Program Description
Animal Care and Use Program

Division of Vector-Borne Diseases

Unit # 001292

Centers for Disease Control and Prevention

Fort Collins, CO

March 21, 2018

For

AAALAC International

Table of Contents

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.

Division of Vector-Borne Diseases (DVBD), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Office of Infectious Diseases (OID), Centers for Disease Control and Prevention (CDC), Fort Collins, Colorado. DVBD is the accreditable unit. DVBD has its own Institutional Animal Care and Use Committee (IACUC) and PHS Assurance (#A4366-01) because it is administratively and geographically separate from other divisions within NCEZID and CDC. There is, however, alignment of DVBD IACUC policies and standard operating procedures with those of CDC and the Atlanta IACUC where feasible. Subsequent use of the term IACUC refers to the CDC Fort Collins IACUC at DVBD.

Comparative Medicine Branch (CMB), Division of Scientific Resources (DSR), NCEZID, Center for Infectious Disease, CDC, Atlanta, Georgia. DSR oversees the contract with [redacted] for [redacted] personnel to provide animal care services at DVBD. DSR also oversees a separate contract with [redacted] for provision of veterinary services. [redacted] provides an Attending Veterinarian (AV) with back-up veterinarians who provide veterinary services to DVBD.

The Animal Care and Use Program Office (ACUPO) is within the Office of Laboratory Safety, Office of the Associate Director for Laboratory Science and Safety, Office of the Director, CDC, Atlanta, Georgia supervises the Fort Collins IACUC Administrator/Compliance Officer.

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.

CDC is one of 11 major operating components of the United States Department of Health and Human Services, the principal agency in the United States government for protecting the health and safety of all Americans and for providing essential human services. CDC's mission is to promote health and quality of life by preventing and controlling diseases, injury, and disability. Composed of the Office of the Director, the National Institute for Occupational Safety and Health, and six centers/offices, including global health, infectious diseases, non-communicable diseases, injury and environmental health, public health

preparedness and response, public health scientific services, and state, tribal, local and territorial support. CDC employs more than 12,000 employees in 120 countries in nearly 150 occupations.

Critical to the mission and organization of CDC is the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). NCEZID provides leadership, expertise, and service in laboratory and epidemiological science, bioterrorism preparedness, applied research, disease surveillance, and outbreak response for infectious diseases and is home to the Division of Vector-Borne Diseases (DVBD). DVBD serves as a national and international reference center for vector-borne viral and bacterial diseases. DVBD supports extensive research and prevention programs as well as national bioterrorism preparedness and response programs related to vector-borne diseases. At DVBD, live vertebrate animals are used in biomedical research, reference diagnostic activities, and field research in support of public health.

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 primary standards used for the DVBD institutional animal care and use program are the PHS Policy on Humane Care and Use of Laboratory Animals and the Guide for the Care and Use of Laboratory Animals (2011) for all animals. The Animal Welfare Act and Animal Welfare Regulations are used for covered species. In addition, the 2016 Guidelines of the American Society of Mammologists for the Use of Wild Mammals in Research, and the Ornithological Council Guidelines for the Use of Wild Birds in Research, Third Edition, 2010 are utilized for evaluating protocols covering wild mammals and birds.

D. Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note:* For individuals whose information is publically

available, provide the titles and names; for individuals whose information is not publically available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

CDC's top organizational components include the Office of the Director, the National Institute for Occupational Safety, Health and Environment, and six overarching centers/offices. The Institutional Official (IO) and ACUPO reside in the CDC Office of the Director. DVBD and Comparative Medicine Branch reside in the National Center for Emerging and Zoonotic Infectious Diseases under the Office of Infectious Diseases. Organizational charts are provided as Appendix 1.

1. Institutional line of authority from the Institutional Official to the Attending Veterinarian (AV):

CDC Director (acting)	Anne Schuchat,
Associate Director for Laboratory Science and Safety Institutional Official (IO)	Steve Monroe
Office of Infectious Diseases, Director	Sonja Rasmussen
National Center for Emerging and Zoonotic Infectious Diseases, Director	Rima Khabbaz
Division of Scientific Resources, Director	(b)(6)
Contract Officer's Representative (COR)	
Attending Veterinarian (contractor)	

2. Institutional line of authority from the IO to the IACUC (direct line of communication described in I.C.4)

CDC Director (acting)	Anne Schuchat
Associate Director for Laboratory Science and Safety, Institutional Official (IO)	Steve Monroe
Office of Infectious Diseases, Director	Sonja Rasmussen
National Center for Emerging and Zoonotic Infectious Diseases, Director	Rima Khabbaz
DVBD, Director	(b)(6)
DVBD, Deputy Director	
DVBD, Assoc. Director for Science	
DVBD, Assoc. Director for Laboratory Science	
DVBD, IACUC Chair	(b)(6)

3. Institutional line of authority from the IO to ACUPO (direct line of communication described in I.C.4)

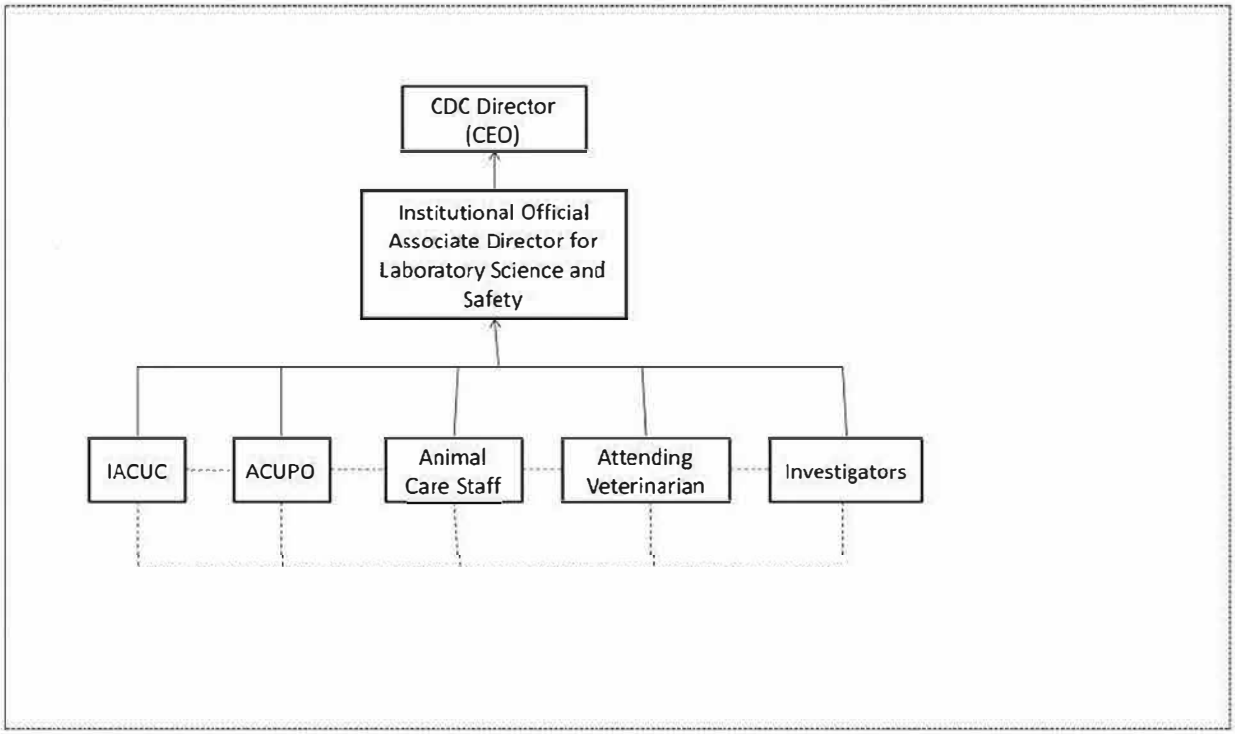
CDC Director (acting)	Anne Schuchat
Associate Director for Laboratory Science and Safety, Institutional Official (IO)	Steve Monroe
Office of Laboratory Safety	(b)(6)
Animal Care and Use Program Office, Chief	
IACUC Administrator/Compliance Officer assigned to DVBD	(b)(6)

4. Institutional line of authority from the IO to the Animal Care Staff

CDC Director (acting)	Anne Schuchat
Associate Director for Laboratory Science and Safety Institutional Official (IO)	Steve Monroe
Office of Infectious Diseases, Director	Sonja Rasmussen
National Center for Emerging and Zoonotic Infectious Diseases, Director	Rima Khabbaz
Division of Scientific Resources, Director	(b)(6)
Project Officer	
Project Manager	
Project Lead	

5. Direct lines of communication between the AV and IACUC to the IO

As shown by solid lines in the organizational chart provided below, the AV, IACUC, ACUPO and investigators may communicate directly with the IO without constraint by institutional lines of authority described in Sections I.C.1-4 above.



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.

Steve Monroe, PhD
Associate Director for Laboratory Science and Safety
Institutional Official
CDC, 1600 Clifton Road, MSD-17, Atlanta, GA 30333

(b)(6) MD, MPH
DVBD Director
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(6) ScD
DVBD, Deputy Director for Science
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(6) PhD
DVBD, Associate Director for Laboratory Science
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(6) PhD
DVBD, IACUC Chairperson
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(6) DVM, PhD, DACLAM
Attending Veterinarian (AV, contractor), IACUC Member
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(6) VMD, MPH, DACVPM
Chief, Animal Care and Use Program Office (ACUPO)
CDC, 1600 Clifton Road, MS D-73, Atlanta, GA 30333

(b)(6) DVM
DVBD, IACUC Administrator/Compliance Officer
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(6) BS
DVBD Safety and Occupational Health Specialist, IACUC Member
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(6)
DVBD, Responsible Official, Select Agents
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(6) NP
DVBD Occupational Health Nurse Practitioner
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(7)(E)

(b)(6)
DVBD Building General Engineer
CDC, 3156 Rampart Road, Fort Collins, CO 80521

(b)(4)

(b)(6) ntractor)
Project Lead,
CDC, 3156 Rampart Road, Fort Collins, CO 80521

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 major types of research and testing programs involving animals include:

- Field and laboratory studies of vector-borne viral and bacterial agents and diseases;
- Field and laboratory investigations on the biology, ecology, and control of arthropod vectors;

- Vector-borne viral and bacterial diseases, reference diagnostic services and development.

There are approximately 20 principal investigators (PIs) engaged in animal research and approximately 35 approved protocols. At any given time, approximately 10% of these include studies of wild rodents conducted at domestic or international field locations. Refer to Appendix 5 for a list of current protocols.

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

The animal care and use program at DVBD is funded by the U.S. Congress as part of the CDC annual total budget allocation each year. DVBD annually spends over 42 million dollars with more than $400,000 spent on animal caretaker salaries, feed, bedding, supplies, equipment, and other basic operational needs for the animal facility. New buildings, renovations, and other large-dollar expenditures are considered and approved as separate budgetary items at CDC. Occasionally, some programs or PIs have contracts or grants that allow for the procurement of animals, custom animal products, or equipment.

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.

The Rickettsial Diseases Branch included in the Division of Vector-Borne Diseases is located in Atlanta, GA. Their protocols and animal use are under the oversight of the CDC-Atlanta IACUC and animals are housed in the CDC-Atlanta facility. That facility is accredited separately from DVBD in Fort Collins.

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.

DVBD currently owns no animals housed at contract facilities.

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

DVBD has a PHS Assurance (#A4366-01) and is subject to directives provided in the CDC Laboratory Animal Care and Use Policy. This policy stipulates that all activities involving animals in CDC-funded research, whether the activities are performed at CDC, in the field, at an awardee institution, or through collaborations, shall adhere to the current, and any subsequent revision of, the following materials:

- Office of Laboratory Animal Welfare, Public Health Service (PHS) "Policy on Humane Care and Use of Laboratory Animals" revised 2015.
- Title 7 CFR, Chapter 54, Sections 2131-2159 Animal Welfare Act and amendments, last updated June 14, 2017.
- Title 9 CFR, Chapter 1, Subchapter A, Parts 1 – 4. Animal Welfare Act and amendments, 2017.
- National Research Council "Guide for the Care and Use of Laboratory Animals" revised 2011.
- "Biosafety in Microbiological and Biomedical Laboratories", 5th Edition, 2009.
- National Research Council "Occupational Health and Safety in the Care and Use of Research Animals", 1997.

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 Associate Director for Laboratory Science and Safety (ADLSS), Office of the Director, CDC, serves as the Institutional Official (IO) for all of CDC as delegated from the CDC Director to exercise (1) the responsibility of the CDC Director regarding appointments to the CDC Institutional Animal Care and Use Committees; (2) the authority and responsibility for assuring CDC-wide compliance with all applicable laws, regulations, policies, and standards regarding the humane care and use of laboratory animals at CDC; and (3) to serve as the IO for purposes of compliance, including through management authority, with the PHS Policy on Humane Care and Use of Laboratory Animals and relevant regulations issued by the U.S. Department of Agriculture under the Animal Welfare Act (9 CFR Parts 1, 2, and 3). The current Associate Director for Laboratory Science and Safety for CDC is Steve Monroe, Ph.D.

The IACUC submits a semi-annual report to the IO with the results of the semi-annual program evaluation and facility inspection. In this report, recommendations for improvements in the program or facility are included. The Attending Veterinarian is able to directly communicate with the IO.

Routine reports and non-compliance/animal welfare issues are submitted directly to the IO.

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)(4) holds a contract for the provision of veterinary services to CDC-DVBD in Fort Collins. (b)(6) DVM, PhD, DACLAM is the (b)(4) (b)(6) s the Attending Veterinarian and provides veterinary services to DVBD. (b)(6) l is supported by (b)(6) DVM, DACLAM as the alternate AV, along with two comparative medicine veterinarian residents from (b)(6) when he is not available. (b)(6) is the Associate Director for Laboratory Animal Resources at (b)(4)

The qualifications, authority, and percent of time contributed by the veterinarian(s) who participate in the program are as follows:

Name: (b)(6)
Qualifications:
Degrees: DVM, PhD, Diplomate American College of Laboratory Animal Medicine
Training and/or experience in laboratory animal medicine: (b)(6) has over 16 years of experience in laboratory animal medicine with professional training that includes completion of a post-DVM laboratory animal residency program, a PhD in veterinary pathobiology and is a Diplomate of the American College of Laboratory Animal Medicine.
Authority: (b)(6) has delegated program authority as the Attending Veterinarian and responsibility for the Institution's animal care and use program.

Time Contributed to Program: Part time contracted laboratory animal veterinarian; present at facility approximately 1 hour per month all of which is dedicated to the animal care and use program. (b)(6) is available via telephone and e-mail and can be on site within approximately 30 minutes during the week and 60 minutes on weekends. If (b)(6) is not available, (b)(6) (b)(6) is his back up.

Name: (b)(6) DVM, DACLAM
Qualifications:
Degrees: (b)(6) Diplomate American College of Laboratory Animal Medicine

Responsibilities: (b)(6) is alternate attending veterinarian to (b)(6)
Time Contributed to Program: Part-time contracted veterinarian; present at facility approximately 1 hour per month all of which is dedicated to the animal care and use program.

Comparative Medicine residents provide animal care support approximately 4 hours per week under the direct supervision of [redacted] and [redacted]

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.

Animal Care Staff

[redacted] holds a contract to provide animal care staff for CDC-DVBD. The animal care project lead reports all problems to the AV and the DVBD-ACUPO office. Animal care staff members are trained to properly care for the animals in their charge. Issues detected by animal care staff that involve or may directly or indirectly affect animals at CDC-DVBD are reported to the AV or alternate AV and DVBD-ACUPO office. Problems assessed as potentially threatening the safety or welfare of the animals are reported to the AV, the DVBD-ACUPO office and IACUC Chair for further follow-up.

Principal Investigators (PI)

Principal Investigators are responsible for understanding and applying established policies and guidelines for animal use. Problems detected in the animal care facility are reported to the supervisory staff and/or the AV, and any that the PI deems as potential threats to animal safety or welfare may be reported to animal care personnel, the AV, IACUC, DVBD-ACUPO, the IACUC Chair, or directly to the IO. PI's must consult with a veterinarian during protocol development. PI's and protocol associates are responsible for observing the animals under experimentation and report any unexpected outcomes to the AV and DVBD-ACUPO office.

c. Inter-institutional 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 inter-institutional collaborations.

Collaborations utilizing animals for research at non-CDC sites are reviewed by the ACUPO office in Fort Collins and Atlanta. The collaborating institution must have a PHS Assurance in which case an agreement, contract, memorandum of understanding or equivalent, is signed by both DVBD management and the IACUC Chair and IO of

the other institution agreeing that the other institution has responsibility for oversight of the proposed research and animal welfare. DVBD ACUPO office maintains a copy of the protocol and any amendments. If the collaborating institution does not have a PHS Assurance, both the DVBD IACUC and that of the collaborator must review and approve the proposed use of animals. A CDC point-of-contact must be listed in the protocol. There are currently no inter-institutional agreements involving live animals housed at a collaborating site.

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.

A measure of effectiveness of a training program(s) is the ability of participants to perform the procedures correctly and safely as they were trained. This effectiveness is assessed indirectly by monitoring animal welfare during facility visits by the IACUC, post-approval monitoring, review of animal welfare concern reports, as well as feedback from occupational health related issues. The ACUPO Compliance Officer conducts periodic laboratory visits to assure personnel are performing procedures as described in the IACUC approved protocol and assists in assuring the effectiveness of training. Discussions of animal procedures are also held during post-approval monitoring visits. The Compliance Officer observes protocol procedures and assures that training is appropriate for the species and the project. The AV and alternate AV or designees provide training in specific procedures to the PIs and associates along with the animal care staff.

Protocol related training is documented for each person listed on an approved animal care and use protocol. Specific training records are kept independently by each principal investigator and/or protocol associate; copies are requested for the IACUC files.

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.

1. (b)(6) PhD, DACLAM – (b)(6) received (b)(4) DVM from (b)(6) (b)(6) completed a residency in laboratory animal medicine (b)(6) and completed a PhD in veterinary pathobiology (b)(6) (b)(6) has been board certified sinc (b)(6) and has over 16 years of experience in laboratory animal medicine and program management. (b)(6) regularly attends and participates in professional meetings, is a member of ASLAP and AALAS and is an AAALAC Ad Hoc specialist.
2. (b)(6) DACLAM – (b)(6) received (b)(6) DVM from (b)(6) (b)(6) (b)(6) practiced general practice medicine and surgery for 5 years, and completed a residency in laboratory animal medicine in (b)(6) (b)(6) became board certified in (b)(6) and has 8 years of clinical laboratory animal medicine experience. (b)(4) regularly attends and participates in Lab Animal Professional meetings such as National AALAS and is a National and Local AALAS member as well as an ASLAP member.

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

1) Indicate the number of animal care personnel.

(b)(4) (b)(4) holds the contract to provide animal care services at DVBD. (b)(4) provides 1 on-site project lead plus 3 animal care/cage wash/glassware technicians.

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.

Animal care staff at DVBD consists of one on-site project lead with 10+ years of experience in animal care and cage wash operations who also supervises the insectary and glassware units; one animal care/cage wash technician and insectary assistant with 13+ years of experience, LAT certification, and BS in Psychology; one animal care/cage wash technician with 15+ years of experience, LAT certification, a BS, and prior veterinary technician experience; and one animal care and cage wash/glassware technician with 20+ years of experience. Regular continuing education is provided by bi-weekly CE meetings hosted on the (b)(4) campus, online AALAS Learning Library courses, Refresher Training as required by both CDC and (b)(4) and attendance at national or local AALAS meeting provide continuing education.

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.

All investigators who may perform procedures on live animals as part of the proposed animal use protocol must be properly trained. This requirement applies to all associate investigators as well as the Principal Investigator (PI), and includes research technicians, students, visiting scientists, and all other individuals who are involved in animal care or use. The requirement does not apply to those who will not perform procedures on animals or be responsible for their welfare. Examples include consultants, statisticians, and investigators who may process tissues from animals following euthanasia.

To meet the minimum training requirement, investigators must complete the following:

Two online training courses available from the American Association for Laboratory Animal Science (AALAS) Learning Library (Working with the IACUC) and Introduction to [Mice or Rabbits] (applicable species).

The PI is responsible for: 1) identifying training needs that are not met by the minimum training requirements described above; and 2) providing or acquiring training for unmet needs. The AV or (b)(4) employees may provide hands-on training in specialized procedures upon request by the PI or associate investigators. This training is documented.

a) Briefly describe the content of any required training.

There are 2 AALAS Learning Library (ALL) courses required by the IACUC prior to beginning work with animals. The first course, Working with the IACUC, provides an overview of federal regulations, veterinary consultation, consideration of alternative to the use of animals, describes USDA pain/distress categories, identification of endpoints, surgery, antibody production, blood sample collection, occupational health, use of hazardous agents, animal housing, prolonged restraint, euthanasia, and reporting of non-compliance, misuse and mistreatment.
The second course required, Introduction to [species], provides training regarding the specific animal species that will be utilized. At DVBD, the courses generally taken are for mice and rabbits as they are the most commonly used species. This course covers such topics as occupational health considerations, alternatives to the use of animals, humane standards of care, housing, acclimation and quarantine, detecting pain and distress, genetics, biology, procedures such as injections and blood collection, monoclonal antibody production, use of analgesic, sedatives and anesthetics, supportive care and monitoring and euthanasia.

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

The minimum training must be completed before the protocol or amendment is approved by the IACUC. Hands-on training may be conducted during protocol execution when it is noted in the IACUC-approved protocol that an associate will be trained during the course of the protocol. The PI is responsible for assuring the appropriate training of protocol associates.

c) Describe continuing education opportunities offered.

Continuing education of the investigative staff is at their discretion and based on the job requirements. The AV or alternate provides consultation and training as requested by individual investigators. The AV or alternate also provides continuing education to the animal care staff.

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 procedures are rarely conducted at DVBD. If a protocol includes a surgical procedure, it undergoes pre-review by the AV or alternate with discussions regarding anesthesia, analgesia, identification and experience of the surgeon, procedure specifics and training. The IACUC then reviews the protocol by full committee review (FCR). Post-approval monitoring (PAM) is conducted by the Compliance Officer who observes the surgical procedures and reports back to the IACUC.

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

The AV or alternate AV provides training in anesthesia at the request of investigators. Experienced investigators provide training to their new key associates and documentation is retained by the investigator and associate with a copy forwarded to the Fort Collins ACUPO office.

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

All new investigators are required to complete didactic instruction in euthanasia (required ALL course). Technical proficiency is confirmed by investigator supervisors or the AV or alternate. The AV provides hands-on training as needed. Training is provided to recognize the cessation of vital signs in the species being euthanized. A secondary method of euthanasia is generally required for all species. Proficiency is also evaluated through the PAM process.
Currently, physical methods of euthanasia are not utilized by DVBD PIs and associates, or animal care staff as primary means for euthanasia. Cervical dislocation is used as a secondary means to assure death.
Approved methods for euthanasia are covered in FTC-IACUC Policy 16. The DVBD protocol forms also provide guidance on acceptable euthanasia methods.

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).

CDC's Office of Safety, Security, and Asset Management (OSSAM) is responsible for providing occupational health and safety oversight, leadership, and service for CDC's workforce. The office is comprised of safety officers and professionals with training across a wide range of worker protection areas, including biosafety, chemical safety, industrial hygiene, laboratory animal safety, physical safety, safety training, radiation safety, Select Agents, and emergency response. The OSSAM team is centrally located at CDC Headquarters in Atlanta, but routinely provides remote consultation, guidance, and program evaluations as needed. It also provides regular on-location inspections, hazard surveys, and training activities. DVBD has a full time, on-site dedicated safety professional, the Safety and Occupational Health

Specialist (SOHS). This Safety Officer is responsible for implementing and maintaining components of the OSSAM and OADLSS safety programs on site in Fort Collins. The CDC Occupational Health Clinic has a satellite location on the Fort Collins campus, as well. It is staffed by a full-time occupational health nurse practitioner. They assist in implementing critical components of the occupational health and safety and worker protection programs for the animal care and use program.
DVBD has a safety committee consisting of the SOHS, DVBD Assoc. Director for Laboratory Science, DVBD Assoc. Director for Science, Select Agent RO and others who meet approximately once a month.

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.].

Hazard Identification and Risk Assessment

The identification and assessment of workplace hazards is the combined responsibility of investigators, supervisors, project officers, and the CDC-DVBD Safety Officer (SOHO) to evaluate each work location. Individual risk assessments are conducted by the Safety Officer to determine the appropriate safety practices, immunizations, and protective equipment to be employed commensurate with the activities conducted and the risks posed by the hazardous agent(s). Assessment of risk involved with each protocol during proposal preparation and review is conducted by the Safety Officer in conjunction with the principal investigator. Using the current version of the CDC-NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL) as a guide, risk assessments include review of the virulence, communicability, routes of exposure, shedding patterns, stability and availability of prophylaxis and therapy for the agent being used. The agent, animal biosafety level, and additional requirements for personal protective equipment, immunizations, waste disposal or other special precautions, which apply to the project, are posted outside the anteroom of the animal suite as soon as work on the project begins. Access to the animal rooms is restricted to those individuals identified in the protocol who meet or exceed the requirements set out by the PI and the Safety Officer.

The Safety Officer, branch chiefs, investigators, supervisors, and animal care project lead collaborate to ensure that hazards are identified, occupational

health and safety training requirements are determined, and training is conducted and documented. The Safety Officer conducts periodic audits of all laboratory spaces, including areas where research animals are used or housed, and to monitor compliance with institutional safety policies. Safety personnel from the main CDC office also conduct periodic on-site evaluations of laboratories for compliance with safety policies.

Biological safety policies and procedures adhere to those described in the current edition of the CDC-NIH publication, Biosafety in Microbiological and Biomedical Laboratories (BMBL). A comprehensive health, safety, and environmental committee system is established at CDC (based in Atlanta) that is function-based (e.g. Institutional Biosafety Committee, Radiation Safety Committee, Chemical Safety Committee) and facility-/-organization-based to provide periodic safety policy review, oversight, program evaluation, and to serve as the principal means of employee involvement in the administration of the occupational health and safety program.

The Safety Officer routinely monitors the ongoing use of hazardous agents and provides additional training as needed. Routine monitoring involves the direct visualization and study by trained safety professionals of the work being done by investigators and (b)(4) employees and helps identify risk activities. Appropriate controls to reduce these risks are implemented as needed.

Procedures for reducing or managing risks include:

- Appropriately selecting, screening, orienting, and training workers prior to the initiation of work.
- Having all laboratory staff and animal care staff follow all CDC policies and practices concerning handling and disposing of infectious materials, sharps, toxic substances, and decontaminating all animal areas.
- Having all facility and janitorial staff adhere to established pre-entry safety procedures. The minimal process requires 1) determining the current hazard level of the room (indicated by hazard sign outside door), 2) consulting with the PI to determine in-room activities (questions are prescribed by the Safety Officer), and 3) implementing prescribed protective measures and administrative controls for safe entry.
- Requiring personnel to wear appropriate protective clothing and utilize universal precautions.
- Requiring personnel to be immunized according to the recommendations of the Advisory Committee on Immunization Practices (ACIP), the CDC Immunization Policy, the CDC Medical Advisory Board, and protocol-specific guidelines.

Using the following requirements and records for each individual employee and contract personnel (including (b)(4) employees):

- Completion of yearly health screening to include

animal allergen risk screening.

- Giving a tetanus booster every 10 years and any other required or recommended routine adult immunizations.
- Making protocol-specific, pre-exposure immunizations available to all persons who handle animals at substantial risk of infection with agents such as rabies virus. (For contract employees, vaccinations are done by the contractor's occupational health care provider.)
- Keeping records of work assignments, workplace incidents, risk events, exposures (scratches, bite wounds, splashes, sharps injuries, or other pathogen exposures), and any unexplained symptoms or illness as part of an appropriate plan of medical and/or zoonoses surveillance program.

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

All animal labs and support areas are inspected annually by the Office of the Associate Director for Laboratory Science and Safety (OADLSS) to ensure all required safety measures are still in place and are commensurate with the current risks associated with the research and procedures being performed in each suite.
In addition, lab staff fill out a personal risk assessment form provided by the DVBD safety officer. This provides a current view of the work being performed by the specific individual and allows the safety officer to confirm appropriate safety measures are in place. This risk assessment is updated when duties change.

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]

OSSAM program components for personnel potentially exposed to hazardous agents, injuries, etc.:

All hazardous agent incidents, near misses, potential injuries, or other risk occurrences as well as any actual injury or signs or symptoms of illness are promptly reported. Reporting procedures include:

- Personnel notify their supervisors of illness, injury, or suspected health hazards.

- Personnel can also report directly to the CDC Occupational Health Clinic at Fort Collins.
- Any personnel who are exposed to a hazardous agent are given first aid if needed and immediately accompanied to the DVBD Occupational Health clinic for treatment or referral.
- If (b)(4) employees sustain an exposure or injury which also involves a known or suspected exposure to an infectious agent, the employee is triaged by the onsite clinic and immediate first aid is provided. Additional treatment, ongoing care, and follow-up are provided according to patient needs and contract specifications.
- The clinic maintains appropriate medications, prophylaxis, immunizations, and other post-exposure interventions at all times.
- Onsite treatment at the clinic is available between 8:00 a.m. and 4:30 p.m., Monday through Friday, excluding federal holidays.
- If an injury occurs or a person is exposed to an infectious agent outside of regular working hours, these procedure(s) are followed:

  A process was developed in conjunction with the local medical center's director of emergency services for handling exposed employees. If there is an inadvertent exposure, employees are to go directly to Poudre Valley Hospital emergency department and announce that they have had an exposure to "X" organism. They are then conducted to a special set-aside room where they are to be promptly seen by an emergency department physician. An "MSDS"-like binder was created with all the agents used here, which includes diagnosis and treatment recommendations for all of them. The binder is kept in that room. There is also easy access to the web so that additional information could be obtained from the CDC or elsewhere, if needed.

  Contractors follow their employers' guidance for work-related injuries.
- The clinic assists with necessary worker compensation forms or inquiries for employees.

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.

The Occupational Health Nurse Practitioner assigned to the DVBD Occupational Health Clinic develops and monitors the preventive medicine program to fit the needs of personnel at DVBD.

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

Persons that decline participation in the occupational health program have a note placed in their electronic medical file noting this.
No persons associated with the animal care and use program have declined participation in the medical evaluation program.
For contracted animal care personnel, this is handled by their occupational health program.

c) Describe provisions for assuring confidentiality of medical information.

There is a CDC-wide system for electronic medical records. This system is accessed only by occupational health medical and nursing staff. This system is HIPPA compliant. Questionnaires are answered by individuals online and are reviewed by medical personnel only.

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

Contractors that need access to animal areas to perform maintenance functions are escorted by the Safety Officer or designee. They are trained to

inquire about the risks and appropriate PPE before entering the area. They wear the appropriate PPE as posted for the area.

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

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

Medical Evaluation and Preventive Medicine for Personnel:
1) Brief Description of the CDC Occupational Health Clinic and OSSAM Worker Protection Program

Medical evaluation and prevention services for CDC staff are provided by the Fort Collins satellite location of the CDC Occupational Health Clinic. Services are provided in coordination with the SOHS with input from IACUC, DVBD-ACUPO, and the AV. The clinic is staffed by one full-time nurse practitioner who provide onsite services. Occupational health services are available every workday from 8 a.m. to 4:30 p.m. If occupational health services are needed during non-workday hours, processes have been developed with our local medical center's director of emergency services for handling exposed employees. If there is an inadvertent exposure, employees are to go directly to Poudre Valley Hospital emergency department and announce that they have had an exposure to "X" organism. They are then conducted to a special set-aside room where they are to be promptly seen by an emergency department physician. An "MSDS"-like binder was developed with all the agents used here, which includes diagnosis and treatment recommendations for all of them. The binder is kept in that room. There is also easy access to the web so that additional information could be obtained from the CDC or elsewhere, if needed.

Contractors are to go to their contract occupational healthcare providers. In emergencies, they are to go to the hospital emergency department.

The clinic also provides immediate first-aid for injuries, exposures, or other incidents to contract personnel. All other occupational health services for (b)(4) and other contract personnel are specified in their contract.

All personnel who enter animal areas must be enrolled in the occupational health and safety worker protection program. Elements of the program are based on the risk assessment of the work being done. Risk assessments are conducted by SOHS in collaboration with OSSAM, the PI (for laboratory staff), or the (b)(4) project manager (for animal care employees). Persons needing access to the animal facility fall into three categories based on risk, (i) animal care staff (b)(4) employees), (ii) animal use staff (research and technical staff), or (iii) those with occasional exposure to animals (facility, maintenance, and custodial workers and IACUC members).

The following worker protection elements are implemented for all staff engaged in (i) animal care, (ii) animal use, or (iii) with occasional exposure to animals:

- Recommended ACIP vaccinations.
- TB skin testing if indicated based on risk assessment. (Non-human primates are not utilized at DVBD but the occasional investigator may require this prior to visiting the CDC-Atlanta animal facilities.)
- Additional work-specific vaccines, baseline and/or interval titers, and investigational new drug vaccines if indicated based on risk assessment (such interventions may include vaccines for rabies, hepatitis A and B, tetanus, yellow fever, Japanese encephalitis virus, Venezuelan equine encephalitis, and Rift Valley Fever).
- Respirator medical clearance, pulmonary function evaluation (including spirometry), respirator fit testing, and training if indicated based on risk assessment.

The following are required for all staff engaged in (i) animal care and (ii) animal use:

- Initial and annual general health evaluations including the animal allergy/allergen questionnaire (b)(4) employees have this conducted by their occupational health provider.).
- Instructions for illness monitoring, prompt reporting of all incidents and accidents.

The following are required of, or provided for (i) animal care staff:

- Records of work assignments, workplace incidents, risk events, exposures (scratches, bite wounds, splashes, sharps injuries, or other pathogen exposures), and any unexplained symptoms or illness as part of an appropriate plan of medical and/or zoonoses surveillance program.
- Instructions for prompt reporting of any existing or future medical conditions or treatments that could result in altered immune system

function, including the development of a chronic condition, pregnancy, or immune suppression.

The responsibility for the administration of these requirements is as follows:

Personnel	Responsible Official
(b)(4) employees	(b)(4) Director of Laboratory Animal Resources
Laboratory technicians	Principal Investigator
PIs	Division Director

Records for CDC staff and records for services provided to contract personnel are maintained in an electronic medical records database. OSSAM or the SOHS records medical clearances, immunizations, and surveillance activities into this database. Requirements can be pre-determined by supervisors based on individual needs. E-mail reminders of health, safety, and immunization requirements are automatically sent to workers and their supervisor.

In addition to prevention services, each employee is monitored for illness, instructed to report all incidents and accidents promptly, and has access to safety and occupational health personnel at all times. Incidents and hazard concerns can be reported anonymously if desired.

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.

Personnel that may be exposed to a hazardous agent have access to the Occupational Health Nurse during the week from 8:00 AM to 4:30 PM.

For after-hours emergencies, a process was developed with the local medical center's director of emergency services for handling exposed employees. If there is an inadvertent exposure, employees are to go directly to Poudre Valley Hospital emergency department and announce that they have had an exposure to "X" organism. They are then conducted to a special set-aside room where they are to be promptly seen by an emergency department physician. An "MSDS"-like binder was developed with all the agents used here, which includes diagnosis and treatment recommendations for all of them. The binder is kept in that room. There is also easy access to the web so that additional information could be obtained from the CDC or elsewhere, if needed.

Contractors are to go to their contract occupational healthcare providers. In emergencies, they are to go to the hospital emergency department.

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., nonhuman primates, agricultural animals),
- other considerations regarding occupational health and safety.

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

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

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

Required core training for all CDC-DVBD animal facility personnel include the following courses provided by OSSAM and Comparative Medicine Branch:

i. Survival Safety Skills – General Responsibilities
ii. Hazardous Material Handling
iii. Hazardous Chemical Waste Management
iv. Respirator Fit-Testing and Training
v. Laboratory Waste Disposal
vi. Ergonomics and Hearing Conservation
vii. Fire Safety and Proper Evacuation Procedures
viii. Exposures, First-Aid and Follow-up procedures
ix. Animal Care SOP Review

Nearly all of the training is conducted annually with some on an as needed basis.

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.

1) Work Clothing and Laundering

All DVBD employees using the animal facilities are provided with laboratory coats, disposable laboratory coats, or disposable coveralls, depending upon the area in which they are working. (b)(4) employees are required to don clean scrubs and dedicated footwear before entering the animal housing suites, animal holding/manipulation rooms, and the cage wash areas.

Additional work clothing is provided on an as needed basis for the particular project, such as disposable laboratory coats or disposable coveralls. CDC employees must wear disposable laboratory coats within the main animal rooms. All PPE must be donned in accordance with OSSAM and IACUC requirements as specified in the approved protocol. Work clothing and laboratory coats are not worn outside the specific work areas at any time.

2) Additional PPE

Additional PPE provided consists of face shields, face masks, disposable gloves, hair covers, and shoe covers. Use is based on the risk assessment conducted by the Safety Officer and as specified in the study protocol.

b) Describe arrangements for laundering work clothing.

Soiled scrubs utilized in the BSL-3 areas are autoclaved then laundered; all other soiled scrubs and lab coats are laundered by (b)(4) employees on-site in Building (b)(4)

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.

Personal Hygiene:

Proper hand washing and personal hygiene practices are described in the OSSAM general safety training course, Safety Survival Skills – General Responsibilities, which is required for all CDC workers. In addition, All DVBD employees using the animal facilities must adhere to all personal protective equipment (PPE) requirements posted for the specific work areas. Appropriate PPE items are listed and supplied for each work area, including disposable items. Specific PPE requirements are as follows:

i. All [redacted] workers must wear scrubs and dedicated non-street closed-toe footwear. Disposable gloves must be worn for handling animals. Additional work clothing is provided on an as needed basis for the particular project, such as Tyvek or disposable laboratory coats, face masks, or hair covers. Disposable items are discarded in appropriate containers. At the completion of the day, dirty work uniforms (scrubs and lab coats) are placed in a laundry bag located near the Animal Care office for laundering. Under no circumstances are laboratory coats or scrubs to be taken home for laundering.

ii. Sinks are provided in all animal areas along with restrooms on floors [redacted] There is a restroom with sinks on the [redacted] near the cage wash area. There is a sink in the dirty cage wash area.

iii. Shower and change areas are available in locker rooms on floors [redacted] and [redacted] There is a shower and locker area attached to the [redacted]

iv. Scrubs are not allowed to be worn outside of the building.

