periphery to the clean central area. Next rinse the area that has been scrubbed using 70% alcohol or sterile water. Repeat the scrub/rinse cycle for a total of 3 times, each time beginning at the center and proceeding to the periphery.

To prevent hypothermia, try not to wet the animal any more than necessary. Care should be taken to prevent contamination of the sterile surgical field during subsequent handling and positioning of the animal.

Place the animal on a clean absorbent surface and maintain body temperature using a circulating water blanket, warm water bottle, or equivalent external heat source, taking care to not cause thermal burns to the animal's skin.

Surgeon Preparation
The surgeon must wear a facemask and a clean lab coat or scrub shirt. Hair should be secured in a surgical bonnet or tied back, as needed. The surgeon must wash his/her hands with an antimicrobial detergent (e.g., chlorohexidine or iodophor) and rinse with water.

Sterile surgical gloves should be aseptically donned. Open the outermost package of surgical gloves and place the still wrapped gloves onto a cleansed, dry, flat surface. Carefully open the package so that the gloves remain flat against the paper with the cuffs pointed toward you. With one hand grasp a small portion of the folded cuff (the bottom part towards you), pick up the glove and slip your other hand inside being carefully not to touch any part of the outside with your hands or any other object. Now that you have one glove on, grasp the inner surface of the cuff of the other glove and slip the remaining hand inside, again without touching the outer surface of either glove. Once both hands are gloved, you can arrange them easily to make them comfortable, because both hands are now sterile. Do not touch anything with your gloved hands other than the animal's surgical site and other sterile instruments. If you must touch something else (microscope, anesthesia machine, etc.), use a sterile cover/gauze to touch the equipment and change gloves or wipe down thoroughly with an appropriate disinfectant before returning to surgery.

Surgical gloves must be replaced between animals when any major (eg., laparotomy, thoracotomy) or invasive (e.g., bone fracture or amputation) surgical procedure is performed, if gloves become torn or compromised, if any nonsterile surfaces are touched by gloves, or if there is contamination of gloves with blood and/or tissues.

If working alone, the surgeon should have the animal anesthetized and positioned prior to gloving. If the instruments are in a sterile pack, that first layer of the double-wrapped instrument pack should be opened before gloving.

Guidelines for USDA-covered species surgery are as follows:

Animal Preparation:
Pre-surgical fasting in animals is to be determined by species and is described in the approved protocol.

Animals must be prepared for surgery in a separate room from the surgical area.

Animals are placed under general anesthesia and a drop of lubricating ophthalmic ointment (such as Lacrilube® or Puralube®) must be placed in the animal's eyes to prevent drying and damage of the corneas, unless justified in an approved IACUC protocol for procedures such as eye surgery. Anesthetic records should be initiated at this time.

Prior to taking the animals to the surgery area, remove all hair from the surgical site and surrounding skin. Hair can be removed by clipping, shaving, or by using a depilatory cream followed by a saline rinse. Vacuum or otherwise remove loose hair.

Clean and aseptically prepare the surgical site. Use an effective antiseptic surgical scrub solution (Nolvasan surgical scrub, Betadine Scrub, etc.). Carefully scrub the area with a new clean surgical sponge or sterile cotton swab. Scrub in a gradually enlarging circular pattern from the center of the proposed incision to the periphery. The sponge or swab should not be brought back from the contaminated periphery to the clean central area.

Next rinse the area that has been scrubbed using 70% alcohol or sterile water. Repeat the scrub/rinse cycle for a total of 3 times, each time beginning at the center and proceeding to the periphery.

To prevent hypothermia, try not to wet the animal any more than necessary. Care should be taken to prevent contamination of the sterile surgical field during subsequent handling and positioning of the animal.

Following the above preparation procedures, the animal should be taken to the operating room, placed on a clean absorbent surface, with appropriate body temperature maintenance using a circulating water blanket, warm water bottle, or equivalent external heat source.

Once the animal has been positioned for the procedure, conduct a final preparation of the surgical site with a surgical prep solution that is compatible with the surgical scrub solution you used (i.e. Betadine prep after Betadine scrub, Nolvasan after Nolvasan scrub, etc.). Avoid using unrelated products, as they are frequently incompatible.

For survival surgical procedures, sterile drapes must be positioned over the entire animal with the exception of the incision site. A general method for draping an animal subject's body trunk is to place four drapes with their edges around the immediate incision site. Clamps may be used to fix the drapes in place. A larger fenestrated drape is placed over the animal and the entire surgery table to provide a large sterile field.

Surgeon Preparation:

The surgeon dons surgical scrubs, shoe covers, cap and mask and enters the surgeon prep area. The surgeon prep area should ideally be separate from the animal prep area. If surgeon prep uses the same room as animal prep, the activities must be conducted at separate times so that they do not interfere with one another. The surgeon scrubs his/her hands and forearms 3 times over a period of approximately 3 minutes with an antimicrobial detergent (e.g., chlorohexidine or iodophor). The hands and forearms are washed starting with the fingers and working up to above the elbows. The hands are then dried with a sterile towel, again starting with the fingers and working to above the elbows, with hands elevated above elbows at all times.

A sterile gown is then donned by lifting it off of the pack by the inside of the partly-inverted sleeves, taking care not to touch the outside of the gown with the hands or any nonsterile surface. The arms are then passed into the sleeves without pushing the hands beyond the cuffs. An assistant ties the gown. Sterile gloves are put on after the sterile gown. The bare hand must never touch the outer surface of the glove. Open the glove packet with hands covered with the cuffs of the gown. Hold one glove by the folded-over inner surface edge of glove and insert the other hand into the glove. To put on second glove, hold it with the fingers of the already gloved hand placed under the folded over glove cuff and slip the hand into it.

The Attending Veterinarian or LifeSource Director of Operations provide one-on-one training for all personnel who will be conducting survival surgical procedures. In some cases, outside consultants may be brought in to train personnel on new surgical procedures or techniques.

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.

Mice and rat survival surgery:

Surgical instruments and supplies (e.g., gauze sponges, swabs) must be sterilized for use in survival rodent surgery. Several techniques (steam, dry heat, or chemical agents) can be used to sterilize instruments and other materials that will come in contact with the animal's tissues.

Steam (i.e., autoclave) is the preferred method to sterilize surgical instruments and supplies. Materials may be wrapped in a surgical drape (an internal sterilization monitor should be added to each pack) and sealed with autoclave tape or placed in an autoclave pouch and sealed, marked with date, and autoclaved. Autoclave packs must be dated and used within one month of autoclave date or, if maintained in airtight, sealed, waterproof containment (e.g., Ziploc® bag) used within six months of autoclave date.

Alternatively, instruments may be soaked in a cold sterilant solution (e.g., Cetylcide), following the manufacturer's instructions for appropriate contact times. Instruments must be cleansed of all blood, tissue and other organic material prior to placing in cold

sterilant solution. Instruments should be maintained in cold sterilant for a minimum of 20 minutes or per manufacturer's recommendation. Instruments can be removed from cold sterilant with another sterilized instrument or with sterile gloved hands. If chemical sterilants are used on surgical instruments, instruments must be rinsed in sterile water or physiological saline before use on tissues. Cold sterilants used to sterilize surgical instruments must be changed on a daily basis. Any unused portion should be discarded at the end of each day.

Glass bead sterilization may be used as a secondary, or backup method of sterilization. Note that instruments should be completely sterilized on first use, then tips of instruments glass bead sterilized for up to 5 procedures prior to complete resterilization or use of a new surgical pack. All tools/instruments must be thoroughly cleansed and made free of any tissue, blood or other organic materials. Instruments should be wiped thoroughly with 70% alcohol and allowed to completely dry prior to placing into the hot bead sterilizer. Instruments should be placed halfway down into the beads and left for 10 to 20 seconds. Instruments left longer than that time may be damaged. Carefully remove instruments from the beads, avoiding touching the sides of the container and any non-sterile surfaces. Gently place instruments onto a sterile surface (e.g., sterile stainless-steel tray) and allow them to cool completely prior to use on the animals. Failure to allow complete cooling may cause tissue damage at the surgical site.

When performing surgeries on multiple animals, adequate sets of sterile instruments for the number of planned surgeries should be available at the start of the procedure.

USDA-covered species surgery:

Surgical instruments and supplies (e.g., gauze sponges, swabs) must be sterilized for use in survival surgery for all species. Several techniques (steam, dry heat, ethylene oxide, or chemical agents) can be used to sterilize instruments and other materials that will come in contact with the animal's tissues.

Steam (i.e., autoclave) is the preferred method to sterilize surgical instruments and supplies. Materials may be wrapped (an internal sterilization monitor should be added to each pack) and sealed with autoclave tape or placed in an autoclave pouch and sealed, marked with date, and autoclaved. Autoclave packs must be dated and should be used within one month of autoclave date or, if maintained in an airtight, sealed, waterproof container (e.g., Ziploc® bag) used within six months of autoclave date.

Alternatively, instruments may be soaked in a cold sterilant solution (e.g., Cetylcide), following the manufacturer's instructions for appropriate contact times. Instruments must be cleansed of all blood, tissue and other organic material prior to placing in cold sterilant solution. Instruments should be maintained in cold sterilant for a minimum of 20 minutes or per manufacturer's recommendation. Instruments can be removed from cold sterilant with another sterilized instrument or with sterile gloved hands. If chemical sterilants are used on surgical instruments, instruments must be rinsed in

sterile water or physiological saline before use on tissues. Cold sterilants used to sterilize surgical instruments must be changed on a daily basis. Any unused portion should be discarded at the end of each day.

When performing surgeries on multiple USDA regulated animals during the same session, sterile instruments must be used for each surgery.

All surgical packs and instruments are sterilized in a disposable self-sealing autoclave pack or pouch made of surgical grade paper with a steam indicator on the back. An indicator strip is placed inside the pouch, and the date of autoclaving and initials of technician are written on a strip of indicator tape affixed to the pack. Instrument pack/pouches are autoclaved at 250°F for minimally 30 minutes.

Disposable lab coats, gowns, facemasks, shoe covers and gloves are provided. Non-disposable lab coats and scrubs are laundered and autoclaved as required.

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

Glass bead sterilization may be used as a secondary, or backup method of sterilization. Note that instruments should be completely sterilized on first use, then tips of instruments glass bead sterilized for up to 5 procedures prior to complete resterilization or use of a new surgical pack. All tools/instruments must be thoroughly cleansed and made free of any tissue, blood or other organic materials. Instruments should be wiped thoroughly with 70% alcohol and allowed to completely dry prior to placing into the hot bead sterilizer. Instruments should be placed halfway down into the beads and left for 10 to 20 seconds. Instruments left longer than that time may be damaged. Carefully remove instruments from the beads, avoiding touching the sides of the container and any non-sterile surfaces. Gently place instruments onto a sterile surface (e.g., sterile stainless-steel tray) and allow them to cool completely prior to use on the animals. Failure to allow complete cooling may cause tissue damage at the surgical site.

Alternatively, instruments may be soaked in a cold sterilant solution (e.g., Cetylcide), following the manufacturer's instructions for appropriate contact times. Instruments must be cleansed of all blood, tissue and other organic material prior to placing in cold sterilant solution. Instruments should be maintained in cold sterilant for a minimum of 20 minutes or per manufacturer's recommendation. Instruments can be removed from cold sterilant with another sterilized instrument or with sterile gloved hands. If chemical sterilants are used on surgical instruments, instruments must be rinsed in sterile water or physiological saline before use on tissues. Cold sterilants used to sterilize surgical instruments must be changed on a daily basis. Any unused portion should be discarded at the end of each day.

d. Indicate how effectiveness of sterilization is monitored.