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

Personal hygiene practices established that are applicable to all CDC animal facilities include:

Eating, drinking, smoking, applying cosmetics, shaving or other similar activities that place fingers near the mouth or eyes are prohibited in the animal rooms/ areas or cage wash areas. CDC employees and animal care personnel may eat and drink in the break areas or in the office areas.

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., nonhuman primates, agricultural animals).

Procedures to Reduce the Potential for Physical Injury

Annual comprehensive health and safety surveys are conducted by the Nurse Practitioner (NP) and Safety Officer. Health questionnaires are reviewed by the NP. Work area inspections help identify hazards, the need for workplace monitoring (noise, air, chemical, and other exposures), and additional controls that may be required. A risk assessment is conducted on

new or changing work to assess for new physical hazards. All new animal use protocols are reviewed for any additional potential worker hazards by the Safety Officer.
Routine safety reviews of work areas are conducted by [redacted] animal care employees to identify physical hazards.
Biosafety cabinets are the main form of engineering control for biosafety. These cabinets are re-certified yearly. PAPRs are provided for those personnel as needed. Anesthetic scavenging systems such as charcoal canisters are utilized.

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

The most likely sources of allergens are from mice and rabbits utilized at DVBD. Facility features, equipment and procedures utilized to decrease exposure to these potential allergens consist of:

- The HVAC system provides fresh room air and does not recirculate air, thus further decreasing allergen exposure.
- Use of biosafety cabinets
- Mice are housed mainly in individually ventilated caging.
- Cage changes are conducted in a ventilated cage change station.
- A medical surveillance program is in place and requires annual updates.
- Personnel are encouraged to wear respiratory protection as a preventative measure to decrease allergen exposure.
- The use of gloves is required for handling animals.
- Use of laboratory coats or coveralls over street clothes is required

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

Exposure to zoonotic pathogens at DVBD is unlikely. The animals used here are obtained from commercial suppliers who provide information as to health status of their breeding stock. Facility design features that minimize possible exposure consist of the use of individually ventilated mouse caging, biosafety cabinets, and ventilated cage change stations. The ALL courses "Introduction to [species]" such as mice and rabbits provide information regarding possible zoonotic pathogens that non-SPF animals may harbor.

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

Biosafety cabinets are the main form of engineering control for biosafety. These cabinets are re-certified yearly. PAPRs are provided for those personnel as needed. Anesthetic scavenging systems such as charcoal canisters are utilized and replaced as needed.

e) Respiratory Protection

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

The need for respiratory protection is determined by the Safety Officer after conducting a risk assessment with the individual or the PI overseeing the laboratory.

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

If respiratory protection is needed as determined by the risk assessment, each individual may undergo respiratory clearance by the Occupational Health Clinic. Fit testing is performed initially and annually thereafter for any individual in which the protocol risk assessment has deemed respiratory protection a required safety measure in order to work within the protocol.

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

The Safety Officer determines the most appropriate respiratory protective equipment on an individual basis. All individuals enrolled in the respiratory program are tested annually by quantitative fit testing using a PortaCount Pro+™. This ensures the respirator is functioning appropriately for the individual.

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).

In the DVBD animal facility, there is one rack washer and one tunnel washer. SOPs are in place describing use of each. Prior to use, each person must read the SOP and then undergo training until deemed proficient. The SOP includes descriptions of safety features of the washers. The training is documented in that person's training file. There are 2 bulk autoclaves, one on each floor of the animal facility. There is an SOP for their use which includes a description of the safety features. Each person is trained on the use and safety features of the autoclave and training is documented. For each autoclave, a sign describing emergency shut off procedures is located near the emergency shut off.

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.

No heavy equipment such as farm machinery is used at DVBD.

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.

Motorized vehicles are generally not used in animal transport. On occasion, when a delivery is made to the Main Gate, an animal care technician will drive a temperature-controlled cart to the gate to pick up the animals and take them to the loading dock. The cart is disinfected before and after use.

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

Calibrated vaporizers (checked yearly) are used to provide anesthesia to laboratory animals. Vet-Equip SB-1209 evacuator with CX-R and vented induction chamber units utilize charcoal canisters for scavenging waste anesthetic gases. Canisters are replaced as needed.

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.

Hazardous Agents Currently Used in Animal Research:

Biologic agents—Live, dead, attenuated, antigens, and clones of bacterial and viral agents are used in animal research at DVBD. Bacterial agents include species of the genus *Borrelia* (BSL2) and *Bartonella* (BSL2). Arboviral agents include all members of the genus Alphavirus (BSL 2 and BSL3) and Flavivirus (BSL 2 and BSL3) and family Bunyaviridae (BSL 2 and BSL3).

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

No chemical agents are used experimentally at DVBD.

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

No physical agents such as radiation, UV light, magnetic fields, lasers, etc. are utilized at DVBD.

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.

During protocol development, the PI confers with the Safety Officer to identify and evaluate possible hazards that may be encountered. The protocol form has sections identifying infectious agents to be used along with a section for human biosafety. This review is conducted prior to IACUC review of the protocol. The protocol form contains an assurance page where the PI either obtains the signature of the Safety Officer or a date when the Safety Officer provided their approval. The IACUC then reviews the experimental protocol form as described elsewhere in this document.

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

The Safety Officer reviews the experimental protocol and in conjunction with the PI, identifies and assists in the implementation of appropriate methods to manage risks. The Safety Officer is responsible for implementing the appropriate safety and containment procedures based on the review of the protocol. The IACUC reviews the experimental protocol form as described elsewhere in this document.

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.

All biological waste from the clean insectary, experimental insectary and the vivarium areas of the animal facility is autoclaved at 121.5 C at 18 psi for 60 minutes. This includes carcasses, bedding, cages, infectious sharps, and any other items that require sterilization prior to disposal or re-use. No radioactive material is used at DVBD. Once carcasses are autoclaved, they are frozen until incinerated.

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

The biological and individual risk assessment forms along with the medical evaluation form identify the hazardous agents that each individual may potentially be exposed.

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.

Each PI is responsible for the training of their protocol associates for the use of hazardous agents in animals. This training includes proper animal handling and safely handling of the infectious agents. Use of appropriate PPE and engineering controls is provided by didactic and hand-on training by the PI and/or Safety Officer.

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)(7)(E)

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.

All experimental animal use at DVBD is conducted within the designated animal facility. Animals are not allowed in any other laboratories outside of the containment facilities.

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

All primary containment engineering, (biological safety cabinets, individually ventilated animal cages), controls are certified annually to ensure they are meeting the safety standards established by the manufacturer.

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

Each animal use protocol contains a section where PPE and safety precautions are described. In addition, in the anterooms of each animal suite there is a placard that identifies the agents in use and the PPE required for entry into the room. Animal care staff that provide husbandry are to wear the specific PPE when entering the rooms. If the animal work involves hazardous agents, the animals are housed in individual ventilated caging. Cage changing stations or BSCs are used during cage change-outs.

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.

DVBD does not conduct on-site human-based research.

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.

(b)(7)(E)

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.

The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five

members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. The membership roster is in Appendix 7 and lists the chairperson and members of the IACUC with their names, degrees, profession, titles or specialties, and institutional affiliations.

Committee membership appointment procedures are as follows: Individuals are identified for appointment to the Committee by recommendations from the Division Director, activity Chief, or current committee members. Names of nominees are forwarded to the IO who then appoints members based on those recommendations. The DVBD Charter provides guidance on the constitution of the IACUC with members representing both branches of DVBD, ADB and BDB.

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

The DVBD IACUC meets approximately once a month.

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

New IACUC members are required to complete the following online training courses within 60 days of appointment (available from the American Association for Laboratory Animal Science [AALAS] Learning Library [ALL]):

- Essentials for IACUC Members
- Introduction to Research Animal Methodologies (choose the appropriate animal species from the list of available courses – usually mice)
- Common Compliance Issues

Within one year of appointment to the Committee, members must attend the course "IACUC 101" or other similar course.

It is recommended that committee members also take the following courses (not limited to) on the ALL:

- The Semi-Annual Facility Inspection
- Working with the IACUC

Copies of the Guide, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the ARENA/OLAW Institutional Animal Care and Use Committee Guidebook, Animal Welfare Act and Animal Welfare Regulations, and other pertinent publications (AVMA Guidelines for Euthanasia, etc.) are provided to each member. A list of helpful websites is also provided.

New members receive consultation with other IACUC members, the IACUC Chair, IACUC Administrator, and the AV, as appropriate.

Additional education is provided at meetings if the form of pertinent articles which are discussed as applicable. New guidelines, regulations, etc. are provided to the IACUC as they become available.

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.

In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications (to secure approval), or withhold approval of PHS-supported activities (protocol) related to the care and use of animals. The IACUC procedures for protocol review are as follows:

a. The principal investigator (PI) submits the protocol electronically to the IACUC electronic mailbox after it has been reviewed and approved by their supervisor and branch chief for scientific merit.

b. All protocols are previewed by the AV, the Safety and Occupational Health Specialist, and a staff biostatistician. The biostatistician consults with the PI and provides input in the study design and justification for number of animals requested in the protocol. The Fort Collins IACUC Administrator reviews the protocol for completeness and compliance with policies, guidelines and regulations. The protocol may be returned to the PI to address items prior to being forwarded to the IACUC for review.

c. Protocols involving USDA-covered species or USDA Category E must receive full committee review.

d. If full committee review is required or requested for a protocol, or if the IACUC Chair determines that full committee review is preferable, approval of that protocol may be granted only after review, at a meeting of a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member with a conflicting interest (e.g., personal involvement in the activity) may participate in the review or approval of the activity, except to provide information requested by

the IACUC; furthermore, a member with conflicting interest may not contribute to constitution of a quorum.

e. Protocols eligible for designated review are sent via e-mail to IACUC members for review providing the opportunity to call for full committee review. If full committee review is not requested within 5 business days of notification, the IACUC Chair may (at his/her discretion) designate a subcommittee of one or more qualified reviewers with authority to approve and/or require modifications (to secure approval). The subcommittee decision must be unanimous. The subcommittee does not have the authority to disapprove a protocol, but must request a full committee review if approval agreement cannot be reached.

f. The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not vote with the IACUC unless they are also members of the IACUC.

g. The IACUC notifies principal investigators in writing via e-mail of its decision to approve or withhold approval of activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it will include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing.

IACUC Mechanism for Reviewing Protocols

a. The IACUC conducts a review of each protocol to assure that the proposed activities are in accordance with all laws, polices, and guidelines unless acceptable justification for a departure is presented in writing.

b. The IACUC ensures that the proposed activities or significant changes in ongoing activities meet the following requirements:

i. Procedures involving animals avoid or minimize discomfort, distress, and pain to the animals.

ii. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources (e.g., the Animal Welfare Information Center) used to determine that alternatives were not available.

iii. The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments.

iv. Procedures that may cause more than momentary or slight pain or distress to the animals are performed with appropriate sedatives, analgesics, or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time.

v. The use of procedures that may cause more than momentary or slight pain or distress to the animals are required to be discussed with the attending veterinarian or a designee.

vi. Procedures that may cause more than momentary or slight pain or distress to the animals do not include the use of paralytics without anesthesia.

vii. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved are painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

viii. The animals' living conditions are appropriate for their species, in accordance with Part 3 of CFR Title 9, Chapter 1, Subchapter A, and will contribute to their health and comfort.

ix. The protocol form includes a number of questions for the PI to explain the purpose of the proposed research such as 1) the rationale for the use of animals; 2) how the proposed research will benefit science, medicine, or society in general; and 3) the justification for the use of animals, the procedures utilized, and if in vitro work has been done to decrease the number of animals to be used. The IACUC weighs these responses when determining harm-benefit of the proposed research.

x. The housing, feeding, and non-medical care of the animals are directed by an attending veterinarian trained and experienced in the proper care, handling, and use of the species being maintained or studied.

xi. Medical care for animals is available and provided as necessary by a qualified veterinarian.

xii. Personnel conducting procedures on the species being maintained or studied are appropriately qualified and trained in those procedures.

xiii. Death as an experimental endpoint is not acceptable.

xiv. Methods of euthanasia used are in accordance with the definition of the term set forth in 9 CFR Part 1, Sec. 1.1 of the USDA regulations and in accordance with the current version of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia and DVBD IACUC Policy 16, unless a deviation is justified for scientific reasons, in writing, by the investigator, and approved by the IACUC.

Although currently rarely performed, proposals involving surgical procedures would be reviewed as follows:

i. Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. The AV is consulted during the protocol development process and to assure personnel performing the procedures are appropriately trained.

ii. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques.

iii. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose, which shall be operated and maintained under aseptic conditions.

iv. Non-major operative procedures and any rodent surgeries do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures.

v. 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.

vi. No animal will be used in more than one major operative procedure from which it is allowed to recover, unless required as routine veterinary procedure or to protect the health or well-being of the animal, as determined by the attending veterinarian.

c. Protocols reviewed by full committee are approved by a majority vote of a properly constituted quorum of the IACUC. IACUC members having a potential conflict of interest may neither vote on a proposal nor be counted in the number of members needed to constitute a quorum. The IACUC may determine by majority vote that a proposal may be approved if minor administrative changes are made. In such cases, the IACUC may delegate to the Chair or IACUC Administrator (CDC-DVBD) the authority to grant final approval after assuring that all required changes have been made. The date of approval by the IACUC (approval form signed by the Chair or alternate chair) shall be considered the beginning date of the approved protocol.

d. New protocols and proposed significant changes in ongoing protocols that have been approved by the IACUC may be subject to further appropriate review and approval by CDC officials, such as branch chiefs, division directors, and national center directors. However, those officials may not approve an activity involving the care and use of animals if it has not been approved (or has been disapproved) by the IACUC.

e. Except as specifically authorized by law or regulations, nothing in this part shall be deemed to permit the IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by investigators. The IACUC does not review the scientific merit of the proposal, but can consider the scientific methods as they relate to appropriate use of animal numbers (statistical groups) or validity of the questions proposed. However, the IACUC, including the nonscientist and nonaffiliated members, must be able to understand the scientific rationale for the protocol.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes (amendments) regarding the use of animals in ongoing activities as set forth in the PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

a. Requests for modification are submitted electronically to the IACUC electronic mailbox.

b. The IACUC requires submission of a modification for any minor or major changes to an active protocol.

c. Modification for minor changes requires review by the Fort Collins IACUC Administrator or a designated subcommittee and may include: a) less than or equal to a 10% increase in the number of rodents (bred for research), b) change in associates, other than PI, c) change in sex of animal to be used or d) change in contact information for the PI or associates.

d. Major changes require full committee consideration and may include: a) change in pain or distress category; b) change in procedures; c) change in scope or objective; and d) change in species, e) change in PI.

e. Major changes to protocols are handled as described above for new protocols undergoing designated member review.

f. Significant (major) changes to a protocol that can undergo the VVC process are as follows:

1) Change in analgesic or dose (must be one of approved drugs as listed in protocol form)

2) Change in anesthetic or dose (must be one of the approved drugs as listed in protocol form)

3) Addition of blood collection intervals (must be within blood collection guidelines as listed in protocol form).

The process for VVC is as follows:

1) If the PI has an immediate need for one of the VVC changes listed above, they are to contact the Attending Veterinarian or the Alternate AV by e-mail or telephone.
The request is discussed and documented in an e-mail by the veterinarian and sent to (b)(6)
The PI then submits a protocol amendment the next business day to (b)(6) The amendment is then approved administratively.

2) If the PI knows a day or two in advance that one of the allowed VVC changes is needed, they must send via email, a protocol amendment to either (b)(6) or (b)(6) and (b)(6) The veterinarian will review the amendment and either approve or request changes, copying (b)(6) on all correspondence.

8. Investigators are notified in writing of the IACUC's decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The Committee notifies principal investigators in writing via e-mail of its decision to approve or withhold approval of a protocol involving the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of a protocol, it includes in its written notification a statement of the reasons for its decision and will give the principal investigator an opportunity to respond in person or in writing. DVBD IACUC Administrator prepares a summary report for review and approval by the IACUC Chair to provide to the Institutional Official on a semi-annual basis that lists all IACUC decisions regarding protocol review since the previous reporting period. This report is included with the report for the semi-annual facility inspection and program review.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

a. Animal research protocols are approved for 3 years and reviewed annually by the IACUC. There are no automatic renewals without IACUC review. For all animal studies that continue beyond the three-year approval period, a new protocol must be submitted by the principal investigator and approved by the IACUC prior to expiration of the previous protocol in order for the research to continue. Principal investigators receive an e-mail notification prior to the annual IACUC review date for their approved protocols with instructions to complete a supplemental annual review questionnaire that is reviewed by the IACUC or designated subcommittee along with the IACUC Administrator (completeness of form).

b. As an adjunct measure supplementing annual review of approved protocols, the IACUC has instituted a Post-Approval Monitoring (PAM) Program to strengthen its capabilities to ensure that the animal care and use program is meeting the highest standards of animal welfare. PAM audits of approved protocols and visits of areas where animal activities occur are done by the IACUC Administrator (CDC-DVBD) who provides periodic reports of PAM visit observations to the IACUC and ACUPO Chief.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a

majority of the quorum present. The IACUC may consult with the IO or the DVBD Director to determine corrective actions and inform the investigator and IO in writing of the mandated corrective actions and status of study. Any suspension actions will be reported with a full explanation to OLAW. If at any time, the AV feels animal welfare is compromised, he/she has the authority to immediately restrict further research and request IACUC review of the situation.

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.

The same process for review/approval of protocols is used for amendments. Major and minor amendments are described in an IACUC policy. Major amendments consist of change in pain/distress category, change in procedure(s), change in scope or objective, change in species, change in principal investigator, greater than 10% increase in rodents (bred for research), and any increase in the number of non-rodent species. Minor amendments consist of personnel (other than the principal investigator) changes, change in contact information, less than or equal to a 10% increase in rodent numbers, and change in sex of animals to be used. Significant (major) changes to a protocol that can undergo the VVC process are as follows: 1) Change in analgesic or dose (must be one of approved drugs as listed in protocol form); 2) Change in anesthetic or dose (must be one of the approved drugs as listed in protocol form); and 3) Addition of blood collection intervals (must be within blood collection guidelines as listed in protocol form).

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 DVBD IACUC Policy 019 Endpoints in Animal Use Protocols and Response to Unexpected Morbidity and Mortality provides guidance on determining experimental (humane) endpoints. This policy describes necessary animal care and monitoring procedures to ensure early termination of painful or distressful procedures; and describes appropriate response to unexpected morbidity. Humane endpoints are also part of the veterinary consultation during protocol development.

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).

The DVBD IACUC protocol form has sections that prompt the PI to consider humane endpoints and procedures that will be followed in the event that alternatives are not available. The PI identifies the procedures that will cause pain, discomfort and/or distress and provides information on how they will be relieved. If analgesics, anesthetics, etc. cannot be used for relief, the PI must provide justification. The PI must also provide justification for the use of those procedures that may cause increased pain/distress. DVBD IACUC Policy 019 provides guidance on increased monitoring of animals that may undergo unrelieved pain/distress such as with infectious disease studies or vaccine challenge studies. The AV is available to provide guidance. Pilot studies may be also be conducted.

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 PI and protocol associates are responsible for monitoring animals for pain/distress. The PI is responsible for training of the key associates to identify species-specific signs of pain and distress. Recognition of pain and distress is part of the ALL courses for individual species. Animal care personnel are also trained to recognize pain and distress in the species utilized at DVBD.

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 the event of unexpected occurrences, the animal care project lead, AV, PI, IACUC Chair, and IACUC Administrator are notified. Protocols that may incur unexpected outcomes are required to incorporate increased monitoring of animals by the investigators. IACUC Policy 019 provides guidance to the investigators regarding unexpected occurrences and how to increase animal monitoring. Unexpected mortality is investigated by the Compliance Officer and reported to the IACUC. The PI reports unexpected morbidity to the Chair, Compliance Officer and AV, which is reported to the IACUC at the next convened meeting.

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."

Prolonged physical restraint is generally not utilized at DVBD. The IACUC has adopted a policy on the use of physical restraint should the need arise. There is one protocol that utilizes a sling for mice used during flea feeding, however the mice are anesthetized during this procedure and once completed, are euthanized without recovering from anesthesia.

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.

A sling is utilized for mice during the flea feeding procedure. The mouse is anesthetized and placed in the sling for approximately 1 hour to allow flea feeding. They are not allowed to recover from anesthesia by being euthanized (see 2 above).
Rabbits may be restrained for a short period of time in a rabbit restrainer for procedures such as blood collection and injections.

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.

Surgical procedures are rarely conducted at DVBD however IACUC policy 013 is in place should a protocol potentially be submitted involving multiple survival surgeries.

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.

Currently there are no protocols in place that allow multiple major survival surgeries.

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.

Currently, there are no experimental situations requiring food and/or fluid regulation. The IACUC has adopted a policy (012) on food or fluid restriction should the need arise.

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 use of non-pharmaceutical grade substances is allowed only when adequate scientific justification is provided in the protocol and as approved by the IACUC and Attending Veterinarian. In general it is not permitted unless a pharmaceutical equivalent is not available. DVBD IACUC developed Policy 027 Guidelines for the use of non-pharmaceutical grade ibuprofen salt in water for mice. This policy is very specific and was developed to assist with the safety of the investigators to minimize handling of infected mice. Under no circumstances are non-pharmaceutical grade anesthetics or analgesics used.

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.

DVBD has approximately 5 active protocols involving field investigations utilizing various mammals. The IACUC has multiple members that have conducted field investigations and are well versed in the procedures utilized. In addition, the IACUC utilizes the Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research (2016) and the Guidelines from the Ornithological Council – Guidelines to the use of Wild Birds in Research (3rd Ed. 2010). The Safety Officer is contacted by the PI during protocol development to assure all safety precautions are employed during the field investigation.

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

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

Currently, there are no protocols approved for re-use of animals in experimental protocols. If a protocol were to be submitted that involved animal re-use, the IACUC would carefully weigh the procedures and justifications presented.

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.

Currently there are no protocols approved for the re-use of individual animals in experimental protocols.

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.

Adoption, re-homing, etc. are not allowed at DVBD as the majority of the animals are used in infectious disease research.

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).

Protocols are approved for a 3-year period. At the end of 3 years, the principal investigator must submitted a completely new protocol (assigned a new number by the DVBD ACUPO office) for review and approval in order for any work to continue.

Annual administrative review of all active protocols is conducted at the close of each fiscal year. PIs are provided with a form to supply information on the number of animals used by pain category. Justification for USDA category E pain and distress during the last fiscal year is requested. In addition they describe any changes in personnel, changes in procedures and pain or distress, new developments that might influence a decrease or increase in the number of animals used, and unexpected outcomes since initial approval or last annual review. Reviews of the completed annual report forms are conducted by the IACUC at a convened meeting.

In addition, the DVBD IACUC has developed a policy for post-approval monitoring of ongoing studies. Each protocol is monitored at least once within the 3-year period by the DVBD IACUC Administrator/Compliance Office, and reports of the findings are provided at convened meetings of the IACUC.

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

The IACUC reviews the animal care and use program using Title 9, Chapter I, Subchapter A-Animal Welfare (USDA Regulations), the Guide along with a modified version of the OLAW check list as a basis for the evaluation. Program evaluation is conducted once every 6 months.
IACUC policies are reviewed and modified, if needed, at least once every three years or more often.

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 inspects at least once every six months, the animal facilities, including animal study areas, using Title 9, Chapter I, Subchapter A-Animal Welfare (USDA Regulations), the Guide, and a modified version of the OLAW check list as a basis for the evaluation. Inspections are conducted by at least 2 members of the IACUC escorted by an animal care technician. The AV and alternate "float" and provide assistance and respond to questions as needed.

DVBD does not utilize satellite facilities.

AV and animal care contracts (2 separate contracts) are administered by a Contract Officer's Representative (COR) along with the Comparative Medicine Branch which provides an ACLAM Diplomate for technical assistance. IACUC oversight consists of monitoring the records and animal facility during the semi-annual activities.

The IACUC receives updates on animal care from the contractor AV and the animal care project lead at the monthly meetings. The IACUC Chair is in regular communication with the AV, COR, CMB, and ACUPO through in-person meetings, phone, and email regarding animal facility operations and animal care by contract staff. The IACUC Chair also performs monthly walk-throughs of the animal facility with the IACUC Administrator/Compliance Officer.

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.

According to USDA Regulations, DVBD is exempt from USDA inspection as it is a Federal research facility.

OLAW conducted a site visit on September 21, 2017. OLAW identified some items where additional information and clarification was requested. These items (with responses in italics) are listed here:

1. Review and update the language for the process of DMR subsequent to FCR in the DVBD IACUC policy to be consistent with approved Assurance document and with OLAW guidance.
   Policy 020 was modified to reflect this and an e-mail consensus was obtained from all IACUC members.
2. Update the Reporting of Animal Welfare Concerns signage to include an option for anonymous reporting.
   Signage was modified to include the new e-mail address for anonymous reporting.
3. A BSC in one animal room was cluttered.
   PI was contacted and clutter removed and cabinet cleaned.
4. An activated charcoal canister did not appear to be being weighed to determine when to replace.
   Reminder sent to all PIs and associates using the canisters to weigh before/after use and replace when indicated.
5. Section III.G of approved Assurance should be modified in the next Assurance renewal to describe training to minimize the number of animals utilized and minimize animal distress.

PI's are required to obtain input from a statistician prior to IACUC review of new animal use proposals. This review provides assistance to the PI to optimize the number of animals needed for the goal(s) of the protocol. The AV provides guidance on the use of animals and methods to minimize animal distress to PIs, associates, and animal care staff.

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

Periodic meetings of the IACUC Chair, IACUC Administrator, AV, animal care project lead, representative from the DVBD Office of the Director, and facility engineer are held periodically (monthly or more frequently depending on any issues that need attention) in order to further monitor the animal care and use program.

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

The IACUC procedures for reviewing animal welfare concerns are as follows:

a. Any individual with concerns involving animal care and use within the facility are invited to respond directly –anonymously or otherwise- to the DVBD IACUC Chairperson, IACUC Administrator, Attending Veterinarian, or to the IO directly. An anonymous e-mail box is also available for reporting concerns.

b. Reported concerns are included on the next IACUC meeting agenda for discussion. Concerns are investigated by the Compliance Officer prior to the meeting and a preliminary report generated. If a formal response is necessary, a letter on behalf of the IACUC Chairperson is sent to the individual outlining steps for resolution.

c. Once the report is received, investigated, and reviewed by the IACUC, it is forwarded to the IO, Dr. Steve Monroe, with a copy to the DVBD Director, DVBD Associate Director for Science, and DVBD Associate Director for Laboratory Science.

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.

DVBD has an Animal Disaster Plan that covers various scenarios such as power outages, fire, flood, etc. and is integrated with the overall DVBD Occupant Emergency Program (OEP). Response participation depends on the type of emergency. In a disaster, the safety of DVBD personnel are the priority. The overall DVBD OEP is followed with participation from the DVBD Office of the Director, Safety, Security, Occupational Health, DVBD-ACUPO, AV, and animal care as applicable. Animal care staff assures that food and water are available to all animals when possible without compromising their safety.

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.

The building is designed to minimize facility maintenance work in animal housing areas. Each animal floor is serviced by a full story interstitial level above and below and a two-story mechanical room for the air handling units (AHU) and associated mechanical equipment. All duct work, reheat coils, HEPA Filters, and control devices can be accessed from the mechanical room or the interstitial levels minimizing facility work in animal housing areas.

Air for the entire building (100% outside air) is cooled as it enters the main air handling system. Animal housing suites have a dedicated supply and exhaust airflow control device to maintain directional air flow, a hot water reheat coil to maintain temperature, and a temperature and humidity transmitter to maintain temperature and humidity at desired set points within the range of values given in Table 3.1 in the Guide. Environmental parameters are set using the building's central computer system. Temperature, humidity, and air flow is recorded every 15 minutes by a central facility monitoring system. Temperature and humidity transmitters are calibrated annually.

Readings that exceed assigned set points activate an alarm that notifies the Facilities Management and Engineering Office (FMEO) and pages responsible [redacted] personnel. The [redacted] project lead monitors daily reports of room temperature and humidity for the animal facility, and animal care employees check the local cubicle and/or room temperature and humidity daily using wall-mounted, non-powered temperature and humidity gauges. Readings are recorded on the room check sheet located outside each animal cubicle as a cross-check of the temperature monitoring system. Out of range readings for temperature and humidity are reported to the animal care project lead and FMEO.

Environmental parameters (including HVAC) are provided in Appendix 11. A recent temperature and humidity report is provided as Appendix 11.

No outdoor housing is utilized at DVBD.

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]

Room temperatures for mice are kept at 68-79°F and rabbits are kept at 61-72°F. Relative humidity is kept at 30-70% as described in The Guide Table 3.1.

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]

Macro environment temperature readings that exceed assigned set points activate an alarm that notifies the Facilities Management and Engineering Office (FMEO) and pages responsible [redacted] personnel, as noted above.
Enabling of thermoregulation for mice is accomplished by group housing along with provision of mouse huts and/or nesting material.
IACUC-approved exceptions consist of protocols where ticks are fed on mice. Mice are individually housed for tick feeds so that cage mates do not groom-off the ticks. The mice are housed on a wire grate for approximately 4-5 days during the tick feeds so that replete ticks fall off into a small amount of water in the bottom of the cage for collection. During the tick feeds, a petri dish platform and a hut are provided for comfort.

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.

1) Pressurization

Airflow is based on 100% outside air that is exhausted after a single pass. Vivarium spaces are negatively pressurized by means of offset controls to maintain a 15% difference between exhaust and supply air. The minimum offset for all spaces is 150 CFM. SPF barrier suite is positively pressurized by means of offset controls. All animal holding spaces are designed with a minimum of 10 air changes per hour.

2) Air Systems

Vivarium spaces are served by dedicated air handling units and exhaust fans that serve only that floor. All central station air moving equipment is sized with a 25% safety factor to accommodate system leakage and future growth. All vivarium supply and exhaust systems have N+1 redundancy.

3) Ductwork

No ductwork, piping, or other mechanical equipment is exposed in the vivarium.

4) Air Distribution Devices

All supply air diffusers in small rooms are radial flow diffusers to prevent supply air from interfering with primary containment devices, such as biological safety cabinets. Air diffusers in large rooms are perforated face diffusers. Exhaust registers and grilles are the perforated type when mounted in the ceiling or fixed blade type when mounted vertically. Connections to biological safety cabinets (BCS) are thimble type to prevent the building mechanical system operation from interfering with the BSC operation. Animal holding rooms are provided with pre-filters in the exhaust registers and grilles. High humidity spaces are provided with air distribution devices constructed of stainless steel. Air supply and exhaust systems undergo yearly calibration.

5) Filtration

HEPA filters are located on the exhaust of the enhanced BSL3 vivarium spaces. Filters are located as close as possible to the space to minimize the amount of contaminated ductwork. HEPA filters are sized for a maximum of 250 feet per minute face velocity and have the following components:

- Upstream bioseal damper.
- Upstream DOP/Decontamination port.
- Mixing/test section.
- HEPA filter section.
- Scan section.
- Downstream DOP/Decontamination port.
- Downstream bioseal damper

6) Controls

A dedicated front-end station is provided to trend data from the animal holding rooms. The following points are actively monitored by the system:

- Space temperature.
- Space humidity level.
- Lighting (on/off).
- Space air flow.

Airflow control is based on two-position tracking. Each vivarium space is provided with dedicated supply and exhaust airflow control devices and a hot water reheat coil to maintain proper airflow and temperature. Animal holding rooms are provided with a differential pressure sensor/transmitter for monitoring.

Airflow (100% outside air) is exhausted after a single pass with at least 8 (ante rooms and corridors) or 10 (clean insectary, holding and manipulation rooms, and animal housing suites) air changes per hour. Environmental parameters are provided in Appendix 11. A recent air balancing report is provided in Appendix 11.

Ventilation of Special Primary Enclosures

Negative or positive pressure is maintained by offset controls and monitored continuously with a differential pressure sensor/transmitter. Air differential (positive/negative) is continually monitored by facility engineers. Facility computers alarm FMEO engineers when directional air flow is breached and FMEO engineers immediately investigate alarms and correct deficiencies.

The air flow, directional pressure, temperature, and humidity in individual animal cubicles is programmed, but not monitored, by the main facility computer system (sensors for each cubicle were not included in the final building design). However, the flow transmitters are calibrated annually. During the calibration process the actual air changes are measured and compared to the air changes monitored by the computer system as a double check during the instrument calibration process. Proper directional airflow is visually monitored and temperature and humidity are recorded daily as [redacted] animal care technicians check each animal room and cubicle. Temperature and humidity are manually recorded daily from individual monitors placed in each cubicle. Air flow is monitored using paper strips attached to the animal room and cubicle doors. The air flow strips flow inward towards the animal housing areas (negative air flow relative to the hallway) throughout the facility, except for the SPF barrier suite. The SPF barrier suite that houses the facility's SPF breeding colonies is maintained under positive air flow relative to the hallway. Normal airstrip flow is observed daily and deficiencies are immediately reported to the [redacted] project lead or the AV who contacts FMEO for corrective action. [redacted] animal care staff clean air grilles and keep them free of dust, dirt, hair, and other particulates. This is done weekly in mouse rooms and three times weekly in rabbit rooms. Filters for the intake air handling units and exhaust

units are changed quarterly by animal care personnel. FMEO is also contacted to conduct periodic instrument checks and maintenance of the air handling system. Documentation of testing and results is provided and maintained by FMEO.

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

Primary enclosures that use forced ventilation consist of the Tecniplast IsoCage® microisolator IVC with hermetically-sealed lid, 'U-Temp™ cage body and plastic top with soft silicone gasket, two spring loaded valves, cage pre-filter + cage HEPA filter with retainer, two lid-to-cage clamps, stainless steel (SS) feeder lid with welded divider is used for mice, and the Allentown ventilated rabbit/ferret cage rack, 4 cages per rack is used for individually housing rabbits under negative pressure, HEPA filter air exhaust; SS rack and cage construction, wash-through design with electropolished doors and floors, removable perforated floors, removable rod design doors, J-type feeder 4 1/2" wide, stackable tapered SS excreta pans, individual cage filters, exhaust pre-filter.

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.

No recycled air is used in the animal facility. Ventilated cage racks are deployed in cubicles and suites when needed to support individual protocols. Ventilated rodent racks feature HEPA-filtered supply and exhaust, while ventilated rabbit racks feature HEPA-filtered exhaust. Proper airflow is indicated on each ventilated rack by gauges on the plenum. HEPA filters are changed as needed (as indicated by gauge readings or time-of-active-use log) and new HEPA filters are certified by the SOHS before they are put into use.

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

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

Aquatic species are not utilized at DVBD.

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).

Aquatic species are not utilized at DVBD.

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.

1) Design Features to Control Noise
The HVAC system was designed to provide an NC (Noise Criteria) rating of about NC30 in all rooms. The NC30 sound pressure levels range from below 30 dB at 8000 hz to about 57 dB at 63 hz, below the 85 dB threshold indicated in the manual. Any large rotating and vibrating HVAC equipment is located either on the roof or in mechanical rooms, isolated by distance from the animal rooms. Noise and vibration is diminished by the inverse of the square of the distance from the source. Any construction activities located in the mezzanine spaces above each animal room floor is restricted to no or low vibration and noise activities. Mezzanine spaces above the animal rooms are constructed using concrete floors that will minimize transmission of noise and vibration to the animal rooms. All animal housing areas are separated from noise-producing areas, including cage wash and facilities equipment areas.

2) Background Noise
Background noise (e.g., tapes, radio) is not currently used in animal rooms, except for in the SPF barrier suite where a local country music station plays on a radio during daily health checks and servicing of the suite.

No ductwork, piping, or other mechanical equipment is exposed in the vivarium.

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 IACUC utilizes the Guide to assure that all animals housed are provided with adequate space.
1) Primary Enclosures
(a) All rabbits are single-housed such that they can view, smell and hear conspecifics. Rabbits are housed in stainless steel caging with wire bar doors and stainless steel or (b)(4) tray flooring ((b)(4) cages). These cages feature removable wall panels between adjacent cages to allow large shared housing areas.

During arthropod feedings, rabbits are individually housed in [redacted] Housing units which feature sealed, gasketed doors and a rack-mounted HEPA-filtered exhaust air system to maintain the cages under negative pressure while in use. Arthropod containment screening is utilized over supply vent openings to ensure containment of arthropods during feeding sessions. All rabbit cages feature detachable stainless steel feeders, and each cage is equipped to hold a one quart water bottle, with multiple water bottles used on shared/co-joined cages. The [redacted] cages feature fixed multi-level perching shelves, and removable, sanitizable huts. Manipulanda are provided in all cages, along with scheduled provision of edible enrichment treats (e.g., hay, vegetables).

(b) Rodents are group-housed in micro-isolator (MI) cages of various types, with covered, ventilated cages (for most studies) or generic, non-covered, non-ventilated cages (for occasional use when appropriate). Most covered, [redacted] cages are [redacted] Cages. [redacted] MI cages are used in the SPF barrier suite [redacted] are used selectively for work with arthropods, certain infectious agents, and for select quarantine or isolation applications. Mice may be individually housed if required by IACUC-approved protocol. All rodent MI caging is manufactured of high-temperature, polycarbonate with solid flooring. Generic and [redacted] cages feature use of wire top lids to hold feed and a water bottle or [redacted] water bag, while the [redacted] and [redacted] feature specialized feed and water bottle/bag holding inserts or modifications to the lid. All rodents are provided food and water for ad-libitum feeding and drinking, and all are routinely housed on [redacted] enrichment bedding, except during periods of active arthropod exposure or as described in an IACUC-approved protocol. During arthropod exposure, mice are individually housed within [redacted] that feature a raised wire-bottom cage insert. The wire-bar inserts allow survival of arthropods that detach from the animal after feeding. The water in the cages is changed daily during which time detached arthropods are collected. The mice on tick feeds are provided a petri dish and hut. All rodents are provided with huts and exercise wheels, or paperboard tubes in addition to the shredded cellulose nest-making material contained within the [redacted] enrichment bedding material.

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]

The IACUC utilizes the Guide to verify adequacy of space for the species utilized at DVBD. An exception has been granted by the IACUC for single-housing of female mice with litters. At approximately day 14 after breeding, female mice are single-housed until the pups are weaned (21 days of age). After weaning, the female mice are group housed and the pups separated by sex are group housed.
Mice on tick feeding protocols are allowed to be single-housed during tick feeding to prevent cage mates from grooming off the attached ticks

Rabbits on tick feeding protocols are allowed to be single-housed during tick feeding in ventilated caging. The rabbits are provided additional human contact during this time.

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).

Rabbits are provided with resting boards and cage toys along with hay. They are housed to be within site, sound and smell of conspecifics.

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).

1) Provisions for Species-typical Activity

Environmental and psychological enrichment for rabbits include provision of jingle balls, tin cups, and nylon chew toys. Nutritional enrichment consists mainly of hay. Rabbits that are single housed are provided with additional enrichment by increased human interactions.

Environmental and psychological enrichment for rodents include plastic igloos and exercise wheels, paperboard tubing, and enrichment bedding that includes alpha cellulose shreds, forage-able as a nesting material. Nutritional enrichment is not currently used with rodent species bred for research.

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

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

Animals utilized at DVBD are expected to be socially housed as much as possible. Interaction (presence and contact) between animal care staff and animals is encouraged to promote familiarity and to reduce animal stress when appropriate. Rabbits are single-housed with visual and auditory contact with adjacent cages and

weighed and groomed weekly by [redacted] animal care staff. Rodent species are pair- or group-housed as appropriate.

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.

Animals are individually housed when required and approved by IACUC (e.g. for some infectious disease research, arthropod feeding, and transmission studies, or when combative). When possible, individually housed animals are placed in rooms with cohorts so they can have visual, olfactory, and auditory contact with members of their species. Rabbits are provided increased human interaction.

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

In the absence of other animals for individually housed animals, interaction with humans is utilized and increased.

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.

Animals are individually housed only when required and approved by IACUC (e.g. for some infectious disease research, arthropod feeding, and transmission studies, or when combative). When possible, individually housed animals are placed in rooms with cohorts so they can have visual, olfactory, and auditory contact with members of their species. Rabbits are provided increased human interaction. The IACUC enrichment policy is reviewed at least once every three years. Yearly reports for each protocol from PIs are reviewed by the IACUC and PAM visits also provide review of protocol procedures.

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.

Procedures used at DVBD do not require habituation or training of the animals. The main procedures utilized here consist of inoculation (usually under light anesthesia or sedation), blood collections (may be conducted under light anesthesia or sedation) and observation for effects.

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).

Sheltered or outdoor housing is not present at DVBD.

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.).

Not applicable.

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.

Not applicable.

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).

Naturalistic environments are not utilized at DVBD.

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.

All species are fed commercially prepared diets. The primary vendor is (b)(4), (b)(4) extruded rodent diet (b)(4) is used for all mice. Rabbits are fed (b)(4)

(b)(4) which is supplemented with fresh hay daily and occasionally vegetables and cheerios.

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

All dry commercial animal food is kept in a storage room located on the (b)(7)(E) building [redacted] The storage room is maintained at 72°F or less. Temperature and humidity are monitored and recorded daily by [redacted] employees. Bagged feed is stored on metal racks positioned 6" away from walls with milling dates visible. Feed bags are inspected upon delivery. Outdated or broken bags are not accepted. Spills are promptly removed. Hay is purchased in 9 lb. bags from a local feed store and it is stored in the feed room.
Opened bags of animal feed within animal rooms or service areas are stored within snap-lid, lined containers for use as needed; such containers are clearly marked with a card or sheet that indicates the date the container was filled, and the expiration/discard date for the feed.

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).

No special food preparation is conducted for animals housed at DVBD.

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

Dry food is provided ad libitum to all species. Feed is placed in a feeder attached to, or inside of the animal cage. Food level and consumption is checked daily by [redacted] employees. Wire containers are utilized for mice and J-feeders for rabbits.

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

All commercial feed has the mill date easily visible on the outside of each bag. All feed is inspected upon arrival by [redacted] employees and no feed over 60 days old is accepted. No broken bags or potentially damaged or contaminated feed is accepted. Feed supplies are rotated to ensure that older stocks are used first. Mill dates are double checked when feed is dispensed from the feed room. No feed is used if 180 days past mill date. The mill date (and other vital information) is noted on animal room feed can cards to further ensure that only fresh feeds are given to animals. [redacted] employees are trained to immediately report any visualized abnormalities (e.g., moldy feed, foreign material, and beetles) to the [redacted] project lead. Feed cans are emptied at each loading so that new feed is not continually placed on top of old feed. Periodically, vendors are asked to provide definitive feed analyses on shipments of feed to substantiate contract specifications.
High levels of orderliness and sanitation are enforced to facilitate vermin control and the rooms are actively monitored as part of the building's integrated pest management program. Vermin control is coordinated by the SOHS and FMEO and contracted to a licensed commercial vendor. Pesticide applications are not allowed without prior approval of the SOHS and AV to ensure that animal feeds are not contaminated. A description of the building's integrated pest management program is available from FMEO. Reports of monthly activity are provided to the [redacted] animal care project lead.

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).

Building [redacted] water is from the local municipal supply (treated by standard methods to ensure its fitness for human consumption). Rodents and rabbits receive tap water, provided ad libitum from glass or plastic water bottles with sipper tubes or [redacted] watering system (rodents). The [redacted] system is used preferentially with ventilated MI cages housing mice, but PIs have the option to request the use of traditional water bottles. No automatic water handling systems are used.

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

Drinking water is tested quarterly to ensure that potable uncontaminated water is supplied to laboratory animals. Evaluations are performed by an outside laboratory [redacted]. Water samples are collected from all areas that house animals or provide drinking water for animal housing areas. Samples are collected in sterile 500 cc bottles and labeled with the location (building, floor, and room number), date, time sampled, and the name of the person taking the sample. Test results include total hardness (ppm), pH, heavy metals, and coliform count. If results fall outside acceptable values, re-sampling is conducted within 3 days. Further testing by the [redacted]

[redacted] may be necessary to expound on, or confirm, results. Test results are reviewed by the AV, animal care project lead, and the DVBD ACUPO office. Test results requiring corrective actions are addressed by the AV. Investigators are notified of any results that may affect research results or the health of the research animals.

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

Automatic water delivery systems are not utilized at DVBD.

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

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

A mixture of ground corn cob bedding and alpha-dri cellulose chips [redacted] [redacted] enrichment bedding) is used as contact bedding for rodents, with few IACUC-approved exceptions (e.g., arthropod feeding experiments). During arthropod exposure, mice are individually housed in [redacted] that feature a raised wire-bottom cage insert so that replete ticks fall below the grate to prevent ingestion by the mice. Paper pan liners are used as non-contact bedding for rabbits.

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

Animal bedding and feed are stored in separate, dedicated rooms on the [redacted] of building [redacted] Temperature and humidity readings are monitored and recorded daily.

High levels of orderliness and sanitation are enforced to facilitate vermin control and the rooms are actively monitored as part of the building's integrated pest management program. Vermin control is coordinated by the SOHS and FMEO and contracted to a licensed commercial vendor. Pesticide applications are not allowed without prior approval of the SOHS and AV to ensure that animal feeds are not contaminated. A description of the building's integrated pest management program is available from FMEO. Reports of monthly activity are provided to the [redacted] animal care project lead.

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

Bags of [redacted] bedding are received once a month and are visually inspected for quality, consistency, and cleanliness upon arrival. Broken bags are not accepted.

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.

Animals delivered by vendors are met at the loading dock and moved to their assigned rooms as soon as possible. For the rare occasion that a delivery cannot be made to the loading dock, animal care personnel utilize a temperature controlled motorized cart to collect the shipped animals from the vendor at the security gate and transport them to the loading dock. The vehicle is sanitized after transport to the building.

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.).

DVBD owns five HEPA-filter dry vacuums, eleven scales, 4 isoflurane anesthesia vaporizers, and one (b)(4) unit for mouse tail tattooing.

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.

Mice housed in solid bottom caging have bedding changed 1-2X/week; cage bottoms are changed out 1-2X per week, and complete cage changes are done once every 2 weeks. Rabbits are housed in caging with grid bottoms with a pan underneath that is changed 3X/week and cages are changed once every 2 weeks.

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

IACUC has not had requests for an exception in the frequency of bedding changes.

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

Cages containing soiled bedding are autoclaved upon removal from animal housing rooms/suites prior to transport through clean corridors and to the cage wash facility. Soiled bedding is removed from cages at a downdraft dumping site on the dirty side of the cage washing facility. Clean bedding is dispensed automatically or manually into cages in the clean side of the cage washing facility

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 are no current IACUC approved exceptions to sanitizing intervals.

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 tunnel cage washer and rack washer maintain final rinse temperatures at or above 180°F. Each unit is equipped with monitoring equipment which is checked by [redacted] employees twice daily. All cages and equipment are visually inspected for thoroughness of gross cleaning. Temperature-sensitive tapes are passed through the rack washer attached to caging equipment to double-check final rinse temperature. Water bottles are placed in a basket upside down and run through the tunnel washer with either a temperature strip indicating 180°F or are randomly tested by ATP. The interior surfaces of rabbit cages are checked with [redacted] swab test kits to provide immediate evaluation of surface decontamination. For rabbit pans, 10% of the pans run through cage wash have a temperature strip placed inside to ensure the final rinse water temperature reached 180°F. All used strips are collected, evaluated, and logged post-run.

b) Describe preventive maintenance programs for mechanical washers.

The cage/rack washers are on the following preventive maintenance schedule:

Once a week: Lock-out/tag out procedures; check for proper operation, clean sump strainer, check nozzles and clean, check alignment of carriage assembly, check carriage assembly strokes, check carriage assembly gearbox and motor – lubricate as needed, rebuild water and steam valves first week in January, April, July and October, check motorized valve for proper opening and closing.

Monthly: Lock-out/tag out procedure; adjust the emergency release inside of the rack washer so anyone trapped inside could escape; remove hard water deposits from sump, chamber interior and accessories; inspect water level ball float – clean if necessary; inspect self-cleaning screen – disassemble and remove debris from screens as necessary.

Every 2 months: Lock-out/tag out procedures; inspect printouts for signs of trouble; inspect door for ease of operation; verify condition of washer accessories; verify operational test on each safety cable; verify each cable has a minimum of 2" of free play; check piping system for leaks; verify pump suction strainer for debris; inspect oscillating carriage drive and clutch system; test clutch for slippage; verify drive cable rollers for wear; inspect supply live strainers for debris – water and steam; inspect steam trap for proper operation; inspect and lubricate detergent supply and injection hose - replace as necessary; verify proper pump operation ; inspect pump for excessive noise and vibration; electrical control box – verify all sockets for proper seating of electrical components; inspect wiring terminals and socket connections for damage or fraying; clean lint and dirt from components; run unit through two cycles to verify proper operation; verify all displays and printouts; verify proper water level in sump after filling function; inspect pump seal for leakage.

Every 6 months: Lock-out/tag out procedures; verify operation of interlock door system; verify operation of door safety switch; inspect each valve – clean if necessary; inspect each solenoid valve for proper operation – replace as needed; inspect check valve – clean and replace as necessary; calibrate temperature set points.

Yearly: Lock-out/tag out procedures; inspect condition of door gasket for wear – replace if needed; grease pump motor bearings where applicable.

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.

All soiled bedding and refuse from research animals is autoclaved when removed from the animal housing suites and rooms using pass-through autoclaves that separate dirty and clean areas. Soiled bedding remains inside cages during autoclaving. Bedding and refuse from the SPF mouse colonies is discarded in the dirty cage wash area. Pans from rabbit caging are heavily disinfected prior to moving to cage wash. After autoclaving, cages are transported to the dirty cage wash area for bedding removal and disposal within a downdraft bedding disposal station. All other discarded materials (contaminated or not) are double-bagged in biohazard bags, and autoclaved prior to removal for ultimate disposal. Trash cans in all animal areas are emptied daily, and all waste bags are autoclaved upon removal. Discarded bedding and other post-autoclave bagged waste collected in the dirty cage wash area are placed into opaque trash bags and collected in covered transport containers for ultimate disposal. Covered transport containers are emptied at the end of every day and more frequently as needed, with waste bags transported to the (b)(6) and discarded into municipal waste.

ii. Animal carcasses.

Each animal housing area contains a small, dedicated carcass refrigerator/freezer. Carcasses are double-bagged and placed in the appropriate section of the refrigerator/freezer unit. Refrigerator/freezer units are checked at least once daily by (b)(4) employees. Double-bagged carcasses are removed daily, autoclaved, and placed in a large freezer prior to incineration.

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).

Pest control and monitoring is provided by a contractor. The SOHS serves as the CDC Project Officer for this contract and coordinates the program with input from FMEO, the AV, and investigators. The integrated pest management plan is designed to reduce pests (insects and rodents) using a combination of physical controls (traps, seals, barriers), trap monitoring (live rodent traps checked daily), monthly inspection of facilities, monthly exterior pesticide applications, and, as needed, response to reports of insects or rodents.

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.

Prior to interior application of pesticide, the contractor is required to contact the SOHS who consults with investigators to determine acceptability and timing of proposed applications.

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.

Provision of Weekend and Holiday Care:

Weekend and holiday animal care is provided by regular animal care staff. Weekend and holiday care duties consist of health monitoring, feeding and watering, and mandatory sanitation practices. The AV or backup veterinarian is available by cell phone for emergencies on weekends and holidays.

The AV, [redacted] resident veterinarians, [redacted] project lead or designee are on-call at all times and each carries a cell phone to ensure that they can be reached quickly in case of emergency.

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

Regular animal care staff provide care on weekends/holidays.

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

[redacted] employees, investigators, and any other personnel may contact responsible animal care and veterinary staff in case of an emergency 24 hours a day. Contact numbers for the AV, [redacted] project lead, [redacted] employees, and emergency veterinary alternates are posted throughout the animal facility and are available in the security control center.

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 are used for all species and contain the investigator's name, the animal vendor/source, date received, species, protocol title and number, sex, and age or date of birth. Individual cage cards are used for all USDA-regulated species and group cage cards are used for cages of one or more mice that are not individually tagged.

Methods of identification are as follows: rabbits and some mice are ear tagged; rodents may also be identified by a radio frequency identification (RFID) implant when required for a specific research protocol; some mice have a tail tattoo applied by hand tattoo unit or the LabStamp; others may utilize a permanent marker pen.

b. Breeding, Genetics, and Nomenclature

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

The AV serves as a consultant in animal use protocol development, as well as at other times, to advise investigators regarding animal selection based on genetic characteristics.

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 AV or designee advises investigators on the proper nomenclature to use for strain and substrains. DVBD investigators do not generate new strains of mice which would require knowledge of appropriate nomenclature.

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

DVBD maintains SPF breeding colonies of SKH-1 and AG129 mice.

The current AG129 colony grew from a founding stock of 12 males and 36 females obtained from a commercial vendor in October of 2007. The AG129 colony is a closed breeding colony, with breeding age mice selected and bred using a coding system designed to optimize uniform breeding within the group to enhance homozygosity of inbred strains. New breeding stock (10 males and 20 females) was added in September, 2016. Genetic monitoring of AG129 mice is performed periodically. DNA analysis is performed on tail snips from a representative sample

of mice. Analysis is performed by Transnetyx® to assure continuation of the knockout status.

The current SKH-1 colony grew from a founding stock of 20 males, 60 females and 10 timed-pregnant females obtained from a commercial vendor in October, 2007, with additional males and female breeders added in July, 2014. The SKH-1 colony is a closed breeding colony with breeding age mice selected and bred using a coding system designed to optimize uniform breeding within the group to enhance homozygosity of the strain. Genetic monitoring of the SKH-1 colony is currently not conducted as it is considered an outbred mouse.

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."

Generation of new genotypes is not conducted at DVBD.

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.).

Animals purchased by DVBD are from known and established SPF strains or stocks procured from commercial vendors. Vendors are defined sources with satisfactory quality control histories, and they provide recent quality assurance documentation to satisfy purchase specifications of both animal care personnel and the investigators. Vendors supply current health monitoring results as requested.

Animals are received, inspected, and logged by the (b)(4) project lead or designee who records species, strain, source, number, age, and sex. Animal room assignment and identification numbers are then given. Room assignment is based upon the etiologic agent, species of animal and planned duration of the study. The AV is immediately notified about abnormal findings associated with the animal shipment.

Evaluation procedures for each species are based on source and health status. Animals arriving from reliable vendors go directly to the animal housing room or suite and are released for use after a 5-7 day acclimation period. If animals are received from questionable sources or with undefined health status, a quarantine period of usually 7-28 days is instituted by the AV while appropriate health monitoring procedures are conducted. Disposition or release from quarantine is at the discretion of the AV.

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).

Animals purchased from commercial vendors are delivered directly to buildin g(b)(7)(E) via commercial transport and unloaded at the loading dock.

Upon initial receipt (b)(6), animals received from outside of the facility are transported to their assigned room/cubicle in their original shipping container. Animals that will be entering the SPF colony area, the surface of the container is decontaminated with an appropriate agent (10% sodium hypochlorite solution or Amphyl).

Animals are not transported between buildings since all animal work is performed in building [redacted] Within building [redacted] non-infected animals are transported in covered cages and infected mice are transported in (b)(4) mounted to a double HEPA-filtered mobile rack. The movement of animals within DVBD is between (b)(6) floor by a dedicated, (b)(7)(E) controlled elevator. Access to the animal facility is restricted by individual employee [redacted]

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.

DVBD has a rodent health monitoring program in place for the breeding colonies and in the research animal area of the vivarium. Studies that are expected to last longer than 8 weeks have sentinel animals placed in cage racks shared by study animals. There is an IACUC-approved protocol and an animal care SOP in place that specify procedures used for the sentinel animals.

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

The main method to control infectious agents that may affect research animals at DVBD is the use of purpose-bred SPF animals from commercial suppliers or from the in-house SPF mouse colonies. DVBD also maintains a rodent health monitoring program which assists in the identification of pathogens.

If an infectious disease or infestation problem is diagnosed and proposed experiments preclude depopulation, affected animals are maintained in isolation for experimental use at the discretion of the AV once appropriate quarantine practices are put into effect.

Sick animals are initially isolated in a cage within their animal room until examination and determination of their status by the AV. They may be treated in the animal room, euthanized, or removed from the rest of the colony for the duration of treatment. Empty animal rooms may also be used for isolation and treatment of sick animals when they are available.

Isolation procedures may include depopulation, posting isolation signage at the animal room door and restricting (b)(7)(E) access to only a few authorized individuals, prohibiting the movement of animals to other rooms, and directing dedicated staff to provide husbandry support for sick animals after all other animals in the facility have been serviced.

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

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

Animals purchased by DVBD are from known and established SPF strains or stocks procured from approved commercial vendors. Vendors are defined sources with satisfactory quality control histories, and they provide recent quality assurance documentation to satisfy purchase specifications of the investigators. Animals are given an initial physical evaluation by the animal care staff as they are placed in their assigned housing areas. Any abnormalities are reported to the AV for follow-up.

Animals from reliable commercial sources that are received with acceptable health verification may be housed in the same rooms/cubicles as resident study animals as long as the resident animals are in good health and in on-going studies. Animals from reliable commercial sources that are received with acceptable health verification and destined for new studies are placed in sanitized animal rooms or cubicles that house no other animals. In accordance with standard operating procedures, rabbits and rodents received from reliable commercial vendors may be acclimated for a specified time period according to the IACUC-approved protocol. All other animals are subject to extended quarantine and/or isolation as directed by the AV.

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.

DVBD utilizes only purpose-bred animals. Animals received from approved commercial vendors are placed directly in the housing area where the study is to take place. Quarantine practices are put in place as determined by the AV or designee.

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

All purpose-bred animals received from reliable commercial vendors are acclimated for approximately 5-7 days before release to research projects.

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.

Different species are housed in separate rooms or in separate cubicles within multi-cubicle rooms. Select agent program restrictions, biosafety level, and type of infectious agents being studies take precedence when making room/cubicle assignments.

Animals of the same species, but from different sources, may be housed in the same room and/or cubicle when used in the same protocols. Animals are handled in groups, with no new animals from outside sources brought into a room during an ongoing study unless the new animals are part of the ongoing study. If not part of an ongoing study, new animals are brought in only after a room/cubicle has been cleaned and sanitized following completion of prior study work and removal of all animals.

Animals from the same source are routinely housed together. Clinically ill animals are separated or quarantined from healthy animals to prevent disease transmission.

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

Species such as rabbits and mice may be housed in the same room but are housed in separate cubicles. The cubicles each have separate ventilation, heating, lighting etc.

c. Describe isolation procedures and related facilities for animals.

Isolation procedures may include depopulation, posting isolation signage at the animal room door and restricting (b)(7)(E) access to only a few authorized individuals,

prohibiting the movement of animals to other rooms, and directing dedicated staff to provide husbandry support for sick animals after all other animals in the facility have been serviced.

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

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

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

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

All animals are observed twice daily during the week and once daily during weekends by [redacted] employees for morbidity/mortality and abnormal behavior along with assurance there is adequate food and water. [redacted] employees have extensive experience as described above. Animals that are not in good health have a color-coded (yellow) observation card placed over the cage card with a comment regarding the animal. The veterinary staff is notified by e-mail or telephone (if urgent) of the need for veterinary observation. E-mails are sent copying all veterinary staff, the PI, and the compliance officer to assure all are aware of new and ongoing clinical cases. For non-USDA covered species such as purpose-bred research mice, a notebook is kept in the animal housing area in which an illness, diagnosis, treatment, etc. is recorded on the clinical event form. For rabbits, observations are recorded in the clinical record and a member of the veterinary staff is notified by e-mail or telephone. Follow-up for rabbits is documented in the clinical records.

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

[redacted] employees report animal health issues to the [redacted] project lead who in turn contacts the AV by cell phone and/or e-mail. The PI is informed by telephone and e-mail regarding the health of their study animals. The AV may confer with a PI regarding the health of an animal in order to determine if treatment will interfere with study results.

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

Mice and rabbits are the main species utilized at DVBD. Sentinel mice are utilized in study rooms if the expected study duration is greater than 8 weeks. Sentinel mice are routinely kept in the breeding colonies. Rabbits are groomed at least once weekly, nails are trimmed every other week and body weights are measured weekly.
Approved animal vendors provide health status of their animals with health monitoring reports. USDA surveillance reports of approved vendors are also monitored.

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.

Veterinary emergency care is available during regular work hours within approximately 30 minutes after cell phone contact. The comparative medicine residents each have office hours on site for approximately 2 hours each week. Outside of regular work hours, veterinary emergency care is available within approximately 60 minutes after cell phone contact.

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

The AV or designee has the authority, in the event of a pressing health problem, if the PI or associate cannot be reached or if a consensus cannot be reached, the AV may treat the animal, remove it from study, relieve severe pain or distress, or perform euthanasia if necessary. This authority is designated by the CDC Director's directive dated December 15, 2005, "Memorandum of Veterinary Authority over Animals Being Used for Research and/or Training at CDC."

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.

The AV is responsible for the clinical record keeping at DVBD. The AV oversees the establishment and review of the medical records. The [redacted] project lead assists the AV in the maintenance of clinical records. For USDA-covered species, each animal has its own medical record that is kept either inside or near the animal room. Clinical findings, diagnoses, treatment, progress records are recorded on this log.
For non-USDA covered species such as purpose-bred research mice, a notebook is kept in the animal housing area in which an illness, diagnosis, treatment, etc. if applicable is recorded on the clinical event form. All medical records are filed after the animal is euthanized and kept in the animal care office.

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

The AV assisted by the animal care project lead is responsible for maintaining the medical records. Comparative medicine residents from [redacted] under the direct supervision of the AV or alternate AV record findings, diagnoses, and treatment as applicable. Active records are kept in the animal room or in the central corridor of the animal facility on each floor. Once animals are euthanized the records are stored in the animal care office area. IACUC members, PIs (for their own animals) and the DVBD IACUC administrator have access to the records.

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

The AV is responsible for oversight of all animal care records, including daily room sheets, census sheets, and medical records, etc.

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

a. In-house diagnostic laboratory capabilities.

In-house diagnostic capabilities consist of provision for endoparasite determinations and cytology.

b. Commercially provided diagnostic laboratory services.

Diagnostic laboratory services such as hematology and clinical chemistry, histopathology, etc., if needed, are provided by (b)(4) (b)(6) (b)(6) health is monitored by serology conducted by (b)(4)

c. Necropsy facilities and histopathology capabilities.

Necropsies are conducted in an area away from other animals or at least separated by a door and directional airflow, out of sight of other animals such as in an anteroom outside of a cubicle where cages are kept. Histopathology is provided by [redacted] (b)(6).

d. Radiology and other imaging capabilities.

Radiology and imaging are not utilized at DVBD.

5. Drug Storage and Control

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

A controlled substances standard operating procedure is in place to ensure appropriate accountability of controlled substances. The DVBD Director holds the DEA registration for the CDC-Fort Collins facility. The AV was appointed by the DVBD Director to oversee the controlled substances program. Quarterly audits of controlled substances are conducted by the AV or designee. [redacted] staff routinely review expiration dates and remove drugs prior to the end of their shelf life. Short-dated supplies are used first. All dates are checked before a supply is used, and outdated materials are discarded. A central log is used to track all drugs received by the facility and to aid in monitoring drug expiration dates.

All drugs ordered for and received by CDC-Fort Collins are stored in a locked central supply pharmacy, located within a secure area of building [redacted] within the pharmacy, non-controlled drugs are stored on shelves, and controlled drugs are stored within a wall-mounted lockbox. Drugs are issued from the central supply pharmacy to research staff or [redacted] staff. Controlled drugs issued to PIs and/or research staff are stored in small wall-mounted combination safes located in each animal suite, with the combination set/controlled by the PI for the area; combinations to all wall-mounted safes are logged and maintained by [redacted] staff. Safes are inspected periodically by the AV or designee and [redacted] project lead to monitor proper record keeping, residual volumes, and discard of expired drugs. Non-controlled drugs issued to PIs and research staff are similarly stored.

b. Describe record keeping procedures for controlled substances.

The [redacted] project lead on behalf of the AV maintains a central notebook for logging receipt and issuance of all controlled drugs brought into and removed from the locked central supply pharmacy. All controlled drugs issued from the central supply have an assigned usage log card. Upon issuing controlled drugs to PIs and research staff, the [redacted] project lead and/or designee mark the log cards identifying the PI and protocol number and issue the card to the recipient, charging the recipient(s) with proper logging of drug usage. The [redacted] project lead and/or designee are also responsible for filing completed log cards and emptying/discarding drug vials form the PI and/or research staff for return. The AV or designee reconciles usage for issued drug vials with the central supply log, and then ensures proper disposal of empty and/or discarded vials.

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.

The AV or designee provides a consultation with the PI prior to IACUC review of the protocol that includes survival surgery. The consultation consists of appropriate selection of analgesics, anesthetics, and post-operative care. The AV or designee may assist with pre-planning as requested by the PI.

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.

Surgery is rarely conducted at DVBD. Currently the IACUC has approved one protocol with major survival surgery in mice. Surgery was conducted in the PI's animal suite on a disinfected lab bench by a veterinarian experienced in the procedure. Mice were anesthetized, and the abdomen clipped and cleansed for aseptic surgery. Aseptic surgical technique was utilized. Mice were visually monitored during the procedure. Recovery was monitored and post-operative analgesics administered. Specifics of the procedure were described in the protocol.

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).

Surgery is not generally conducted at DVBD, barring the rare exception as described above. Major survival surgery is any procedure that exposes a body cavity, results in substantial impaired physical or physiologic function. Minor survival surgery would not enter a body cavity and causes little to no physical impairment.

b. How is non-survival surgery defined?

Non-survival surgery is defined as any procedure conducted from which the animal is not allowed to recover 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.

Surgery is not generally conducted at DVBD, barring the rare exception as described above. Instruments are sterilized prior to use. The surgeon cleanses their hands with an appropriate surgical scrub. They wear appropriate clothing such as a sterile gown, face mask, hair cover, and sterile gloves. The patient is prepared by clipping the fur from the surgical site followed by cleansing with appropriate surgical scrubs. A sterile drape covers the surgical site.

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.

Instruments are sterilized by the use of an autoclave. If surgical gowns are needed, disposable one are used and discarded. Liquid sterilants are not utilized.

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

If serial surgeries are conducted in rodents, instruments may be re-sterilized after cleaning with sterile water or saline and placed in a hot-bead sterilizer for the manufacturer's recommended time.

d. Indicate how effectiveness of sterilization is monitored.

Autoclave tape is used on the surgical instrument packs to assure that the appropriate temperature was reached during the cycle. Spore tests are conducted on the autoclaves quarterly.

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

The AV or designee is available to investigators for consultation when planning a protocol which includes surgery. The AV or designee or another veterinarian may conduct the procedure. Pre- and post-operative planning along with anesthetic and analgesic regimen is discussed during protocol preparation.

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.

Intraoperative monitoring is achieved by evaluation of breathing, heart rate and reflexes. Monitoring is required at least every 15 minutes and recording is done for USDA-covered species. Non-survival procedures have the same monitoring requirements.

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 are monitored post-operatively at least every 15 minutes with evaluation of breathing, heart rate, reflexes, and ability to ambulate. Generally the PI and associates conduct the monitoring and recording as appropriate.

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

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

USDA pain and distress categories are defined in the protocol form. PIs assess and categorize pain based on proposed procedures and in consultation with the AV. These categories are reviewed by the IACUC.

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

The PI is responsible for training of research associates in monitoring animal well-being. Contracted animal care staff training for monitoring pain and distress is provided by the contracted AV. The required ALL courses (Intro. to [species]) also provide information on monitoring animals for well-being and pain/distress.

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.

IACUC Policy 25 provides guidance and doses for commonly used anesthetics and analgesics in species that may be utilized at DVBD. The IACUC protocol form also provides some of this information for the PI to refer to while preparing the protocol. Examples of agents and species are as follows:

Mouse Anesthesia

Ketamine plus Xylazine: 60–70 mg/kg; 5-10 mg/kg; IP
Halothane or isoflurane: 1%– 4% (to effect); inhaled

Mouse Analgesic:
Xylazine; 2 mg/kg: SC, BID
Ibuprofen: 1-2 mg/ml drinking water, Oral

Rabbit Anesthesia
Ketamine plus Xylazine: 45 mg/kg; 5–10 mg/kg, IM
Halothane or isoflurane: 1%– 4% (to effect), inhaled
Acepromazine: 0.75-1[redacted] mg/kg IM or SC

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

Investigators are required to consult with the AV in the development of any research protocol. Anesthetic, analgesic, and other drug choices are a specific topic of discussion during this consult. The IACUC approves the protocol which includes the use of analgesics and anesthetics.

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.

Animals are anesthetized by injectable or inhalation anesthetic agents, with inhalation agents delivered by use of induction chambers. The PI is responsible for proper use of anesthetics and analgesics when indicated and approved for the study. PIs and investigators are trained to deliver and monitor anesthetic induction, maintenance, and recovery as related to their respective projects. Protocol-specific issues regarding pain are carefully considered by the AV, PI, and IACUC prior to protocol approval, and anticipated pain must be accurately indicated and a treatment plan described in the protocol. PIs bear the responsibility of providing and administering analgesics as approved in their protocols. If unexpected pain is evident, the PI consults the AV or designee regarding management.

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.

Neuromuscular blocking agents are not utilized at DVBD.

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

Vaporizer calibration is checked approximately once a year. The anesthetic systems are checked for leaks and scavenging systems are checked prior to use. Vaporizers are checked prior to use to assure adequate anesthetic. Oxygen tanks are periodically checked to assure they contain a suitable amount of oxygen and that the tanks are appropriately secured.

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.

a. Methods

The IACUC policy on euthanasia stipulates the following as acceptable methods of euthanasia for rodents and small laboratory animals, birds, and rabbits:
Rodents and small laboratory animals:

- CO_2 asphyxiation in home cage if possible with gradually increasing concentrations as outlined in the AVMA Guidelines on Euthanasia (2013). Death must be assured by: bilateral thoracotomy in animals other than rodents, cervical dislocation of poultry, other small birds, mice, and rats weighing < 200 g, and rabbits weighing < 1 kg when performed by individuals with a demonstrated high degree of technical proficiency.
- Halothane, isoflurane, or other halogenated agent overdose
- Cervical dislocation with prior sedation or anesthesia.
- Decapitation with prior anesthesia.
- Barbiturate overdose.

Rabbits:

- Barbiturate overdose.

The IACUC will consider allowing cervical dislocation without anesthesia, decapitation without anesthesia, or exsanguinations with anesthesia when scientifically justified and by persons with proven technical proficiency.

Euthanasia is conducted in areas physically and visually separate from live animal line of sight.

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

CO_2 euthanasia is periodically used at DVBD. In the event that it is, the (b)(4) equipment is checked to assure that there is an appropriate amount of CO_2 and O_2 contained in the tanks.

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

Death is confirmed by a secondary method of euthanasia such as cervical dislocation or thoracotomy. In species less than 200 g, cervical dislocation is used. In larger species such as rabbits, thoracotomy is utilized along with assurance of cessation of heart and breathing functions.

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.

All animal housing, procedure, and support areas are located in Building [redacted] Fort Collins, CO. 80521. Animal facilities are housed on th[redacted] floors All spaces are in good condition.

Building [redacted] is constructed as a biocontainment facility and supports biosafety level one, biosafety level two (BSL2), and biosafety level three (BSL3) laboratory research. Systems support operating parameters required to maintain a modified clean/dirty concept and to manage the flow of materials, animals, equipment and personnel into and out of the facility. Clean or dirty refers to the potential for the animal or material to transmit diseases to other animals or humans. Barriers within the facility are "clean" and receive only "clean" approved animals and materials; used cages are "dirty" and do not move into designated "clean" areas because they may be a source of contamination. Refer to Appendix 3 for a Summary of Animal Housing and Support Sites. Appendix 3 also has a satellite image of the facility location.

The species currently housed in building [redacted] include mouse and rabbit. The current daily average animal inventory and annual use by species are provided as Appendix 3.

The animal housing suites are designed with two layouts of similar dimensions: 1) a single, large holding room; and 2) an isolation room, which has five smaller rooms, each sized to accommodate racks of cages, pens, or static rodent boxes on adjustable shelves. Floor plans are provided in Appendix 4. A compilation of animal facility room, suite, and area square footage is provided as Appendix 2 and 4.

The management structure consists of animal care personnel provided by (b)(4) under a contract. (b)(4) provides a project lead, animal care personnel and cage wash personnel. (See above for reporting structure.)

(b)(4) is contracted to provide all daily maintenance and janitorial services for the facility. They provide a facility manager who is responsible for supervising (b)(4) personnel. A project lead oversees the day to day facility maintenance operations. (b)(4) provides all maintenance and janitorial staff necessary to accomplish any maintenance and cleaning services at the facility. CDC's (b)(6) located in Atlanta) is the contracting officer for the contract with (b)(4) Energy who oversees the contractual requirements with (b)(4) with input from the DVBD Facility Engineer on their day to day performance. DVBD has an on-site building engineer who provides day to day oversight of the (b)(4) activities and engineering support for building operations.

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. General arrangement of the animal facilities:
The DVBD animal facilities is arranged using clean/dirty corridor. All animals are kept within the animal facility. No animals are moved to laboratories on other floors.

2. Physical relationship of the animal facilities to the research laboratories where animals may be used.
Animals used for research are housed within the animal facility. No animals are housed or moved to areas other than designated animal research or breeding locations.

3. Types of available animal housing spaces used
The animal housing suites are designed with two layouts of similar dimensions: 1) a single, large holding room; and 2) an isolation room, which has up to five smaller cubicles, each sized to accommodate racks of cages, pens, or static rodent boxes on adjustable shelves. Floor plans are provided in Appendix 3. A compilation of animal facility room, suite, and area square footage is provided as Appendix 3.

4. Finishes used throughout the facility

Floors:

- Masonry floors covered by methyl methacrylate acrylic with self-leveling full flake acrylic floor coating system and two coats of clear resin.
- Floors in good condition.

Animal Room Doors:

- Fiberglass reinforced polyester flush doors with fiberglass reinforced polyester face sheets; poured-in-place polyurethane foam core; factory installed vision lights, louvers, and panels.
- 1-3/4 inches thick; stiles and rails are a minimum of 2-5/16-inch depth aluminum alloy; corners are mitered; extrusions are secured or closed.
- Single door dimensions 6' 0" x 7' 10".
- Double door for animal cubicles: 4' 0" x 7' 10" (pair).
- Double doors into cage processing: 6' 0" x 7' 10" (pair).

Ceilings:

- Gypsum board suspended ceiling.
- Finished with SPC-2 (100% solids, multi-functional, pigmented high build epoxy novolac wall coating system; applied at 10-15 mils total wet film thickness).
- Ceilings in good condition.

Hallways:
Walls:

- (b)(6) walls composition in animal holding areas:
  - Gypsum board construction.
  - Finished with either SPC-1 (100% solids, fiberglass reinforced, high build epoxy wall coating system; applied at 25-35 mils wet film thickness; primer, body coat, and two topcoat system) or SPC-2 (100% solids, multi-functional, pigmented high build epoxy (b)(4) wall coating system; applied at 10-15 mils total wet film thickness).
  - (b)(7)(E) floor walls in good condition.

- (b)(6) wall composition in animal areas:
  - Concrete masonry unit construction.
  - Finished with either SPC-1 (100% solids, fiberglass reinforced, high build epoxy wall coating system; applied at 25-35 mils wet film thickness; primer, body coat, and two topcoat system) or SPC-2 (100% solids, multi-functional, pigmented high build epoxy (b)(4) wall coating system; applied at 10-15 mils total wet film thickness).
  - (b)(6) walls in good condition.

5. Engineering Features

a. Heating Ventilation and Air Conditioning (HVAC)

The building is designed to minimize facility maintenance work in animal housing areas. Each animal floor is serviced by a full story interstitial level above and below and a two-story mechanical room for the air handling units (AH) and associated mechanical equipment. All duct work, reheat coils, HEPA Filters, and control devices can be accessed from the mechanical room or the interstitial levels minimizing facility work in animal housing areas.

b. Indoor Conditions

Each zone contains an individual thermostat set to maintain space temperature set point (65°F–80°F) and humidistat set to hold relative humidity within 30%-70% depending on the animal species housed. A temperature/humidity monitor is placed in each animal cubicle and monitored daily by (b)(6) employees.

c. Pressurization

Airflow is based on 100% outside air that is exhausted after a single pass. Vivarium spaces are negatively pressurized by means of offset controls to maintain a 15% difference between exhaust and supply air. The minimum offset for all spaces will be 150 CFM. SPF barrier suite is positively pressurized by means of offset controls. All animal holding spaces are designed with a minimum of 10 air changes per hour.

d. Air Systems

Vivarium spaces are served by dedicated air handling units and exhaust fans that serve only that floor. All central station air moving equipment is sized with a 25% safety factor to

accommodate system leakage and future growth. All vivarium supply and exhaust systems have N+1 redundancy.

e. Ductwork

No ductwork, piping, or other mechanical equipment is exposed in the vivarium.

f. Air Distribution Devices

All supply air diffusers in small rooms are radial flow diffusers to prevent supply air from interfering with primary containment devices, such as biological safety cabinets. Air diffusers in large rooms are perforated face diffusers. Exhaust registers and grilles are the perforated type when mounted in the ceiling or fixed blade type when mounted vertically. Connections to biological safety cabinets are thimble type to prevent the building mechanical system operation from interfering with the BSC operation. Animal holding rooms are provided with prefilters in the exhaust registers and grilles. High humidity spaces are provided with air distribution devices constructed of stainless steel.

g. Filtration

HEPA filters are located on the exhaust of the enhanced BSL3 vivarium spaces. Filters are located as close as possible to the space to minimize the amount of contaminated ductwork. HEPA filters are sized for a maximum of 250 feet per minute face velocity and have the following components:

- Upstream bioseal damper.
- Upstream DOP/Decontamination port.
- Mixing/test section.
- HEPA filter section.
- Scan section.
- Downstream DOP/Decontamination port.
- Downstream bioseal damper

h. Controls

A dedicated front-end station is provided to trend data from the animal holding rooms. The following points are monitored:

- Space temperature.
- Space humidity level.
- Lighting (on/off).
- Space air flow.