All packs/pouches have external indicators to verify steam exposure. Indicator strips are also placed inside the packs and pouches to verify steam penetration. Self-contained biological indicators are used every 6 months to verify the effectiveness of the autoclave.

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

The LifeSource Director of Operations and or trained ACF staff provide support in the areas of anesthesia, pre and post-operative care, surgical assistance and surgical planning. The ACF also provides anesthetic and surgical equipment that is available as part of the shared use of the procedure rooms and surgical suites. The ACF provides standard anesthetic and analgesic medications as well as surgical supplies as needed.

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.

Animals that undergo anesthesia are required to be monitored irrespective of the length of the procedure or whether it is survival or terminal. Animals are regularly monitored throughout the surgical procedure. Documentation of the time of induction, time of any supplemental anesthesia, and intra-operative monitoring must be maintained on a surgical record, which should include information on the date, IACUC protocol number, surgery being performed, surgeon's name, animal identification, type of surgical procedure, and any other pertinent comments (e.g., antibiotics or analgesics administered). Cardiovascular and respiratory parameters, along with body temperature are useful indicators of physiologic status in most surgeries. Respiratory rhythm and rate, heart rate and color of mucous membranes, and surgical plane of anesthesia should be monitored and recorded in a surgical log at least once every 15 minutes. Maintaining body temperature and hydration are surgical support procedures that are especially important. Intraoperative records are not required for (b) (4) procedures of a standard duration. However, during post approval monitoring (PAM), personnel are interviewed about any surgical procedures and the inquiries include questions on the intraoperative monitoring of the animals.

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 should be monitored continuously throughout recovery from general anesthesia and returned to their normal holding cages/room only after they have become ambulatory. Recumbent animals should be turned from side to side frequently (e.g., every 15 minutes) to prevent dependent pulmonary congestion and edema, and muscle damage.

Recovering animals should be housed individually until they are recovered from anesthesia.

The most common complication that occurs during and after surgery is the development of hypothermia. This is often exacerbated by performing surgery directly on a heat conducting surface (stainless steel). This can be avoided by using sterile pads under the animal and/or utilizing a circulating water pad. Electrical heating pads cannot be appropriately regulated and should never be utilized as a heat source.

The surgical site must be monitored daily to ensure that the surgical wound is healing properly, and that stitch abscesses, dehiscence or other complications have not occurred. Documentation of this postoperative monitoring and care must be maintained and include date and time, observations and/or treatments, and initials of person making observations. Records must be maintained until the surgical incision is healed and all skin closures (sutures or staples) are removed. Usually the skin closures are removed from a properly healed incision 7 to 10 days post-operatively. Note that all skin closures must be removed, including absorbable suture materials. The use of silk should be restricted to vascular sites. Sutures may not be removed in cannulated animals as long as the cannula is still patent.

Pain in animals may be identified by observing the animal's reluctance to move, eat or drink, guarding of the painful site, and/or vocalization with handling. The use of post-operative analgesia should be considered for all surgeries, but is an absolute requirement for any major survival surgeries, unless a deviation is specifically stated and justified in an IACUC approved protocol.

Post-operative monitoring records are maintained by the LifeSource Director of Operations or her staff and/or by research staff. Records may be maintained in an electronic format or hard copy and are available from the research staff or may be located in the LifeSource Director of Operations' Office, [redacted]

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

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

The NASA IACUC, which includes the Attending Veterinarian and the LifeSource Director of Operations, carefully reviews all protocols to assure that appropriate use of anesthetics, analgesics and other measures aimed at minimizing pain or distress are addressed. The protocol form includes sections that request information on methods used to minimize pain or distress—or justification as to why that cannot be accomplished. The protocol form requests information on postoperative monitoring and care and identifies the personnel responsible for monitoring the animals, and an alternatives section for providing the methods and sources used to determine that the proposed procedures are the most appropriate for the study. The IACUC seeks to assure that animals are adequately monitored for possible pain or distress by appropriately qualified personnel and that all efforts are made (such as the use of proper surgical technique and the provision of timely monitoring and supplemental care) to minimize pain or distress. In addition, appropriate and humane endpoints are developed for each protocol on a case-by-case basis and in

conjunction with the NASA Institutional Animal Care and Use Guidelines for Defining Humane Endpoints and the Use of Death as an Endpoint.

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

It is essential that properly qualified personnel monitor the animals at appropriate intervals to ensure adequate observation and care of the animals. Optimally, studies should be terminated when animals begin to exhibit adverse clinical signs, IF this endpoint is compatible with meeting research objectives, since such endpoints minimize pain or distress.

All procedures conducted using animals, including surgeries, must be reviewed and approved as part of a research animal protocol by the Institutional Animal Care and Use Committee (IACUC). The names and qualifications of all personnel performing procedures must be listed on the approved protocol. All personnel must read and abide by procedures as listed in the IACUC approved protocol.

All personnel involved with a study need appropriate training to adequately perform the duties required of them in the appropriate species.

Training is available at all times by the Attending Veterinarian, the Director of Operations, and consultants may be brought in if necessary. The proficiency of everyone working in the animal facility is confirmed by either the Attending Veterinarian or the Director of Operations and continual oversight is provided by the veterinary care staff and though Post Approval Monitoring (PAM).

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.

(b) (4) Inhalant isoflurane, injectable ketamine/ xylazine, avertin, buprenorphine (IM, IV, or IP),

(b) (4) Inhalant isoflurane, injectable ketamine/ xylazine, buprenorphine (IM, IV, or IP)

(b) (4) Inhalant isoflurane, injectable acepromazine, ketamine or ketamine/ xylazine, buprenorphine (IM. SC, or IV), topical ophthalmic analgesics

(b) (4) Inhalant isoflurane, injectable ketamine or ketamine/ xylazine, telazol, buprenorphine (IM, SC, or IV)

(b) (4) Inhalant isoflurane, injectable telazol, diazepam, buprenorphine (IM or IV)

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

Researchers are encouraged to consult with the Attending Veterinarian prior to submission of a protocol. If research staff do not avail themselves of this opportunity, the Attending Veterinarian will review the protocol during the normal review process to assure that the most appropriate drugs and/or methods for pain/distress minimization or alleviation are used. As needed, the Attending Veterinarian provides reference materials on alternative drugs, dosages and methods.

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 husbandry staff performing health checks, investigators/research staff and the Director of Operations.

Non-pharmacological means to diminish pain and distress are used in all species and may include: quiet, darkened recovery area on a soft, warm surface, quiet, calming interaction with veterinary care staff, highly palatable treats, rehydration with oral or parenteral fluids, additional bedding material, placing food and water sources on the cage floor for easy access, decreasing the number of animals in the cage.

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.

There are currently no approved protocols that use neuromuscular blocking agents. If a proposal was submitted the IACUC would require strong scientific justification, a description of alternatives and parameters that would be measured and documented to assure that the animal was adequately anesthetized during the procedure. A pilot study may be performed and observed by the Attending Veterinarian to ensure the well-being of the animal.

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

All anesthetic equipment is covered by a service contract with Vet-Equip. The equipment is serviced annually. The contract includes all anesthetic machines that are located in the ACF. Hoses, nose cones, masks, anesthesia bags, endo-tracheal tubes, etc. are all checked for signs of wear, cracks before use and disinfected and/ or replaced as necessary.

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.

Methods of euthanasia comply with the 2013 AVMA Guidelines on Euthanasia. The IACUC reviews all euthanasia procedures during protocol review.

The following are the methods currently in use, by species:

(b) (4) Carbon dioxide inhalation or barbiturate overdose IP followed by secondary physical means such as cervical dislocation or bilateral thoracotomy. General anesthetic followed by exsanguination. IV, IC, or IP commercial euthanasia solution.

(b) (4) - Decapitation by sharp scissors.

(b) (4) Inhalant isoflurane followed by a secondary method such as exsanguination. IV or IC administration of commercial euthanasia solution.

(b) (4) IV or IC administration of a commercial euthanasia solution.

(b) (4) - IV administration of a commercial euthanasia solution.

Procedures occur in the Necropsy Room, Building (b) (7)(F), (b) (7)(E) surgical suite (b) (7)(F), (b) (7)(E) and, nonhuman primate procedure room (Building N236, B wing), or procedure rooms in (b) (7)(F), (b) (7)(E) (b) (7)(F), (b) (7)(E)

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

Scissors are sharpened as needed or are replaced. The ACF maintains regulated CO2 tanks in Building (b) (7)(F), (b) (7)(E) that are used for rodent euthanasia.

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

A secondary method of euthanasia is required and may include cervical dislocation, thoracotomy, exsanguination or perfusion depending upon the species and the requirements described in the approved protocol.

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.

(b) (7)(F), (b) (7)(E) There are rooms dedicated in this building for food storage and diet preparation, shower and locker rooms as well as office space for animal facility personnel. This building is located across a covered breezeway from the ACF.

Building (b) (7)(F), (b) (7)(E) The main animal facility is located on the corner of (b) (7)(F), (b) (7)(E) (b) (7)(F), (b) (7)(E) at the NASA Ames Research Center. The ACF is comprised of 5 wings labeled Wings A-E. The wings run parallel with the cage wash area. The cage wash area is located in the central area of the ACF and is bordered by C and B wings. The E wing is not connected to the main ACF and is located on the northside of the ACF. There is also a dedicated loading dock and workshop.

Building (b) (7) (F), (b) (7)(E) First Floor: Necropsy and a survival surgical suite with adjacent storage room are located on the first floor of this (b) (7)(F), (b) (7)(E) building that is located across a covered breezeway from the ACF. NASA Offices and research laboratories occupy the remainder of the first floor of this building.

Building (b) (7) (F), (b) (7)(E) Second Floor: There are several NASA procedural rooms located at the end of the hallw esearch laboratories and office spaces on the second floor of this (b) (7)(F), (b) (7)(E) building. All procedures conducted here are terminal.

Building (b) (7)(F), (b) (7)(E) This room is dedicated for NASA procedure training of the crew trainers. All procedures conducted here are terminal.

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. Building (b) (7)(F), (b) (7)(E) is a conventional, restricted access, centralized animal facility. It is approximately 26,000 square feet.

The layout is as follows:
Wings A and B share a common corridor and wings C and D share a common corridor, with the cage wash facility located between C and B wings. There are 2 sets of doors leading to the dirty side of the cage wash area, one set located in C wing and the other set in B wing. There are 2 sets doors leading to the clean side of the cage wash area, one set from C wing and a set from B wing. Wing D is currently dedicated to housing and procedural space for (b) (4) (b) (4) Wing C is currently dedicated to (b) (4) and procedure space, Wing B is dedicated to (b) (4) Wing A is dedicated to (b) (4) and Wing E is currently dedicated to (b) (4) The necropsy room in building (b) (7) (F), (b) is accessible from both the breezeway across from the main ACF as well as an interna ding corridor. The surgical suite is accessible only from the internal building corridor. NASA procedure rooms/labs on the second floor are accessible via internal stairways.

2. All animal work is conducted in the ACF.

3. The Vivarium consists 25 holding rooms that house competent or immunocompromised (b) (4) Rooms are either positive

(immunocompromised animals, surgery suite) or negative (immunocompetent animals, [redacted] (b) (4) [redacted] .

4. Finishes:

Floors are either troweled epoxy floors, painted epoxy floors over concrete, or linoleum over concrete and are all in fair to good condition.

The walls are made up of either concrete, concrete filled block, or concrete filled block with plaster painted with washable epoxy paint and are in fair to good condition.

Ceilings are cement, plaster, stainless steel panels, inter-locking aluminum strips or steel girders with corrugated metal. Ceilings are finished with washable epoxy paint. All ceilings have wood and metal studding or joists. All ceilings are in fair to good condition.

Double and single steel doors are present in the ACF.

5. The ACF consists of 5 main wings. The air handling systems serving the ACF supply conditioned airflow from a total of 12 air handling units and 43 exhaust fan systems. Wings A, B, and E are served by constant volume air handling units and exhaust fan systems serving one to two rooms each. Wings C and D are served independently by 2 separate constant volume air handling units serving multiple rooms. All wings are equipped with individual exhaust fan systems to control odors, room pressure, and room air exchange rates in each room. The air handling units are supplied by 1 cooling tower and 2 heating boilers which are designed to control temperature, humidity, and building pressure via a SIEMENS Insight™ BMS (building management system) system.

6. The ACF is located on the secure campus of a fenced federal facility that requires badging of all personnel. All individuals accessing the federal facility must pass through a gate attended by security guards. The area around the ACF is patrolled 24 hours a day every day by NASA Ames Research Center security guards. The ACF is locked at all times. All entrances have card readers and can only be accessed with approved badges that act as key cards. The LifeSource Director of Operations must approve all personnel entering the ACF.

7. Not Applicable

8. There are 2 flammable cabinet is located in D11 and D12 where ethyl alcohol, formalin, formaldehyde, when present in the facility, is stored. Disinfectants are stored in a storage room inside the ACF. Cage wash chemicals are stored on the loading dock located outside the dirty side of cage wash in secondary containers.

C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17)**, “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.

Not Applicable

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.

Not Applicable

D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) 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.

Two emergency generators are in place that will provide power to all intake and exhaust fans, the electrical panels for both surgery suites, and electrical outlets located in all corridors of the ACF. In addition, overhead lighting and emergency exit lights will illuminate in the case of a power outage. The generators are checked monthly. NASA has onsite diesel storage tanks to allow replacement of generator fuel. Portable heating and cooling units are available in the animal facility. There have been no power failures in the last ten years.

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).

Not applicable

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.

There is a (b) (7)(E), (b) (7)(F) in the ACF that is maintained and used only by NASA.

2. Other Animal Program Support Facilities

Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

Food preparation: Building (b) (7)(F), (b) (7)(E) is dedicated to preparation of fresh and frozen food items for the animals.

Appendix 1

Appendix 1: Glossary of Abbreviations and Acronyms

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

Abbreviation/Acronym	Definition
AAALAC	Association for the Assessment and Accreditation of Laboratory Care
AALAS	American Association for Laboratory Animal Science
ACF	Animal Care Facility
ARC	Ames Research Center
AEM	Animal Enclosure Module
BMS	Building Monitoring System
DEA	Drug Enforcement Agency
DMR	Designated Member Review
EH&S	Environmental, Health and Safety
FIO	For Information Only
FMCS	Facility Management Control System
HEPA	High Efficiency Particulate Air
HVAC	Heating, Ventilation and Air Conditioning
IACUC	Institutional Animal Care and Use Committee
IO	Institutional Official
JED	Job Exposure Descriptor
LSBS	LifeSource Biomedical Services
NASA	National Aeronautics Space Administration
NCB-AALAS	Northern Calif. Branch- American Assoc. for Laboratory Animal Science
PAM	Post Approval Monitoring
PI	Principal Investigator
PPE	Personnel Protective Equipment
TWA	Time Weighted Average
USDA	United States Dept. of Agriculture
VPP	Voluntary Protection Program

Appendix 2

Appendix 2: Summary of Animal Housing and Support Areas

Briefly summarize in the following Table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, satellite housing facilities, etc.), the total square footage/metres (or acreage) for animal care and use, and the total square footage/metres (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, cagewashing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). Detailed information for satellite housing facilities is requested in Appendix 17. Include only one line entry for satellite housing facilities in this table to provide the total square footage for all satellite housing areas listed in appendix 17. If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) to each facility from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an additional Appendix (Appendix 2.1) to provide this information. See Instructions, Addendum A - Animal Facility Square Footage/Meters Compilation Form for guidance in calculating the size of your animal care and use program.

Animal Housing and Support Sites

Location (building, site, farm name, etc.[a])	Distance from main facility[b]	Approx. ft², m², or acreage for animal housing	Approx. ft², m², or acreage for support or procedures	Species housed	Approx. Daily Animal Census by species	Person in charge of site
(b) (7)(F), (b) (7)(E)	(b) (7)(F), (b) (7)(E)	15,521sq ft	5,484sq ft	(b) (4)		(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)
(b) (7)(F), (b) (7)(E)	(b) (7)(F), (b) (7)(E)		1248sq ft			
(b) (7)(F), (b) (7)(E)						
(b) (7)(F), (b) (7)(E)	(b) (7)(F), (b) (7)(E)		3767sq ft			
(b) (7)(F), (b) (7)(E)	(b) (7)(F), (b) (7)(E)		157sq ft			
Satellite Housing Facilities Total (Expand in Table 17)						

Totals:	**15,521sq ft**	**10,656sq ft**
Total animal housing and support space:		

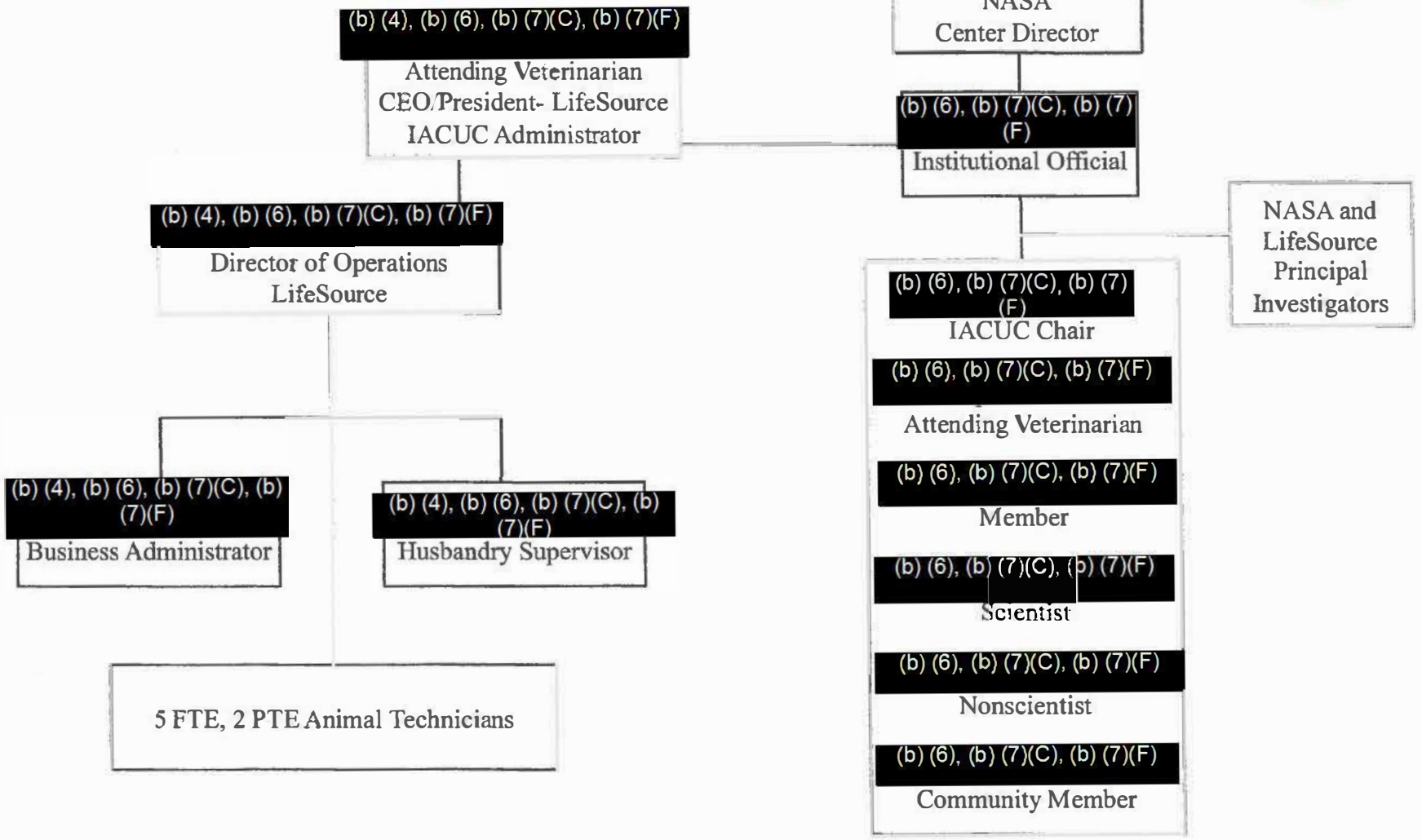
Appendix 3

NASA Research Park

(b) (7)(E), (b) (7)(F)

Appendix 4

NASA Animal Care and Use Program Organizational Chart



Appendix 5

Appendix 5: Animal Usage

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

Project/Protocol Title	IACUC/OB 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)
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	C						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB 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)
			(b) (4)	(b) (4)							
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7) (F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7) (F)	(b) (4)		D						

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB 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)
(b) (4)				(b) (4)							
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E					√	
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E					√	
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E					√	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB 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)
(b) (4)											
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D					√	
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E					√	
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D					√	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB 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)
(b) (4)											
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E					√	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB 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)
(b) (4)											
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB 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)
(b) (4)											
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E					√	
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	C				√		
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E				√		

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB 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)
(b) (4)											
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	C						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	C						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB 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)
(b) (4)											
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	C						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	C						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	E						
(b) (4)	(b) (4)	(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)	(b) (4)	(b) (4)	D						

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB 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)
(b) (4) [redacted]											

(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.

Pain/Distress Classification Description/Definition, if applicable:

Category C: *No pain and distress* (Use of Pain Relieving Drugs Is Not Indicated). Procedures that may result in only slight or momentary pain such as routine injections, blood collections, or other minor procedures are included in this category.

Category D: *Tests or Procedures Involving the Potential for Pain or Distress*
(Appropriate Anesthetic, Analgesic or Tranquilizing Drugs are Used). Animals in Type D studies have the potential to experience pain/discomfort, but the necessary drugs to alleviate the symptoms are provided. This includes terminal bleeding performed under anesthesia or retro-orbital sinus bleeding of rodents under general anesthesia, because these procedures would result in pain if anesthetics were withheld. All surgical procedures where anesthesia is used to alleviate pain or distress, including studies on anesthetized animals that do not regain consciousness are included in this category.

Category E: *Category E*: Pain or Distress Without the Benefit of Pain Relief* These are procedures (e.g., efficacy studies of novel pain therapeutics) or situations (induction of chronic illness/disorder such as arthritis or liver failure) for which the use of analgesics, anesthetics or tranquilizing drugs would adversely affect the procedures, results or interpretation of data.

Appendix 5: Animal Usage

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

Animal Type or Species	Approximate Annual Use	Animal Type or Species	Approximate Annual Use
(b) (4)	(b) (4)	(b) (4)	(b) (4)

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 6

JOB EXPOSURE QUESTIONNAIRE

To be completed for a new Animal Exposure Badge, on a yearly basis when renewing your badge, or anytime your exposure changes.