Airflow control is based on two-position tracking. Each vivarium space is provided with dedicated supply and exhaust airflow control devices and a hot water reheat coil to maintain proper airflow and temperature. Animal holding rooms are provided with a differential pressure sensor/transmitter for monitoring.

6. Security features

(b)(7)(E)

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.

DVBD has no satellite facilities.

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.

Emergency Power
Two diesel-powered generators are available. Each can provide 100% of the facility demand power load within 10 seconds of utility power loss; switch to generator power is automatic. The generators are maintained and tested on a regular basis by facilities engineering personnel who provide 24 hours a day coverage. Emergency lighting is activated immediately after power failure with a 90-minute capacity.

Facility engineering personnel maintain a log of scheduled and unscheduled power outages. A recent report of power failures is provided as Appendix 11.

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).

There have been a few mouse deaths due to individually ventilated cages not being seated correctly on the racks. Re-training of staff was conducted.

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 are no other facilities utilized other than those described above.

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

Diagnostic Laboratory provides hematology, clinical chemistries, and histopathology. Water Evaluation Lab provides chemistries and microbiological testing of submitted water samples.

According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we wish to advise you that the personal data in the Program Description will become part of a permanent file owned by AAALAC International, and that can be shared with AAALAC International offices and representatives in order to perform an evaluation of the institution´s animal care and use program and provide accreditation services. The institution has the option of exercising rights of data access, rectification, cancellation, and opposition at: accredit@aaalac.org

Appendix 1: Glossary of Abbreviations and Acronyms

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

Abbreviation/Acronym	Definition
ABSL	Animal biosafety level
ACIP	Advisory Committee on Immunization Practices
ACUPO	Animal Care and Use Program Office
ADB	Arboviral Diseases Branch
ALL	AALAS Learning Library
AV	Attending Veterinarian
BDB	Bacterial Diseases Branch
BSC	Biosafety cabinet
CDC	Centers for Disease Control and Prevention
CMB	Comparative Medicine Branch
COR	Contract Officer's Representative
(b)(4)	(b)(4)
DMR	Designated member review
DVBD	Division of Vector-Borne Diseases
FCR	Full committee review
FMEO	Facilities management and engineering office
IO	Institutional Official
MI	Micro-isolator cages
NCEZID	National Center for Emerging and Zoonotic Diseases
OADLSS	Office of the Associate Director for Laboratory Science and Safety
OD	Office of the Director
OADLSS	Office of the Associate Director for Science and Safety
OSSAM	Office of Safety, Security and Asset Management
NP	Nurse Practitioner
PAM	Post-approval monitoring
PI	Principle Investigator
PPE	Personal protective equipment
SPF	Specific-pathogen free
SS	Stainless steel
VVC	Veterinary verification and consultation

Appendix 2: Summary of Animal Housing and Support Sites

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**
3156 Rampart Road, Building [redacted]	Main animal facility (only 1 facility)	3798 ft²	15,721 ft²	Mouse Rabbit	650 7	[redacted] DVBD Director
Satellite Housing Facilities Total (Expand in Table 17)		0	0			

Totals:	**3897 ft²**	**15,721 ft²**
Total animal housing and support space:	**(please specify ft² or m²)**	

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

Appendix 2: Summary of Animal Housing and Support Sites

Google Maps Address Rampart Rd
Fort Collins, CO 80521

)(7)(E)

)(6) ; (b)(7)(E)

)(7)(E)

Appendix 3: Line Drawings

Animal Facility Square Footage Compilation

Animal Housing Square Footage: 3,798

Animal Rooms

clean flea	(100 sq ft)
clean tick	(125 sq ft)
animal holding room	(100 sq ft)
animal holding room	(100 sq ft)
animal holding room	(100 sq ft)
animal holding room	(100 sq ft)
SPF animal holding	(100 sq ft)
animal holding	(372 sq ft)
isolation/quarantine room	(400 sq ft)
isolation/quarantine room	(400 sq ft)
isolation/quarantine room	(400 sq ft)
isolation/quarantine room	(400 sq ft)
holding room	(400 sq ft)
isolation/quarantine room	(400 sq ft)
isolation/quarantine room	(400 sq ft)

Support Square Footage: 15,721

Corridors

work corridor	(415 sq ft)
post autoclave room	(241 sq ft)
decon	(50 sq ft)
soiled corridor	(621 sq ft)

Appendix 3: Line Drawings

post autoclave room (257 sq ft)

decon (50 sq ft)

Food and Bedding storage rooms

food storage (116 sq ft)

bedding storage (116 sq ft)

Cagewash rooms

soiled cage (1319 sq ft)

clean cage (944 sq ft)

Bottlewash room

glassware (284 sq ft)

Supply and equipment storage areas

storage (51 sq ft)

Treatment and procedure rooms

clean flea (*)

clean tick (*)

holding room (150 sq ft)

manipulation room (161 sq ft)

holding room (150 sq ft)

manipulation room (161 sq ft)

holding room (150 sq ft)

manipulation room (161 sq ft)

holding room (179 sq ft)

manipulation room (163 sq ft)

air lock (77 sq ft)

SPF work area (344 sq ft)

ante room (100 sq ft)

ante room (80 sq ft)

ante room (100 sq ft)

Appendix 3: Line Drawings

ante room	(80 sq ft)
ante room	(100 sq ft)
ante room	(80 sq ft)
ante room	(100 sq ft)
ante room	(80 sq ft)
ante room	(100 sq ft)
procedure lab	(124 sq ft)
ante room	(100 sq ft)
ante room	(100 sq ft)
ante room	(80 sq ft)
ante room	(100 sq ft)
ante room	(80 sq ft)

Incinerator rooms

incinerator room	(509 sq ft)

Waste storage areas

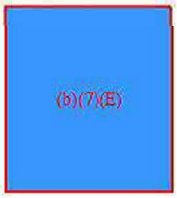
waste holding	(89 sq ft)
chemical waste holding	(91 sq ft)

Restrooms (within the animal facility)

male restroom	(300 sq ft)
female restroom	(300 sq ft)
change room	(101 sq ft)
change room	(98 sq ft)
change room	(150 sq ft)
male restroom	(300 sq ft)
female restroom	(300 sq ft)
change room	(115 sq ft)
male restroom	(61 sq ft)
female restroom	(75 sq ft)

Appendix 3: Line Drawings

Employee lounge areas



break room	(86 sq ft)
break room	(315 sq ft)
break room	(378 sq ft)

Laboratories within the facilities related to animal research

air lock	(111 sq ft)
work room	(770 sq ft)
work room and corridor	(522 sq ft)
holding room	(103 sq ft)
manipulation room	(167 sq ft)
holding room	(181 sq ft)
holding room	(103 sq ft)
manipulation room	(167 sq ft)
holding room	(181 sq ft)
isolation laboratory	(99 sq ft)
work room and corridor	(522 sq ft)
change room	(101 sq ft)

Offices within the animal facilities associated with the animal care and use program

shipping room (ARB staff) (474 sq ft)

Loading docks (calculated on the amount of use dedicated to the animal facility)

loading dock (550 sq ft)

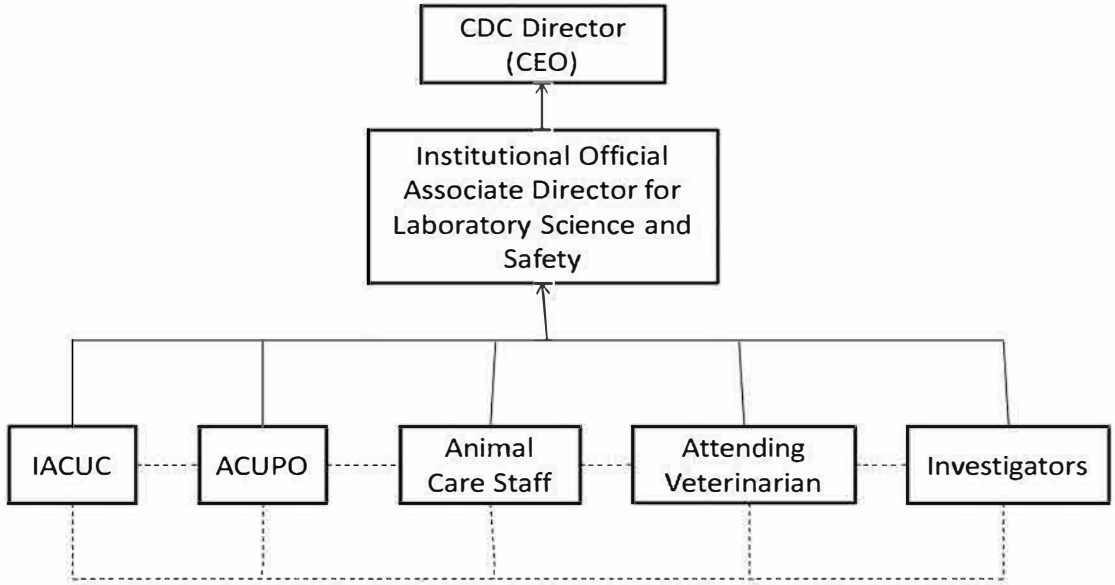
Elevators (calculated on the amount of use dedicated to the animal facility)

elevator lobby	(156 sq ft)
elevator lobby	(156 sq ft)
elevator lobby	(156 sq ft)
elevators	(270 sq ft)

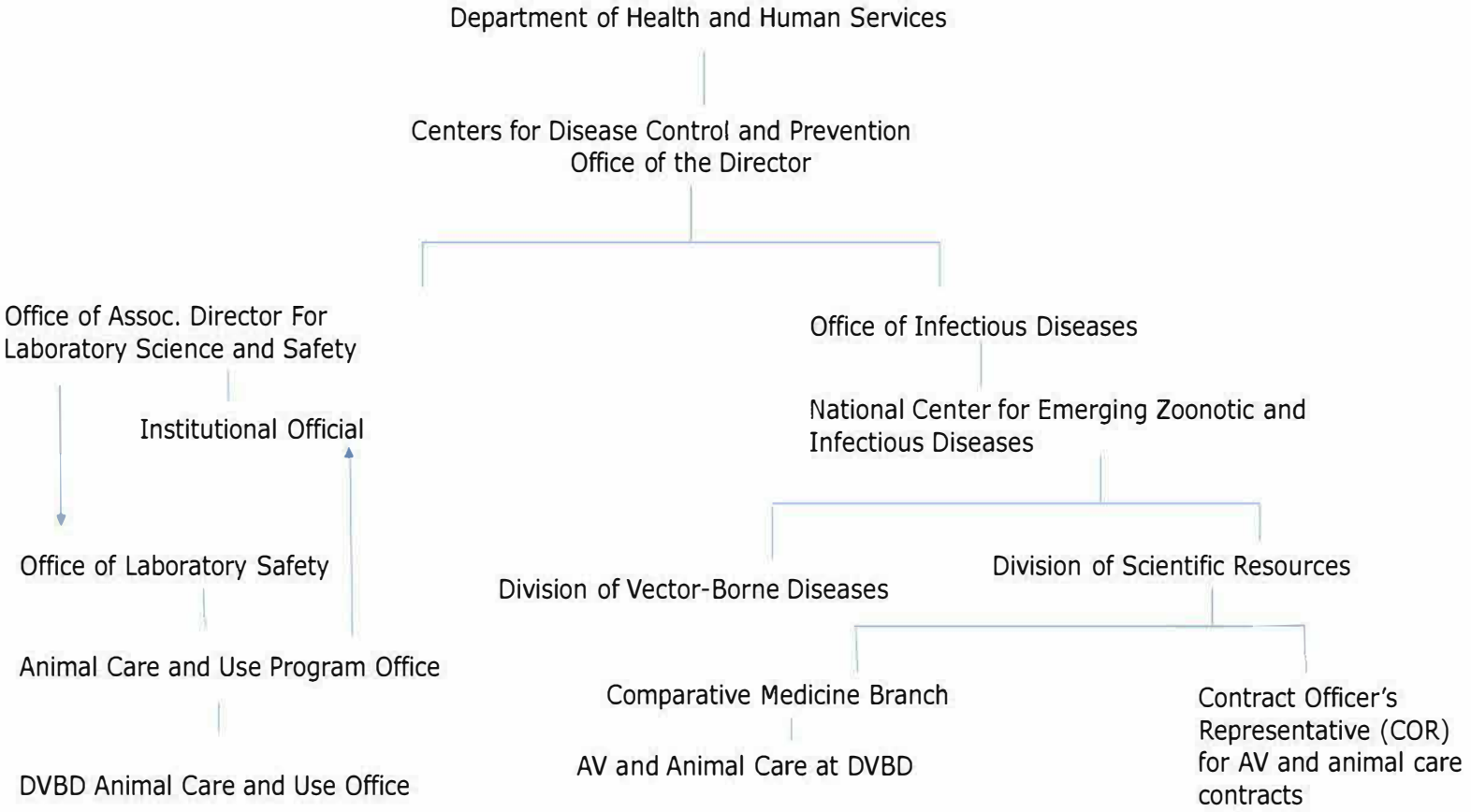
* room number and square footage included in a previous section

Appendix 4: Organizational Chart(s)

Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.

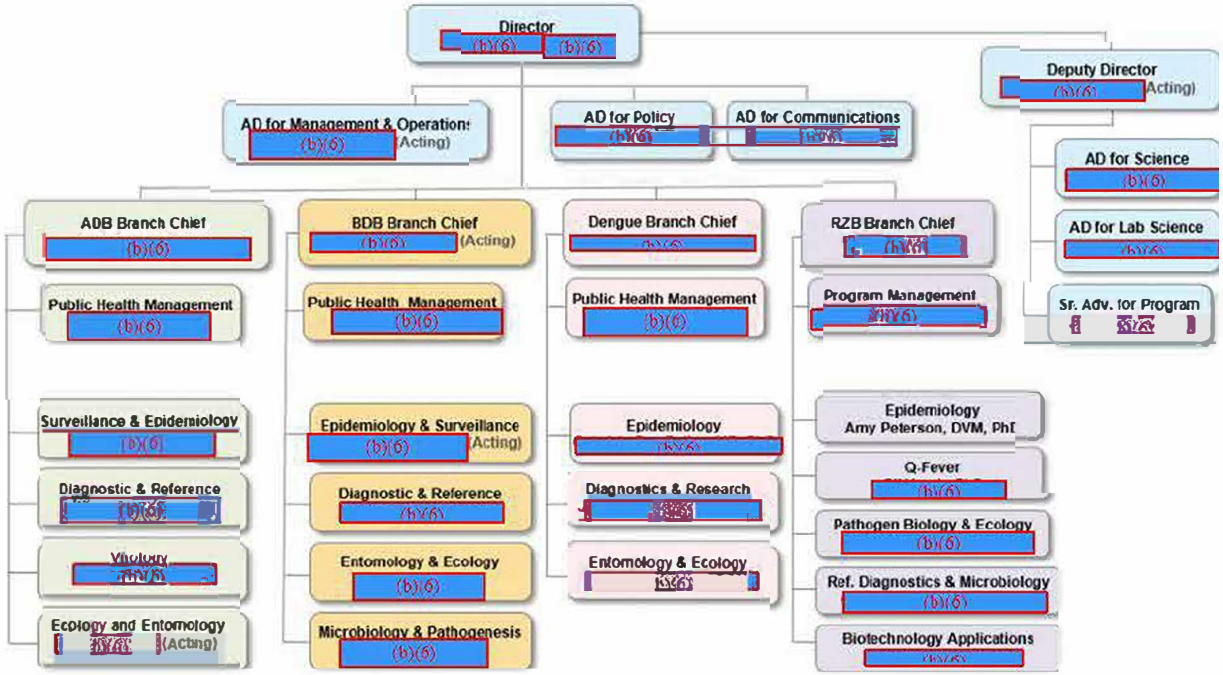


Appendix 4: Organizational Chart(s)



Appendix 4: Organizational Chart(s)

DVBD Organization Chart



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)(6)	Maintenance of ixodid (hard) ticks, including the Ixodes scapularis vector of Borrelia spp. spirochetes, via rabbit feedings	15-003		Rabbit	54	C						
(b)(6)	DNA vaccines expressing mature dengue virus-like particles as a new strategy for dengue virus vaccines	15-004		Mouse	104	C, E					X	
(b)(6)	Animal Holding Protocol	15-005		Mouse, Rat, Rabbit	900	B						
(b)(6)	Environmental Investigations following human	15-008		Wild caught rodents and	900	D					X	

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)
cases of vector-borne bacterial zoonoses in the United States			small mammals								
Production of rabbit derived polyclonal serum antibodies to flaviviruses	15-009	(b)(6)	Rabbit	32	D					X	
Borrelia spirochete infection dynamics in rodents and spirochete acquisition, maintenance and transmission by ticks	16-003	(b)(6)	Mouse, Peromyscus, Rabbit	1562	E					X	
Immunization of Mice for the Production of Murine Hybridomas	16-006	(b)(6)	Mouse	135	C					X	
Mosquito colony maintenance-mice as blood-meal sources	16-008	(b)(6)	Mouse	360	D						
Reservoir Host composition for maintenance of Borrelia burgdorferi in Minnesota	16-009		Wild caught rodents, squirrels	1760	D					X	

	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)(6)	Production of Mouse Hyperimmune Ascitic Fluid to Zika Virus	16-010		Mouse	150	D					X	
(b)(6)	Development of mouse hybridomas sereting Zika and other flaviviruses specific monoclonal antibodies	16-011		Mouse	126	D					X	
(b)(6)	Immunogenicity and protection efficacy of Zika vaccine candidates in mice	16-012		Mouse	690	E					X	
(b)(6)	Potential for intrauterine infection and venereal transmission of Zika virus in Ag129 mouse model	16-013		Mouse	1734	E					X	
(b)(6)	Assessment of Zika virus host tropism and vaccination approaches	16-014		Mouse	1147	E					X	
(b)(6)	Evaluation of Borrelia burgdorferi antigens as	16-015		Mouse	852	E					X	

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)
protective immunogens against tick-transmitted infectious challenge											
Recovery and Isolation of Bacterial Zoonotic Pathogens utilizing Mus musculus	16-016	(b)(6)	Mouse	312	E					X	
Study of multiple flavivirus-host tropism and evaluation of dengue and Zika vaccine candidates	16-017	(b)(6)	Mouse	1165	E					X	
Evaluation of total release aerosol insecticide foggers (aka "bug bombs" for the control of on-host felas inside huts in a plague endemic region of Uganda	16-018	(b)(6)	Wild caught rats, rodents and shrews	4919	C					X	
Evaluation of Habitat for Humanity-constructed homes to exclude small	16-019	(b)(6)	Wild caught rodents and shrews	442	C					X	

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)
mammals (Rodentia, Insectavora) vs traditionally constructed homes in two rural regions of Uganda.											
Assessment for infectivity of Borrelia spp. strains throughout the mouse-tick enzootic cycle	16-020	(b)(6)	Mouse	373	E					X	
Propagation and isolation of Borrelia spp.	17-001	(b)(6)	Mouse	225	E					X	
Laboratory Animal Training Protocol	17-002	(b)(6)	Mouse, rat, hamster, rabbit	450	B,D						
Specific Pathogen Free (SPF) Breeding Colony – AG129 Mice	17-003	(b)(6)	Mouse	4161	B						
Developing an optimal method for infecting ticks with Borrelia miyamotoi	17-004	(b)(6)	Mouse	60	D, E					X	
Flea colony maintenance feeding	17-005	(b)(6)	Mouse	7488	D						

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)
Rodent Health Monitoring Program	17-007	(b)(6)	Mouse, rat, hamster	330	C						
Kinetics of Borrelia miyamotoi in Ixodes scapularis and the relative efficiency of vertical vs. horizontal transmission Part I.	17-008	(b)(6)	Mouse, rabbit	355 (M) 7 (R)	D, E					X	
Maintenance of Ixodes ticks, the primary vectors of Borrelia spirochetes, via mouse feedings	17-009	(b)(6)	Mouse	630	E						
Identification of risk factors in villages with and without a history of plague in the West Nile region of Uganda: a prospective study	17-010	(b)(6)	Rodents, insectivores	3423	C					X	
Specific Pathogen Free (SPF) Breeding Colony – SKH1 Hairless Mice	17-011	(b)(6)	Mice	3900	B						

(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:

The following classification system is used:

Class B. Includes animals bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes

Class C. (Non-painful/non-stressful): Animals upon which teaching, research, experiments, or tests will be conducted involving slight or momentary pain, distress, or discomfort. Includes routine procedures such as venipuncture, injections, and the use of non-inflammatory adjuvants.

Class D. Painful/stressful WITH anesthesia/analgesia/tranquilizers: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used. Examples include survival surgery, exposure of blood vessel for catheter placement, transcardial perfusion under anesthesia, and infectious disease induction with analgesics provided.

Class E*. Painful/stressful WITHOUT anesthesia/analgesia/tranquilizers*: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will not be used due to adverse effects on the procedures, results, or interpretation of the teaching, research, experiments, surgery, or test. Examples include food or water deprivation, application of noxious stimulus, toxicological or microbiological testing that may result in clinical symptoms for which an animal cannot be treated.

Justification for Class E: **Additional explanation is required for Category E protocols.

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

Animal Type or Species	Approximate Annual Use
Mouse, laboratory	3520
Rabbit, New Zealand White	11
Mouse, wild caught	155
Chipmunk, wild caught	49
Gerbil, wild caught	19

Animal Type or Species	Approximate Annual Use
Rat, wild caught	573
Shrew, wild caught	151
Bats, wild caught	110
Squirrel, wild caught	5
Vole, wild caught	20

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

Appendix 6: Personnel Medical Evaluation Form

Provide a ***blank*** copy of form(s) used by medically-trained personnel to review individual health assessment, individual risk assessment, health history evaluation, health questionnaire, periodic medical evaluation, etc. If form(s) are not used, include a description of how such evaluations are performed in the Program Description (Section 2.I.A.2.b.ii.1).d), Section 2 (Description). I (Animal Care and Use Program). A (Program Management). 2 (Personnel Management). b (Occupational Health and Safety or Personnel). ii (Standard Working Conditions and Baseline Precautions). 1) (Medical Evaluation and Preventive Medicine for Personnel). d).

Appendix 6: Personnel Medical Evaluation Form

Question	Response	Comment
1. ANNUAL ANIMAL ALLERGY QUESTIONNAIRE		
2. Do you currently work with or around laboratory animals?	☐ Yes ☐ No	4000
3. Describe what sort of contact you have with laboratory animals, bedding, cages, or areas where animals are housed or studied.	4000	4000
4. On average, how often does your work expose you to animal allergens?		
4.1. Days per week	4000	4000
4.2. Days per month	4000	4000
4.3. Days per month	4000	4000
4.4. Days per year	4000	4000

Appendix 6: Personnel Medical Evaluation Form

4.5. How many hours per day? 4000 4000

5. What types of PPE (Personal Protective Equipment) do you use when in the animal areas?

5.1. Lab Coat 4000

5.2. Eye Protection 4000

5.3. Scrubs/overalls 4000

5.4. Gloves 4000

5.5. Respirator 4000

6. What type of respirator do you use?

6.1. N-95 or N-100 4000

6.2. PAPR 4000

Appendix 6: Personnel Medical Evaluation Form

6.3. Other	☐	4000
6.4. None	☐	4000
7. In the past year, have you experienced any of the following allergy symptoms related to your work with or around laboratory animals?		4000
7.1. Asthma/wheezing		4000
7.2. Itchy/watery eyes		4000
7.3. Runny/stuffy nose		4000
7.4. Swollen lips or eyes		4000
7.5. Skin rash or itching		4000
8. Do you have indoor pets?		

Appendix 6: Personnel Medical Evaluation Form

	4000	4000
9. Do you smoke?	☐ Yes ☐ No	4000
10. In the past year, have you had allergy symptoms while not at work?	☐ Yes ☐ No	4000
11. Do you take any prescription medications?	☐ Yes ☐ No	4000

Question	Response	Comment
1. ANIMAL AREA ENTRY SCREENING QUESTIONNAIRE		
2. Certain medical conditions and treatments can weaken your immune system. Diabetes, cancer treatment, and pregnancy are examples of this. A weakened immune system can put you at increased risk for infections or lead to more danger or complicated infections.		
3. Your work in the animal areas may expose you to infectious agents, so it is important to report any known or suspected problems with your immune system. The information below is being gathered to help protect you. The CDC Occupational Health Clinics and the Environment, Safety, Health Compliance Office will use this information to determine whether your condition and your job duties place you at increased risk and to suggest ways to lower your risk.		
4. The specific information you provide is confidential and will not be shared with your supervisors or co-workers.		
5. Do you now have or have you ever had any of the following conditions or treatments?		
5.1. Diabetes	☐ Yes ☐ No	

Appendix 6: Personnel Medical Evaluation Form

5.2. Cancer requiring chemotherapy or radiation	☐ Yes ☐ No	
5.3. Spleen removal	☐ Yes ☐ No	
5.4. Thymus removal	☐ Yes ☐ No	
5.5. Treatment for Lupus	☐ Yes ☐ No	
5.6. Treatment for Rheumatoid Arthritis	☐ Yes ☐ No	
5.7. Treatment with steriods for any condition	☐ Yes ☐ No	
5.8. Treatment for any other auto-immune disorder	☐ Yes ☐ No	
6. Are you currently pregnant?	☐ Yes ☐ No	
7. Are you contemplating or planning pregnancy within the next year?	☐ Yes ☐ No	
8. List all of your current chronic or ongoing		

Appendix 6: Personnel Medical Evaluation Form

medical conditions.

9. List all of your current prescription medications.

Go To Top

Question	Response	Comment

1. INDIVIDUAL HEALTH RISK QUESTIONNAIRE FOR LABORATORY WORKERS

2. Your work in the laboratory has the potential to expose you to infectious agents. Certain medical conditions may put you at increased risk of acquiring a work-related infection or may increase the severity or complications of an infection should it occur.

3. If you have a condition that could increase your risk, the CDC Occupational Health Clinic will help develop strategies to decrease your risk. Such interventions may involve altered work practices, additional personal protective equipment, or other work restrictions or accommodations.

4. This information will be updated annually. However, because your health may change at any time, please promptly report any new conditions, medications, or other concerns that develop when they arise and do not wait until your next visit.

5. Please list all of your current prescription medications.

6. Please list any/all current, chronic or recurrent medical conditions;

7. Do you now have or have you ever had any of the following conditions or treatments?

7.1. Diabetes	☐ Yes ☐ No	
7.2. Cancer requiring chemotherapy or radiation.	☐ Yes ☐ No	

Appendix 6: Personnel Medical Evaluation Form

7.3. Spleen removal.	☐ Yes ☐ No	
7.4. Thymus removal.	☐ Yes ☐ No	
7.5. Treatment for Lupus.	☐ Yes ☐ No	
7.6. Treatment for Rheumatoid Arthritis.	☐ Yes ☐ No	
7.7. Treatment for any other autoimmune disorder.	☐ Yes ☐ No	
7.8. Any other immune system disorder.	☐ Yes ☐ No	
7.9. If yes to any of the questions above, please explain.		
8. Are you currently pregnant or are you contemplating pregnancy in the next year?	☐ Yes ☐ No	
9. Please provide any other health information that you would like to share.		

Go To Top

Appendix 6: Personnel Medical Evaluation Form

Question	Response	Comment
1. INTERVAL RESPIRATOR MEDICAL QUESTIONNAIRE		
2. Have you had any problems using a respirator?	☐ Yes ☐ No	
3. Have you developed any new medical problems associated with heart, lungs, or blood pressure?	☐ Yes ☐ No	
4. Have you ever smoked?	☐ Yes ☐ No	
5. Have you had a significant increase in weight?	☐ Yes ☐ No	
6. Have you had a significant decrease in your overall fitness?	☐ Yes ☐ No	
7. Have you experienced chest pain or tightness, shortness of breath, or persistent palpitations at rest or with excercise?	☐ Yes ☐ No	
8. Have you started taking any new prescription medications?	☐ Yes ☐ No	

Appendix 6: Personnel Medical Evaluation Form

9. Has the type of respirator you use or the type of work you do while using a respirator changed significantly?	☐ Yes ☐ No	
10. Has anything else occurred that gives you concern over your ability to use a respirator?	☐ Yes ☐ No	

Go To Top

Top of Form

Question	Response	Comment
1. RESPIRATORY MEDICAL QUESTIONNAIRE (OSHA FORM)		
2. Part A, Section 1		
3. To the employee:		
4. Can you read:	☐ Yes ☐ No	
5. Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.		
6. Part a. Section 1. (Mandatory) The following information must be provided by every employee who has been selected to use any type of respirator (please print).		

Appendix 6: Personnel Medical Evaluation Form

7. Today's Date:	mm/dd/yyyy
8. Your name:	4000
9. Your age (to nearest year): (21 - 67)	
10. Sex (Select one):	
11. Your height: _____ft._____ _in.	4000
12. Your weight _____lbs.	
13. Your job title:	4000
14. A phone number where you can be reached by the health care professional who reviews this questionnaire (include Area Code):	4000
15. The best time to phone you at this number:	4000
16. Has your employer told you how to contact the health care professional who will review this	☐ Yes ☐ No

Appendix 6: Personnel Medical Evaluation Form

questionnaire (select one):

17. Check the type of respirator you will use (you can select more than one category):

17.1. N, R, or P disposable respirator (filter-mask, non-cartridge type only). ☐

17.2. Other type (for example, half- or full-facepiece tyupe, powered-air purifying, supplied-air, self-contained breathing apparatus). ☐ 4000

18. Have you worn a respirator ☐ Yes ☐ No

19. Part A. Section 2.

20. Do you currently smoke tobacco, or have you smoked tobacco in the last month? ☐ Yes ☐ No

21. Have you ever had any of the following conditions? (If yes, please select all that apply) ☐ Yes ☐ No

21.1. Seizures (fits): ☐

Appendix 6: Personnel Medical Evaluation Form

21.2. Diabetes (sugar disease): ☐

21.3. Allergic reactions that interfere with your breathing: ☐

21.4. Claustrophobia (fear of closed-in places): ☐

21.5. Trouble smelling odors: ☐

22. Have you ever had any of the following pulmonary or lung problems? (If yes, please select all that apply) ☐ Yes ☐ No

22.1. Asbestosis: ☐

22.2. Asthma: ☐

22.3. Chronic bronchitis: ☐

22.4. Emphysema: ☐

22.5. Pneumonia: ☐

22.6. Tuberculosis: ☐

Appendix 6: Personnel Medical Evaluation Form

22.7. Silicosis: ☐

22.8. Pneumothorax (collapsed lung): ☐

22.9. Lung cancer: ☐

22.10. Broken ribs: ☐

22.11. Any chest injuries or surgeries: ☐

22.12. Any other lung problem that you've been told about: ☐

23. Do you currently have any of the following symptoms of pulmonary or lung illness? (If yes, please select all that apply) ☐ Yes ☐ No

23.1. Shortness of breath: ☐

23.2. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: ☐

23.3. Shortness of breath when walking with other people at an ordinary pace on level ground: ☐

Appendix 6: Personnel Medical Evaluation Form

23.4. Have to stop for breath when walking at your own pace on level ground: ☐

23.5. Shortness of breath when washing or dressing yourself: ☐

23.6. Shortness of breath that interferes with your job: ☐

23.7. Coughing that produces phlegm (thick sputum): ☐

23.8. Coughing that wakes you early in the morning: ☐

23.9. Coughing that occurs mostly when you are lying down: ☐

23.10. Coughing up blood in the last month: ☐

23.11. Wheezing: ☐

23.12. Wheezing that interferes with your job: ☐

23.13. Chest pain when you breathe deeply: ☐

Appendix 6: Personnel Medical Evaluation Form

23.14. Any other symptoms that you think may be related to lung problems:

24. Have you ever had any of the following cardiovascular or heart problems? (If yes, please select all that apply)

- Yes
- No

24.1. Heart Attack:

24.2. Stroke:

24.3. Angina:

24.4. Heart failure:

24.5. Swelling in your legs or feet (not caused by walking):

24.6. Heart arrhythmia (heart beating irregularly):

24.7. High blood pressure:

24.8. Any other heart problem that you've been told about:

4000

Appendix 6: Personnel Medical Evaluation Form

25. Have you ever had any of the following cardiovascular or heart symptoms? (If yes, please select all that apply)
- ☐ Yes
- ☐ No

25.1. Frequent pain or tightness in your chest: ☐

25.2. Pain or tightness in your chest during physical activity: ☐

25.3. Pain or tightness in your chest that interferes with your job: ☐

25.4. In the past two years, have you noticed your heart skipping or missing a beat: ☐

25.5. Heartburn or indigestion that is not related to eating: ☐

25.6. Any other symptoms that you think may be related to heart or circulation problems: ☐

4000

26. Do you currently take medication for any of the following problems? (If yes, please select all that apply)
- ☐ Yes
- ☐ No

Appendix 6: Personnel Medical Evaluation Form

26.1. Breathing or lung problems: ☐

26.2. Heart trouble: ☐

26.3. Blood Pressure: ☐

26.4. Seizures: ☐

27. If you've used a respirator, have you ever had any of the following problems? (If yes, please select all that apply) ☐

27.1. Eye irritation: ☐

27.2. Skin allergies or rashes: ☐

27.3. Anxiety: ☐

27.4. General weakness or fatigue: ☐

27.5. Any other problem that inteferes with your use of a respirator: ☐

4000

28. Would you like to talk to the health care professional who will review this questionnaire about ☐ Yes ☐ No

Appendix 6: Personnel Medical Evaluation Form

your answers to this questionnaire:

29. Questions 30 to 35 below must be answered by every employee who has been selected to use either a full-facepiece respirator or a self-contained breathing apparatus (SCBA). For employees who have been selected to use other types of respirators, answering these questions is voluntary.

30. Have you ever lost vision in either eye (temporarily or permanently): ☐ Yes ☐ No

31. Do you currently have any of the following vision problems? (If yes, please select all that apply) ☐ Yes ☐ No

31.1. Wear contact lenses: ☐

31.2. Wear glasses: ☐

31.3. Color blind: ☐

31.4. Any other eye or vision problem: ☐

4000

32. Have you ever had an injury to your ears, including a broken ear drum: ☐ Yes ☐ No

33. Do you currently have any of the following hearing problems? (If yes,

Appendix 6: Personnel Medical Evaluation Form

please select all that apply)

33.1. Difficulty hearing: ☐

33.2. Wear a hearing aid: ☐

33.3. Any other hearing or ear problem: ☐

4000

34. Have you ever had a back injury: ☐ Yes ☐ No

35. Do you currently have any of the following musculoskeletal problems? (If yes, please select all that apply) ☐ Yes ☐ No

35.1. Weakness in any of your arms, hands, legs, or feet: ☐

35.2. Back pain: ☐

35.3. Difficulty fully moving your arms and legs: ☐

35.4. Pain or stiffness when you lean forward or backward at the waist: ☐

Appendix 6: Personnel Medical Evaluation Form

35.5. Difficulty fully moving your head up or down: ☐

35.6. Difficulty fully moving your head side to side: ☐

35.7. Difficulty bending at your knees: ☐

35.8. Difficulty squatting to the ground: ☐

35.9. Climbing a flight of stairs or a ladder carrying more than 25 lbs: ☐

35.10. Any other muscle or skeletal problem that interferes with using a respirator: ☐

4000

36. Part B. Any of the following questions, and other questions not listed, may be added to the questionnaire at the discretion of the health care professional who will review the questionnaire.

37. In your present job, are you working at high altitudes (over 5,000 feet) or in a place that has lower than normal amounts of oxygen:

☐ Yes
☐ No

38. At work or at home, have you ever been exposed to hazardous solvents,

☐ Yes
☐ No

Appendix 6: Personnel Medical Evaluation Form

hazardous airborne chemicals (e.g., gases, fumes, or dust), or have you come into skin contact with hazardous chemicals:

39. Have you ever worked with any of the materials, or under any of the conditions, listed below: (If yes, please select all that apply)

- ☐ Yes
- ☐ No

- 39.1. Asbestos: ☐
- 39.2. Silica (e.g. in sandblasting): ☐
- 39.3. Tungsten/cobalt (e.g. grinding or welding this material): ☐
- 39.4. Beryllium: ☐
- 39.5. Aluminum: ☐
- 39.6. Coal (for example, mining): ☐
- 39.7. Iron: ☐
- 39.8. Tin: ☐

Appendix 6: Personnel Medical Evaluation Form

39.9. Dusty environments: ☐

39.10. Any other hazardous exposures: ☐

39.11. If yes, describe these exposures:

4000

40. List any second jobs or side businesses you have:

4000

41. List your previous occupations:

4000

42. List your current and previous hobbies:

4000

43. Have you been in the military services?

☐ Yes
☐ No

44. Have you ever worked on a HAZMAT team?

☐ Yes
☐ No

Appendix 6: Personnel Medical Evaluation Form

45. Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter medications):

☐ Yes
☐ No

46. Will you be using any of the following items with your respirator(s)?

☐ Yes
☐ No

46.1. HEPA Filters: ☐

46.2. Canisters (for example, gas masks): ☐

46.3. Cartridges: ☐

47. How often are you expected to use the respirator(s). (Indicate yes or no for all answers that apply to you)?:

48. During the period you are using the respirator(s), is your work effort:

49. Light (less than 200 kcal per hour):

☐ Yes
☐ No

49.1. Examples of a light work effort are sitting while writing, typing, drafting, or performing light assembly work; or standing while operating a drill press (1-3 lbs.) or controlling machines.

Appendix 6: Personnel Medical Evaluation Form

49.2. If yes, how long does this period last during the average shift: _____hrs._____ _mins.

50. Moderate (200 to 350 kcal per hour): ☐ Yes ☐ No

50.1. Examples of moderate work effort are sitting while nailing or filing; driving a truck or bus in urban traffic; standing while drilling, nailing, performing assembly work, or transferring a moderate load (about 35 lbs.) at trunk level; walking on a a level surface about 2 mph or down a 5-degree grade about 3 mph; or pushing a wheelbarrow with a heavy load (about 100 lbs.) on a level surface.

50.2. If yes, how long does this period last during the average shift: _____hrs._____ mins.

4000

51. Heavy (above 350 kcal per hour): ☐ Yes ☐ No

51.1. Examples of heavy work are lifting a heavy load (about 50 lbs.) from the floor to your waist or shoulder; working on a loading dock; shoveling; standing while bricklaying or or chipping castings; walking up an 8-degree grade about 2 mph; climbing stairs with a heavy load (about 50 lbs.).

51.2. If yes, how long does this period last during the average shift: _____hrs._____ mins.

4000

Appendix 6: Personnel Medical Evaluation Form

52. Will you be wearing protective clothing and/or equipment (other than the respirator) when you're using your respirator:

- ☐ Yes
- ☐ No

53. Will you be working under hot conditions (temperature exceeding 77 degrees F):

- ☐ Yes
- ☐ No

54. Will you be working under humid conditions:

- ☐ Yes
- ☐ No

55. Describe the work you'll be doing while you're using your respirator:

4000

56. Describe any special or hazardous conditions you might encounter when you're using your respirator(s) (for example, confined spaces, life-threatening gases):

4000

57. Provide the following information, if you know it, for each toxic substance that you'll be exposed to when you're using your respirator(s):

58. Name of the first toxic substance:

4000

Appendix 6: Personnel Medical Evaluation Form

59. Estimated maximum exposure level per shift:

4000

60. Duration of exposure per shift:

4000

61. Name of the second toxic substance:

4000

62. Estimated maximum exposure level per shift:

4000

63. Duration of exposure per shift:

4000

64. Name of the third toxic substance:

4000

65. Estimated maximum exposure level per shift:

4000

66. Duration of exposure per shift:

4000

67. The name of any other toxic substances that you'll be exposed to while using your respirator:

4000

Appendix 6: Personnel Medical Evaluation Form

68. Describe any special responsibilities you'll have while using your respirator(s) that may affect the safety and well-being of others (for example, rescue, security):

4000

Go To Top

Bottom of Form

Appendix 6: Personnel Medical Evaluation Form

OADLSS Office of the Associate Director for Laboratory Science and Safety

CDC BIOLOGICAL RISK ASSESSMENT FORM

RA Title: _____

RA conducted by: _____

Center/Division/Branch/Lab: _____

(Indicate Location) Building: Select a building Room(s): _____

OADLSS USE ONLY:

RA #: _____

Review Date: _____

The work described includes (check all relevant):

- Recombinant or Synthetic Nucleic Acids ☐ Yes ☐ No
- Select Agents ☐ Yes ☐ No
- Research animals ☐ Yes ☐ No
- Chemical Hazards ☐ Yes ☐ No
- Radiation Hazards ☐ Yes ☐ No
- Dual Use Research (DUR) of Concern (DURC) ☐ Yes ☐ No
- Human Blood and Body Fluids ☐ Yes ☐ No
- Use of High Containment Laboratories (BSL3E* or BSL4) ☐ Yes ☐ No
- Import/Export or Transfer of Infectious Material ☐ Yes ☐ No

It is the responsibility of the Laboratory Supervisor to conduct a risk assessment before conducting any procedure in the laboratory. All laboratory staff members must be familiar with the risk assessments (hazards, evaluation, and mitigation) for the work in which they are involved. To adequately assess risk, the characteristics of the agent, the equipment that will be used, procedures to be performed, use of animal models, available facilities, and capabilities of the laboratory staff must all be considered.

* BSL3 Enhanced

Appendix 6: Personnel Medical Evaluation Form

OADLSS Office of the Associate Director for Laboratory Science and Safety

PART I: Hazard Identification

Microorganisms

Risk Group[1]	Taxon or group[2]	Select Agent?[3]	Tier 1?
Select a group		☐ Yes ☐ No	☐ Yes ☐ No
Select a group		☐ Yes ☐ No	☐ Yes ☐ No
Select a group		☐ Yes ☐ No	☐ Yes ☐ No
Select a group		☐ Yes ☐ No	☐ Yes ☐ No
Select a group		☐ Yes ☐ No	☐ Yes ☐ No
Select a group		☐ Yes ☐ No	☐ Yes ☐ No

[1]Reference: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines
[2]A list can be attached if more convenient
[3]Reference: https://www.selectagents.gov/

Toxins ☐ Yes ☐ No Select agent? ☐ Yes ☐ No Tier 1? ☐ Yes ☐ No LD50 _____
If yes, please specify: _____ source organism: _____

Recombinant/Synthetic Nucleic acids ☐ Yes ☐ No **Viral Vectors?** ☐ Yes ☐ No
If yes to either, please specify: _____ IBC Protocol#: _____

Vertebrate Animals ☐ Yes ☐ No Reference (b)(7)(E)
Wild caught? ☐ Yes ☐ No
If yes, please specify species: _____ IACUC Protocol#: _____

Invertebrate Laboratory Animals ☐ Yes ☐ No If yes, please specify: _____
Are these animals disease vectors? ☐ Yes ☐ No If yes, please specify disease: _____
Wild caught Invertebrate Animals ☐ Yes ☐ No If yes, please specify: _____

Research Plants ☐ Yes ☐ No If yes, please specify: _____

Cell Culture ☐ Yes ☐ No If yes, name: _____ source organism: _____

Human Clinical Specimens ☐ Yes ☐ No
Sample matrix (e.g., sputum, blood, serum) _____
Indigenous? ☐ Yes ☐ No If no, geographical origin of the material? _____

Appendix 6: Personnel Medical Evaluation Form

OADLSS Office of the Associate Director for Laboratory Science and Safety

Animal Specimens ☐ Yes ☐ No
Sample matrix (*e.g.*, blood, serum) _____
Indigenous? ☐ Yes ☐ No If no, geographical origin of the material? _____

Environmental Specimens ☐ Yes ☐ No Sample matrix (e.g. soil, water) _____
Indigenous? ☐ Yes ☐ No If no, geographical origin of the material? _____

For inactivated material received from a Non-CDC source:
Has the material been sent with documentation of inactivation? ☐ Yes ☐ No

Imported live agent or culture from outside the US? ☐ Yes ☐ No

Note: When working with specimens which may contain unknown pathogens, one should assess the risk assuming the presence of the most virulent pathogen(s) in the specimen. New and emergent pathogens should be assumed to have similar risks as the most closely related known organisms.

Part II: Risk Evaluation (for multiple agents please attach in table format)

Name of agent_____
Infectious Dose_____ Case Fatality Rate_____
Incubation period_____ Endemic? ☐ Yes ☐ No
Person to person transmission? ☐ Yes ☐ No Airborne? ☐ Yes ☐ No
Zoonotic? ☐ Yes ☐ No if yes, host range_____
Vector borne? ☐ Yes ☐ No if yes, vector_____
Stable in the environment? ☐ hours ☐ days ☐ longer ☐ unknown

Routes of transmission (check all that apply):

☐ Inhalation
☐ Mucosal membrane exposure
☐ Ingestion
☐ Percutaneous (e.g. animal/insect bite/needlestick)

Additional information: (*e.g.*, history of laboratory-acquired infection (LAI), symptoms/severity of infection)

Appendix 6: Personnel Medical Evaluation Form

OADLSS Office of the Associate Director for Laboratory Science and Safety

Describe the laboratory activity planned with this material.

Aerosol Generation? ☐ Yes ☐ No Sharps use? ☐ Yes ☐ No Inactivation and transfer? ☐ Yes ☐ No
Large Scale? (10 L or greater) ☐ Yes ☐ No Work performed on open bench? ☐ Yes ☐ No

Equipment used in lab activities with this material: (check all that apply):

- ☐ Centrifuge/micro-centrifuge
- ☐ Sonicator
- ☐ Aerosolization chamber
- ☐ Homogenizer
- ☐ Plate washer
- ☐ Shaking incubator
- ☐ Bead Beater
- ☐ Vacuum/aspirating equipment Cell sorters
- ☐ Pipettes
- ☐ Sharps (*e.g.* needles, scalpels) Grinding equipment
- ☐ Vortex
- ☐ Robotics
- ☐ Cytospin
- ☐ Vacuum concentrator
- ☐ Other _____

Considering the risk of release or exposure:

Severity: ☐ Negligible ☐ Minor ☐ Serious ☐ Critical ☐ Catastrophic

Probability: ☐ Improbable ☐ Remote ☐ Occasional ☐ Probable ☐ Frequent

Inherent Project Risk (prior to mitigation): ☐ Low (minimal) ☐ Moderate ☐ High

Appendix 6: Personnel Medical Evaluation Form

Part III: Risk Mitigation (how do you plan to reduce the risk?)

Elimination/Substitution

Microorganisms

Is it feasible to do this work with avirulent/attenuated strains? ☐Yes ☐ No ☐ N/A

Toxins

Is it feasible to do this work with toxoids/incomplete toxins? ☐Yes ☐ No ☐ N/A

Animal work

Is it feasible to do this work *in vitro*? ☐Yes ☐ No ☐ N/A

Use of sharps

Needleless or other safer options considered? ☐Yes ☐ No ☐ N/A

Glassware substituted with plasticware whenever possible? ☐Yes ☐ No

Engineering Controls (Primary barriers)

- ☐ Class I BSC
- ☐ Class II BSC
- ☐ Class III BSC
- ☐ Chemical fume hood
- ☐ Retracting/Shielding safety syringes
- ☐ Ventilated animal cage rack system
- ☐ Sealed centrifuge rotors
- ☐ Centrifuge safety cups
- ☐ Animal restraint
- ☐ PCR workstation
- ☐ Downdraft table
- ☐ Sample transfer carrier
- ☐ Other_____

Laboratory Facilities and Equipment (Secondary barriers)

- ☐ Entry through two self-closing doors or anteroom
- ☐ Autoclave in the suite or on the same floor
- ☐ Interlocking pass-through autoclave in the lab
- ☐ Arthropod Containment
  - ☐ ACL1 ☐ ACL2 ☐ ACL3 ☐ ACL4
- ☐ Fumigation chamber
- ☐ Lab or animal facility separate from areas open to unrestricted personnel traffic
- ☐ Sealed laboratory seams/floors/walls/ceiling/surfaces
- ☐ Visual monitoring device to verify directional airflow
- ☐ Hands-free hand washing sink
- ☐ Effluent decontamination system
- ☐ Shower-out capability
- ☐ Pass-through Decontamination tanks
- ☐ HEPA filtration of room exhaust
- ☐ Other _____

Appendix 6: Personnel Medical Evaluation Form

Administrative Controls

Personnel

The following staff have been verified by the supervisor as competent and trained in agent specific and laboratory specific procedures and techniques[1]:

Name	Job Title	Employment type	Years working with agent/material	Initials/ Date*	Supervisor Initials/ Date**
		Select a type			
		Select a type			
		Select a type			
		Select a type			
		Select a type			
		Select a type			
		Select a type			
		Select a type			
		Select a type			
		Select a type			

*By initialing this document, personnel indicate they have reviewed this risk assessment and the lab biosafety manual, discussed the hazards with their supervisor, and have been authorized to perform the procedures addressed by this risk assessment.

**By initialing this document, laboratory supervisors indicate that staff are trained and competent.

[1] A list can be attached

Personnel Training

- List all required training that laboratory personnel must complete prior to being authorized by their supervisor to work with these agent(s), material(s), and procedure(s). Include training specific to the laboratory, equipment used and procedures performed as well as basic safety training provided by CDC. Annual Blood Borne Pathogen (BBP) training is required for work with human samples.

Appendix 6: Personnel Medical Evaluation Form

OADLSS Office of the Associate Director for Laboratory Science and Safety

Immunizations and Treatment

Required Vaccines? ☐ Yes ☐ No If yes, list: _____
Use of Investigational New Drugs (IND)? _____
Local availability of effective prophylaxis? ☐ Yes ☐ No If yes, specify _____
Local availability of effective treatment? ☐ Yes ☐ No If yes, specify _____

Medical surveillance requirements:
Baseline serum required: ☐ Yes ☐ No
TB Screening: ☐ Yes ☐ No
Enrollment in Respiratory Protection Program required: ☐ Yes ☐ No
Routine serologic testing: ☐ Yes ☐ No If yes, frequency of testing: _____
Enrollment in Hearing Conservation Program: ☐ Yes ☐ No

Access Restriction: (Click all that apply) Biometric reader ☐ Cardkey ☐ Physical Locks ☐ Numeric Pad (PIN) ☐

Contingencies:

Disinfectant approved by OADLSS?	☐ Yes ☐ No if yes, specify: _____
Spill response procedures listed in SOP and rehearsed?	☐ Yes ☐ No
Waste decontamination procedures listed in SOP?	☐ Yes ☐ No
Emergency Drills conducted annually?	☐ Yes ☐ No

Personal Protective Equipment (PPE):
Laboratory supervisors are responsible for providing the appropriate PPE for laboratorians. Refer to [redacted] information. Be sure to consider all the hazards associated with the procedure when selecting PPE (*e.g.*, chemical hazards, animal hazards, heat from ovens, and cold from cryogens).

☐ Latex Gloves	☐ Scrub suit	☐ Shoe covers/boots
☐ Double glove requirement	☐ Disposable coverall/suit	☐ Safety glasses
☐ Nitrile Gloves	☐ Disposable wrap-around gown	☐ Goggles
☐ Face shield	☐ Open Front Lab Coat	☐ Positive-pressure supplied-air suit
☐ Hearing Protection	☐ Tyvek sleeves	☐ Puncture resistant gloves
☐ N-100 respirator	☐ N-95 respirator	☐ Other _____
☐ Solid Front Lab Coat	☐ PAPR	

Special Practices:		☐ BSL2	☐ BSL3	☐ BSL3E	☐ BSL4
Laboratory Facilities:	☐ BSL1	☐ BSL2	☐ BSL3	☐ BSL3E	☐ BSL4
Vivaria:	☐ ABSL1	☐ ABSL2	☐ ABSL3		☐ ABSL4

Residual Project Risk (after mitigation): ☐ **Low (minimal)** ☐ **Moderate** ☐ **High**

Appendix 6: Personnel Medical Evaluation Form

OADLSS Office of the Associate Director for Laboratory Science and Safety

I agree to follow CDC safety policies and the recommendations in the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*. I certify that the information provided above is accurate to the best of my knowledge.

_____ _____
Laboratory Supervisor Date

_____ _____
Branch Chief (or designee) Date

DIVISION REVIEW ☐ Yes ☐ No

Reviewed by: _____
Name/title

Signature _____ **Review date:** _____

CENTER REVIEW ☐ Yes ☐ No

Reviewed by: _____
Name/title

Signature _____ **Review date:** _____

Additional Safety Recommendations:

Does project risk require board review? ☐ Yes ☐ No

IBC ☐ **IBB** ☐ **LSRB** ☐ **IACUC** ☐ **RO** ☐ **CHO** ☐ **RSO** ☐

Appendix 6: Personnel Medical Evaluation Form

OADLSS Office of the Associate Director for Laboratory Science and Safety

RA forwarded to OADLSS? ☐ Yes ☐ No

Reviewed by: _____
Name/title

Signature _____ **Review date:** _____

Responsible official: _____ (for select agents only)

Signature _____ **Review date:** _____

OADLSS USE ONLY

RA #: _____

Review Date: _____

Appendix 6: Personnel Medical Evaluation Form

Instructions for Use

Definitions:

Risk: the probability that some harm (injury, infection, or damage) will occur
Hazard: a potential source of harm
Inherent risk: risk that is intrinsically connected to the nature of the hazard in the absence of any mitigation control
Residual risk: risk that remains after mitigation strategy is taken into account

The following tables can be used as tools to help evaluate risk:

Criteria for Severity Classification	
Negligible	• Potential for minor material cost • Scope of impact limited to the team or branch • Work with nucleic acid extracts or other inactivated material
Minor	• Potential for minor material cost • Scope of impact limited to the team or branch • Work with risk group 1 organisms
Serious	• Potential for appreciable material cost • Scope of impact reaching outside the branch • Work with risk group 2 pathogens
Critical	• Potential for appreciable material cost • Scope of impact reaching outside CDC • Work with risk group 3 pathogens
Catastrophic	• Potential for appreciable material cost • National or international impact • Work with risk group 4 pathogens

Criteria for Probability Classifications	
Improbable	Statistically insignificant
Remote	<1% of testing
Occasional	1-10% of testing
Probable	11-50% of testing
Frequent	>50% of testing

Appendix 6: Personnel Medical Evaluation Form

Risk Matrix

Probability	SEVERITY				
	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	Low	Moderate	High	High	High
Probable	Low	Moderate	High	High	High
Occasional	Low	Moderate	Moderate	High	High
Remote	Low	Low	Moderate	Moderate	High
Improbable	Low	Low	Low	Moderate	Moderate

Completing the CDC Biological Risk Assessment Form

Purpose: To provide step by step directions on how to complete the risk assessment form.

Prerequisite: Please note that under current CDC policy (found here), only those individuals who have completed the risk assessment course may complete a formal risk assessment.

Please complete all sections of this form. Incomplete forms will be returned to the submitter.

1. **Cover Sheet**
   - Enter title for this risk assessment
   - Enter the name of the person(s) who completed the risk assessment (not necessarily the same person that filled out the form). You can enter multiple names as appropriate.
   - Enter the information about the laboratory's organization and location (building and room number(s)) where the work will take place.
   - Ignore the box for OADLSS use only. The RA number is a unique identifier assigned by OADLSS when it completes a review and remains the same throughout the life of the risk assessment.
   - Answer the yes/no questions related to the work covered by this risk assessment. The intent for this section is to offer brief information to the reviewer at a glance.
     - Only answer yes for recombinant or synthetic nucleic acids (NA) if you are actually inserting NA in living organisms or viruses. For more information please consult the NIH guidelines

Appendix 6: Personnel Medical Evaluation Form

2. **Part I: Hazard Identification**
   - Enter the name of the organism(s) involved and risk group. You may enter a specific genus and species, or a group of related organisms. You should only combine organisms in the same RA form if they present similar risks. You can attach a list of agents if more convenient. Then answer the questions pertaining to select agents and toxins.
   - Answer the brief questions about the biological material (toxins, animals, plants, cell culture, etc.) used in your work.
   - Where an IBC or IACUC protocol # is requested, please provide the number if available. It is not mandatory to have those approvals before completing a risk assessment. If not yet available, please enter pending. OADLSS will, however, inform the respective boards.
   - If the material comes from multiple geographic origins, you can answer "multiple US locations" or "multiple worldwide location" as appropriate.
3. **Part II: Risk Evaluation**
   - Provide details about the risks posed by the agents used. The intent here is to provide as much information as possible to describe the *severity* of the risks of working with these agents.
   - Indicate the known routes of transmission.
   - Provide any known information from the literature about the history of laboratory infections and the consequences of infection with these agents.
   - Describe briefly the procedures involved, paying particular attention to steps that may pose significant risk, such as aerosolization, handling animals, use of sharps, and dissections. The types of procedures used mostly affect the *probability* of the risks. You should be thinking "what could go wrong?"
   - Indicate equipment used during this procedure, as appropriate.
   - For the entire procedure, indicate severity and probability, the two main variables in risk. Use the tables in the back of the form as a guide.
   - Use the selected severity and probability and the risk matrix on the last page of the form to assign the *inherent* risk. This is the risk that is intrinsic to the nature of the hazard and procedure before mitigation.
4. **Part III: Risk Mitigation**
   - The intent of this section is to indicate how the identified risks will be mitigated using the hierarchy of controls. The mitigation strategy is always based on the inherent risks as evaluated in the previous section. After completing this section one should ask whether the risks have been properly mitigated and everything that "could go wrong" is addressed.

Appendix 6: Personnel Medical Evaluation Form

- **Elimination and Substitution.** The most effective means to mitigate risk is elimination and substitution. If it is feasible to use something less hazardous in place of the agent, toxin, instrument, or a specific technique, then you should.
- **Engineering Controls.** Indicate the engineering controls you plan to use to mitigate risk
- **Laboratory Facilities.** Indicate the facility features available to you for this work
- **Administrative Controls.**
  - **Personnel.** Provide the names and other information pertaining to the staff involved in this work. Attach additional sheets if necessary. It is essential that all staff are properly trained and this training is documented. Training should include site specific, agent specific, CDC safety courses, and other required safety courses as applicable.
  - **Immunizations and treatment.** What is the plan to prevent and/or treat infection?
    - Please note that the use of an IND requires a human use protocol and IRB approval along with informed consent
    - "Local availability" means available in the local community where the work is performed.
  - **Medical Surveillance.** Please consult with the Occupational Health provider if necessary
  - **Access restriction.** Indicate how access is restricted at the laboratory entry
  - **Contingencies.** Answer the brief questions
- **Personal Protective Equipment (PPE).** Review the CDC guidance on PPE and indicate the specific PPE the staff will use for this project. Keep in mind that CDC has minimum PPE requirements for laboratory entry.

- **Biosafety level and residual risk.**
  - Indicate the biosafety level to be used. Please note that it is possible to use special practices for one level higher than the facility biosafety level. For example, BSL3 practices can be used in a BSL2 laboratory.
  - Residual risk is the estimated risk that remains after the mitigation strategy is implemented. Considering that the goal of the risk assessment is to reduce risk to an acceptable level, it follows that the residual risk should be lower than the inherent risk. Use the risk matrix provided. If you find that the risk cannot be properly mitigated please consult with OADLSS.

Appendix 6: Personnel Medical Evaluation Form

5. **Signatures and Review**
   - Supervisor and Branch Chief sign indicating concurrence with and approval of the risk assessment.
   - Center or Division may require further review and clearance
   - The rest of the form is completed by OADLSS if forwarded to us. A CDC-level (OADLSS) review is REQUIRED if the risk assessment involves new or modified projects that use
     - Select agent or toxin
     - RG3 or RG4 infectious agent
   - Each RA form requires annual review by staff and supervisor. OADLSS staff will ask to see RA forms during the annual laboratory survey.

Appendix 6: Personnel Medical Evaluation Form

Revision History

Rev #	Change Summary
01	New Document

Document Issued by: Director, Office of Laboratory Safety, OADLSS

Appendix 6: Personnel Medical Evaluation Form

Current Date	10/31/17

DVBD

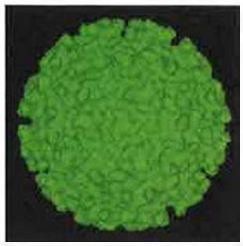
INDIVIDUAL BIO-SAFETY RISK ASSESSMENT

Please enter your name:	

Appendix 6: Personnel Medical Evaluation Form

VIRUS LIST

PLEASE LIST ANY VIRUS OR VIRUSES YOU MAY WORK WITH IN YOUR RESEARCH THIS YEAR.



Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	
Virus List	

Enter any virus and it's risk group (RG) value that you did not find in the list above

Appendix 6: Personnel Medical Evaluation Form

BACTERIA LIST

PLEASE LIST ANY BACTERIA YOU MAY WORK WITH IN YOUR RESEARCH THIS YEAR.

Bacteria List	Borrelia afzelii
Bacteria List	Borrelia americana
Bacteria List	Borrelia andersonii
Bacteria List	Borrelia bissettii
Bacteria List	Borrelia burgdorferi
Bacteria List	Borrelia carolinensis
Bacteria List	Borrelia garinii
Bacteria List	Borrelia hermsii
Bacteria List	Borrelia kurtenbachii
Bacteria List	Borrelia lonestari
Bacteria List	Borrelia miyamotoi
Bacteria List	Borrelia miyamotoi

Enter any bacteria and it's risk group (RG) value that you did not find in the list above

Appendix 6: Personnel Medical Evaluation Form

HAZARD WORKSHEET

Please answer the following questions so as to assist in identifying hazards

1. Do you use centrifuges with removable buckets and/or rotors? ☐ YES ☐ NO

2. Do the buckets and rotors have intact gaskets that are in good condition? ☐ YES ☐ NO

3. When centrifuging infectious material, do you load your buckets and rotors inside a biological safety cabinet? ☐ YES ☐ NO

4. What disinfectant do you use to decontaminate the outside of the buckets or rotors before removing from the BSC.

Disinfectant: 70%Ethanol

5. Do you ever have a procedure that requires you to pipette infectious material outside of a BSC? ☐ YES ☐ NO

6. Do you ever use a pipette for mixing infectious material? ☐ YES ☐ NO

7. Do you use an open flame in any of your work? ☐ YES ☐ NO

8. Do you use an open flame inside the BSC? ☐ YES ☐ NO

9. How many years of experience do you have working with infectious material in a BSC?

YEARS: > 10 years

10. How many years of experience do you have working with the risk group 3 organisms that you listed?

YEARS:

11. Do you perform any procedures with risk group 3 organisms outside of primary containment?

If yes, please list the procedure(s):

If you have any comments for questions above, please note them here:

Appendix 6: Personnel Medical Evaluation Form

12. How do you currently mitigate possible aerosol, percutaneous or mucosal exposure during the procedure(s) mentioned in question 11?

Explain Here:

13. Do you ever handle samples of human blood and body fluid? ☐ YES ☐ NO

14. Do you inoculate blood with any of the organisms you listed? ☐ YES ☐ NO

15. Do you prepare the blood within a BSC? ☐ YES ☐ NO

16. If you perform infectious blood feeds, do you prepare your feeders within the BSC? ☐ YES ☐ NO

17. Will you work with infected arthropods? ☐ YES ☐ NO

18. If yes to question 17, please explain the method and equipment you will use to homogenize your infected arthropods for further testing.

Explain Here: Bead beating in 96 well plate in plate shaker which is in a hood or a mortar and pestle.

19. Will you be collecting arthropods in the field this year? ☐ YES ☐ NO

20. Will you be doing any vertebrate trapping this year? ☐ YES ☐ NO

21. Do you foresee performing any necropsies in the field this year? ☐ YES ☐ NO

22. Do you foresee performing any necropsies on known or potentially infected vertebrates in the lab? ☐ YES ☐ NO

23. If you perform DNA/RNA extractions, what method and equipment will you use to homogenize your raw sample?

Explain Here: Bead beating in 96 well plate in plate shaker, which is in a hood, followed by enzyme digestion or just an enzyme digestion.

If you have any comments for questions above, please note them here:

Appendix 6: Personnel Medical Evaluation Form

24. If power is lost to your BSC or all the power is lost to your lab, do you know how to safely stop work in the BSC?

Explain Here:

25. If you are injured by a sharp in the lab, do you know the proper procedure to follow for treating the injury and communicating the incident here at the fort?

Explain Here:

26. Do you know the proper procedure to follow if you spill infectious material outside of primary containment?

Explain Here:

27. How long do you allow a disinfectant to remain on a lab surface before wiping up?

Contact Time: 1 to 3 minutes

28. Describe how you transport infectious material outside the laboratory?

Explain Here:

If you have any comments for questions above, please note them here:

Appendix 7: IACUC/OB Membership Roster

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

Member	Degree	Membership Role	Affiliation
(b)(6)	PhD	Chair Member, Scientist	Bacterial Disease Branch, DVBD
	PhD	Member, Scientist Alternate Chair	Arboviral Diseases Branch, DVBD
	MS	Member, Scientist	Bacterial Diseases Branch, DVBD
	PhD	Member	Non-affiliated
	BS	Member	Non-affiliated
	MS	Community member, non-scientist	Non-affiliated
	PhD	Non-scientist, statistician	Office of the Director, DVBD
	MS	Non-scientist, safety	Office of the Director, DVBD
	DVM, PhD, ACLAM	Attending Veterinarian	Contractor
	DVM, ACLAM	Alternate AV	Contractor
	PhD	Non-scientist, statistician alternate	Office of the Director, DVBD
	PhD	Member, Scientist, alternate	Bacterial Diseases Branch, DVBD
	PhD	Member, Scientist, alternate	Arboviral Diseases Branch, DVBD
	PhD	Member	Non-affiliated

Appendix 8: IACUC/OB Minutes

Please provide the latest two Minutes of the IACUC/OB meetings.

Institutional Animal Care and Use Committee
September 12, 2017 — 0900–1100
Bldg (b)(7)(E)

Meeting Attendees:

Committee members:	In Attendance (quorum=6)	Not In Attendance
(b)(6) (Chair)	X	
		X
	X	
(Alternate Chair)	X	
	X	
(alternate)	X	
	X	
(b)(6) (AV)	X	
(alternate AV)	X	
	X	
	X	
(alternate)		X
(alternate)	X	
(alternate)	X	
Non-committee attendees:		
	X	
	X	
(by phone)	X	

1. Meeting Minutes

July 11, 2017 minutes reviewed. All approved.

2. CMB update (b)(6)

Discussion regarding FTC SOP 501, 502, and 506; sections 502 conflict with existing SOPs 501 and 506. (Further discussion with occurred on 9-21-2017.)

3. Recent protocol actions

No comments. One outstanding amendment for 17-009 - finalizing the statistics section.

4. Discussion Items

4.1. Policy FTC-030 Drug Dispensing, Use, and Disposal at DVBD
Discussion, request to re-word paragraph under section "CMB Procedures" to provide to

4.2. Animal welfare incidents and
A memo for each of these was prepared by Each was discussed separately.

Mouse deaths

IACUC agreed that mouse deaths be reported to OLAW [redacted] to write letter to IO/OLAW and IACUC review via DMR process). Post-meeting note: minor additions to letter incorporated; letter sent to IO 9-26-2017 who forwarded to OLAW 9-27-2017.

Unexpected litters

Memo discussed. IACUC requested: 1) re-training of animal care staff on mouse sexing (completed 9-13-2017) and 2) have PI's more clearly mark cages when males moved in for breeding and then removed along with better communication with animal care when this is being done (email sent out to PIs and associates on 10-2-2017 that have protocols involving breeding).

Power outage – additional information requested from [redacted] was provided to the IA.

Mice not checked over a weekend – IACUC requested re-training which was completed 9-13-2017

Mice found with no water, cage not seated properly

IACUC discussed, requested that re-training of animal care staff be conducted. (Post-meeting note: re-training completed on 9-13-2017).

5. Semi-Annual Facility Inspection and Program Review

Minor items noted during facility inspection. IACUC requested correction times within a week. Post-meeting note: individuals notified for corrections.
Items in central hall that cannot pass certification tests to be scrapped and 1 item to be excessed [redacted] to contact appropriate personnel to begin process).
Safety discussion – there have been 10 needle sticks in 11 years all of which occurred when handling mice.

(b)(6)

6. Reports

Census report: no discussion (only July reviewed, August will be reviewed in Oct.)

AV update – [redacted] ntacted [redacted] regarding the AG129 uterine hemorrhage findings. [redacted] indicated they cull breeders at approx. 6 months of age and do not see this. The AG129 mice used for health monitoring were older. They are still observing this in the AG129 mice.

PAMs: none

IACUC Announcements: work continues on updating AAALAC Program Description due Dec 1, 2017.

7. New Business

OLAW here on Sept. 21, 2017 for site visit. IACUC to have lunch with site visitors.

Meeting adjourned at 11:38 am.

Next meeting:
Tuesday, October 10, 2017, 9:00am-11:00am
Bldg [redacted] Room [redacted]

Appendix 8: IACUC/OB Minutes

Institutional Animal Care and Use Committee
July 11, 2017 — 0900–1100
Bldg (b)(7)(E)

Meeting Attendees:

Committee members:	In Attendance (quorum=6)	Not In Attendance
(b)(6) (Chair)	X	
	X	
		X
(Alternate Chair)	X	
	X	
(alternate)		X
	X	
(b)(6) (AV)	X	
alternate AV)	X	
	X	
	X	
alternate)		X
alternate)	X	
(alternate)	X	
Non-committee attendees:		
	X	
	X	
	X	

1. Meeting Minutes

June 13, 2017 minutes reviewed. All approved with minor corrections.

2. CMB update

(b)(6) was not able to dial in due to technical difficulties with the (b)(4) in Fort Collins. Post-meeting note: IT fixed the problem.

(b)(6)

3. Protocol Review

(b)(6)

17-008 Kinetics of Borrelia miyamotoi in Ixodes scapularis and the relative efficiency of vertical vs. horizontal transmission Part I.

(b)(6)

PI provided overview of the new protocol and responded to questions from the IACUC. was thanked and excused. IACUC requested the following additions to the protocol:

1. Please meet with regarding the statistics and show his approval on the signature page with a date.
2. Please obtain approvals from (Safety Officer) and Branch Chief. Emails are okay – please keep them in your file or you can forward to to keep in the IACUC file. Place their initials along with a date on the assurance page near the end of the protocol.

(b)(6)
(b)(6)
(b)(6)
(b)(6)

3. Add that animals are checked for infection prior to adding ticks – this should include the blood collection procedure and estimated volume and if any sedatives are utilized. Reminder – any procedures done on the animals such as blood collections, etc. need to be included in the protocol.
Once PI has addressed the comments, revised protocol will be reviewed via DMR.

4. Recent protocol actions

Addition:
15-001 Amend 3 and 17-003 Amend 1 approved by Alt. Chair.

5. Discussion

a. Policy FTC-006 Major and Minor Changes to Protocols
After discussion, it was agreed to add a section for Veterinary Verification and Consultation which would include approval by the AV or Alt. AV for changes in analgesics, anesthetics, and blood collection intervals which fall under the guidelines listed in the IACUC protocol forms. Procedure for this will also be added to the policy. Addition of non-significant change to also include change in Co-PI. [redacted] to revise and sent out via DMR.

(b)(6)

b. DVBD Drug Dispensing Procedure
All agreed to make this an IACUC Policy. Modifications include removing names and adding "CMB personnel" and adding statement that PI's should check supplies in advance prior to beginning procedures. [redacted] to put in policy format and distribute

(b)(6)

c. Protocol Pre-Initiation Meeting (PIM) – introduction
[redacted] provided overview of PIM process as conducted in Atlanta. Following lively discussion, IACUC determined that this would be burdensome to the PI's and felt there was good communication between the animal care staff and PI and associates that this was not needed. [redacted] to speak to [redacted] with decision.

(b)(6)

(b)(6)

6. Reports

Census report: no discussion; [redacted] indicated he is having some trouble getting into the lighting report system but is working with Facilities to fix this.

AV update: [redacted] contacted [redacted] regarding the AG129 uterine hemorrhage findings, he is waiting on a response.

PAMs: 15-009, 17-004, 16-020 all in compliance

IACUC Announcements: work continues on updating AAALAC Program Description due Dec 1, 2017.

7. New Business

None.

Meeting adjourned at 10:20 am.

Next meeting:
Tuesday, August 8, 2017, 9:00am-11:00am
Bldg [redacted] Room [redacted]

Appendix 8: IACUC/OB Minutes

Institutional Animal Care and Use Committee
September 12, 2017 — 0900–1100
Bldg (b)(7)(E)

Meeting Attendees:

Committee members:	In Attendance (quorum=6)	Not In Attendance
(b)(6) (Chair)	X	
(b)(6)		X
	X	
(Alternate Chair)	X	
	X	
(alternate)	X	
	X	
(b)(6) (AV)	X	
alternate AV)	X	
	X	
	X	
(b)(6) (alternate)		X
(alternate)	X	
(alternate)	X	
Non-committee attendees:		
(b)(6)	X	
	X	
(by phone)	X	

(b)(6) **1. Meeting Minutes**

(b)(6) July 11, 2017 minutes reviewed. All approved.

2. CMB update (b)(6)

Discussion regarding FTC SOP 501, 502, and 506; sections 502 conflict with existing SOPs 501 and 506. (Further discussion with occurred on 9-21-2017.)

3. Recent protocol actions

No comments. One outstanding amendment for 17-009 - finalizing the statistics section.

(b)(6) **4. Discussion Items**

(b)(6) 4.1. Policy FTC-030 Drug Dispensing, Use, and Disposal at DVBD
Discussion, request to re-word paragraph under section "CMB Procedures" to provide to

(b)(6) 4.2. Animal welfare incidents and
A memo for each of these was prepared by Each was discussed separately

Mouse deaths
IACUC agreed that mouse deaths be reported to OLAW to write letter to IO/OLAW and IACUC review via DMR process). Post-meeting note: minor additions to letter incorporated; letter sent to IO 9-26-2017 who forwarded to OLAW 9-27-2017.

Unexpected litters
Memo discussed. IACUC requested: 1) re-training of animal care staff on mouse sexing (completed 9-13-2017) and 2) have PI's more clearly mark cages when males moved in for breeding and then removed along with better communication with animal care when this is being done (email sent out to PIs and associates on 10-2-2017 that have protocols involving breeding).

Power outage – additional information requested from [redacted] was provided to the IA.

Mice not checked over a weekend – IACUC requested re-training which was completed 9-13-2017

Mice found with no water, cage not seated properly
IACUC discussed, requested that re-training of animal care staff be conducted. (Post-meeting note: re-training completed on 9-13-2017).

5. Semi-Annual Facility Inspection and Program Review
Minor items noted during facility inspection. IACUC requested correction times within a week. Post-meeting note: individuals notified for corrections.
Items in central hall that cannot pass certification tests to be scrapped and 1 item to be excessed [redacted] to contact appropriate personnel to begin process).
Safety discussion – there have been 10 needle sticks in 11 years all of which occurred when handling mice.

6. Reports
Census report: no discussion (only July reviewed, August will be reviewed in Oct.)

AV update: [redacted] contacted [redacted] regarding the AG129 uterine hemorrhage findings. [redacted] indicated they cull breeders at approx. 6 months of age and do not see this. The AG129 mice used for health monitoring were older. They are still observing this in the AG129 mice.

PAMs: none

IACUC Announcements: work continues on updating AAALAC Program Description due Dec 1, 2017.

7. New Business
OLAW here on Sept. 21, 2017 for site visit. IACUC to have lunch with site visitors.

Meeting adjourned at 11:38 am.

Next meeting:
Tuesday, October 10, 2017, 9:00am-11:00am
Bldg [redacted] Room [redacted]

Appendix 9: IACUC/OB Protocol Form

Please attach a ***blank*** copy of form(s) used by the IACUC/OB to review and approve studies. Include forms used for annual (or other periodic) renewal, modifications, amendments, etc., as applicable.

DVBD utilizes two protocol forms, one for laboratory animals and one for field investigations. Also included below is the annual report form.