Name: **Date of Birth:**
Job Title: **Phone#:**
Employer:
Supervisor: **Phone#:**

Please answer ALL questions with regards to your planned exposure in this facility only:

To which laboratory animals and/or their tissues/ fluids will you be exposed to? Exposure is considered either direct or indirect contact.	**Yes**	**No**
Mice		
Rats		
Guinea Pigs		
Rabbits		
Farm Animals (indicate species):		
Non-human primates (indicate species):		
Other:		
Did you work with laboratory animals prior to your work at this facility? (if yes, indicate species):		
Do you have allergies to any animals? (if yes, indicate species and list any symptoms that occur when you are exposed to those animals):		
Have you ever been diagnosed with allergies to animals? (if yes, indicate your physician's recommendations):		
Have you ever been instructed by medical personnel to wear respiratory protection beyond basic PPE, such as an N95 mask or air-purifying respirator? (if yes, indicate your physician's recommendations and submit your current fit test/ certification (within 1 year) with this form):		
Do you have any other medical conditions which could affect your ability to work safely within this facility? (if yes, describe):		
Other Animal Exposure	**Yes**	**No**
Do you have any pets? (if yes, describe):		
Do you work in or enter any other animal facility? (if yes, describe):		
My work also includes exposure to the following:	**Yes**	**No**
Hazardous Chemicals (if yes, describe):		
Volatile Anesthetics (e.g.: Isoflurane)		
Infectious diseases, agents, recombinant DNA or viral vectors (if yes, describe):		
Physical hazards (e.g.: loud noise, irradiation) (if yes, describe):		
Other (if yes, describe):		

VACCINATION HISTORY	Yes	No	N/A	Date of Last Test or Vaccination
Have you had a tetanus vaccine within the last ten years?				
If working with non-human primates, have you had a negative TB Test within the last year?				
If working with non-human primates, have you had a measles titer in the last year?				
If working with human cells, tissues, blood, etc., have you completed the Hepatitis B three-dose series?				

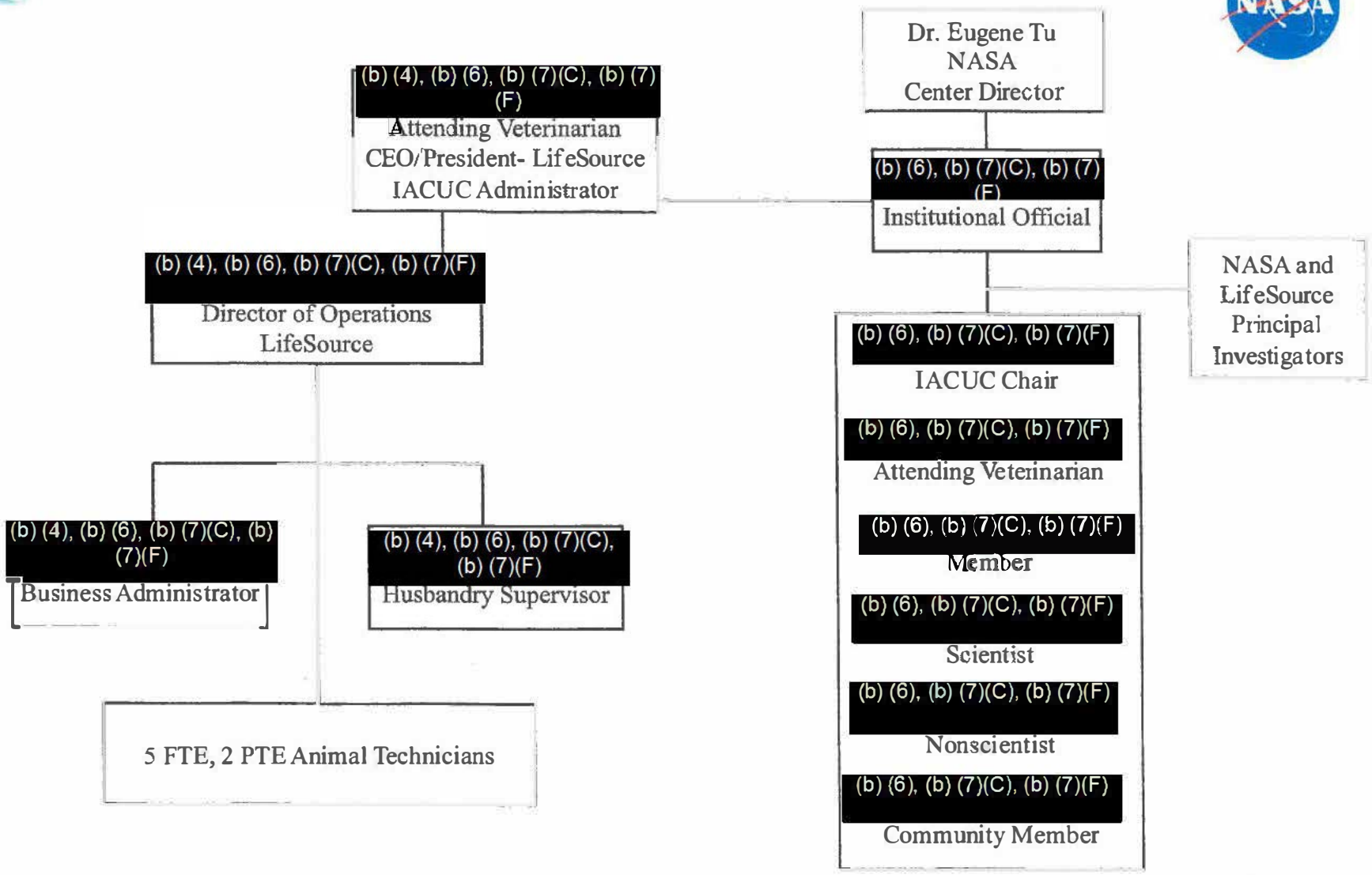
I certify that the information provided in this questionnaire is true and accurate to the best of my knowledge.

Signature

Date

Appendix 7

NASA Animal Care and Use Program Organizational Chart



Appendix 8

NASA Institutional Animal Care and Use Committee
Meeting Minutes
19 September 2018
CONFIDENTIAL

MEMBERS PRESENT (Voting)

(b) (4), (b) (6), (b) (7)(C), (b) (7)(F) DVM (ex oficio)
(b) (4), (b) (6), (b) (7)(C), (b) (7)(F) PhD
(b) (6), (b) (7)(C), (b) (7)(F) ex officio)

SC: (b) (7)(E), (b) (7)(F)
LifeSource (b) (7)(E), (b) (7)(F)
LifeSource (b) (7)(E), (b) (7)(F)
SLR: (b) (7)(E), (b) (7)(F)
Community Member (Call)
DL: (b) (7)(E), (b) (7)(F)

MEMBERS ABSENT
None

GUESTS PRESENT
None

Meeting started at 9:01AM with a quorum present. (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) had an emergency and arrived at 10:45AM.

AGENDA

I. Old Business

a. Reminder that the AAALAC Site Visit will occur during the first part of 2019. The program description will be due the end of 2018.

II. New Business

(b) (6), (b) (7)(C), (b) (7)(F) is beginning phased retirement- his replacement for the committee has been identified and she will begin attending meetings in February 2019.

b. The NASA Animal Policy Review Board (APRB) meeting will be held in October. (b) (6), (b) (7)(C), (b) (7)(F) and (b) (6), (b) (7)(C), (b) (7)(F) will attend.

(b) (6), (b) (7)(C), (b) (7)(F) has been appointed interim Flight IACUC Chair, replacing (b) (6), (b) (7)(C), (b) (7)(F)

d. The heat pumps that supply the Animal Care Facility have been successfully replaced.

e. All IACUC Guidelines were reviewed and approved as revised.

f. Master Protocol Update: no work performed since the last meeting.

g. Veterinary Update- (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) reviewed animals currently in-house and studies in progress

h. DMR since last meeting:

- (b) (4) protocol renewal reviewed at last meeting approved via DMR 22 August 2018.
- NAS-18-002-Y1- amendment to change PI approved 22 August 2018.
- (b) (4) amendment to add personnel approved 22 August 2018.

- (b) (4) protocol reviewed at last meeting approved via DMR 22 August 2018.
- NAS-18-001-Y1- protocol reviewed at August meeting approved 19 September 2018.
- (b) (4) protocol renewals reviewed at the last meeting were approved via DMR 6 September, 29 August, 29 August, 29 August, 6 September, and 20 September 2018.

III. SemiAnnual Program Review and Inspection.

Meeting adjourned at 2:37PM. Submitted by (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) IACUC Administrator.

NASA Institutional Animal Care and Use Committee
Meeting Minutes
15 August 2018
CONFIDENTIAL

MEMBERS PRESENT (Voting)

(b) (6), (b) (7)(C), (b) (7)(F)
(b) (4), (b) (6), (b) (7)(C), (b) (7)(F) DVM (ex oficio)
(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)
(b) (4), (b) (6), (b) (7)(C), (b) (7)(F) PhD

SC: (b) (7)(E), (b) (7)(F)
LifeSource (b) (7)(E), (b) (7)(F)
LifeSource (b) (7)(E), (b) (7)(F)
SLR: (b) (7)(E), (b) (7)(F) (Call)

MEMBERS ABSENT

(b) (6), (b) (7)(C), (b) (7)(F)
(b) (6), (b) (7)(C), (b) (7)(F) ex officio)

Community Member
DL: (b) (7)(E), (b) (7)(F)

GUESTS PRESENT
None

Meeting started at 9:06AM with a quorum present.

AGENDA

I. Old Business

a. The next SemiAnnual Program Review and Inspection will occur in September 2018 (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) send out final guidelines approved in January 2018 for review at this meeting. VVC language will be added to the Protocol Submission Guidelines once the committee has a chance to review and approve.
b. Reminder that the AAALAC Site Visit will occur during the first part of 2019. The program description will be due the end of 2018.

II. New Business

a. The Chair notified the committee that (b) (6), (b) (7)(C), (b) (7)(F) has been appointed the new Institutional Official for Flight, replacing (b) (6), (b) (7)(C), (b) (7)(F)
b. Master Protocol Update: no work performed since the last meeting.
c. Veterinary Update- (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) reviewed animals currently in-house and studies in progress.
d. DMR since last meeting:
   - (b) (4) amendment to add personnel approved 14 June 2018.
   - (b) (4) amendment to change PI and add personnel approved 18 June 2018.
   - (b) (4) amendment to add procedure approved 20 June 2018.
   - NAS-17-001-Y2- protocol renewal approved via DMR 11 July 2018.
   - NAS-18-002-Y1- protocol reviewed at last meeting approved via DMR 12 July 2018.
   - (b) (4) amendment to change PI approved 12 July 2018.

NASA Institutional Animal Care and Use Committee
Meeting Minutes
15 August 2018
CONFIDENTIAL

- NAS-15-007-Y4- protocol renewal reviewed at May meeting approved via DMR 20 July 2018.
- NAS-17-001-Y2- protocol renewal approved via DMR 20 July 2018.
- NAS-13-004-Y5- protocol renewal approved via DMR 26 July 2018.

III. Protocol/ Amendment Review

(b) (4) (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) was the primary reviewer (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) was the secondary reviewer and the following questions/ comments/ edits were presented:

- Section 7B- Elaborate briefly on how you come up with your total number of animals requested, including offspring, breeding animals, etc.
- Section 7C- Add the following statement: "Offspring of some models may develop slower than others, therefore, weaning will be based on individual pup size and may occur past the typical weaning ages of mice or rats".
- Section 8- Under "Weaning" please provide size range for rats as well.
- Section 8- Remove all references to guinea pigs.
- Section 8- Indicate that The NASA IACUC approved Humane Endpoints guidelines will be followed.
- Section 13- Confirm and add the statement "Any novel compounds used for tumor studies will not require any special handling instructions beyond normal PPE".