Appendix 9: IACUC/OB Protocol Form

Protocol No.

Title:
PI:

CDC-FORT COLLINS INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE PROTOCOL FOR THE USE OF LABORATORY ANIMALS

NOTE: The information requested, including personnel qualifications, rationale for animal use (including species and numbers), experimental design, search for alternatives, plan for alleviation of pain and distress, and method of euthanasia, is required under the Animal Welfare Regulations (9 CFR Chapter 1, Subchapter A, Part 2) and/or the PHS Policy on Humane Care and Use of Laboratory Animals, Section IV.

DOUBLE CLICK THE ☐ TO CHANGE THE DEFAULT VALUE TO "CHECKED"

CLICK ON TABLE OF CONTENTS AND IN UPPER LEFT CORNER OF TABLE CLICK ON 'UPDATE TABLE' AND CHOOSE "UPDATE ENTIRE TABLE" THEN CHOOSE "UPDATE ENTIRE TABLE" OR "UPDATE PAGE NUMBERS ONLY'.

REQUIRED: ALL PROTOCOLS MUST INCLUDE THIS INFORMATION

Table of Contents

Appendix 9: IACUC/OB Protocol Form

PROCEDURAL APPENDICES (A-D): COMPLETE ONLY THOSE APPENDICES RELATED TO THIS PROTOCOL. DELETE NON-REQUIRED APPENDICES.

1. GENERAL INFORMATION

Principal Investigator (PI):
Division/Branch:
E-mail address:
Telephone:

Describe Principal Investigator's specific training with species and procedures to be used.

Is the PI current on Occupational Health and Safety (OHS) enrollment and respiratory program (if applicable)? Provide a copy of current card to the IACUC office (b)(6)

Source of funding if other than CDC:

Provide a copy of all grant applications to the IACUC office with the protocol.

Is any portion of this work supported by CDC funds and being performed at other (non-commercial) institutions?

☐ Yes, to _____ (name of PI) at _____ (name of institution).
USDA # OLAW Assurance # AAALAC Accredited?
☐ No

If CDC funds are supporting animal studies at another institution, what is the mechanism of fund transfer?

☐ Contract
☐ Grant
☐ Cooperative agreement
☐ Other:
☐ Not applicable

PROPOSED STARTING DATE OF PROJECT: _____

Appendix 9: IACUC/OB Protocol Form

THE PROPOSED PROJECT IS: (check all that apply)
☐ New protocol
☐ Amendment to Approved Protocol
☐ Identical to Protocol #:

Amendment/Modification

Amendments/Modifications to the protocol are described here. Refer to the section number and/or appendix (as appropriate) from the approved protocol that is being changed. Then describe the modification. Add a reason for the modification.
Reason for Modification: Change in PI; Change in personnel other than PI; Adding a procedure or timepoint; Changing a procedure(s) or timepoint(s); Adding/changing a species/strain; Less than 10% increase in number of rodents; Other increase in animal numbers, Other – with explanation

Please add each new amendment above the previous one and number them sequentially.

For Example:

Amendment # 2

Section 2. Personnel

(b)(6) is added as a new Key Associate. He has completed the IACUC - required training and has over 10 years of experience working with mice and ticks. He will be assisting with setting up tick feedings on mice. Occupational hazards have been discussed with him by the PI. He is current on the OHS enrollment.

Reason for Change: Change in personnel other than PI.

Amendment # 1

8.5. Euthanasia/Disposition of Animals

Euthanasia method is being changed from CO2 under anesthesia confirmed with cervical dislocation to cervical dislocation under isoflurane inhalation anesthesia

Reason for Change: Changing a procedure(s) or timepoint(s)

AMENDMENT #_____

---

2. PERSONNEL

List all individual performing the experimental manipulations or working with animals (other than the PI). Individual must have completed all IACUC-required training as described in CDC-Fort Collins IACUC Policy 021 "Training of Investigators" before beginning work on the project. This

Appendix 9: IACUC/OB Protocol Form

policy can be found at [redacted] Personnel must be enrolled in the Occupational Health and Safety (OHS) program and the respiratory program (if applicable). See CDC-Fort Collins IACUC Policy 029 "Policy and Guidance on Occupational Safety and Health Program Enrollment and Respirator Fit Testing ". Yearly updates are required for both OHS and respiratory programs. Provide copies of current OHS cards to the IACUC office [redacted] for each person listed. Provide documentation of hands-on training for species and/or procedures to [redacted]

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

List any personnel working with animals that are not affiliated with the CDC Fort Collins. Provide their professional title, email address, phone number and mailing address. Describe the individual's specific training with species and procedures to be used and provide documentation. Have them contact the IACUC office for instructions on completing IACUC-required training.

*Key Associate – Any individual who contacts animals covered by this protocol; may include, but not limited to, employees, students, guests, collaborators, and field participants (including capture and transport).

PI RESPONSIBILITIES:

Have you discussed potential occupational health hazards with your Co-PIs, associates, and animal care staff (when appropriate)?
☐ Yes
☐ No

Persons to be contacted in case of an emergency or clinical deterioration of animals outside of normal working hours.

Name:	Name:
Phone # (W)	Phone # (W)
(H)	(H)
(C)	(C)

3. RATIONALE FOR THE USE OF ANIMALS

Provide a brief but complete lay description of the proposed use of animals. Include in this description the purpose of the study, outline the hypotheses that will be tested and describe how the hypotheses will be tested. Do not include specifics about proposed procedures or manipulations. Please avoid the use of scientific jargon, acronyms, and abbreviations. This portion of the proposed protocol should be readily understood by a non-scientist or lay person (8th grade reading level preferred).

4. ANIMAL USAGE CATEGORY (USDA)

The placing of animal usage into categories and annual reporting to the U.S. Department of Agriculture is required by the Animal Welfare Act. Please read the category definitions carefully and indicate the categories that apply to this project. If more than one category applies, specify in the table below the species/number of animals per category/year.

☐ Class B. Includes animals bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes

☐ Class C. (Non-painful/non-stressful): Animals upon which teaching, research, experiments, or tests will be conducted involving slight or momentary pain, distress, or discomfort. Includes routine procedures such as venipuncture, injections, and the use of non-inflammatory adjuvants.

☐ Class D. Painful/stressful WITH anesthesia/analgesia/tranquilizers: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used. Examples include survival surgery, exposure of blood vessel for catheter placement, transcardial perfusion under anesthesia, and infectious disease induction with analgesics provided.

☐ Class E*. Painful/stressful WITHOUT anesthesia/analgesia/tranquilizers*: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will not be used due to adverse effects on the procedures, results, or interpretation of the teaching, research, experiments, surgery, or test. Examples include food or water deprivation, application of noxious stimulus, toxicological or microbiological testing that may result in clinical symptoms for which an animal cannot be treated.

Appendix 9: IACUC/OB Protocol Form

Justification for Class E: **Additional explanation is required for Category E protocols. Use the space below or an attachment to explain why pain and distress cannot be minimized with anesthesia, analgesia, and/or tranquilizers. Provide literature references to substantiate rationale for not using anesthesia, analgesia, and/or tranquilizers
**

Summarize information for each species/strain and pain category to be used during the project covered by this protocol.

Species* (scientific/ common name)	Strain (s)	Sex	Age or Weight	Source(s)	1st Year number	2nd Year number	3rd Year number	Total	USDA Pain Class
				TOTAL Per Year					

*If transgenic/knockout animals are to be bred / used, complete Appendix A.

5. SPECIAL HOUSING/ENVIRONMENTAL, NUTRITIONAL REQUIREMENTS

5.1. Describe any modified housing conditions this project may require (e.g., Isocages, wired bottomed cages, change in feed, environmental enrichment, changes in bedding, feeding schedule, lighting, hazardous waste, biohazard containment, etc.).

Briefly explain why this modification is necessary.

5.2. Acclimation to a new environment is very important to obtaining quality research results. It takes approximately 5-7 days or more for animals to acclimate to new conditions after being shipped from the vendor to the Fort Collins facility. Plan for an acclimation period of approximately 1 week when ordering animals.

If an acclimation period is not needed, explain why not:

5.3. Will the animals be socially housed (in pairs or groups)? If not, justification is required (based on the new 2011 *Guide for the Care and Use of Laboratory Animals*). Please provide below:

☐ Yes
☐ No:

5.4. Where will these animals be housed?

Campus: Fort Collins Building: (b)(7)(E) Room:

Is this a Select Agent-Registered space?
☐ Yes – send protocol to RO for review/ signature
☐ No

5.5. Person coordinating changes with ARB staff.
Name
Phone number

5.6. Does this protocol require deprivation of a normal caloric intake?
☐ Yes, because:
☐ No

5.7. Does this protocol require deprivation of a normal fluid intake?
☐ Yes, because:
☐ No

5.8. Does this project require an alteration in diet or specific feed?
☐ Yes, because:
☐ No

5.9. Who will feed and water the animals if normal feeding and watering is not followed?
☐ ARB staff
☐ PI and/or key associates
☐ Other:
☐ NA

6. LOCATION OF ANIMALS

6.1. Where will animals be housed and where will procedures be conducted (if different room)?
☐ DVBD building (b)(7)(E) specify room number(s)

Is this a Select Agent room?
☐ Yes – send protocol to RO for review/ signature
☐ No

☐ (b)(4) facility; specify**
☐ Other facility; specify**

**Facilities not owned by DVBD must first be inspected (when feasible) and approved by the Attending Veterinarian.

6.2. Will any portion of this study be conducted at another institution?
☐ Yes
☐ No (skip to 6.4.)

6.3. Will that portion of this study include the use of animals?
☐ Yes, that work will be done at (name and address of institution).

Appendix 9: IACUC/OB Protocol Form

Please provide contact information for the off-site PI, Co-PI, or Associate (name, phone number, and address):

☐ No, (skip to 6.4.)

6.3.1. Has this study received IACUC approval at the above institution?

☐ Yes, and a copy of the approved protocol is attached.

The PHS Assurance Number for the institution is: _____

USDA Number: OLAW Assurance Number:

☐ No, because

6.3.2. Has this study received IBC clearance at the above institution?

☐ Yes, and the IBC approval number is

☐ No, because it was not necessary to obtain IBC clearance

6.4. Is any portion of the use of animals supported by CDC funds and contracted to commercial sources?

☐ Yes, it is contracted out to _____

The PHS Assurance Number for the contract facility is: _____

USDA Number AAALAC Accredited?

☐ No

6.5. If animals are to be transported between facilities, between areas of the DVBD facility, or between the field and facilities, describe the means of transport including caging and vehicle. How will the animals be transported through the facility to prevent exposure of personnel?

If the animals are infected, describe how the caging will prevent vector access to the animal.

6.5.1. Caging description:

6.5.2. Transportation description:

6.5.3. Prevention of vector access to infected animals:

☐ Not applicable

7. EXPERIMENTAL DESIGN

Explain the experimental design in the sections below. Provide details of all procedures to be used on the animals. Tables can be used to outline test groups and administration of agents/test articles. Details of how pain/distress will be reduced, methods of anesthesia, euthanasia, etc. are to be provided in the sections below.

Survival surgeries are not conducted at Fort Collins. If you are submitting a protocol that involves survival surgeries conducted at a collaborating institution, write to [redacted] for guidance.

Behavioral and physical restraint studies are not conducted at Fort Collins. If you are submitting a protocol that involves behavioral and physical restraint conducted at a collaborating institution, write to [redacted] for guidance.

Appendix 9: IACUC/OB Protocol Form

Nonhuman primate studies are not conducted at Fort Collins. If you are submitting a protocol that involves nonhuman primate studies conducted at a collaborating institution, write to (b)(6) for guidance.

7.1. METHODS

7.1.1. Give a brief scientific description of the project and the use of animals in it, including: Scientific Goals and Aims – Concisely state the protocol's long-term scientific goals. Provide specific aims for each scientific goal (for example, to test a stated hypothesis, solve a specific problem, or develop new technology). A bullet or number format is preferred.

7.1.2. Experimental Design and General Procedures - Describe concisely the research design and methods for achieving each of the stated aims. This section should be informative and understandable to a technically literate reader. Include: a) groups and numbers of animals used; b) agents, drugs, or biologics administered in each group; c) all procedures that will be conducted on the animals; d) experimental endpoints, and e) a timeline (duration) for each stated aim.

7.1.4. Will immunizations for antibody production be done?
- ☐ Yes, Complete Appendix B
- ☐ No

7.1.5. Will in vivo maintenance of hybridomas/ascites be conducted?
- ☐ Yes, Complete Appendix C
- ☐ No

7.1.6. Will this study utilize the administration of test drugs/compounds? (This does not include anesthetics, analgesics or biological agents.)
- ☐ Yes, Complete Appendix D
- ☐ No

7.2. MANAGEMENT OF NON-SURGICAL PAIN AND DISTRESS

7.2.1. Will animals experience distress, discomfort, suffering, or pain as a result of the procedures? Distress is defined by the USDA as "a state in which an animal cannot escape from or adapt to the internal or external stressors or conditions it experiences, resulting in negative effects on its well-being."

Read more about distress and pain (including definitions) in the ACLAM paper Pain and Distress in Research Animals July, 2016 found at (b)(4), (b)(7)(E)

☐ Yes, the following procedures will cause distress, pain, and / or discomfort to the animals at some point during the study. Routine procedures such as injections and limited blood sampling do not need to be reported here. (complete table below)
- ☐ No

Procedures

Appendix 9: IACUC/OB Protocol Form

7.2.2. Criteria for scheduled termination of animals from protocol:

7.2.2.1. When will animals be euthanized?

7.2.2.2. What are the study endpoints?

7.2.3. Animals must be euthanatized if moribund/severely debilitated (unscheduled termination). See CDC-Fort Collins IACUC Policy 019 "Endpoints in animal protocols and response to unexpected morbidity and mortality" at (b)(4); (b)(7)(E) (b)(4); (b)(7)(E)

The criteria used for removing (unscheduled termination) an animal from the study will be:

☐ Signs of moribundity including abnormal posture, rough hair coat, head tucked into abdomen, exudates around eyes and/or nose, skin lesions, abnormal breathing, difficulty with ambulation, decreased food or water intake, or self-mutilation.
☐ Tumor size (> 1 cm^2)
☐ > 10% body weight loss
☐ Other (explain)

Examples of Analgesics:
More information is available in CDC-Fort Collins IACUC Policy 25: Anesthesia and Analgesia Guidelines (b)(4); (b)(7)(E) (b)(4); (b)(7)(E)

Species	Analgesic Drug	Dose/ Route
Mouse	Ibuprofen	40 mg/kg, administered as 0.2 mg/ml in drinking water
	Meloxicam	1-2 mg/kg PO or SQ every 12-24 hrs
	Buprenorphine	0.05-0.1 mg/kg SQ BID
	Carprofen	5 mg/kg SQ BID
Rabbit	Buprenorphine	0.02-0.05 mg/kg SQ or IV TID or BID

Examples of Anesthetics:
More information is available in CDC-Fort Collins IACUC Policy 25: Anesthesia and Analgesia Guidelines and contact the Attending Veterinarian.

Species	Anesthetic Drug(s)	Dose/ Route	Approximate Duration of Surgical Plane of Anesthesia
Mouse	Ketamine / Xylazine	50-100 mg/kg + 5-10 mg/kg IP	20-30 minutes (note: high mortality possible)
	Ketamine/Xylazine/ Acepromazine	65 mg/kg + 13 mg/kg + 2 mg/kg IP	45-120 minutes (note: recommended for non-survival procedures only

			unless otherwise directed by the AV)
	Ketamine / Dexmedetomidine*	50-75 mg/kg + 1 mg/kg IP or SC	60-120 minutes (note: recommended for survival procedures)
	*Atipamizole to reverse	5 mg/kg IP or SC	5-10 minutes to reverse medetomidine; Ketamine effect may last longer
	Isoflurane	1-4% - to effect – Inhalation	Monitor level of anesthesia, adjust concentration as needed; removal of drug leads to quick recovery
Rabbit	Ketamine / Xylazine	35 mg/kg IM + 5 mg/kg IM	25-40 minutes
	Ketamine / Xylazine	10 mg/kg IV + 3 mg/kg IV	20-30 minutes
	Isoflurane	1-4 % - to effect – Inhalation	Monitor level of anesthesia, adjust concentration as needed; removal of drug leads to quick recovery

7.2.4. Will anesthetic, analgesic, or tranquilizing drugs be used to relieve pain or distress?
☐ Yes, the following will to be used to relieve pain or distress:

Drug	Dosage	Route	Frequency

☐ No, although the proposed studies involve distress, discomfort, suffering, or pain, the use of anesthetics, analgesic, or tranquilizing drugs is not planned because:

7.2.5. Please identify the individual(s) who will monitor the animals and the frequency of monitoring, for example, animal recovering from anesthesia should be monitored every 15 minutes until ambulatory. Heart rate, respiratory rate, and posture should be monitored.

NAME	FREQUENCY	PROPER TRAINING RECEIVED ON**:

** Provide copies of training records to the IACUC office.

7.2.6. What non-pharmaceutical measures will be used for post-procedural recovery?
☐ Fluids, such as:
☐ Warming pads,
☐ Heating pads,
☐ Soft bedding, and or

☐ Other:

7.3. COLLECTION OF BLOOD AND BODY FLUIDS (OTHER THAN ASCITES)

7.3.1. Body fluid to be collected:
☐ NA Skip to 7.4.

7.3.2. Frequency of collection:

7.3.3. Volume of fluid to be collected (see table below for examples of blood volumes):

7.3.4. Method/site of collection:

7.3.5. Will the animal be anesthetized or sedated during this procedure?
☐ Yes, using the following:
Anesthetic agent or sedative:
Dosage:
Route of administration:
☐ No, it is not necessary, because

7.3.6. If blood is to be collected, does the blood volume for a single or multiple blood draw(s) conform to the volumes specified in the CDC-Fort Collins IACUC Policy 026 "Blood Collection Guidelines"? [redacted]
☐ Yes
☐ No, an exemption is requested because

Examples of acceptable blood sample volumes:

Recommended Maximum Blood Sample Volumes - Species / Body Weight

Species	Weight	Total Blood Volume (ml)	7.5% (ml)	10% (ml)	15% (ml)	20%* (ml)
Mouse	25 g	1.8	0.1	0.2	0.3	0.4
Rat	250 g	16	1.2	1.6	2.4	3.2
Syrian Golden Hamster	100 g	7.2	0.54	0.72	1.08	1.44
Guinea Pig	800 g	60	4.5	6.0	9	12
Rabbit	4 kg	224	17	22	34	45

*generally terminal bleed

Guidelines for Repeated (serial sampling)

(1) Weekly blood collection volume should be limited to 7.5% of the total blood volume (TBV).

(2) For repeated bleeds at shorter intervals, a maximum of 1.0% of an animal's TBV can be removed every 24 hours.

(3) Repeated (serial) sampling will not exceed 7.5% TBV within a 7 day period.

(4) Amount of blood samples required on serial bleedings as per protocol will be adjusted based on the actual weight of the animal assigned to the protocol.

(5) When performing serial bleeds, 24 hours of rest should be allowed for each 1% of body weight sampled. Protocols requiring serial bleeds in amounts that do not meet the guideline for rest, and are scientifically justified, may be approved by the IACUC, but may not exceed the 7 day or 2-week (14 days) maximums.

7.4. INFECTIOUS AGENT INFORMATION

7.4.1. Will Select Agents be utilized?

☐ Yes, and the use has been approved by the Select Agent Program - Responsible Official will need to do pre-review and sign signature page, e-mail approval is acceptable
☐ Yes, but approval is not required because
☐ No

7.4.2. Will infectious agents be utilized?

☐ Yes
☐ No, skip to 7.4.4.

7.4.3. Name the primary agent(s) used in this study:

Agent	Concentration (CFU/PFU)	Risk/Hazard Group	Infectious Dose	Virulence (Low/Mod/High)

7.4.4. Will you be using human blood or other potentially infectious human body fluids?
☐ Yes
☐ No

7.4.5 Is this a genetically modified microorganism?
☐ Yes, the IBC approval number is
☐ No

7.4.6. Is the source of the organism indigenous or foreign?
☐ Indigenous
☐ Foreign

7.4.7. Is the source from a rodent?
☐ Yes - Go to Question # 7.4.8
☐ No (skip to question # 7.4.9)

7.4.8. Has it been MAP tested or PCR tested? Testing is required for all cell lines or tumors used at CDC to determine that the cells are free of adventitial viral particles. Cell lines or tumors and sera

generated outside the CDC should be tested. Suspect cells will require injection into naïve mice with serologic evaluation at least three weeks post exposure. Alternatively, cells may be submitted for multiplex PCR assays.
☐ Yes
☐ No
☐ NA

7.4.9. Indicate the proposed animal biosafety level(s) of this study.
☐ ABSL 1
☐ ABSL 2
☐ ABSL 3

7.4.10. Check All possible modes of agent transmission?
☐ Animal bite
☐ Animal excretion or egestion
☐ Animal bedding
☐ Percutaneous injury with sharp implement
☐ Percutaneous injury from contact with cage
☐ Mucosal Surface exposure
☐ Dermal exposure
☐ Ingestion
☐ Inhalation
☐ Vector
☐ Not applicable
☐ Other:

7.4.11. Is a vector used in this protocol?
☐ Yes Describe:
☐ No

7.4.12. Will you be performing any procedures with the infectious agent outside of primary containment?
☐ Yes, Describe:
☐ No

7.5. HUMAN BIOSAFETY

Information in questions # 7.5.1. through #7.5.6. is required for all persons listed on this protocol (to be filled out after consultation / risk assessment with safety officer):

7.5.1. Required Immunizations:
☐ JEvax
☐ Yellow Fever
☐ Hep A
☐ Hep B
☐ Rabies
☐ Tetanus
☐ None

7.5.2. Respiratory Program Enrollment required for this protocol?
☐ Yes
☐ No

7.5.3. Personal Protective Equipment Requirements:
☐ Shoe covers
☐ Solid Front gown
☐ Laboratory Coat
☐ Gloves
☐ Disposable coveralls or Tyvek® suit
☐ Face shield or Safety glasses
☐ N-95 filtering face-piece
☐ Powered air purifying respirator (PAPR)
☐ None
☐ Other:

7.5.4. List and describe any aerosol producing procedures and where they will be conducted (consider filling syringes, etc.):

7.5.5. Will sharps be used in any procedure (e.g. scalpels, scissors, needles)?
☐ Yes and provide details:
☐ No

7.5.6. Additional Safety Requirements:

7.6. EUTHANASIA/DISPOSITION OF ANIMALS

Euthanasia of experimental animals, when necessary, must be accomplished in a humane manner and by acceptable techniques as recommended by the American Veterinary Medical Association Guidelines on Euthanasia, 2013 and as provided in Fort Collins IACUC Policy 16 Euthanasia found at: (b)(4); (b)(7)(E) (b)(4); (b)(7)(E)

Examples of Euthanasia methods by species:

Species	Method of Euthanasia
Mouse / Rat	Ketamine/ Xylazine (80-100 mg/kg + 10 mg/kg IP) anesthesia followed by CO2 inhalation overdose; confirmed with cervical dislocation
	Ketamine/ Xylazine (80-100 mg/kg + 10 mg/kg IP) with cervical dislocation
	Ketamine/ Xylazine/ Acepromazine (65 mg/kg + 13 mg/kg + 2 mg/kg IP followed by cervical dislocation
	Isoflurane anesthesia via inhalation to effect - overdose; confirmed by cervical dislocation
Rabbit	IV of barbiturate euthanasia solution followed by thoracotomy

7.6.1. ☐ Check here if Veterinary Staff and/or Animal Care staff will euthanize the animals.

7.6.2. Indicate the method(s) of euthanasia for the species used (check all that apply):

☐ Anesthesia followed by CO_2 inhalation, confirmed with cervical dislocation
1. Anesthetic agent:
2. Dosage:
3. Route of administration:

☐ Halogenated anesthetic agent overdose (waste anesthetic gases must be scavenged)
1. Halongenated agent:
2. Dosage: to effect
3. Route of administration: Inhalation

☐ Anesthesia followed by cervical dislocation
1. Anesthetic agent:
2. Dosage:
3. Route of administration:

☐ Decapitation under anesthesia
1. Anesthetic agent:
2. Dosage:
3. Route of administration:

☐ Barbiturate overdose
1. Agent:
2. Dosage:
3. Route of administration:

☐ Other method(s) acceptable with conditions:
☐ Cervical Dislocation without anesthesia. Requires justification:
☐ Decapitation without anesthesia. Requires justification:
☐ Exsanguination with anesthesia confirmed by:
Requires justification:
☐ Other: Requires justification:
☐ None

7.6.3. Methods used to confirm euthanasia:
☐ Cervical dislocation (small animals <200 gm)
☐ Thoracotomy (large animals >200 gm)
☐ Other (explain)

Describe the method(s) used to verify euthanasia:
☐ Absence of respiration
☐ Absence of cardiac function
☐ Absence of toe/tail pinch reflexes
☐ Other

7.6.4. Disposition of animals if other than by euthanasia:

☐ NA

8. JUSTIFICATIONS

Appendix 9: IACUC/OB Protocol Form

8.1. JUSTIFICATION FOR THE CHOICE OF EACH OF THE SPECIES SELECTED

Why is this species the most appropriate for your study? Note that saving money or time is not an acceptable justification.

8.2. JUSTIFICATON FOR THE NUMBER OF ANIMALS REQUESTED IN THIS PROTOCOL

How were the numbers of experimental groups and the number of animals per group provided in Section 8 - Experimental Design obtained? Check all categories that apply. Provide text or tables to demonstrate your computations and/or justify how your numbers were determined. Refer to Fort Collins IACUC Policy 008 "Justification for the Animals for DVBID IACUC Protocols"

☐ Pilot or preliminary project; group variances unknown at present.
Explain:

☐ Group sizes determined statistically.
Explain:

☐ Breeding, maintenance, or training protocol.
Explain:

☐ Group sizes based on quantity of harvested cells or amount of tissue required.
Explain:

☐ Other
Explain:

8.3. REFINEMENT, REDUCTION, AND REPLACEMENT OF THE USE OF ANIMALS

Justify the use of live animals by completing the following section.
An explanation for the use of animals must be made when an in vitro method is available for any model/method proposed in this protocol. (Examples: use of the ascites model to produce monoclonal antibodies.)

Visit the Animal Welfare Information Center http://awic.nal.usda.gov and National Library of Medicine Alternatives website https://www.nlm.nih.gov/pubs/factsheets/altbibfs.html to search for alternatives to animal use.

8.3.1. Can mathematical models and/or in vitro systems be used to reduce the number of animals requested in this proposal?
☐ Yes, but I am not using them because
☐ No, because

8.3.2. Have in vitro systems been used to limit the parameters of the study or to limit the test substances or groups prior to the use of animals?
☐ Yes. Please describe briefly:
☐ No, because

8.3.3. Are there alternatives to the use of live animals in any of the proposed procedures that would be compatible with your experimental design?

☐ Yes, but I am not using them because
☐ No, because

8.3.4. Are there alternatives to the procedures proposed that would be compatible with your experimental design?

☐ Yes, but I am not using them because
☐ No, because

8.3.5. As Principal Investigator, I have determined by means of the following sources or searches that alternatives to the procedures that may cause animal pain and/or distress proposed in the protocol are not available and this protocol does not duplicate previous experiments.

☐ Yes, but duplication is scientifically justified because

☐ No, it does not duplicate previous experiments

8.3.6. For 1-5 above, in your attempts to reduce, refine or replace the use of animals, please complete the following table: At least 2 different databases should be searched.

Database	Date(s) of Search	Period of Search (mm/yyyy to mm/yyyy)	Keywords Used

Do you have additional comments regarding your search to find alternatives to animal use?

8.3.7. How will the results of this study benefit science, medicine or society in general?

Appendix 9: IACUC/OB Protocol Form

9. PRINCIPAL INVESTIGATOR ASSURANCE STATEMENT

The CDC-Fort Collins has on file with the Public Health Service (PHS) a written Assurance which commits the CDC-Fort Collins to following the standards established by the Animal Welfare Act and PHS Policy. As part of the Assurance, the CDC-Fort Collins has established the IACUC to review proposed protocols involving animals to ascertain if proposals are consistent with the NIH "Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Education," the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and other applicable public laws and regulations. These documents describe requirements that must be met for humane care and treatment of research animals, to assure that animals do not suffer unnecessary discomfort, pain, or injury, and that animals receive proper care and husbandry. Laboratory animals must be cared for and used in a manner that complies with the above documents to protect current and future PHS support. Protocol progress reports must be submitted yearly, and a complete updated application must be submitted every three years.

☐ I certify that I have read the above statement and will adhere to all regulations therein, and that I will make written notification (protocol amendment/modification) to the Institutional Animal Care and Use Committee of any changes in the proposed project, relative to this proposed protocol, prior to proceeding with any animal experimentation.

☐ I assume responsibility for ensuring that all personnel involved in this project are informed of the Occupational Health hazards and are appropriately trained in all procedures.

☐ I certify that the proposed use of animals does not unnecessarily duplicate previous experiments.

☐ I certify that the information contained herein is a true and accurate description of the work I plan to conduct.

☐ I certify that my supervisor reviewed this proposal and she/he supports its scientific merit. Supervisor

I assure that the DVBD Attending Veterinarian reviewed this protocol prior to submission.
☐ Yes _____ (AV Initial) ☐ No, because:

I assure that the IACUC Statistician reviewed this protocol including, Section 8, prior to submission.
☐ Yes _____ (Statistician Initial) ☐ No, because:

I assure that the DVBD Responsible Official has reviewed this protocol if Select Agents or a Select-Agent-Registered space will be used.
☐ Yes _____ (RO Initials) ☐ NA

I assure that the DVBD Safety and Occupational Health Specialist reviewed this protocol including, Section 7.4 and 7.5 prior to submission and commit to participating in a risk assessment before initiation of work described in this protocol. All Safety and Occupational Health pre-requisites have been met by all individuals listed on this protocol.
☐ Yes _____ _____
Signature (safety officer) Date ☐ No, because:

_____
Principal Investigator Date

_____
Supervisor Date
As the Principal Investigator's supervisor, I have reviewed this proposal and confirm its scientific merit (required prior to submission).

_____
Branch Chief Date
As the Principal Investigator's branch chief, I have reviewed this proposal and confirm its scientific merit (required prior to submission).

Appendix 9: IACUC/OB Protocol Form

APPENDIX A – TRANSGENIC/KNOCKOUT ANIMALS

Species: Species: 3 Year Total Number of Animals:

1. Will you be breeding or generating transgenic/knockout animals at CDC?

☐ Yes:

Describe your breeding plan:

Indicate in text or table form how many animals will be used to produce the number of animals required for experimentation:

☐ No: From what source will you obtain the animals?

Will they have been screened for murine pathogens? Please provide documentation to ARB and IACUC office.

What are the anticipated phenotypes and potential problems of this strain?

Are they immunocompromised (SCID, etc.)? ☐ Yes ☐ No

2. Please provide the following information:

	Anticipated Consequences of Genetic Manipulation	
DNA/Transgene or Gene to be Disrupted	Homozygous	Heterozygous

Choice of Biopsy Methods for DNA Testing - Based on Age of Mice

	Less than 2 weeks	3-4 weeks	> 4 weeks
Saliva or fecal samples	Y	Y	Y
Tail biopsy*	N	Y*	N
Ear notching / punching (2 mm diameter section)	N	Y**	Y**
Blood	N	Y	Y
Toe amputation	N	N	N

Y =allowed
N =not allowed unless in exceptional circumstances; unless it is absolutely unavoidable
Y*=unless there is good scientific justification to the contrary, tail biopsies should not be taken from mice significantly less than 3 weeks of age or older than 4 weeks of age
*Requires anesthesia/analgesia, hemostasis; less than 5 mm of tail; repeat biopsies should be avoided
**Preferred method

3. For DNA testing, will you employ (see table for ages & preferred methods)

☐ Ear notching
☐ Toe clipping (must be justified below), or
☐ Saliva/oral mucosal sampling
☐ Tail snipping
☐ Fecal samples
☐ Other tissue sampling procedures (explain)

If you checked any of the above:

Identify the age of the animal when this will be done

3.1. What anesthetics/analgesics will be used?
Anesthetic/analgesic:

Dose:

Route:

3.2. What techniques will be used for hemostasis (i.e., silver nitrate sticks, tissue glue, pressure, suture, clips, etc.)?

Choice of Identification Methods - Based on Age of Mice

	Less than 2 weeks	3-4 weeks	> 4 weeks
Non-invasive methods*	Y	Y	Y
Ear notching	N	Y	Y
Ear tags	N	Y	Y
Microchips	N	Y	Y
Tattoos**	Y	Y	Y

Y=allowed
N=not allowed unless in unavoidable exceptional circumstances
*= use of spirit-based pens to apply circular band at varying positions on the tail to individually identify the mice
**= Tail or footpad; use of tattoo instrument or needle, local anesthetic used

3.3 How will animals be identified (tags, tattoos, chips, etc.)?

Please justify use of these procedures. Toe clipping is not recommended by the Guide, and should be used only when no other method is feasible, and only in altricial neonates:

3.4. Describe management of anticipated adverse effects that could result from the genetic manipulation.

4. If pain or distress might result, complete Section 8.2 above.

APPENDIX B – IMMUNIZATIONS FOR ANTIBODY PRODUCTION

Species: 3 Year Total Number of Animals:

1. What antigen(s) will be used?

2. What vehicle/adjuvant(s) will be used?
For the initial immunization:
For subsequent immunizations:
Complications/anticipated side effects:

Note: The use of Complete Freund's Adjuvant (CFA) is strongly discouraged and must be well justified. If the use of CFA is proposed, usage must comply with CDC-Atlanta IACUC Policy 001 "Use of Complete Freund's Adjuvant in Laboratory Animals" found at (b)(7)(E) and it's use must be justified here:

3. Indicate the site(s) for immunization:

4. Indicate the route of immunization:

5. Describe the immunization(s) including:
Total and per site injection volume:
Frequency of immunization:

6. Will any of these activities be contracted to commercial sources?
   - ☐ Yes, to
   - ☐ No

APPENDIX C – IN VIVO MAINTENANCE OF HYBRIDOMAS/ASCITES FORMATION

Species: 3 Year Total Number of Animals:

Because in vitro techniques are available as alternatives to in vivo ascites production, justification for choosing this in vivo technique must be given in Section 5.3. The IACUC requires adherence to the OLAW policies concerning the Production of Monoclonal Antibodies Using Mouse Ascites Method found at http://grants.nih.gov/grants/olaw/references/dc98-01.htm.

1. Will hybridoma proteins be prepared at CDC?
   ☐ Yes.
   ☐ No (Skip to the next section)

2. Will hybridomas be maintained in vivo?

   ☐ Yes

Fluid accumulation associated with ascites/hybridoma should not become greater than 10% of body weight.
Animals are to be weighed every _____ days.
Written justification must be presented here for larger fluid burdens.

More frequent monitoring is required. Draining ascites from animals is not always predictable – to maximize recovery & minimize animal discomfort animals should be closely monitored.
Describe the animal monitoring schedule that will be used: _____

   ☐ No (Skip to Appendix D)

3. Mouse antibody production (MAP) tests are required for all cell lines or tumors used at CDC to determine that the cells are free of adventitial viral particles. Multiplex PCR assays may also be utilized. Cell lines or tumors and sera generated outside the CDC should be tested. Novel cells will be required to be injected into naïve mice followed by serologic evaluation at least three weeks post exposure.

Has MAP testing been completed?
   ☐ Yes, by: _____
   ☐ No

4. What ascites collection technique will be used?
   _____

5. Indicate the anticipated frequency and number of ascites fluid collections with a time line or schedule including the point of euthanasia.
   _____

6. Criteria for termination of animals from protocol:

☐ Signs of moribundity including abnormal posture, rough hair coat, head tucked into abdomen, exudates around eyes and/or nose, skin lesions, abnormal breathing, difficulty with ambulation, decreased food or water intake, or self-mutilation.

☐ Body condition scoring

☐ Other (explain)

Protocol #

APPENDIX D – ADMINISTRATION OF DRUGS/COMPOUNDS (except anesthetics, analgesics, or biological agents)

Species: 3 Year Total Number of Animals:

1. Which of the following will be used in this project?
   - ☐ Radioactive material (isotopes):
   - ☐ Chemical carcinogen:
   - ☐ Toxins:
   - ☐ Recombinant Nucleic Acids
   - ☐ Drugs/Chemicals:
   - ☐ Other:

2. Please provide the following information:

Drug/Compound	Dose, Volume, Vehicle	Route of Administration	Frequency and Duration

Please consider the following regarding preparation of compounds for administration to animals: sterility, endotoxins, pH, osmolality, etc., especially when compounds are being administered parenterally (IM, IV, IP) for example – recombinant proteins for vaccines.

3. Discuss any potential adverse side effects that might result from administration of the above agents. Provide results of any toxicology studies that have been conducted (in vivo and in vitro).

4. Who will provide training to ARB and technical personnel regarding safety considerations important to this study?

5. What special procedures need to be followed with toxins, radioisotopes, carcinogens, etc. to be used in the study?

6. Who will provide consultation for personnel exposed to hazardous agents?

Protocol #

Field Protocol Form

Protocol No.
Title:
PI:

CDC-FORT COLLINS INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE PROTOCOL FOR THE USE OF VERTEBRATE ANIMALS IN A FIELD or OUTBREAK INVESTIGATION

NOTE: The information requested, including personnel qualifications, rationale for animal use (including species and numbers), experimental design, search for alternatives, plan for alleviation of pain and distress, and method of euthanasia, is required under the Animal Welfare Regulations (9 CFR Chapter 1, Subchapter A, Part 2) and/or the PHS Policy on Humane Care and Use of Laboratory Animals, Section IV.

Research studies of field animals require special consideration. Please review the following guidance documents prior to submitting a study protocol that involves field animals.

POLICY 18, PAIN CATEGORIES, can be found at:

(b)(7)(E)

POLICY 28, POLICY AND GUIDANCE FOR FIELD INVESTIGATIONS can be found at:

(b)(7)(E)

FIELD STUDIES AND THE IACUC: PROTOCOL REVIEW, OVERSIGHT, AND OCCUPATION HEALTH AND SAFETY CONSDIERATIONS can be found at
http://www.labanimal.com/laban/journal/v36/n1/pdf/laban0107-27.pdf

2016 Guidelines of the American Society of Mammalogists for the use of wild mammals in research and education (Journal of Mammalogy, 97(3):663–688, 2016) can be found at:
http://www.mammalsociety.org/uploads/Sikes%20et%20al.%202016.pdf

DOUBLE CLICK THE ☐ TO CHANGE THE DEFAULT VALUE TO "CHECKED"

PLEASE BE SURE PAGE NUMBERS LISTED MATCH ACTUAL PAGES IN PROTOCOL

Table of Contents

1. GENERAL INFORMATION

Principal Investigator:
Division/Branch:
E-Mail Address:
Telephone:

Describe Principal Investigator's (PI) specific training with species and procedures to be used, include field investigation experience as applicable to this protocol:

Is the PI current on OSHE enrollment and respiratory program (if applicable)? Provide copy of current card(s) to IACUC office. Yearly updating is required.