(b) (4), (b) (6), (b) (7)(C), (b) (7)(F) was the ethical reviewer and had no additional comments.

This protocol was not approved and will return to the IACUC office with minor revisions for review and approval via DMR.

(b) (4) (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) was the primary reviewer, (b) (6), (b) (7)(C), (b) (7)(F) was the secondary reviewer and this protocol renewal was approved as submitted.

(b) (4) (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) was the primary reviewer (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) was the secondary reviewer and the following questions/ comments/ edits were presented:

- Define all acronyms throughout protocol.
- Section 7A- why was the NSG strain selected for use?
- Section7B- add suggested language regarding statistical significance.
- Section 7C- confirm if any animals will be singly housed.

NASA Institutional Animal Care and Use Committee
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This protocol was not approved and will return to the IACUC office with minor revisions for review and approval via DMR.

None of the LIF protocols were reviewed at this meeting, as with the PI recusing herself, we did not have a quorum. The Chair approved request of DMR, so the Administrator will send out a request for DMR for all of these renewals.

Meeting adjourned at 10:47AM. Submitted by (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) IACUC Administrator.

Appendix 9

Protocol Number:

Institutional Animal Care and Use Protocol

Federal animal welfare regulations require that the Institutional Animal Care and Use Committee (IACUC) must review and approve all activities involving the use of vertebrate animals prior to initiation of such use. Once approved by the IACUC, any change(s) to the following protocol must be submitted in a written amendment for review and approval by the IACUC prior to implementation of the change(s). Protocols and related amendments are active for 1 year from protocol approval date and must be renewed yearly.

PLEASE DO NOT REMOVE SECTION DIRECTIONS

1. **Title**
   Provide a descriptive title for the proposed study that includes the common name of the species to be used.

2. **Principal Investigator**
   (The ONE individual responsible and accountable for the design, conduct and monitoring of the protocol.)
   Provide the following information on the Principal Investigator (PI) and Responsible Point-of-Contact for this protocol. Please identify all other personnel (including Co-PIs) who will perform experimental manipulations on animals in section 19.

   PI
   Name:
   Title:
   Affiliation:
   Mailing Address:
   Email:
   Phone Number:
   Fax Number:
   Emergency Contact Number:

   Responsible Point-of-Contact
   Name:
   Title:
   Affiliation:
   Mailing Address:
   Email:
   Phone Number:
   Fax Number:
   Emergency Contact Number:

3. **Protocol Information**
   Protocols are approved for one year. Please indicate if this is a new or renewal protocol.

   3A. ☐ **New Protocol**

Institutional Animal Care and Use Protocol

If this is a new protocol, please move on to section 4

☐ **Renewal Protocol**

If this is a renewal protocol, please complete the following:

3B. Previously Approved Protocol Number

3C. Problems/Adverse Events: *Have there been any unanticipated problems that have affected animal use, welfare, morbidity, or mortality?*

☐ No ☐ Yes

*If **YES**, provide a summary of the problems, the cause(s), if known, and how these problems were resolved.*

3D. Progress Report: *Provide a brief statement of progress to date. State what was done in the previous approval period, how many animals were used, what was learned, and why additional animals are required to continue the study. If this work resulted in any changes in how you will proceed, please explain.*

4. Nature of the Project/Study

4A.

Project Types: (indicate all that are applicable)	Type of Procedures: (indicate all that are applicable)	Hazardous Procedures: (indicate all that are applicable)
☐ Research/ Discovery Project	☐ Behavioral/Neurobehavioral Studies	☐ Biohazardous/Infectious Agents
☐ Testing –Preclinical Development	☐ Blood/Tissue/Embryo Collection	☐ Rodent Cell Lines/Biological Materials
☐ Training	☐ Breeding Colony	☐ Human Cell Lines/Biological Materials
☐ Other (specify):	☐ Prolonged Restraint (>15min)	

Institutional Animal Care and Use Protocol

Species:
Indicate all applicable:
- ☐ Mice
- ☐ Rats
- ☐ Guinea Pigs
- ☐ Rabbits
- ☐ Nonhuman Primates
- ☐ Other (specify):

- ☐ Compound Dosing
- ☐ Single Dose
- ☐ Multiple Doses
- ☐ Induction of Acute Disease
- ☐ Induction of Chronic Disease
- ☐ Surgery
- ☐ Vendor performed
- ☐ Multiple Survival
- ☐ Single Survival
- ☐ Terminal
- ☐ Tumor Inducement/Xenograft
- ☐ Expts. done (partially) at another institution
- ☐ Other (specify):

- ☐ Recombinant DNA
- ☐ Chemical Hazards
- ☐ Radioactive Materials/ Radioisotopes
- ☐ X-Ray Machine Usage
- ☐ Irradiator Usage

4B. Is this a Pilot/Feasibility Study?
(Small-scale discovery trial of limited duration and animal numbers designed to evaluate, refine, or modify devices, techniques, methodology and/or study design prior to submitting a protocol for a full-scale project. Duration of study is usually limited to six months or less and fifty animals or less)

☐ Yes ☐ No

4C. Federal Funding Source(s) and Peer Review
Is this project currently or proposed to be funded by either federal or other funding agencies?

☐ No. Please move on to section 5.
☐ Yes. Please complete the following:

Current and Proposed Federal (or other) Funding Sources:

Title(s) of Grant Submittal:

Has this proposed activity undergone peer review? ☐ Yes ☐ No

*If **YES**, who provided peer review and when?*
(For new protocols include one copy of the grant proposal with protocol submission.)

5. Location of Work
Please mark all areas where work pertaining to this protocol will be conducted. If you will be doing work outside of the Contract Research Services (CRS) Facility, please list the institution's full name under 'other'. Please note all areas used for animal housing or procedures must first be approved by the IACUC and will be

included in all facility inspections.

☐ **Contract Research Services Facility At Ames Research Center**
- ☐ Building (b) (7)(E), (b) (7)(F)
- ☐ Building (b) (7)(E), (b) (7)(F)
- ☐ Other (list buildings/ room number):

(Please complete the attached form *IACUC PERSONNEL SIGNATURE PAGE)*

☐ **NASA Facilities**
- ☐ Johnson Space Center (list buildings/ room number):
- ☐ Kennedy Space Center (list buildings/ room number):

☐ **Other** (Including Field Studies. List facility or location, address, and room number):

6. Project Overview

Using layperson terms, describe the purpose of the study and its intended benefits to science, medicine, or mankind. Please avoid the use of technical jargon and abbreviations that would not be understood by a non-scientist.

7. Animal Information

Please provide the specifications for all of the animals requested for use in this protocol. Please list each species separately. Please put 'any' if no preference.

Species: Common Name/ Scientific Name	Breed/Strain	Preferred Sex	Preferred Age Range	Preferred Weight Range	Preferred Vendor or Source	Total Number Requested

7A. Justification of Species

Please explain why the species and/or strain(s) requested is/are the most appropriate for this research. Statements that the planned species is traditionally used for the proposed research are not sufficient.

7B. Justification of Animal Numbers

Provide a detailed justification for the number of animals requested. Include number of animals/group X number and composition of groups/study X number of studies. Whenever possible, the number of animals requested should be justified statistically. These numbers are

the annual maximum that will be used, inclusive of breeding, animals used for maintaining colony size, animals used for developing and practicing techniques, or animals required for unforeseen circumstances.

7C. Special Animal Care

If housing or care of animals is different from standard Animal Facility procedures (e.g., individual housing of rodents; change in caging type or light cycle or diet or cleaning schedule), provide detailed description and scientific justification.

8. Description of Animal Use

Provide a complete description of the proposed use of the animals, including the approximate time period the animals will be on study. Include descriptions of: animal identification methods; radiation (dosage and schedule); use of restraint devices (note that prolonged restraint of greater than 15 minutes must be justified); sites, volumes, and frequency of collections of bodily fluids; names/type, dosages, and routes of administration of compounds and other materials administered; animal manipulations (such as centrifugation, microgravity exposure, etc.); summary of surgical manipulations; and similar details. If surgical manipulations are to be included in the protocol, details must be provided in Section 9.
This description should allow the IACUC to understand the entire experimental design, from the arrival of an animal at the Vivarium, through the experiment and its endpoints, and final disposition of the animal(s). A diagram or chart may be helpful to explain what is being done.

9. Surgery (To be completed only if surgery is involved.)

All surgical procedures must be performed in compliance with the relevant IACUC guidelines for surgery.

Check the statements that describe your project:

☐ Non-survival surgery (animals are euthanized under anesthesia without regaining consciousness)
☐ Vendor conducted
☐ Major survival surgery (penetration and exposure of a body cavity, or resulting in a permanent impairment of physical or physiologic functions)
☐ Minor survival surgery
☐ Multiple survival surgical procedures (provide the timeframe between surgeries, describe any differences in surgical procedures, and provide a scientific justification for conducting multiple survival surgical procedures, if applicable)

9A. Location (where surgery will be performed—building and room number)

9B. Anesthetics

List the anesthetic(s), including dosage(s), frequency of dosing, and route(s) of administration that will be used, and describe how you will monitor the depth/quality of anesthesia to ensure it is adequate.

9C. Preoperative Care

Describe the preoperative care of the animal (e.g. withholding of feed for 18 hours prior to surgery or administration of prophylactic antibiotics).

9D. Minimization of Contamination

Describe the methods employed to minimize microbial contamination of the surgical site. Include brief descriptions of the preparation of the animal, surgeon, and instruments.

9E. Surgical Procedures

Describe the surgical procedure. Include descriptions of methods and materials for ligatures and wound closure.

9F. Postoperative Surgical Care

Describe the post-surgical care. Include information regarding the use of pain-relieving drugs (give the drug(s), dosages, route(s) of administration, frequency), monitoring of animals for normal recovery from anesthesia and wound healing, and provision of supportive care, such as supplemental heat and fluid or antibiotic therapy. Describe who will perform post-surgical observations, and the frequency and duration of observations.

Reminder: Documentation of the surgical procedure and post-surgical care is required and is the responsibility of the Principal Investigator. Copies of the surgical/post-surgical records must be readily available to the veterinary staff, the IACUC, and regulatory officials.

10. Minimizing Pain and Distress- Clinical Outcomes and Humane Endpoints

Describe any pain, distress, or clinical outcomes (e.g.: tumors/ lesions, weight loss, behavioral abnormalities, etc.) that an animal may experience as a result of this study

Please indicate any treatment/ procedures designed to ensure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of this project. Describe objective criteria/ parameters (e.g.: weight loss of 20%, loss of mobility, etc. and endpoints, as well as the frequency/ schedule of monitoring of animals during the entire experiment. Clearly indicate when animals will be euthanized should any of these endpoints be reached.

11. Pain, Discomfort, and Distress

11A. USDA Pain/Distress Classification

Check the category that indicates the highest level of pain/distress the animals will experience during the course of these studies (use the reference chart below for determination).

☐ C ☐ D ☐ E*

Category C: No Pain or Distress
(Use of Pain Relieving Drugs Is Not Indicated). Procedures that may result in only slight or momentary pain such as routine injections, blood collections, or other minor procedures are included in this category.

Category D: Tests or Procedures Involving the Potential for Pain or Distress
(Appropriate Anesthetic, Analgesic or Tranquilizing Drugs are Used). Animals in Type D studies have the potential to experience pain/discomfort, but the necessary drugs to alleviate the symptoms are provided. This includes terminal bleeding performed under anesthesia or retro-orbital sinus bleeding of rodents under general anesthesia, because these procedures would result in pain if anesthetics were withheld. All surgical procedures where anesthesia is used to alleviate pain or distress, including studies on anesthetized animals that do not regain consciousness are included in this category.

Category E: Pain or Distress Without the Benefit of Pain Relief* These are procedures (e.g., efficacy studies of novel pain therapeutics) or situations (induction of chronic illness/disorder such as arthritis or liver failure) for which the use of analgesics, anesthetics or tranquilizing drugs would adversely affect the procedures, results or interpretation of data.

**For all E category classifications complete the Category E Explanation Sheet at the end of this form.*

12. Alternatives to Potentially Painful/Distressful Procedures

Institutional Animal Care and Use Protocol

12A. Written Statement

*Provide a written statement of the methods and sources used to determine that alternatives to potentially painful/distressful procedures are not available. **Reduction** of animal numbers and **Refinement** of procedures to eliminate or minimize pain and distress must be considered, as well as **Replacement** of animals with non-animal alternatives. If alternatives to painful or distressful procedures exist, but were not chosen, explain the reasons for not using the alternatives.*

Reduction:

Refinement:

Replacement:

12B. Alternatives Search

*Describe your consideration of alternatives to procedures listed for categories D and E that may cause more than momentary or slight pain or distress to the animals, and your determination that alternatives were not available. Delineate the methods and SPECIFIC SOURCES used in the table below. Examples of appropriate sources include Biological Abstracts, Index Medicus, the Current Research Information Service, and the Animal Welfare Information Center. You must use at least two different databases. **The key words "Alternative" and/or "Alternatives to Animal Testing" and common name(s) of species must be included and combined with the potentially painful procedures.***

Date Literature Search Conducted:		
Date Range Used in Search:	From:	To:
Keywords Used in Search:		
Database(s) Consulted:		
Other Information Source: (provide details)		

Summary of findings:

12C. Assurance of Non-duplication

Provide a written statement that the experiments covered under this proposal do not unnecessarily duplicate previous experiments.

13. Method of Euthanasia or Disposition of Animals

Provide details on method(s) of euthanasia or final disposition of animals. Euthanasia methods must comply with the current recommendations of the American Veterinary Medical Association's Guidelines on Euthanasia (http://www.avma.org/resources/euthanasia.pdf). Justification must be provided for any proposed alternative methods. If injectable agents are used, provide agent name, dose, and route of administration.

(Check All Applicable Boxes)

☐ CO_2- followed by secondary method (e.g. bilateral thoracotomy, cervical dislocation)
☐ Isoflurane overdose
☐ Cervical Dislocation (rodents < 200 gm) w/ sedation
☐ Decapitation/Guillotine w/ sedation
☐ IV Euthanasia Solution (*Specify agent, route, dose):*
☐ IP Euthanasia Solution (*Specify agent, route dose):*
☐ Excess/Deselected Animals may be transferred per approved process to another protocol, if applicable
☐ Other (*Specify method and provide justification*):

14. Use of Hazardous Agents or Biological Materials

Will animals be exposed to any of the following agents? If yes, specify the agent, including CDC biosafety level, as applicable.

Agent	Name, Type or Description of Agent
Radioisotopes	
Chemical Hazards	
Biohazards	
Recombinant DNA	
Biological Materials	
Other	

For specific agents used, provide special handling instructions for animals, caging and equipment, and other special precautions (e.g., special housing, personal protective equipment requirements and any decontamination procedures). Use of radioactive materials will take place in designated areas only.

15. Safety Precautions

Protocols involving radiation or biosafety hazards must be approved by the appropriate official before IACUC approval will be granted.

Institutional Animal Care and Use Protocol

Environmental Health & Safety Representative (Print and Sign Name, Date)

Biosafety Officer (Print and Sign Name, Date)

Radiation Safety Officer (Print and Sign Name, Date)

16. Photo Documentation

As per the NASA Photo-documentation Policy, images involving animals may be obtained for purposes of animal welfare, scientific data collection, operational verification of hardware or procedures, and/or education, training, and public outreach purposes. However, all photo-documentation must be approved in advance by the Institutional Animal Care and Use Committee (IACUC) and, in cases involving flight downlinks, by the NASA Chief Veterinary Officer (CVO) or designee. Only those purposes listed above provide sufficient justification for approval of photo-documentation. No unofficial or personal photos of animal activities are allowed. The IACUC or CVO may require, as a condition of approval, an opportunity to review, prior to their use, images that will be used in publications or presentations.

This policy applies to all animal activities that are conducted at NASA facilities, use NASA personnel, and/or use NASA hardware or vehicles for any portion of the activity.

It should be noted that the Public Affairs Office (PAO) must additionally review and approve release to the media of any images involving animals. The PAO may not approve the release of images that the IACUC and/or CVO have disapproved, but the PAO may prohibit the release to the media of images that the IACUC/CVO has approved for collection for approved purposes.

Note that appropriate personal protective equipment (PPE) must be worn by all individuals working with the animals. Images that include people without the appropriate PPE will not be approved.

☐ I have read the photo documentation policy above. No photo-documentation will be conducted during this experiment.

☐ Yes, photo-documentation will be conducted during this experiment. I have completed, signed, and attached the photo-documentation approval sheet to this protocol for IACUC review for approval.

Institutional Animal Care and Use Protocol

17. Permits

17A. Are Special Permits required? ☐Yes ☐No

If Yes: Permit type:

17B. Does the NASA facility (or PI) already have this permit? ☐Yes ☐No

If Yes: Permit Expiration Date:

17C. Are the animal numbers requested in Section 7 within the limits of the permit? ☐Yes ☐No

18. Experience and Qualifications

List the experience and qualifications of the PI and all personnel who will be supporting this protocol, along with their role in each procedure listed. Only personnel listed on the protocol are approved to work with animals, and only for the procedures indicated in the protocol. All personnel who perform any animal manipulations, including, but not limited to anesthesia or surgery, must be qualified through training or experience to accomplish these tasks in a humane and scientifically acceptable manner. For any personnel who require training to participate in a procedure, describe what training will be provided. Current training files documenting experience, continuing education and/or training must be provided for all personnel in conjunction with participation in an Occupational Health Program and maintained in the IACUC Office.

Name Title/ Affiliation Email address Phone Number	List all procedures this individual will perform and their experience for each procedure listed.

19. Principle Investigator Assurances

I hereby certify that the foregoing information is complete and correct and that professionally acceptable, ethical and humane standards governing the care, treatment and use of animals will be followed.

I affirm that all procedures involving animals will be carried out humanely and will be performed by qualified personnel, and that as the Principal Investigator, I am responsible for all work conducted under this protocol.

I understand that federal regulations authorize the Attending Veterinarian to utilize his/her discretion in the implementation of the procedures herein described in order to assure the welfare of the animal subjects.

I understand that any other variance from what is written in the protocol form would constitute a violation of regulatory guidelines. Any changes in this project will be forwarded promptly to the IACUC for review. Changes to protocols will not be implemented until IACUC approval has been obtained.

I agree to abide by all applicable laws, regulations and guidelines for the care and use of animals. I agree to cooperate with the IACUC and the Attending Veterinarian to assure compliance with federal, state and institutional regulatory requirements and policies.

I hereby certify that these studies do not unnecessarily duplicate previous experiments.

Signature of Principal Investigator: _____ Date ___/___/___

ANY INDIVIDUAL MAY CONTACT THE IACUC CHAIRPERSON, ATTENDING VETERINARIAN OR ANY MEMBER OF THE IACUC (ANONYMOUSLY, IF SO DESIRED) IF THERE ARE ANY COMPLAINTS OR CONCERNS REGARDING THE CARE OR USE OF RESEARCH ANIMALS AT OUR FACILITIES. PERSONNEL SHALL NOT BE DISCRIMINATED AGAINST OR BE SUBJECT TO ANY REPRISAL FOR REPORTING ANY CONCERNS.

Institutional Animal Care and Use Protocol

NASA Management Approval and Assignment of Point Of Contact (NASA Protocols Only)

I have reviewed this protocol and affirm that the use of animals for this protocol is necessary to achieve our organization's scientific or engineering goals. The work is consistent with NASA's guidelines on the ethical use of animals, and will be carried out in accordance with the relevant federal, agency, and institutional regulations and policies. Resources are available to complete these activities as described.

Manager's Name and Title (Print)	Date	Signature
Point of Contact (Print)	Date	Signature

Protocol Number:

Institutional Animal Care and Use Protocol

IACUC Chairperson Signature

This protocol has been approved by the IACUC.

Chairperson (Print)	Date	Signature

For IACUC Office Use Only

Species: USDA Category:

Date Submitted:

IACUC Approval Date:

Date Notification of IACUC Decision Sent to PI:

Protocol Number: Protocol Expiration Date:

A copy of the signed protocol will be sent directly to the PI listed in Section 2 of this document.

Protocol Number:

Institutional Animal Care and Use Protocol

Category E Explanation Form

This form is intended as an aid to completing the Category E explanation. A Category E Explanation must be written so as to be understood by laypersons, as well as scientists.

Species (common name) of animals used in these studies:

Explain the procedure producing pain and/or distress:

Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results:

Signature of Principal Investigator: _____ Date: _____

Investigator: **Protocol No.:**

AMENDMENT to Protocol for Animal Use

Please read through this entire document. Fill out the form completely. Fill in an answer for each section including the investigator and protocol number in the header of the document. **Please describe your amendment and justify the change in section 3,** providing details as necessary in the following sections (not all changes have additional sections for details). Contact the IACUC Office if you have questions. All amendments will be received by the IACUC Administrator and reviewed by the IACUC.

1. **Approved Protocol Title:**

2. **Approved Protocol Approval Date:**

3. **Amendment Descriptions and Justification**
   Provide a general description of and justification for the proposed amendment to the protocol. Describe why the amendment is needed and outline any changes. (Please provide the specific details in the following sections as appropriate).

4. **Location of work**

   _____ This amendment does NOT require a change in location.

   _____ This amendment DOES require a change in location. Check all locations where work will be performed. If "other" is checked, indicate where the work will be performed. Please also indicate if this is a room change within the same location.

   ☐ ARC ☐ KSC ☐ JSC ☐ Other

5. **Experimental Plan/Animal Procedures Details**

   _____ This amendment does NOT request a change to existing or the use of new procedures.

   _____ This amendment DOES request a change to existing or the use of new procedures. Please list all procedures described above and indicate if it is a changed (e.g., new method, increased frequency, etc.) or new procedure. Provide details for the procedure, and the expected effect on the animal. Surgery details including method of anesthesia, surgical procedures, post-operative care and monitoring should be described.

6. **Pain, Discomfort and Distress**

   Please address the pain, discomfort and/or distress associated with all new procedures. Otherwise, state that the consideration of pain, discomfort and distress remain the same as described in the approved protocol.

   _____ This amendment does NOT result in any changes to pain, discomfort and distress.

_____This amendment DOES result in a change to pain, discomfort and distress. Describe the changes, explain how the effects will be minimized, and scientifically justify their use.

7. Animal Requirements

7a. Species Required: Please provide information on new species requested.

_____ This amendment does NOT require a change in species. Leave table blank.

_____This amendment DOES require a change in species. Provide information in table and explain why this species is appropriate in section 7b.

Species	Sex	Strain	Age	Weight Range	Source/ Vendor

7b. Animal Species Justification

7c. Animal Numbers: Provide information on the number of new animal requested and new animal total for year in the appropriate boxes. Adjust the total number of animals required as necessary.

_____ This amendment does NOT require a change in animal numbers. Leave table blank.

_____This amendment DOES require a change in animal numbers. Complete table to provide information on the additional number of animals requested, and the new total for animals requested each year, as applicable. Justify the need for the change in animal numbers in section 7d.