Funding Agency if other than CDC:

Provide a copy of all grant applications to the IACUC with the protocol.

Is any portion of this work supported by CDC funds and being performed at other (non-commercial, university, collaborator, etc.) locations?

☐ Yes, to _____ (name of PI) at _____ (name of institution).
☐ No

If CDC funds are supporting animal studies at another institution, what is the mechanism of fund transfer?

Protocol

- ☐ Contract
- ☐ Grant
- ☐ Cooperative agreement
- ☐ Other:
- ☐ Not applicable

Provide the following for the other institution:

USDA #
AAALAC Accreditation #
Assurance #

Proposed starting date of project:

THE PROPOSED PROJECT IS: (check all that apply)

☐ New Protocol

☐ Amendment to Approved Protocol

☐ Identical to Protocol #:

AMENDMENT/MODIFICATION

Amendments/Modifications to the protocol are described here. Refer to the section number and/or appendix (as appropriate) from the approved protocol that is being changed. Then describe the modification. Add a reason for the modification.

Reason for Modification: Change in PI; Change in Personnel other than PI; Adding a procedure or timepoint; Changing a procedure(s) or timepoint(s); Adding/changing a species/strain; Less than 10% increase in number of rodents; Other increase in animal numbers; Other-with explanation.

Please add each new amendment above the previous one and number them sequentially.

For Example:

Amendment #2

Section 2. Personnel

 is added as a new Key Associate. He has completed the IACUC-required training and has over 10 years of experience working with mice and ticks. He will be assisting with setting up tick feedings on mice. Occupational hazards have been discussed with him by the PI> He is current on his OHS enrollment.

Reason for change: Change in personnel other than PI.

Amendment # 1

Protocol

8.5.. Euthanasia/Dispostion of Animals

Euthanasia method is being changed from CO2 under anesthesia confirmed with cervical dislocation to cervical dislocation under isoflurane inhalation anesthesia

Reason for Change: Changing a procedure(s) or timepoint(s)

AMENDMENT # _____

Add new amendment here.

Protocol

2. PERSONNEL

List all individuals performing the experimental manipulations or working with animals (other than the PI). Individuals must have completed all IACUC-required training as described in CDC-Fort Collins IACUC Policy 021 "Training of Investigators" before beginning work on this project. The policy can be found at
[redacted] (b)(7)(E) (b)(7)(E)

Personnel must be enrolled in the Occupational Safety, Health and Environment (OSHE) program and the respiratory program (if applicable). Yearly updates are required for both OSHE and respiratory programs. Provide copies of current OSHE cards to the IACUC office for each person listed.
Provide documentation of training for species and/or procedures to the IACUC office.

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

Name
E-Mail Address:
☐ Co-PI ☐ Key Associate* ☐ Veterinarian# ☐ Animal Care Staff#
Describe individual's specific training with species and procedures to be used:

List any personnel working with animals that are not affiliated with CDC Fort Collins. Provide their professional title, email address, phone number and mailing address. Describe the individual's specific training with species and procedures to be used and provide documentation. Have them contact the IACUC office for instructions on completing IACUC-required training.

*Key Associate – Any individual who contacts animals covered by this protocol; may include, but not limited to, employees, students, guests, collaborators, and field participants (including capture and transport).

#Attending Veterinarian and/or Animal Care Staff must be included ONLY when they will participate in, conduct, or provide training for protocol specific treatments, procedures or manipulations.

PI Responsibilities :

Have you discussed potential occupational health hazards with your Co-PIs, associates, and animal care staff (when appropriate)?

☐ Yes
☐ No

Persons to be contacted in case of an emergency or clinical deterioration of animals outside of normal working hours.

Name:	Name:
Phone # (W)	Phone # (W)
(H)	(H)
(C)	(C)

3. RATIONALE FOR THE USE OF ANIMALS

Provide a brief but complete lay description of the proposed use of animals. Include in this description the purpose of the study, outline the hypotheses that will be tested and describe how the hypotheses will be tested. Do not include specifics about proposed procedures or manipulations. Please avoid the use of scientific jargon, acronyms, and abbreviations. This portion of the proposed protocol should be readily understood by a non-scientist or lay person (8th grade reading level preferred).

Protocol

4. ANIMAL INFORMATION and USDA USAGE CATEGORY

The placing of animal usage into categories and annual reporting to the U.S. Department of Agriculture is required by the Animal Welfare Act. Please read the category definitions carefully and indicate the categories that apply to this project. If more than one category applies, specify in the table below the species/number of animals per category/year.

☐ Category B. Includes animals bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes

☐ Category C. (Non-painful/non-stessful): Animals upon which teaching, research, experiments, or tests will be conducted involving slight or momentary pain, distress, or discomfort. Includes routine procedures such as venipuncture injections, and tissue collection procedure that involves none or only momentary pain. . Free-ranging animals captured in live traps subsequently euthanized (by accepted methods) that produces no obvious signs of pain or distress. Category C is also appropriate in instances where peripheral tissue sampling or tagging and release of free-ranging animals requires use of chemical immobilization to facilitate the procedure to protect the animal and the researcher from injury but not to alleviate pain or distress induced by the procedure. Animals taken by kill trap could be Category C provided the trap functions properly.

☐ Category D. Painful/stressful WITH anesthesia/analgesia/tranquilizers: Animals upon which experiments, teaching, research, surgery, or tests wil be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used. Examples include survival surgery, transcardial perfusion under anesthesia, and infectious disease induction with analgesics provided.

☐ Category E*. Painful/stressful WITHOUT anesthesia/analgesia/tranquilizers*: Animals upon which experiments, teaching, research, surgery, or tests wil be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will not be used due to adverse affects on the procedures, results, or interpretation of the teaching, research, experiments, surgery, or test. Examples include food or water deprivation, application of noxious stimulus, toxicological or microbiological testing that may result in clinical symptoms for which an animal cannot be treated. If a problem occurs in the field that causes pain or distress such as a live trap causing injury and the animal is subsequently euthanized, that is Category E.

Justification for Category E: **Additional explanation is required for Category E protocols. Use the space below or an attachment to explain why pain and distress cannot be minimized with anesthesia, analgesia, and/or tranquilizers. Provide literature references to substantiate rationale for not using anesthesia, analgesia, and/or tranquilizers

**

Protocol

Choose one of the following A or B to complete depending on the purpose of this protocol.

A. **<u>For animal outbreak investigations and some animal surveillance,</u>** (*e.g.*, identification of possible animal reservoirs) which types of animals will be sampled or collected?
Please list type of domestic animal (*e.g.*, horses, cows, chickens, etc.) or general type of wild animal (*e.g.*, small rodents, bats, birds) and provide an **upper limit estimate** of total numbers to be collected or sampled per year.
Please note that you will be responsible for providing genus/species/common names (making a best effort to identify) and actual total numbers collected or sampled in your monthly field reports.

Animals	1st Year number	2nd Year number	3rd Year number	Total	USDA Pain Category	Endangered or Threatened? Y/N
Total:						

Protocol

B. **<u>For experimental field studies</u>** identify target species and numbers of animals to be sampled or collected for each year of the protocol in the table below:

Genus/species	Common name(s) if known	1st Year number	2nd Year number	3rd Year number	Total	USDA Pain Category	Endangered or Threatened? (Y/N)
	Totals:						

Appendix 9: IACUC/OB Protocol Form

5. PERMITS, etc.

5.1. Have you or will you obtain all applicable federal, state, or international permits for animals before
initiating this field investigation?

☐Yes; provide copies to the IACUC office
☐No; provide justification

5.2. Will scheduled substances controlled by the Drug Enforcement Administration be used in this protocol? (e.g. ketamine, barbiturates)

☐Yes
☐No (skip to next section 6.0)

5.3. Describe your plans to gain access to scheduled substances and include your plan for drug security and record keeping.

6. EXPERIMENTAL DESIGN

Explain the experimental design in the sections below. Provide details of all procedures to be used on the animals. Tables can be used to outline test groups and administration of agents/test articles. Details of how pain/distress will be reduced, methods of anesthesia, euthanasia, etc. are to be provided in the sections below.

Survival surgeries are not conducted at Fort Collins. If you are submitting a protocol that involves survival surgeries conducted at a collaborating institution, write to (b)(6) for guidance.

Behavioral or physical restraint studies are not conducted at Fort Collins. If you are submitting a protocol that involves behavioral or physical restraint conducted at a collaborating institution, write to (b)(6) for guidance.

Nonhuman primates studies are not conducted at Fort Collins. If you are submitting a protocol that involves nonhuman primates conducted at a collaborating institution, write to (b)(6) for guidance.

6.1. METHODS

6.1.1. Give a brief scientific description of the project and the use of animals in it, including: Scientific Goals and Aims – Concisely state the protocol's long-term scientific goals. Provide specific aims for each scientific goal (for example, to test a stated hypothesis, solve a specific problem, or develop new technology). A bullet or number format is preferred.

6.1.2. Experimental Design and General Procedures - Describe concisely the research design and methods for achieving each of the stated aims. This section should be informative and

understandable to a technically literate reader. Include: a) groups and numbers of animals used; b) agents, drugs, or biologics administered in each group; c) all procedures that will be conducted on the animals; d) experimental endpoints, and e) a timeline (duration) for each stated aim.

6.2. ADMINISTRATION OF DRUGS OR COMPOUNDS (OTHER THAN ANESTHESIA OR ANALGESICS)

6.2.1. Which of the following will be used in this project?

- ☐ Radioactive material (isotopes):
- ☐ Chemical carcinogen:
- ☐ Toxins:
- ☐ Recombinant DNA/RNA
- ☐ Drugs/Chemicals:
- ☐ Other:
- ☐ NA (skip to Section 6.3.)

6.2.2. Please provide the following information:

Drug/Compound	Dose, Volume, Vehicle	Route of Administration	Frequency and Duration

Please consider the following regarding preparation of compounds for administration to animals: sterility, endotoxins, pH, osmolality, etc., especially when compounds are being administered parenterally (IM, IV, IP) for example – recombinant proteins for vaccines.

6.2.3. What are the potential adverse side effects that might result from administration of the above agents? Provide results of any toxicology studies that have been conducted (in vivo and in vitro).

6.2.4. Who will provide training to technical personnel regarding safety considerations important to this study?

6.2.5. What special procedures need to be followed with toxins, radioisotopes, carcinogens, etc. to be used in the study?

6.2.6. Who will provide consultation for personnel exposed to hazardous agents?

6.3. LOCATION(S) OF FIELD INVESTIGATION

Please provide the name of the state, county, area of country, as applicable where the field investigation will take place. If there will be multiple locations, please list. Maps with specific location(s) marked are acceptable.

6.3.1. Have representatives of CDC or other personnel assisting in the project investigated the area and identified potential social, cultural, or environmental concerns of the local population ?

☐Yes*
*Describe:

☐No Why not?

☐Not applicable

6.3.2. How will these concerns or issues be mitigated?

6.4. CAPTURE AND RESTRAINT OF ANIMALS

6.4.1. Briefly describe the technique(s) of wild animal capture. Include what type of trap is used and where will it be placed.

6.4.2. Will collection/capture by lethal event (e.g. kill trap, gun shot) be used? If so, describe method and how killing of non-target species will be avoided.
☐Yes*
*Describe:
*Justification:
☐No

6.4.3. Water and food should be provided in the trap that is appropriate for the species being captured. Please describe what will be used.

6.4.4. How often will the traps be checked? Frequency of checks will depend on the species.

6.4.5. What is the expected maximum duration of time the animal spends in the trap? Justify the duration.

6.4.6. What actions will be taken if non-target species or endangered species are trapped?
☐ Non-target or endangered species will be released at the point of capture.
☐ Other (explain)

6.4.7. Is it possible that lactating female animals will be captured? If so, please explain how they would be handled.

☐ Yes: Explain
☐ No

6.4.8. Identify the fate of any animals found ill or wounded by trapping.

☐ Any animals found ill or wounded by trapping will be assessed for severity of their injuries, and will be euthanatized if they are unable to be released, based on criteria outlined in FtC -IACUC Policy #19.
☐ Other (explain)

6.4.9. What method will be used for animal restraint once removed from the trap?

6.4.10. How long will the animal be restrained once removed from the trap?

6.4.11. If drug-induced (chemical) immobilization is used to trap, transport, or facilitate sample collection, indicate what is used, dose, and route of administration. (e.g. halothane or isoflurane, by inhalation, to effect)

Drug:
Dose:
Route of administration:
NA ☐

Reversal agent (if used):
Drug:
Dose:
Route of administration:
NA ☐

6.4.12. Monitoring (heart rate, breathing, depth of immobilization) of chemical immobilization needs to be conducted. Indicate who will monitor the animals and frequency of checks.

NAME	FREQUENCY	PROPER TRAINING RECEIVED ON**:

** Provide copies of hands-on training records to the IACUC office.

6.5. PROCEDURES CONDUCTED ON ANIMALS

6.5.1. Where will animal procedures be conducted? (blood collection, euthanasia, etc.)
- ☐ Field location: Specify
- ☐ Other facility:

6.5.2. List all of the procedures that will be conducted on the animals after removal from the trap (use bulleted list).

6.5.3. Will the intended captured animals be transported away from the capture area to another area?
- ☐ Yes*
- ☐ No

*If yes, provide details of how far away the processing area will be, how it will be chosen, method of transport – caging and vehicle, protection of personnel from injury or exposure to pathogens, disinfection of vehicle, etc.
Give the name of the institution (if applicable) and provide housing details, etc. in Section 6.6. and 6.8.

6.5.4. Are animals euthanized immediately upon removal from the trap for post-mortem tissue collection or other purposes?
- ☐ Yes; Complete section 6.13. as appropriate for each taxa or species.
- ☐ No Explain:

6.5.5. Is this a mark and recapture study?
- ☐ Yes; Complete section 6.7
- ☐ No

6.6. LOCATION OF ANIMALS

If animals are moved from the trap area to a facility where they will be housed ≥ 12 hours, husbandry must be in accordance with the needs of the specific taxa. This may also trigger the need for a semi-annual inspection of the facility by the IACUC.

6.6.1. Will any portion of this study be conducted at another institution?
- ☐ Yes
- ☐ No (skip to 6.6.5.)

6.6.2. Will that portion of this study include the use of animals?
- ☐ Yes, that work will be done at (name and address of institution).
  Please provide contact information for the personnel overseeing the facility (name, phone number, and address):
- ☐ No, (skip to 7.3.)
- ☐ NA

6.6.3. Has this study received IACUC approval at the above institution?
- ☐ Yes, and a copy of the approved protocol is attached.

The PHS Assurance Number for the institution is:

USDA Registration Number:
AAALAC Accredited?
☐ No, because

6.6.4. Has this study received IBC clearance at the above institution?
☐ Yes, and the IBC approval number is
☐ No, because it was not necessary to obtain IBC clearance

6.6.5. Is any portion of the use of animals supported by CDC funds and contracted to commercial sources?
☐ Yes, it is contracted out to _____.
The PHS Assurance Number for the contract facility USDA registration Number
AAALAC Accredited?
☐ No

6.7. MARKING

6.7.1. Is this a mark-recapture study?
☐ Yes*
☐ No (Skip to 6.8.)

*If yes, briefly describe the marking technique that will be used, the nature or duration of restraint required during marking, the amount of tissue affected by the technique, and whether the method of marking will cause animals momentary or prolonged distress.

6.7.2. After marking, is it anticipated that the animals will be at greater than normal risk of infection, predation, or survival, or have reduced reproductive fitness?
☐ Yes*
☐ No

*If yes, please justify why this marking technique must be used and why other techniques that may have less impact on the animals may conflict with the purpose of this research activity.

6.8. ANIMAL MAINTENANCE AND CARE (HOUSING, ENVIRONMENT, NUTRITION, WATER)

6.8.1. Will animals be confined or restricted to an enclosure (not the trap) in their natural setting for longer than 12 hours or transported to and housed within an enclosure in a research facility, laboratory, or other area? Note: Methods must accommodate features of the animals' ecology, morphology, physiology, and behavior and contribute to their health and well-being.
☐ Yes*
☐ No (skip to section 6.8.7.)

*If yes:

6.8.2. Indicate the period of time that animals will be cared for in the field.

6.8.3. Describe the enclosure that will be used.

6.8.4. Describe the methods for maintaining appropriate living conditions that contribute to the animals' health and well-being, including their diet and frequency of feeding if applicable.

6.8.5. Describe how environmental conditions will be controlled.

6.8.6. Describe the factors that will be monitored to ensure that these methods of animal maintenance in the field contribute to the health and well-being of the confined animals (e.g., appearance, behavior, activity, growth).

6.8.7. Will surgery be performed on animals as part of this protocol?
☐Yes; (please contact (b)(6) if surgeries will be performed)
☐No

6.8.8. As a result of the methods in this protocol, will animals be subjected to more than slight or momentary discomfort or pain that cannot be alleviated with analgesics or anesthetics?
☐Yes*
☐No

*If yes, describe the methods and/or clinical criteria that will be used to ensure timely intervention and removal of the animals from the study in advance of the anticipated discomfort or pain, or why avoidance or alleviation of pain or discomfort adversely affects the outcome of this protocol.

6.8.9. Does this protocol require deprivation of a normal caloric intake?
☐ Yes, because:
☐ No

6.8.10. Does this protocol require deprivation of a normal fluid intake?
☐ Yes, because:
☐ No

6.8.11. Does this project require an alteration in diet or specific feed?
☐ Yes, because:
☐ No

6.8.12. Describe contingency plan(s) (e.g. will appropriate food and water be provided, do animals just need to be released without sampling, etc.)

6.8.13. What is the impact of the number of animals taken on the local animal population

6.9. END OF STUDY

6.9.1. Does this animal use end with the release of the animals (with no planned recapture)?
☐Yes (skip to 6.10.)
☐No

6.9.2. If the location of the study takes place outside of the USA, will local community leaders be consulted with regards to the trapping/release of "pest" animals such as *Rattus rattus*?
☐ Yes,
☐ No Reason:
☐ Not applicable

6.9.3. Does this animal use end after the same marked animals are recaptured again, one or more times, with or without the collection of tissue specimens, or the administration of test substances, using methods identical to those previously described in this proposal.
☐Yes
☐No

6.9.4. If yes, what are the sampling intervals and is there is an equal probability of capture across intervals?

6.9.5. If no, explain why not.

6.9.6. Will tissue specimens be collected, or test substances administered during each episode of restraint/recapture?
☐Yes
☐No

6.9.7. If this is a recapture study, at what point does the animal use data collection end?

☐NA

6.9.8. Will animals be released at the site of capture, within 12 hours of their capture without impairment of their ability to survive, and when environmental conditions are conducive to their survival?
☐Yes
☐No

6.9.10. Are animals euthanized at the end of this study?
☐ Yes; Complete Section 6.12 for each taxa or species.
☐No

6.10. MANAGEMENT OF NON-SURGICAL PAIN AND DISTRESS

6.10.1 Will animals experience distress, discomfort, suffering, or pain as a result of the procedures? Distress is defined by the USDA as "a state in which an animal cannot escape from or adapt to the internal or external stressors or conditions it experiences, resulting in negative effects on its well-being."

Appendix 9: IACUC/OB Protocol Form

Read more about distress and pain (including definitions) in the ACLAM policy Pain and Distress in Research Animals (July 2016) here: (b)(7)(E) (b)(7)(E)

☐ Yes, the following procedures will cause distress, pain, and / or discomfort to the animals at some point during the study. Routine procedures such as injections and limited blood sampling do not need to be reported here. (complete table below)
☐ No

Procedures

6.10.2 Criteria for scheduled termination of animals from protocol:
6.10.2.1 When will animals be euthanized?

6.10.2.2 What are the study endpoints?

6.10.3 Animals must be euthanatized if moribund/severely debilitated.
The criteria used for removing (unscheduled termination) an animal from the study will be:

☐ Signs of moribundity including abnormal posture, rough hair coat, head tucked into abdomen, exudates around eyes and/or nose, skin lesions, abnormal breathing, difficulty with ambulation, decreased food or water intake, or self mutilation. In the field, such signs as injuries to limbs that compromise mobility and ability to survive.
☐ Tumor size (> 1 cm^2)
☐ > 10% body weight loss
☐ Other (explain)

Examples of Analgesics:
(More information is available in Fort Collins IACUC Policy 25: Anesthesia and Analgesia Guidelines and contact the Attending Veterinarian.)

Species	Analgesic Drug	Dose/ Route
Mouse	Ibuprofen	40 mg/kg, administered as 0.2 mg/ml in drinking water
	Acetaminophen	1-2 mg/ml in drinking water
	Buprenorphine	0.05-0.1 mg/kg SQ BID
	Butorphanol	1-5 mg/kg SQ QID
Rabbit	Buprenorphine	0.02-0.05 mg/kg SQ or IV TID or BID
	Butorphanol	0.1-0.5 mg/kg IV every 4 hours

Examples of Anesthetics: (More information is available in Fort Collins IACUC Policy 25: Anesthesia and Analgesia Guidelines and contact the Attending Veterinarian.)

Appendix 9: IACUC/OB Protocol Form

Species	Anesthetic Drug(s)	Dose/ Route	Approximate Duration of Surgical Plane of Anesthesia
Mouse	Ketamine / Xylazine	80-100 mg/kg + 10 mg/kg IP	20-30 minutes (note: high mortality possible)
	Ketamine/Xylazine/ Acepromazine	65 mg/kg + 13 mg/kg + 2 mg/kg IP	45-120 minutes (note: recommended for non-survival procedures only unless otherwise directed by the AV)
	Ketamine / Medetomidine*	50-75 mg/kg + 1 mg/kg IP or SC	60-120 minutes (note: recommended for survival procedures)
	*Atipamizole to reverse	5 mg/kg IPor SC	5-10 minutes to reverse medetomidine; Ketamine effect may last longer
	Isoflurane	1-4% - to effect – Inhalation	Monitor level of anesthesia, adjust concentration as needed; removal of drug leads to quick recovery
Rabbit	Ketamine / Xylazine	35 mg/kg IM 5 mg/kg IM	25-40 minutes
	Ketamine / Xylazine	10 mg/kg IV 3 mg/kg IV	20-30 minutes
	Isoflurane	1-4 % - to effect – Inhalation	Monitor level of anesthesia, adjust concentration as needed; removal of drug leads to quick recovery

6.10.4 Will anesthetic, analgesic, or tranquilizing drugs be used to relieve pain or distress?

☐ Yes, the following will to be used to relieve pain or distress:

Drug	Dosage	Route	Frequency

☐ No, although the proposed studies involve distress, discomfort, suffering, or pain, the use of anesthetic, analgesic, or tranquilizing drugs is not planned because:

6.10.5 Please identify the individual(s) who will monitor the animals during anesthesia and recovery and the frequency of monitoring. For example, animals recovering from

anesthesia should be monitored at least every 15 minutes until ambulatory. Heart rate, respiratory rate, and posture should be monitored.

NAME	FREQUENCY	PROPER TRAINING RECEIVED ON**:

** Provide copies of hands-on training records to the IACUC office.

6.10.6 What non-pharmaceutical measures will be used for post-procedural recovery?

- ☐ fluids, such as:
- ☐ warming pads,
- ☐ heating pads,
- ☐ soft bedding, and or
- ☐ Other:
- ☐ Not applicable

6.11. COLLECTION OF BLOOD AND BODY FLUIDS

6.11.1 Body fluid to be collected:
None ☐ Skip to 6.12.

6.11.2 Frequency of collection:

6.11.3 Volume of fluid to be collected (see table below for examples of blood volumes):

6.11.4 Method/site of collection:

6.11.5 Will the animal be anesthetized or sedated during this procedure?

- ☐ Yes, using the following:
  - Anesthetic agent or sedative:
  - Dosage:
  - Route of administration:
- ☐ No, it is not necessary, because

6.11.6 If blood is to be collected, does the blood volume for a single or multiple blood draw(s) conform to the volumes specified in the CDC-Fort Collins IACUC Policy 026 "Blood Collection Guidelines" ?

(b)(7)(E)

- ☐ Yes
- ☐ No, an exemption is requested because

Examples of acceptable blood sample volumes:

Recommended Maximum Blood Sample Volumes - Species / Body Weight

Species	Weight	Total Blood Volume (ml)	7.5% (ml)	10% (ml)	15% (ml)	20% (ml)
Mouse	25 g	1.8	0.1	0.2	0.3	0.4
Rat	250 g	16	1.2	1.6	2.4	3.2
Syrian Golden Hamster	100 g	7.2	0.54	0.72	1.08	1.44
Guinea Pig	800 g	60	4.5	6.0	9	12
Rabbit	4 kg	224	17	22	34	45

Guidelines for Repeated (serial sampling)

(6) Weekly blood collection volume should be limited to 7.5% of the total blood volume (TBV).

(7) For repeated bleeds at shorter intervals, a maximum of 1.0% of an animal's TBV can be removed every 24 hours.

(8) Repeated (serial) sampling will not exceed 7.5% TBV within a 7 day period.

(9) Amount of blood samples required on serial bleedings as per protocol will be adjusted based on the actual weight of the animal assigned to the protocol.

(10) When performing serial bleeds, 24 hours of rest should be allowed for each 1% of body weight sampled. Protocols requiring serial bleeds in amounts that do not meet the guideline for rest, and are scientifically justified, may be approved by the IACUC, but may not exceed the 7 or 30-day maximums.

6.12. INFECTIOUS AGENT INFORMATION

6.12.1. Name the primary agent(s) used or investigated in this study:

Agent(s) that may be recovered	Risk/Hazard Group	Virulence (Low/Mod/High)

6.12.2. Will you be using/collecting human blood or other potentially infectious human body fluids? ☐ Yes
☐ No

6.12.3 Is the source of the organism indigenous or foreign?
☐ Indigenous
☐ Foreign

6.12.4. Indicate the proposed animal biosafety level(s) of this study.
- ☐ ABSL 1
- ☐ ABSL 2
- ☐ ABSL 3

6.12.5. Will infectious material(s) collected in the field be transported back to CDC or another facility for analysis?
- ☐ Yes Explain:
- ☐ No

Transport permits obtained?
- ☐ Yes
- ☐ No Explain:

6.12.6. Check All possible modes of agent transmission to humans.
- ☐ Animal bite
- ☐ Animal excretion or egestion
- ☐ Animal shedding
- ☐ Animal bedding
- ☐ Percutaneous injury with sharp implement
- ☐ Percutaneous injury from contact with cage
- ☐ Mucosal Surface exposure
- ☐ Dermal exposure
- ☐ Ingestion
- ☐ Inhalation
- ☐ Vector
- ☐ Not applicable
- ☐ Other:

6.12.7. Will ectoparasites be collected?
- ☐ Yes Describe:
- ☐ No

6.12.8. Will necropsy be performed in the field?
- ☐ Yes
- ☐ No

6.12.9. List additional zoonotic hazards anticipated during this field investigation capturing wild animals:

6.12.10. Is there a possibility of incidental capture of carnivores or bats?
- ☐ Yes
- ☐ No

6.12.11. How will infectious waste be disposed?

6.13. HUMAN BIOSAFETY

Appendix 9: IACUC/OB Protocol Form

Information in questions # 6.13.1 through 6.13.10. is required for all persons listed on this protocol (to be filled out after consultation / risk assessment with the Safety Officer):

6.13.1. Required Immunizations:

- ☐ JEvax
- ☐ Yellow Fever
- ☐ Hep A
- ☐ Hep B
- ☐ Rabies
- ☐ Tetanus
- ☐ None

6.13.2 Respiratory Program Enrollment required for this protocol?

- ☐ Yes
- ☐ No

6.13.3 Personal Protective Equipment Requirements:

- ☐ Boots, gators, etc. ☐ Gloves
- ☐ Disposable coveralls or Tyvek® suit
- ☐ Face shield or Safety glasses
- ☐ N-95 filtering facepiece
- ☐ Powered air purifying respirator (PAPR)
- ☐ Other:

6.13.4. List and describe any aerosol producing procedures and where they will be conducted (consider filling syringes, etc.):

6.13.5. Will sharps be used in any procedure (e.g. scalpels, scissors, needles)?

- ☐ Yes and provide details:
- ☐ No

6.13.6. Do the animals that will be captured or handled pose a risk to human health?

- ☐ Yes Explain:
- ☐ No

6.13.7. Are ectoparasites a concern for human health?

- ☐ Yes Explain:
- ☐ No

6.13.8. Are zoonoses known in the local population either associated with the subject species or other animals in the vicinity – what are handling precautions?

6.13.9. List any biological (endemic or epidemic), environmental and/or physical risk factors that may exist in the geographical location you intend to work.

6.13.10. Additional Safety Requirements:

6.14. EUTHANASIA/DISPOSITION OF ANIMALS

Euthanasia of experimental animals, when necessary, must be accomplished in a humane manner and by acceptable techniques as recommended by the American Veterinary Medical Association Guidelines on Euthanisa, 2013 and as provided in Fort Collins IACUC Policy 16 Euthanasia found at

(b)(7)(E

For wild-caught animals, carcass disposal must be considered when determining euthanasia method. If injectable agents such as KX or KXA are used, carcasses should be incinerated or disposed of in such a manner as to prevent predators or scavengers from acquiring the carcass.

Examples of Euthanasia methods by species:

Species	Method of Euthanasia
Mouse / Rat / other small rodents	Ketamine/ Xylazine (80-100 mg/kg + 10 mg/kg IP) anesthesia followed by CO2 inhalation overdose; confirmed with cervical dislocation
	Ketamine/ Xylazine (80-100 mg/kg + 10 mg/kg IP) with cervical dislocation
	Ketamine/ Xylazine/ Acepromazine (65 mg/kg + 13 mg/kg + 2 mg/kg IP followed by cervical dislocation
	Isoflurane or halothane anesthesia via inhalation to effect - overdose; confirmed by cervical dislocation
Rabbit	IV of barbiturate euthanasia solution followed by thoracotomy

6.14.1. Indicate the method(s) of euthanasia for the species used (check all that apply):

☐ Anesthesia followed by CO_2 inhalation, confirmed with cervical dislocation
4. Anesthetic agent:
5. Dosage:
6. Route of administration:

☐ Halogenated anesthetic agent overdose. Waste anesthetic gases must be scavenged if working in a closed space.
4. Halongenated agent:
5. Dosage: to effect
6. Route of administration: Inhalation

☐ Anesthesia followed by cervical dislocation
4. Anesthetic agent:
5. Dosage:
6. Route of administration:

☐ Decapitation under anesthesia
4. Anesthetic agent:
5. Dosage:
6. Route of administration:

☐ Barbituate overdose
5. Agent:

6. Dosage:
7. Route of administration:

☐ Other method(s) acceptable with conditions:
- ☐ Cervical Dislocation without anesthesia. Requires justification:
- ☐ Decapitation without anesthesia. Requires justification:
- ☐ Exsanguination with anesthesia confirmed by Requires justification:
- ☐ Other: Requires justification:

☐ None

6.14.2. Secondary methods used to confirm euthanasia:
- ☐ cervical dislocation (small animals <200 gm)
- ☐ thoracotomy (large animals >200 gm)
- ☐ other (explain)

Describe the method(s) used to verify euthanasia:
- ☐ absence of respiration
- ☐ absence of cardiac function
- ☐ absence of toe/tail pinch reflexes
- ☐ other

6.14.3. Disposition of animals if other than by euthanasia (e.g. released once blood collected):

6.14.4. Describe carcass disposal.

7. JUSTIFICATIONS

7.1. JUSTIFICATION OF THE CHOICE OF EACH OF THE SPECIES SELECTED

Why is this species the most appropriate for your study? Note that saving money or time is not an
acceptable justification.

7.2. JUSTIFICATION OF THE NUMBER OF ANIMALS REQUESTED IN THIS PROTOCOL

How were the numbers of experimental groups and the number of animals per group provided in Section 8 - Experimental Design obtained? Check all categories that apply. Provide text or tables to demonstrate your computations and/or justify how your numbers were determined. Refer to Fort Collins IACUC Policy 8 "Justification for the Animals for DVBD IACUC Protocols"

(b)(7)(E)

(b)(7)(E)

☐ Pilot or preliminary project; group variances unknown at present.
Explain:

☐ Group sizes determined statistically.
Explain:

☐ Breeding, maintenance, or training protocol.
Explain:

☐ Group sizes based on quantity of harvested cells or amount of tissue required.
Explain:

☐ Other
Explain:

7.3. REFINEMENT, REDUCTION AND REPLACEMENT OF THE USE OF ANIMALS

Justify the use of live animals by completing the following section. An explanation for the use of animals must be made when an in vitro method is available for any model/method proposed in this protocol. (Examples: use of the ascites model to produce monoclonal antibodies.)

Visit the Animal Welfare Information Center http://awic.nal.usda.gov and National Library of Medicine Alternatives website https://www.nlm.nih.gov/pubs/factsheets/altbibfs.html to search for alternatives to animal use.

7.3.1. Can mathematical models and/or in vitro systems be used to reduce the number of animals requested in this proposal?
☐ Yes, but I am not using them because
☐ No, because

7.3.2. Have in vitro systems been used to limit the parameters of the study or to limit the test substances or groups prior to the use of animals?
☐ Yes Please describe briefly:
☐ No, because

7.3.3. Are there alternatives to the use of live animals in any of the proposed procedures that would be compatible with your experimental design?
☐ Yes, but I am not using them because
☐ No, because

7.3.4. Are there alternatives to the procedures proposed that would be compatible with your experimental design?
☐ Yes, but I am not using them because
☐ No, because

7.3.5. As Principal Investigator, I have determined by means of the following sources or searches that alternatives to the procedures that may cause animal pain and/or distress proposed in the protocol are not available and this protocol does not duplicate previous experiments.
☐ Yes, but duplication is scientifically justified because

☐ No, it does not duplicate previous experiments

7.3.6. For 1-5 above, in your attempts to reduce, refine or replace the use of animals, please complete the following table. At least 2 different databases should be searched. Consider alternatives to the painful/distressful procedures in this study

Database	Date(s) of Search	Period of Search (mm/yyyy to mm/yyyy)	Keywords Used

Please provide a narative regarding your search strategy to find alternatives to animal use including relevant results.

7.3.7. How will the results of this study benefit science, medicine or society in general?

Appendix 9: IACUC/OB Protocol Form

8. PRINCIPAL INVESTIGATOR ASSURANCE STATEMENT

The CDC-Fort Collins has on file with the Public Health Service (PHS) a written Assurance which commits the CDC-Fort Collins to following the standards established by the Animal Welfare Act and PHS Policy. As part of the Assurance, the CDC-Fort Collins has established the IACUC to review proposed protocols involving animals to ascertain if proposals are consistent with the NIH "Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Education," the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and other applicable public laws and regulations. These documents describe requirements that must be met for humane care and treatment of research animals, to assure that animals do not suffer unnecessary discomfort, pain, or injury, and that animals receive proper care and husbandry. Laboratory animals must be cared for and used in a manner that complies with the above documents to protect current and future PHS support. Protocol progress reports must be submitted yearly, and a complete updated application must be submitted every three years.

☐ I certify that I have read the above statement and will adhere to all regulations therein, and that I will make written notification (protocol amendment/modification) to the Institutional Animal Care and Use Committee of any changes in the proposed project, relative to this proposed protocol, prior to proceeding with any animal experimentation.

☐ I assume responsibility for ensuring that all personnel involved in this project are informed of the Occupational Health hazards and are appropriately trained in all procedures.

☐ I certify that the proposed use of animals does not unnecessarily duplicate previous experiments.

☐ I certify that the information contained herein is a true and accurate description of the work I plan to conduct.

☐ I certify that my supervisor reviewed this proposal and she/he supports its scientific merit. Supervisor

I assure that the DVBD Attending Veterinarian reviewed this protocol prior to submission.
☐ Yes _____ (AV Initial) ☐ No, because:

I assure that the IACUC Statistician reviewed this protocol including, Section 8, prior to submission.
☐ Yes _____ (Statistician Initial) ☐ No, because:

I assure that the DVBD Safety and Occupational Health Specialist reviewed this protocol including, Sections 6.12 and 6.13, prior to submission and commit to participating in a risk assessment before initiation of work described in this protocol. All Safety and Occupational Health pre-requisites have been met by all individuals listed on this protocol.
☐ Yes _____ _____
Signature (safety officer) Date ☐ No, because:

I assure that the DVBD Responsible Official (select agents) reviewed this protocol prior to submission.
☐ Yes _____ (AV Initial) ☐ No, because:

_____
Principal Investigator Date

_____
Supervisor Date
As the Principal Investigator's supervisor, I have reviewed this proposal and confirm its scientific merit (required prior to submission).

_____
Branch Chief Date
As the Principal Investigator's branch chief, I have reviewed this proposal and confirm its scientific merit (required prior to submission).