	Year 1	Year 2	Year 3	Total
Number added				
New Total				

7d. Animal Number Justification

8. Husbandry

_____ This amendment does NOT request a change in husbandry.

_____This amendment DOES include a change in husbandry. Please include any deviation from standard husbandry, housing, or handling, especially if the change results in a deviation from the Guide

9. Drugs

_____ This amendment does NOT request a change in drugs required for the protocol.

_____This amendment DOES include a change in drugs (including a change in dose and/or route of administration) required for the protocol. Please complete the table below.

Drug	Purpose	Dose	Route of Administration	Schedule

10. Disposition of Animals

Please address any new procedures with regards to euthanasia.

_____ This amendment does NOT request a change to the method of euthanasia

_____This amendment DOES request a change to the method of euthanasia. Please describe the method and state whether or not it is an AVMA-approved method.

11. Safety Precautions

The appropriate officer must approve protocols involving radiation or biosafety hazards before IACUC approval will be granted. If this amendment adds any procedures that are biohazardous or include radiation this section must be filled out and signed by the appropriate official.

Radiation Safety Officer Signature

_____
(Print name and sign)

Biosafety Officer Signature

_____
(Print name and sign)

12. Photo Documentation

Please check the appropriate box below. If your answer is yes, or if any procedures are being added that include any type of photo images (i.e. video, still photography, daily observations that include photo images, etc.), please submit a signed copy of the photo-documentation form along with this amendment. Please contact the IACUC Office if you have any questions.

_____ This amendment does NOT request a change in photo documentation.

_____This amendment DOES request a change in photo-documentation. I have completed, signed, and attached the photo-documentation approval sheet to this amendment for IACUC review for approval.

13. Personnel

If your amendment includes a change in personnel please include their experience and qualifications with respect to their specific role in the protocol.

_____ This amendment does NOT request a change in personnel.

_____ This amendment DOES request a change in personnel. List all new personnel, their role in the study, and their qualifications and training.

14. Principal Investigator Signature

_____ _____

Principal Investigator Date

Investigator: **Protocol No.:**

This Section for IACUC use only
The IACUC will use this section to record the actions taken by the committee on your protocol.

Reviewed by IACUC Administrator .....

Reviewed by Attending Veterinarian .....

Amendment Classification

_____ **Significant**

Approved _____ Disapproved _____

_____ **Minor**

Approved _____ Disapproved _____

Review Process

_____ **IACUC Review**

Approved _____ Disapproved _____

_____ **Designated Review**

Approved _____ Disapproved _____

_____ **Administrative Review**

Approved _____ Disapproved _____

IACUC Chairperson Signature Date

Appendix 10

National Aeronautics and
Space Administration

Ames Research Center
Moffett Field, CA 94035-1000

Memorandum to: (b) (6), (b) (7)(C), (b) (7)(F) Institutional Official

From: Institutional Animal Care and Use Committee

Subject: Semiannual Report of the Program Review and Facility Inspection

Date: 19 September 2018

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the *Guide for the Care and Use of Laboratory Animals* (*Guide*), and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.): [*optional*]

None

I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA

Departures from the PHS Policy, the *Guide*, and the AWA.
Select A or B:
[ ] A. There were no departures during this reporting period.
[X] B. The following departures have been reviewed and approved by the IACUC: [*include reason for each departure*]

1. Change in caging and less frequent cage changes- ground-based testing of the Animal Enclosure Modules (AEMs) to be used to house rodents during space flight.
2. Spaceflight housing simulation studies in mice performed by NASA investigators- the dimensions of the Animal Enclosure Modules (AEMs) are 11.9 in2/mouse and their use is described in an approved IACUC protocol.
3. Hindlimb Unloading studies in mice performed by NASA investigators- the dimensions of the hindlimb unloading cage for mice are 7.6" X 11" X 12" and their use is described in an approved IACUC protocol.
4. Metabolic studies in rats performed by commercial investigators- the metabolic cages are 14"X11"X19" and their use is described in an approved IACUC protocol.

II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s):
Select A or B:
[X] A. There were no deficiencies in the program during this reporting period.
[ ] B. The following deficiencies have been identified: [*describe each deficiency, identify*

each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]

III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s):
Select A or B:
[ ] A. There were no deficiencies in the animal facility during this reporting period.
[X] B. The following deficiencies have been identified: [*describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table*]
Table attached.

IV. Minority Views

Select A or B:
[X] A. No minority views were submitted or expressed.
[ ] B. The following minority views were expressed: [*insert minority views here or attach*]

V. Status of AAALAC Accreditation [*identify accredited facilities, if applicable*]

The Institution's Program for Laboratory Animal Care and Use is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAAALAC).

VI. Signatures [*signatures of a majority of the IACUC members*]

See attached.

Respectfully Submitted,

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F) Chair

(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)

(b) (4), (b) (6), (b) (7)(C), (b) (7)(F) Science Member

(b) (4), (b) (6), (b) (7)(C), (b) (7)(F)

(b) (4), (b) (6), (b) (7)(C), (b) (7)(F) DVM, Attending Veterinarian

CALL IN

(b) (6), (b) (7)(C), (b) (7)(F) Science Member

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F) J.D., L.L.M, Non-science Member

CALL IN

(b) (6), (b) (7)(C), (b) (7)(F) Non-affiliated Member

I. Semiannual Program Review Checklist [1]

Institutional Policies and Responsibilities

Date: 19 September 2018

1. Animal Care and Use Program NEW	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (*Guide*, p 1)	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. Disaster Planning and Emergency Preparedness NEW	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				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (*Guide*, p 35)	X				

3. IACUC NEW	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				

4. 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 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
- 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

5. 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)[ii]	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[iii] (PHS Policy, IV.B.)	X				
• Procedures are in place for review, approval, and suspension of animal activities[iv] (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[v] (*Guide*, p 30) [must]					X

6. IACUC Training NEW

	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				

7. IACUC Records and Reporting Requirements[vi]

	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	X				

reasons for each departure[vii]					
○ Distinguishes significant from minor deficiencies	X				
○ Includes a plan and schedule for correction for each deficiency identified[viii]	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[ix]					
○ Annual report to USDA contains required information including all exceptions/exemptions	X				
○ 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]	X				
○ Records of IACUC reviews are maintained for 3 years after the completion of the study	X				
8. Veterinary Care (See also next section - 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[xi]	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				
9. 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) [xii]	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)[xiii]					
○ Research/testing methods that minimize numbers necessary to obtain valid results	X				

(PHS Policy, IV.A.1.g.)
- 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

10. Occupational Health and Safety of Personnel	A*	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				
○ 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

11. Personnel Security NEW	A*	M	S	C	NA
• Preventive measures in place include pre-employment screening, and physical and IT security (*Guide*, p 23)	X				

12. Investigating & Reporting Animal Welfare Concerns NEW	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

* **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

NOTES:

1. Clinical Care and Management NEW	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				
• 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				

2. 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 105)	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				

3. Surgery	A*	M	S	C	NA
• 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,	X				

anesthetic and analgesic use, perl-operative care, recordkeeping) (*Guide*, p 116)

	A*	M	S	C	NA
• 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				

4. 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 postprocedural 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[xiv] (*Guide*, p 123)					X

5. 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				

6. Drug Storage and Control NEW

	A*	M	S	C	NA
• 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				

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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

NOTES:

II. Endnotes

[i] 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.

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

[iii] 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]

[iv] 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]

[v] 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]

[vi] 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]

[vii] 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]

[viii] 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*]

[ix] 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]

[x] 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..."

[xi] 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]

[xii] 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."

[xiii] 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].

[xiv] 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."

NASA SEMIANNUAL PROGRAM & FACILITY REVIEW REPORT

DATE: 9/19/18

MEMBERS IN ATTENDANCE: Laura Lewis, (b) (4), (b) (6), (b) (7)(C), (b) (7)(F), (b) (4), (b) (6), (b) (7)(C), (b) (7)(F), (b) (4), (b) (6), (b) (7)(C), (b) (7)(F) and (b) (6), (b) (7)(C), (b) (7)(F)

Deficiency Category (S or M)	*	Location	Deficiency & Plan for Correction	Responsible Party	Correction Schedule & Interim Status	Date Complete
M		(b) (7)(E), (b) (7)(F)	2 bottles of expired Septanol. **Plan: Corrected at time of inspection by discarding. Notified PI.**	PI	Corrected at time of inspection.	9/19/18
M		(b) (7)(E), (b) (7)(F)	Single chain only securing compressed gas tank. **Plan: Corrected day of inspection, bottom chain was not re-secured when tank was changed.**	ACF	Correct by day of inspection.	9/19/18

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

**Check if repeat deficiency*

Appendix 11

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, ***including all satellite facilities***. Include ***all animal holding rooms*** (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

Location/Building/Facility: (b) (7)(E), (b) (7)(F)

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, *etc.*)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

All rooms in the ACF are supplied with 100% fresh air that is filtered with prefilter/bag, prefilter/box and prefilter/box/HEPA filters.

The air handling systems serving the ACF supply conditioned airflow from a total of 12 air handling units and 43 exhaust fan systems. Wings A, B, and E are served by constant volume air handling units and exhaust fan systems serving one to two rooms each. Wings C and D are served independently by 2 separate constant volume air handling units serving multiple rooms. All wings are equipped with individual exhaust fan systems to control odors, room pressure, and room air exchange rates in each room. The air handling units are supplied by 1 cooling tower and 2 heating boilers which are designed to control temperature, humidity, and building pressure via a SIEMENS Insight™ BMS (building management system) system.

Reheat coils fail in the closed position and are monitored by a direct digital control system (DDC powered by the BMS). The system recognizes the last recorded temperature prior to failure and retains the appropriate temperature ranges that are required in the rooms. In the event of any HVAC equipment failure, there are several redundant alarms in addition to the SIEMENS BMS system. There are direct alarms from the air handlers that alarm directly to the LifeSource Director of Operations.

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

The cooling tower and boiler systems are maintained, serviced, and monitored by NASA contractors through the FMCS (Facility Management Control System). These components alarm at the main monitoring station according to set point failure. These components are regularly maintained and serviced on a preventive maintenance schedule as well as monitored for any deficiencies and/or alarms.

The BMS system electronically monitors the performance of the HVAC system, which includes temperature, pressures and relative humidity of the animal rooms. This monitoring is continuous and includes the air handlers, exhaust fan systems, cold and hot water control valves, and other related equipment. In addition to the electronic monitoring, HVAC components have separate alarms that shut equipment down in the event of a component failure.

In the event of a system or HVAC component failure, backup generator support is available for the entire system, as well as all plant operations, including boilers and chillers.

All major equipment, such as the cooling tower and boilers alarm directly to the FMCS, providing redundancy to the system. If there is a steam or heat boiler failure, an alarm is sent to the FMCS and a mechanic is sent out to assess the situation. This is monitored 24/7. In the event of a significant failure, all personnel on the call tree are notified. Auxiliary equipment, such as portable heaters and free-standing cooling fans, are available inside the animal facility in case of failure.

The Director of Operations has full access full access to the BMS system on site as well as remotely and can make adjustments as needed.

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. *Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed* ***within the 12 months preceding completion of this Program Description.*** Air exchange rates may be important to maintain air quality in other areas; *however, measurements may be left at the discretion of the institution.* Information may be provided in another format, providing all requested data is included. **[*Note*: Please remove the examples provided in the Table below.]**

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b) (7)(E), (b) (7)(F)	(b) (4)	75°F	Y	±2°F	N	Neg.	12.9	10/01/18
		68°F	Y	±2°F	N	Neg.	12.2	10/01/18
		68°F	Y	±2°F	N	Neg.	17.2	10/01/18
		72°F	Y	±2°F	N	Neg.	12.5	10/01/18
		72°F	Y	±2°F	N	Neg.	13.0	10/01/18
		72°F	Y	±2°F	N	Neg.	12.8	10/01/18
		72°F	Y	±2°F	N	Neg.	15.6	10/01/18
		72°F	Y	±2°F	N	Neg.	14.4	10/01/18
		75°F	Y	±2°F	N	Neg.	12.9	10/01/18
		75°F	Y	±2°F	N	Neg.	12.7	10/01/18

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatur°es (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b) (7)(E), (b) (7)(F)	(b) (4)	70°F	Y	±2°F	N	Neg.	16.1	10/01/18
		68°F	Y	±2°F	N	Neg.	13.9	10/01/18
		72°F	Y	±2°F	N	Neg.	15.2	10/01/18
		72°F	Y	±2°F	N	Neg.	12.5	10/01/18
		70°F	Y	±2°F	N	Neg.	12.3	10/01/18
		68°F	Y	±2°F	N	Neg.	12.2	10/01/18
		72°F	Y	±2°F	N	Neg.	12.2	10/01/18
		Not applicable	N		N	FIO		10/01/18
		Not applicable	N		N	FIO		10/01/18

and repeat the Description and Table for each location, including all satellite housing locations.

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable, define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b) (7)(E), (b) (7)(F)	(b) (4)	68°F	Y	±2°F	N	Pos.	13.1	10/01/18
		68°F	Y	±2°F	N	Neg.	18.3	10/01/18
		72°F	Y	±2°F	N	Neg.	19.3	10/01/18
		68°F	Y	±2°F	N	Neg.	21.0	10/01/18
		75°F	Y	±2°F	N	Neg.	18.9	10/01/18
		72°F	Y	±2°F	N	Neg.	18.9	10/01/18
Dirty side Cage wash		Not applicable	Not applicable			Neg.	9.3	10/01/18
Clean side cage wash		Not applicable	Not applicable			Pos.	Not applicable	10/01/18

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b) (7)(E), (b) (7)(F)	(b) (4)	72°F	Y	±2°F	N	Pos.	26.2	10/01/18
		72°F	N	±2°F	N	Neg.	12.5	10/01/18
		72°F	Y	±2°F		Pos.	20.8	10/01/18
		72°F	Y	±2°F	N	Neg.	12.7	10/01/18
		72°F	Y	±2°F	N	Neg.	15.8	10/01/18
		72°F	Y	±2°F	N	Neg.	12.9	10/01/18
		72°F	Y	±2°F	N	Neg.	13.6	10/01/18
		72°F	Y	±2°F	N	Neg.	15.4	10/01/18
		72°F	Y	±2°F	N	Pos.	14.8	10/01/18
		72°F	Y	±2°F	N	Pos.	15.3	10/01/18
		72°F	Y	±2°F	N	Pos.	12.5	10/01/18
		72°F	Y	±2°F	N	Pos.	17.5	10/01/18
		68°F	Y	±2°F	N	Pos.	13.2	10/01/18
		68°F	Y	±2°F	N	Pos.	15.4	10/01/18
		Not applicable	N		N	Not applicable	5.7	10/01/18

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b) (7)(E), (b) (7)(F)	(b) (4)	72°F	Y	±2°F	N	Pos.	19.3	10/01/18
		72°F	N	±2°F	N	Neg.	17.6	10/01/18
		72°F	Y	±2°F	N	Pos.	17.4	10/01/18
		72°F	Y	±2°F	N	Neg.	18.1	10/01/18
		72°F	Y	±2°F	N	Neg.	17.3	10/01/18
		73°F	Y	±2°F	N	Neg.	15.6	10/01/18
		73°F	Y	±2°F	N	Neg.	14.7	10/01/18
		73°F	Y	±2°F	N	Neg.	15.3	10/01/18
		73°F	Y	±2°F	N	Neg.	15.2	10/01/18
		73°F	Y	±2°F	N	Neg.	16.1	10/01/18
		Not applicable	N	±2°F	N	Neg.	10.5	10/01/18

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
						(Neg to the corridor and the outside)		
(b) (7)(E), (b) (7)(F)	(b) (4)	Not applicable	N		N	Pos.	18.6	10/01/18
		Not applicable	N	Not applicable	N	Pos. (to outside)	3.8	10/01/18
		Not applicable	N	Not applicable	N	Pos. (to food prep area)	5.8	10/01/18
			N		N	Neg.	8.4	10/01/18
			N		N	Neg.	25.4	10/01/18
		Not in Use	N	Not in Use	N	*Pos.	18.4	10/01/18
		Not in Use	N	Not in Use	N	*Pos.	15.4	10/01/18
		Not in Use	N	Not in Use	N	Pos.	16.3	10/01/18
		Not in Use	N	Not in Use	N	Neg.	32.4	10/01/18

(b) (7)(E), (b) (7)(F)

(b) (7)(E), (b) (7)(F)

Appendix 12

Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, 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)
Not applicable							

Note: Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, *etc.*) should be available for review.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 12: Aquatic Systems Summary – Part 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):**
Not applicable									

Note: This information may be provided in another format, provided that all requested data is included.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 13

Appendix 13: 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.

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**
(b) (4)	75"²	5 adults or female + litter	The Guide	Static cage/polysulfone
	153"² low profile	10 adults or 2 females + litters	The Guide	Static cage/polysulfone
	60'X30"X70"	5 adults	The Guide	IVCS/stainless steel/polysulfone
	60'X25X75"	5 adults	The Guide	IVCS/Stainless steel/disposable
	153"²	Depends on size of the (b) (4)	The Guide	Static cage/polysulfone
	153"²	1 juvenile or adult	Based on rodent weights in The Guide	Static cage/polysulfone
	Inside run 32'² Outside run 32'²	Depends on size of animal	The Guide	Cement floors/cinder block /stainless steel/coated wire fencing

Appendix 13: 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**
(b) (4)	153"²	(b) (4)	The Guide	Static cage/polysulfone
	153"² low profile	Depends on size of the (b) (4)	The Guide	Static cage/polysulfone
	4.0'²	(b) (4)	The Guide	Stainless steel
	3.0'²	(b) (4) up to 4kg	The Guide	Stainless steel
	5.1'²	(b) (4)	The Guide	Stainless Steel frame/plastic cages
	5.0'²	(b) (4)	The Guide	Stainless Steel
	6.0'²	(b) (4)	The Guide	Stainless Steel
	Inside run 65'² Outside run 65'²	(b) (4)	The Guide	Slatted floors over concrete/stainless steel/ coated wire fencing

Appendix 14

Appendix 14: 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				
Solid-bottom cages (static)	Cage washer	Twice weekly	Alkaline or acid detergent	Autoclaved as need
Solid-bottom cages (IVC)	Cage washer	Every 2 weeks	Alkaline or acid detergent	Autoclaved as needed
Suspended wire-bottom or slotted floor cages	Cage washer	Every other week		
Cage wire lids	Cage washer	Every other week or as needed	Alkaline or acid detergent	Autoclaved as needed
Filter tops	Cage washer	Every other week or as needed	Alkaline or acid detergent	
Cage racks and shelves	Cage washer	Every other week	Alkaline or acid detergent	
Cage pans under suspended cages	Cage washer	Every other week	Alkaline or acid detergent	
Play pens, floor pens, stalls, etc.	Sanitized and hand rinsed	Daily	Quaternary ammonium	
Runs [redacted] or outdoor paddocks for livestock	Sanitized and hand rinsed	Daily	Quaternary ammonium	
Aquatic, amphibian, and reptile tanks and enclosures	Not applicable			

Appendix 14: 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)
Feeders	Cage washer	Every other week	Alkaline or acid detergent	
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Cage washer	Weekly	Alkaline or acid detergent	
Transport cages	Cage washer	After every use	Alkaline or acid detergent	
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)	Cage washer or hand wash	After every use	Depends on type of restrainer	
Euthanasia chambers	Cage washer	After every use	Alkaline	
Macro -environment				
Animal Housing Rooms:				
Floors	Mop	Daily	Quaternary ammonium	
Walls	Hand wash/mop	As needed	Quaternary ammonium	
Ceilings	Hand wash/mop	As needed	Quaternary ammonium	
Ducts/Pipes	Hand wash	As needed	Quaternary ammonium	
Fixtures	Hand wash	As needed	Quaternary ammonium	

Appendix 14: 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)
Corridors:				
Floors	Floor scrubber	Every other week	Floor cleaner/sanitizer	
Walls	Hand wash/mop	As needed	Quaternary ammonium	
Ceilings	Hand wash/mop	As needed	Quaternary ammonium	
Ducts/Pipes	Hand wash	As needed	Quaternary ammonium	
Fixtures	Hand wash	As needed	Quaternary ammonium	
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors	Mop	After every use	Quaternary ammonium	
Walls	Hand wash/mop	As needed	Quaternary ammonium	
Ceilings	Hand wash/mop	As needed	Quaternary ammonium	
Ducts/Pipes	Hand wash	As needed	Quaternary ammonium	
Fixtures	Hand wash	As needed	Quaternary ammonium	
Implements (note whether or not shared):				
Mops	Cage washer	Every other week	Alkaline detergent	
Mop buckets	Cage washer	Every other week	Alkaline detergent	
Feed bins	Cage washer	Monthly	Alkaline detergent	
Aquaria nets	Not Applicable			

Appendix 14: 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)
Other				
Other:				
Vehicle(s)	Not Applicable			
Transport Carts	Cage washer	After every use	Alkaline detergent	

*Please provide chemical, not trade name.

Appendix 15

Appendix 15: 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
(b) (7)(E), (b) (7)(F)	(b) (7)(E), (b) (7)(F)	Rack washer/Cage washer	Emergency "off" button; labeled exit door, de-energizing cord on one side, instructional signage	Guarantee 180-degree final hot water rinse; temperature-sensitive tape used on first and last cycle; Swabs of various pieces of equipment done quarterly
(b) (7)(E), (b) (7 (F)	(b) (7)(E), (b) (7)(F)	Bulk Autoclave	Pressure relief valve	Sterilization strips; autoclave tape; biological indicators used semi-annually.

Appendix 16

Appendix 16: 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: (b) (7)(E), (b) (7)(E)

[*Note*: Please remove the examples provided in the Table below.]

Room Type[a]	Light Intensity Range	Lighting Fixture Construction Features[b]	Photo-period (hrs)[c]	Photoperiod and Lighting Control	Override Mechanisms (if applicable)
(b) (4) Holding Rooms	130-392Lux	gasketed water resistant	12:12	Automatic via wall mounted timer box	All timers have manual override
(b) (4) Holding Rooms	313-432Lux	Gasketed, water resistant	12:12	Automatic via wall mounted timer	All timers have manual override
(b) (4) Holding Room	541Lux	Gasketed, water resistant	12:12	Automatic via wall mounted timer	All timers have manual override
(b) (4) Holding Rooms	354Lux	gasketed, water resistant	12:12	Automatic via wall-mounted timer box	All timers have manual override
Surgery	Not measured	Recessed, water resistant; arm-mounted, water resistant	Not Applicable	Not applicable	Not applicable
Necropsy	Not measured	Recessed, water resistant; arm-mounted, water resistant	Not Applicable	Not applicable	Not applicable
Cage-Washing Room	Not measured	gasketed, water proof	Not Applicable	Not applicable	Not applicable

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

Appendix 17

Appendix 17: Satellite Housing Facilities

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 11)** and Lighting Systems Summary **(Appendix 16)**.

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
Not applicable							