Appendix 9: IACUC/OB Protocol Form

Annual Report Form

Annual Record of Animal Usage and Protocol Review

A. PROTOCOL INFORMATION

Investigator	
Protocol Number	
Title	
Species (common)	
Expiration Date	

B. PROTOCOL STATUS

(Double click on the box to enter a check mark)

1. Were any animals used on this protocol during FY 2014? _____ Yes _____ No

2. Please indicate the status of this protocol as of 09/30/14 (fiscal year end):
   - ☐ Active and ongoing
   - ☐ Study not yet initiated
   - ☐ Completed – provide date of study termination: _____

C. ANIMAL USAGE BY PAIN CATEGORY

(Enter applicable animal numbers in right column)

USDA Pain Category *	IACUC Approved 3-year Total	Actual Number Used in FY 2014
B		
C		
D		
E		

* USDA Pain Categories:

- B refers to animals bred or held, but not yet used for any research or teaching procedures
- C refers to no pain, distress, or use of pain-relieving drug
- D refers to pain or distress for which appropriate anesthetic, analgesic, or tranquilizing drugs were used
- E refers to pain or distress for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, experiments, research, surgery, or tests

1. Were any animals included in the numbers above used in multiple protocols during FY 2014?
   - ☐ No
   - ☐ Yes, please list the additional protocol numbers here: _____

2. Further comments or explanation for animal usage numbers above (if needed):
   _____

3. Were any animals used in the previous fiscal year carried over to this fiscal year?
   ☐ No
   ☐ Yes, how many: _____

D. JUSTIFICATION FOR CATEGORY E PAIN

(Enter text in boxes below)

1. Please provide a brief explanation of the procedure(s) producing pain and/or distress, including reason(s) for species selected.
   _____

2. Please provide the scientific justification for withholding drugs for relieving pain and/or distress. State methods or means used to determine that pain and/or distress relief would adversely affect the test/study results.
   _____

E. ANNUAL PROTOCOL REVIEW QUESTIONNAIRE

(Double click on the box to enter a check mark and provide a brief explanation where noted)

1. For this protocol, this review is:
   ☐ First year
   ☐ Second year
   ☐ Third year

2. Please list any changes in protocol associates that have occurred for this protocol since the last annual review or IACUC approval.
   _____

3. Have all protocol associates completed the required regulatory training in accordance with CDC-FTC IACUC Policy 21?
   ☐ Yes
   ☐ No, please explain: _____

4. Have all protocol associates who will access facilities where study animals are housed received Animal Area Access (AAA) clearance from the CDC Office of Health and Safety (OHS) within the past year?
   ☐ Yes
   ☐ No, please explain: _____

5. Are current animal use procedures being conducted as described in the latest IACUC-approved version of this protocol?
   ☐ Yes
   ☐ No, please explain: _____

6. Have any new developments occurred in this protocol or in the literature that might influence a decrease (or increase) in the number or the use of animals?
   ☐ No
   ☐ Yes, please explain: _____

7. In your judgment, is the level of pain or distress for animals used to date about the same as when the protocol was first approved?
   ☐ Yes
   ☐ No, please explain: _____

8. Have there been any instances of animal morbidity and/or mortality that were higher or lower than anticipated?
☐ No
☐ Yes, please explain: _____

9. Does this study involve anesthesia?
☐ No
☐ Yes,

10. Are the same anesthetic agents and doses being used as those listed in the protocol?
☐ Yes
☐ No, please list agents and/or dose levels being used: _____

11. Have there been unexpected deaths due to anesthesia?
☐ No
☐ Yes, please explain, including the number of animals affected: _____

12. Does this protocol involve any of the following:
- deviations from regulatory requirements (e.g., Animal Welfare Act regulations, or PHS Policy), or
- exceptions to animal welfare standards (e.g., *Guide for the Care and Use of Laboratory Animals*), or
- deviations from CDC or IACUC policies?

☐ No
☐ Yes, please explain: _____

Examples of the above situations include but are not limited to:
- ❖ **Exceptions to specific housing standards (e.g., minimum cage size) noted in the *Guide*.**
- ❖ **Animal husbandry provided by investigator or research staff and not ARB staff.**
- ❖ **Multiple species housed in the same room.**

13. Please provide a brief summary of the results, conclusions, advancements, and/or benefits gained from animal usage on this protocol since the last annual review or IACUC approval.
_____

F. CERTIFICATION BY INVESTIGATOR

Entry of name and date below certifies that the Principal Investigator for this protocol understands the requirements of the PHS Policy on Human Care and Use of Laboratory Animals, applicable USDA animal welfare regulations, and CDC and IACUC policies governing the use of vertebrate animals for research, teaching, or testing. Investigator also agrees to conduct activities with animals in full compliance with the IACUC-approved protocol and the aforementioned requirements. (typed name and date are okay–then e-mail to (b)(6)

Investigator Name: _____ Date: _____

Appendix 10: IACUC/OB Periodic Report

Please attached a copy of the latest facilities (including laboratory inspections) and program assessment report conducted by the IACUC/OB.

Appendix 10: IACUC/OB Periodic Report

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Centers for Disease Control and Prevention
Division of Vector-Borne Diseases
3156 Rampart Road
Fort Collins, CO 80851
970-221-6400

MEMORANDUM

To: (b)(6)
Institutional Official, Acting Deputy Associate Director for Science
Office of the Associate Director for Science
Office of the Director, Centers for Disease Control and Prevention

From: (b)(6)
Chairperson, CDC-Fort Collins Institutional Animal Care and Use Committee

Subject: Semiannual Evaluation of Animal Care and Use Program and Inspection of Facilities – Division of Vector-Borne Diseases, Fort Collins, CO

Date: October 25, 2017

CC: (b)(6) OID/NCEZID/DVBD/OD
(b)(6) OID/NCEZID/DVBD/OD
(b)(6) OID/NCEZID/DVBD/OD
(b)(6) OID/NCEZID/DVBD/OD
OID/NCEZID/DVBD/OD
(b)(6) OID/NCEZID/DVBD/OD
OID/NCEZID/DSR/OD
(b)(6) OID/ NCEZID/DSR/OD
OID/NCEZID/DSR
(b)(6) OD/OADS/OSI
(b)(6) OD/OADS/OSI/ACUPO
DVBD Institutional Animal Care and Use Committee (IACUC)

This memorandum documents the September 12, 2017 Semiannual Evaluation of the Centers for Disease Control and Prevention (CDC) – Division of Vector-Borne Diseases animal facility inspection and program review by the Institutional Animal Care and Use Committee (IACUC), as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and as a condition of this Institution's Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW) and United States Department of Agriculture (USDA) Animal Welfare Regulations, 9 CFR Chapter I, subchapter A, as applicable. This evaluation utilized the National Research Council's *Guide for the Care and Use of Laboratory Animals* (2011).

Findings of the September 12, 2017 Semiannual Review of the CDC-Fort Collins Animal Care and Use Program

The CDC-Fort Collins IACUC conducted the Semiannual Evaluation of the Institution's

Animal Care and Use Program on September 12, 2017 using the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the *Guide for the Care and Use of Laboratory Animals*, 2011 (the "*Guide*"), and Title 9 CFR Chapter I, Subchapter A – Animal Welfare Regulations (USDA Regulations), as applicable.

CDC-Fort Collins IACUC members who participated in the Program review included: [redacted] and [redacted] provided administrative support.

No significant or minor deficiencies were noted. The modified OLAW checklist was utilized for the review with discussion.

The CDC-Fort Collins IACUC members reviewed records and inspected the animal facilities on September 12, 2017 using the PHS Policy on Humane Care and Use of Laboratory Animals, the *Guide for the Care and Use of Laboratory Animals*, 2011 (the "Guide"), and Title 9 CFR Chapter I, Subchapter A – Animal Welfare Regulations (USDA Regulations), as applicable. Currently approved exceptions to the 2011 Guide were also reviewed.

CDC-Fort Collins IACUC members who participated in the facility inspection included [redacted] and [redacted] provided administrative support. [redacted] and [redacted] all from animal care contractor services) escorted IACUC members through the animal facilities and/or answered questions.

No significant deficiencies were noted by the IACUC during the facility inspection and records review. There were a few minor deficiencies noted and their status is listed in Appendix A below.

Minority Views

There were no minority views concerning the semiannual evaluation of the program and animal facilities. There have been no minority views on protocol or amendment approvals during this reporting period.

Approved Protocol Exceptions to the *Guide*

The following are exceptions to the 2011 *Guide* that were reviewed and approved by the IACUC for individual protocols.

Eight (8) approved protocols allow mice to be individually housed on a metal grate for up to 5 days while ticks feed (ticks drop off into ½" of water kept under metal grate, replete ticks are removed from water daily). Mice are provided with a plastic petri dish bottom (as a platform for respite from any discomfort incurred by the metal grate) for days 2-4 before ticks begin dropping off. A mouse hut is provided for additional comfort. Mice are euthanized at the end of the tick-feeding session or returned to regular housing, depending on the study protocol. One protocol allows rabbits to be single-housed with an Elizabethan-collar to facilitate feeding and biocontainment of ectoparasites or to prevent fighting. Six (6) mouse protocols allow pregnant females to be housed individually when they are ready to litter. For the purpose of

disease surveillance, one (1) mouse protocol allows for the placement of soiled bedding from other cages housing mice in cages with SPF mice as a means of exposure.

Program Changes

IACUC policies were reviewed and updated since the last semi-annual are as follows:

FTC-006 Major and Minor Changes to Protocols
FTC-014 Reporting Animal Welfare Concerns
FTC-019 Endpoints in Animal Use Protocols and Response to Unexpected Morbidity and Mortality
FTC-020 Full Committee Review
FTC-021 Training of Investigators
FTC-022 Training of IACUC Members

Program Exceptions

There were no program exceptions during this period since the last report to the IO.

Appendix 10: IACUC/OB Periodic Report

Names of IACUC Members	Signatures/ Initials
(b)(6) Chairperson	(b)(6)
Member	(b)(6)
Member	
Nonaffiliated, non-scientist member	
(b)(6) Attending Veterinarian Member	(b)(6)
Statistician Member	(b)(6)
Health and Safety Member	
(b)(6) Scientist Member	
Scientist Member	
Alternate Scientist	
Scientist Alternate	(b)(6)
Member, Alternate	(b)(6)
Statistician Alternate	
Attending Veterinarian Alternate	(b)(6)

Appendix A

RESULTS OF IACUC SEMI-ANNUAL PROGRAM REVIEW AND FACILITY INSPECTION FOR DVBD

FOLLOW-UP RECORD

September 12, 2017

Location and Item to Fix	(S) or (M)*	Correction Plan	Person Responsible	Corrective Action Performed	Correct by date	Date Corrected
[redacted] Incinerator area Eyewash fountain last checked April, 2017	M	Check eyewash fountain, record on card, reminder to do monthly	[redacted]	Eyewash checked	9-19-2017	10-3-2017
[redacted] Eyewashes in lab areas need to be checked Shower in lab area needs to be checked	M	Check eyewash fountains Check shower	[redacted] Facilities maintenance	Eyewash checked Shower checked	9-19-2017 9-19-2017	9-14-2017 9-19-2017
[redacted] Eyewashes need to be checked	M	Check eyewash fountains	[redacted]	Eyewashes checked	9-19-2017	10-3-2017
[redacted] SOP book found with outdated SOPs and ADRP	M	Remove notebook	[redacted]	Notebook removed, outdated SOPs to be shredded during next shred cycle	9-19-2017	9-14-2017
[redacted] outside protocol holder Expired protocol 14-011 still present	M	Removed expired protocol	[redacted]	Protocol removed	9-19-2017	9-13-2017

Location and Item to Fix	(S) or (M)*	Correction Plan	Person Responsible	Corrective Action Performed	Correct by date	Date Corrected
Dirty Cage Wash area Emergency guide last checked in 2008 (Note: same guides are in place throughout the animal facility)	M	Need to check that it is still current and initial when reviewed	(b)(6) (b)(6)	Emergency guide is current, date inadvertently not changed; will be replaced in near future with CDC-wide guide (per (b)(6)	9-19-2017	10-3-2017
All emergency contact sheets -need to update with new personnel and remove personnel no longer working here	M	Update contact sheets	(b)(6)	Contacts updated	9-19-2017	9-13-2017
Animal Care Form – Room Sheet Cage changes occurring 1X/wk Form has Q2W Modify form to reflect what is actually being done	M	Modify form as appropriate	[redacted]	Form modified	9-19-2017	9-13-2017
Records Review: Cage wash records: tunnel washer instances where time and user ID not recorded; rack washer several temperature records missing. Clean and dirty cage wash: not all activities done daily per check sheet, missing data; one month missing. Feed room and bedding	M	Multiple instances of forms missing data, tasks not completed, initials missing	(b)(6) (b)(6)	[redacted] training on form completion	10-10-2017	10-4-2017

(b)(6)

Location and Item to Fix	(S) or (M)*	Correction Plan	Person Responsible	Corrective Action Performed	Correct by date	Date Corrected
room records – missing data; rarely sweep floors based on missing data; no date/month and times on one record. Animal census form: initials missing Items to file stuffed in binder						

*Significant (S) or Minor (M)

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:	

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.

Heating Ventilation and Air Conditioning (HVAC)

The building is designed to minimize facility maintenance work in vivarium and animal housing areas. Each vivarium and animal floor is serviced by a full story interstitial level above and below and a two-story mechanical room for the air handling units (AH) and associated mechanical equipment. All duct work, reheat coils, HEPA Filters, and control devices can be accessed from the mechanical room or the interstitial levels minimizing facility work in vivarium and animal housing areas.

1) Indoor Conditions

Each zone contains an individual thermostat set to maintain a space temperature set point (65°F–80°F) and a humidistat set to hold relative humidity within 30%-70% depending on the animal species housed. A temperature/humidity monitor is placed in each animal cubicle and monitored daily by [redacted] employees.

2) Pressurization

Airflow is based on 100% outside air that is exhausted after a single pass. Vivarium spaces are negatively pressurized by means of offset controls to maintain a minimum 15% difference between exhaust and supply air volumes. The minimum offset for all spaces will be 150 CFM. SPF barrier suite is positively pressurized by means of offset controls. All animal holding spaces are designed with a minimum of 10 air changes per hour.

3) Air Systems

Each vivarium and animal floor is served by a dedicated air handling unit and exhaust fans that serve only that floor. All central station air moving equipment is sized with a 25% safety factor to accommodate system leakage and future growth. All vivarium and animal space's supply and exhaust systems have N+1 redundancy.

4) Ductwork

No ductwork, piping, or other mechanical equipment is exposed in the vivarium or animal spaces.

5) Air Distribution Devices

All supply air diffusers in small rooms are radial flow diffusers to prevent supply air from interfering with primary containment devices, such as biological safety cabinets. Air diffusers in large rooms are perforated face diffusers. Exhaust registers and grilles are the perforated type when mounted in the ceiling or fixed blade type when mounted vertically. Connections to biological safety cabinets are thimble type to prevent the building mechanical system operation from interfering with the BSC operation. Animal holding rooms are provided with prefilters in the exhaust registers and grilles. High humidity spaces are provided with air distribution devices constructed of stainless steel.

6) Filtration

Each air handling unit is provided with a pre filtration system and a final HEPA filtration. Exhaust systems of the enhanced BSL3 vivarium and animal spaces are provided with HEPA filters. Filters are located as close as possible to the space to minimize the amount of contaminated ductwork. HEPA filters are sized for a maximum of 250 feet per minute face velocity and have the following components:

- Upstream bioseal damper.
- Upstream DOP/Decontamination port.
- Mixing/test section.
- HEPA filter section.
- Scan section.
- Downstream DOP/Decontamination port.
- Downstream bioseal damper

7) Controls

A dedicated front-end station is provided to trend data from the vivarium and animal holding rooms. The following points are monitored:

- Space temperature.
- Space humidity level.
- Lighting (on/off).
- Space air flow.

Airflow control is based on two-position tracking. Each vivarium space is provided with dedicated supply and exhaust airflow control device and a hot water reheat coil to maintain proper airflow and temperature. Air control devices are designed to fail to an open position to maintain airflow and reheat coils are provided with a fail closed control valve to prevent overheating. Animal holding rooms are provided with a differential pressure sensor/transmitter for monitoring.

A dedicated front-end station is provided to trend data from the animal holding rooms. The following points are monitored:

- Space temperature.
- Space humidity level.
- Lighting (on/off).
- Space air flow.

Airflow control is based on two-position tracking. Each animal holding space is provided with dedicated supply and exhaust airflow control device and a hot water reheat coil to maintain proper airflow and temperature. Air control devices are designed to fail to an open position to maintain airflow and reheat coils are provided with a fail closed control valve to prevent overheating. Animal holding rooms are provided with a differential pressure sensor/transmitter for monitoring.

Temperature readings that are below or above the assigned set point activate a BAS alarm that notifies the Facility Management and Engineering Office (FMEO) and pages the responsible [redacted] personnel. Upon receiving an alarm FMEO dispatches a Facility Tech to investigate. There are at least 2 facility techs on site 24/7 monitoring the BAS system and other facility systems. If an emergency occurs outside of normal work hours the facility staff calls the (b)(4) point of contact.

The (b)(4) project lead monitors daily reports generated by the Apogee system

Air for the entire building (100% outside air) is filtered, heated or cooled and humidified as it passes through the main air handling system. Animal housing suites have dedicated supply and exhaust airflow control device to constant air flow, a hot water reheat coil to maintain temperature, and a temperature and humidity transmitter to maintain temperature and humidity at desired set points within the range of values given by Animal Care in accordance with recommendations in the Guide. Environmental parameters are set using the Building Automation System (BAS). Temperature, humidity, and air flow is recorded every 15 minutes by the BAS. Temperature, humidity, and air flow transmitters are verified and calibrated annually.

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

The BAS system is served by both the emergency generators and the uninterruptible power system (UPS).

The critical mechanical, electrical and plumbing systems have an N+1 redundancy.

- (3) steam boilers, gas or oil fired
- (1) boiler required to meet facility demand
- (2) chillers, (1) required to meet facility demand
- (2) generators, (1) required to meet demand
- 30,000 gallon underground fuel oil storage tank, a minimum of 7 days-worth of fuel is kept at all times
- The [redacted] floors have a redundant exhaust fan
- The [redacted] floors share a redundant air handler. The redundant air handler can serve either the [redacted] or [redacted] floor

The facility has 2 emergency generators, one can provide for 100% of facility demand load, the second generator is the +1 redundancy.

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 Number	Room Name	Room Type	Air Source	Temp Setpoint (F)	BAS Temp Monitoring	BAS Alarm Setpoint (F)	Humidity Control	Pressure (Positive Neutral, Negative)	Pressure (Delta P)
(b)(7)(E)	Chemical Holding	SUPPORT	100% Fresh	NA	No	NA	Yes	Negative	0.0019
	Waste Holding	SUPPORT	100% Fresh	NA	No	NA	Yes	Negative	0.0025
	ARB Office	SUPPORT	100% Fresh	76	Yes	71-81	Yes	Negative	0.0055
	Glassware	SUPPORT	100% Fresh	73	Yes	68-78	Yes	Positive	0.0074
	Women's Restroom	SUPPORT	100% Fresh	73	Yes	68-78	Yes	Negative	0.0041
	Men's Restroom	SUPPORT	100% Fresh	73	Yes	68-78	Yes	Negative	0.0029
	Break Room	SUPPORT	100% Fresh	73	Yes	68-78	Yes	Positive	0.0025
	Animal Bedding	SUPPORT	100% Fresh	68	No	NA	Yes	Positive	0.0090
	Food Storage	SUPPORT	100% Fresh	68	No	NA	Yes	Positive	0.0109
	Elevator Lobby	SUPPORT	100% Fresh	NA	No	NA	Yes	Negative	0.0208
	Loading Dock	SUPPORT	100% Fresh	NA	No	NA	Yes	Negative	0.0543
	Airlock	SUPPORT	100% Fresh	71	Yes	66-76	Yes	Negative	0.0105
	Clean Flea	ANIMAL HOLDING	100% Fresh	71	Yes	66-76	Yes	Negative	0.0010
	Clean Flea Cubicle	ANIMAL HOLDING	100% Fresh	71	Yes	66-76	Yes	Negative	0.0015
	Clean Flea Cubicle	ANIMAL HOLDING	100% Fresh	71	Yes	66-76	Yes	Negative	0.0012
	Clean Tick	ANIMAL HOLDING	100% Fresh	71	Yes	66-76	Yes	Negative	0.1310
	Clean Tick Cubicle	ANIMAL HOLDING	100% Fresh	71	Yes	66-76	Yes	Negative	0.0003
	Clean Tick Cubicle	ANIMAL HOLDING	100% Fresh	71	Yes	66-76	Yes	POSITIVE	0.0002
	Work Lab	ANIMAL HOLDING	100% Fresh	71	Yes	66-76	Yes	Negative	0.0110
	Women's Restroom	SUPPORT	100% Fresh	73	Yes	68-78	Yes	Negative	0.0895

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

Room Number	Room Name	Room Type	Air Source	Temp Setpoint (F)	BAS Temp Monitoring	BAS Alarm Setpoint (F)	Humidity Control	Pressure (Positive Neutral, Negative)	Pressure (Delta P)
(b)(7)E	Men's Restroom	SUPPORT	100% Fresh	73	Yes	68-78	Yes	Negative	0.0575
	Work Corridor	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0160
	Work Lab	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	0.0140
	Isolation Lab	ANIMAL HOLDING	100% Fresh	68	Yes	63-73	Yes	Negative	0.0170
	Elevator Lobby	SUPPORT	100% Fresh	73	No	NA	Yes	Negative	0.0008
	Post Autoclave	SUPPORT	100% Fresh	73	Yes	68-78	Yes	Negative	0.0550
	Decon	SUPPORT	No Air	NA	No	NA	Yes	Negative	0.0150
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	67	Yes	62-72	Yes	Negative	0.0140
	ACL3 Manipulation	ANIMAL HOLDING	100% Fresh	67	Yes	62-72	Yes	Negative	NA
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	67	Yes	62-72	Yes	Negative	NA
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	67	Yes	62-72	Yes	Negative	0.0190
	ACL3 Manipulation	ANIMAL HOLDING	100% Fresh	67	Yes	62-72	Yes	Negative	NA
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	67	Yes	62-72	Yes	Negative	0.0160
	Work Lab	ANIMAL HOLDING	100% Fresh	73	No	NA	Yes	Negative	0.0075
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	0.0750
	ACL3 Manipulation	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	0.0160
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	0.0150
	ACL3 Manipulation	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	0.0170
	Storage	SUPPORT	100% Fresh	NA	No	NA	Yes	Negative	0.0300
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	0.0580
	ACL3 Manipulation	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	0.0150
	Isolation Lab	ANIMAL HOLDING	100% Fresh	73	Yes	68-78	Yes	Negative	0.0190
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	0.0380

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

Room Number	Room Name	Room Type	Air Source	Temp Setpoint (F)	BAS Temp Monitoring	BAS Alarm Setpoint (F)	Humidity Control	Pressure (Positive Neutral, Negative)	Pressure (Delta P)
(b)(7)(E)	ACL3 Manipulation	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ACL3 Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	0.0100
	Air Lock	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0900
	Change	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0200
	Change	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0026
	Work Area	ANIMAL HOLDING	100% Fresh	73	Yes	68-78	Yes	Negative	0.0380
	SPF Holding	ANIMAL HOLDING	100% Fresh	73	Yes	68-78	Yes	Positive	NA
	SPF Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Positive	NA
	Change	SUPPORT	100% Fresh	73	Yes	68-78	Yes	Negative	0.0070
	Soiled Cage	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0230
	Clean Cage	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Positive	0.0200
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0100
	ABSL3 Procedure Lab	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ABSL3 Holding	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0120
	Toilet	SUPPORT	100% Fresh	73	No	NA	Yes	Negative	0.0300
	Toilet	SUPPORT	100% Fresh	73	No	NA	Yes	Negative	0.0200
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0100
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0110
	ABSL3 Ante	SUPPORT	100% Fresh	69	Yes	64-74	Yes	Negative	0.0130
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	100% Fresh	69	Yes	64-74	Yes	Negative	NA
	ABSL3 Ante	SUPPORT	100% Fresh	69	Yes	64-74	Yes	Negative	0.0150

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

Room Number	Room Name	Room Type	Air Source	Temp Setpoint (F)	BAS Temp Monitoring	BAS Alarm Setpoint (F)	Humidity Control	Pressure (Positive Neutral, Negative)	Pressure (Delta P)
[redacted]	Soiled Corridor	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0400
	Elevator Lobby	SUPPORT	100% Fresh	73	Yes	68-78	Yes	Negative	0.0300
	Post Autoclave	SUPPORT	100% Fresh	66	Yes	61-71	Yes	Negative	0.0060
	Decon	SUPPORT	No Air	NA	No	NA	Yes	Negative	0.0050
	Change	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0900
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0090
	ABSL3 olation/Quarantine	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0060
	ABSL3 Ante	SUPPORT	100% Fresh	68	Yes	63-73	Yes	Negative	0.0160
	ABSL3 olation/Quarantine	ANIMAL HOLDING	100% Fresh	68	Yes	63-73	Yes	Negative	NA
	ABSL3 Ante	SUPPORT	100% Fresh	68	Yes	63-73	Yes	Negative	0.0150
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0330
	ABSL3 olation/Quarantine	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0230
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0110
	ABSL3 olation/Quarantine	ANIMAL HOLDING	100% Fresh	70	Yes	65-75	Yes	Negative	NA
	ABSL3 Ante	SUPPORT	100% Fresh	70	Yes	65-75	Yes	Negative	0.0070
	Incinerator	SUPPORT	100% Fresh	NA	No	NA	Yes	Negative	0.0560

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

Air Exchange Summary

Room Number	Room Name	Room Type	AAALAC RQ'D ACH	ACH for TAB based on (S=supply, E=exhaust)	Measured ACH	SCFM Measured	SCFM ACH Measured	ECFM Measured	ECFM ACH-Measured	DATE Measured
(b)(7)(E)	Chemical Holding	SUPPORT	NA	E	7.6	42.0	2.9	109.0	7.6	11/13/17
	Waste Holding	SUPPORT	NA	E	7.7	87.0	6.2	108.0	7.7	11/13/17
	ARB Office	SUPPORT	NA	E	3.2	175.0	2.8	202.0	3.2	11/13/17
	Glassware	SUPPORT	NA	S	21.5	914.0	21.5	0.0	NA	11/13/17
	Women's Restroom	SUPPORT	NA	E	10.0	312.0	6.9	448.0	10.0	11/13/17
	Men's Restroom	SUPPORT	NA	E	8.5	341.0	7.6	382.0	8.5	11/13/17
	Break Room	SUPPORT	NA	S	12.4	151.0	12.4	0.0	NA	11/13/17
	Animal Bedding	SUPPORT	NA	S	10.6	164.0	10.6	90.0	5.8	11/13/17
	Food Storage	SUPPORT	NA	S	15.8	244.0	15.8	135.0	8.7	11/13/17
	Elevator Lobby	SUPPORT	NA	E	NA	0.0	NA	0.0	NA	11/13/17
	Loading Dock	SUPPORT	NA	E	NA	0.0	NA	0.0	NA	11/13/17
	Airlock	SUPPORT	NA	S	20.3	338.5	20.3	0.0	NA	11/13/17
	Clean Flea	ANIMAL HOLDING	10-15	S	28.0	981.7	28.0	940.8	26.8	11/13/17
	Clean Flea Cubicle	ANIMAL HOLDING	10-15	E	87.8	166.4	46.2	316.2	87.8	11/13/17
	Clean Flea Cubicle	ANIMAL HOLDING	10-15	E	43.9	91.0	25.3	158.0	43.9	11/13/17
	Clean Tick	ANIMAL HOLDING	10-15	E	36.3	1300.4	33.9	1392.8	36.3	11/13/17
	Clean Tick Cubicle	ANIMAL HOLDING	10-15	E	79.0	128.2	35.6	284.4	79.0	11/13/17
	Clean Tick Cubicle	ANIMAL HOLDING	10-15	E	29.2	64.0	17.8	105.0	29.2	11/13/17

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

Room Number	Room Name	Room Type	AAALAC RQ'D ACH	ACH for TAB based on (S=supply, E=exhaust)	Measured ACH	SCFM Measured	SCFM ACH Measured	ECFM Measured	ECFM ACH-Measured	DATE Measured
[redacted]	Work Lab	ANIMAL HOLDING	10-15	S	20.1	2322.1	20.1	0.0	NA	11/13/17
	Women's Restroom	SUPPORT	NA	E	19.2	460.0	10.2	862.0	19.2	11/13/17
	Men's Restroom	SUPPORT	NA	E	15.5	448.0	10.0	698.0	15.5	11/13/17
	Work Corridor	SUPPORT	NA	S	16.8	1045.6	16.8	488.9	7.9	11/13/17
	Work Lab	ANIMAL HOLDING	10-15	S	10.1	660.5	10.1	0.0	NA	11/13/17
	Isolation Lab	ANIMAL HOLDING	10-15	E	23.8	201.3	13.6	353.7	23.8	11/13/17
	Elevator Lobby	SUPPORT	NA	E	NA	0.0	NA	0.0	NA	11/13/17
	Post Autoclave	SUPPORT	NA	S	19.3	657.6	19.3	380.0	11.1	11/13/17
	Decon	SUPPORT	NA	E	NA	0.0	NA	0.0	NA	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	E	8.3	104.0	7.1	121.9	8.3	11/13/17
	ACL3 Manipulation	ANIMAL HOLDING	10-15	E	23.9	310.8	12.4	598.8	23.9	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	S	47.4	1286.4	47.4	997.2	36.7	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	E	8.8	130.7	8.5	135.2	8.8	11/13/17
	ACL3 Manipulation	ANIMAL HOLDING	10-15	E	26.4	334.3	13.3	661.3	26.4	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	E	49.4	1214.2	44.7	1341.8	49.4	11/13/17
	Work Lab	ANIMAL HOLDING	10-15	S	17.3	1353.6	17.3	204.6	2.6	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	E	50.6	963.5	42.8	1138.4	50.6	11/13/17

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

Room Number	Room Name	Room Type	AAALAC RQ'D ACH	ACH for TAB based on (S=supply, E=exhaust)	Measured ACH	SCFM Measured	SCFM ACH Measured	ECFM Measured	ECFM ACH-Measured	DATE Measured
(b)(7)(E)	ACL3 Manipulation	ANIMAL HOLDING	10-15	E	27.7	315.7	13.1	669.9	27.7	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	E	10.2	115.9	7.7	152.7	10.2	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	S	46.8	1052.3	46.8	1024.7	45.5	11/13/17
	ACL3 Manipulation	ANIMAL HOLDING	10-15	E	30.1	344.3	14.3	725.8	30.1	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	E	10.1	122.0	8.1	151.8	10.1	11/13/17
	Storage	SUPPORT	NA	S	22.2	170.0	22.2	0.0	NA	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	S	59.5	1339.6	59.5	1189.7	52.9	11/13/17
	ACL3 Manipulation	ANIMAL HOLDING	10-15	E	25.1	355.7	14.7	607.0	25.1	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	E	9.3	122.0	8.1	139.4	9.3	11/13/17
	Isolation Lab	ANIMAL HOLDING	10-15	E	28.2	300.3	20.2	418.6	28.2	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	E	55.1	1137.4	42.4	1479.5	55.1	11/13/17
	ACL3 Manipulation	ANIMAL HOLDING	10-15	E	24.2	386.2	15.8	590.8	24.2	11/13/17
	ACL3 Holding	ANIMAL HOLDING	10-15	E	33.0	152.8	10.2	495.3	33.0	11/13/17
	Air Lock	SUPPORT	NA	E	31.1	73.1	6.3	359.7	31.1	11/13/17
	Change	SUPPORT	NA	S	8.8	134.0	8.8	117.0	7.7	11/13/17
	Change	SUPPORT	NA	E	28.9	98.8	6.7	424.1	28.9	11/13/17

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

Room Number	Room Name	Room Type	AAALAC RQ'D ACH	ACH for TAB based on (S=supply, E=exhaust)	Measured ACH	SCFM Measured	SCFM ACH Measured	ECFM Measured	ECFM ACH-Measured	DATE Measured
(b)(7)(E)	Work Area	ANIMAL HOLDING	10-15	S	25.5	1315.5	25.5	942.1	18.3	11/13/17
	SPF Holding	ANIMAL HOLDING	10-15	S	19.9	1109.3	19.9	763.7	13.7	11/13/17
	SPF Holding	ANIMAL HOLDING	10-15	S	18.2	273.0	18.2	76.2	5.1	11/13/17
	Change	SUPPORT	NA	S	9.9	222.0	9.9	206.1	9.2	11/13/17
	Soiled Cage	SUPPORT	NA	S	35.0	6920.0	35.0	3523.0	17.8	11/13/17
	Clean Cage	SUPPORT	NA	S	33.7	4770.0	33.7	4030.0	28.5	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	5.2	65.4	4.4	77.8	5.2	11/13/17
	ABSL3 Procedure Lab	ANIMAL HOLDING	10-15	E	12.1	140.2	7.5	225.2	12.1	11/13/17
	ABSL3 Holding	ANIMAL HOLDING	10-15	E	13.6	505.5	8.4	813.1	13.6	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	11.6	64.3	4.3	173.3	11.6	11/13/17
	Toilet	SUPPORT	NA	E	9.4	0.0	NA	106.0	9.4	11/13/17
	Toilet	SUPPORT	NA	E	14.1	0.0	NA	129.0	14.1	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	5.8	73.6	4.9	87.0	5.8	11/13/17
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	10-15	E	16.7	722.8	12.0	1002.1	16.7	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	13.7	66.8	5.6	164.0	13.7	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	7.9	77.3	5.2	118.0	7.9	11/13/17
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	10-15	E	14.6	621.3	10.4	873.7	14.6	11/13/17
	ABSL3 Ante	SUPPORT	10-15	E	14.6	72.0	6.0	175.0	14.6	11/13/17

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

Room Number	Room Name	Room Type	AAALAC RQ'D ACH	ACH for TAB based on (S=supply, E=exhaust)	Measured ACH	SCFM Measured	SCFM ACH Measured	ECFM Measured	ECFM ACH-Measured	DATE Measured
(b)(7)(E)	Soiled Corridor	SUPPORT	NA	S	9.7	904.0	9.7	0.0	NA	11/13/17
	Elevator Lobby	SUPPORT	NA	S	13.6	301.6	13.6	0.0	NA	11/13/17
	Post Autoclave	SUPPORT	NA	S	11.3	412.0	11.3	316.0	8.7	11/13/17
	Decon	SUPPORT	NA	E	NA	0.0	NA	0.0	NA	11/13/17
	Change	SUPPORT	NA	S	4.1	71.0	4.1	69.0	4.0	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	55.2	73.1	4.9	827.5	55.2	11/13/17
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	10-15	E	13.8	552.9	9.2	827.5	13.8	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	14.2	63.7	5.3	170.0	14.2	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	5.3	61.7	4.1	79.2	5.3	11/13/17
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	10-15	S	13.8	826.6	13.8	760.9	12.7	11/13/17
	ABSL3 Ante	SUPPORT	10-15	E	9.7	61.6	5.1	116.2	9.7	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	13.3	58.4	3.9	199.2	13.3	11/13/17
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	10-15	E	12.4	515.9	8.6	746.3	12.4	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	10.3	60.1	5.0	123.5	10.3	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	12.7	83.4	5.6	191.1	12.7	11/13/17
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	10-15	S	12.9	774.5	12.9	737.8	12.3	11/13/17
	ABSL3 Ante	SUPPORT	NA	E	11.2	78.4	6.5	134.6	11.2	11/13/17
	Incinerator	SUPPORT	NA	E	NA	0.0	NA	0.0	NA	11/13/17

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)
NA	NA						

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):**
NA									

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.]

DVBD does not have aquatic facilities.

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**
Mouse (Mus spp.)	W: 8.25" D: 13.0" H: 7.5"	5-6	Guide For The Care And Use Of Laboratory Animals	(b)(4)™ (b)(4)™ mouse micro-isolator system with filter top and modular diet delivery system, (b)(4)™ high temperature
Mouse (Mus spp.)	W: 18.0" D: 13.0" H: 7.5	10-12	Guide For The Care And Use Of Laboratory Animals	(b)(4)™ rat/hamster microisolator system with filter top and modular diet delivery system, (b)(4) high temperature plastic
Mouse (Mus spp.)	W: 7.0" D: 14.0" H: 5.0"	5 male or female; 1 female with litter	Guide For The Care And Use Of Laboratory Animals	(b)(4)® mouse microisolator IVC, hi-temp polysulfone body and lid with depression for water bottle or (b)(4) water bag, stainless steel feeder lid
Mouse (Mus spp.)	W: 7.0" D: 13.5 H: 5.0"	1 – 5	Guide For The Care And Use Of Laboratory Animals	(b)(4)® (b)(4) IVC with hermetically-sealed lid, (b)(4)™ cage body and plastic top with soft silicone gasket, two spring loaded valves. cage pre-filter + cage HEPA filter with retainer, two lid to-cage clamps, stainless steel feeder lid with welded divider

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**
Rabbit	W: 30.0" D: 28.5" H: 18.5"	1 rabbit per cage, or 2 rabbits per adjacent cages	Guide For The Care And Use Of Laboratory Animals	[redacted] 1 tier/3 cage multifloor pen system, SS rack with [redacted]® shallow cage body and waste tray, "J" feeder; removable Lucite panels between adjacent cages allow cages to share floor area.
Rabbit	W: 24.0" D: 30.5" H 16.0	1 per cage	Guide For The Care And Use Of Laboratory Animals	Allentown ventilated rabbit/ferret cage rack, 4 cages per rack for individually housing rabbits under negative pressure, HEPA filter air exhaust; SS rack and cage construction, wash-through design with electropolished doors and floors, removable perforated floors, removable rod design doors, J-type feeder 4 ½" wide, stackable tapered stainless steel excreta pans, individual cage

*For aquatic species, provide tank volume.
**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

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)	Mechanical washer	Bi-weekly	Potassium hydroxide, phosphoric acid, sodium hydroxide	
Solid-bottom cages (IVC)	Mechanical washer	Bi-weekly	Potassium hydroxide, phosphoric acid, sodium hydroxide	Breeding colony - autoclaved
Suspended wire-bottom or slotted floor cages	Mechanical washer	After use	Potassium hydroxide, phosphoric acid, sodium hydroxide	
Cage lids	Mechanical washer	Bi-weekly	Potassium hydroxide, phosphoric acid, sodium hydroxide	Breeding colony - autoclaved
Filter tops	Mechanical washer	Bi-weekly	Potassium hydroxide, phosphoric acid, sodium hydroxide	Breeding colony - autoclaved
Cage racks and shelves	Mechanical washer	6 mos.	Potassium hydroxide, phosphoric acid, sodium hydroxide	
Cage pans under suspended cages	Mechanical washer	3x/week	Potassium hydroxide, phosphoric acid, sodium hydroxide	

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)
Play pens, floor pens, stalls, etc.	NA	NA		
Corrals for primates or outdoor paddocks for livestock	NA	NA		
Aquatic, amphibian, and reptile tanks and enclosures	NA	NA		
Feeders	Mechanical washer (rodent) Hand (rabbit)	Bi-weekly rodent Weekly rabbit	Potassium hydroxide, phosphoric acid, sodium hydroxide	Breeding colony - autoclaved
Watering devices	Mechanical washer	Bi-weekly rodent Weekly rabbit	Potassium hydroxide, phosphoric acid, sodium hydroxide	
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Mechanical washer	Bi-weekly	Potassium hydroxide, phosphoric acid, sodium hydroxide	Breeding colony - autoclaved
Transport cages	Mechanical washer	After use	Potassium hydroxide, phosphoric acid, sodium hydroxide	
Operant conditioning & recording chambers, mechanical restraint	Hand wash	After use	Dimethyl benzyl ammonium chloride, triclosan, isopropanol	

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)
devices (chairs, slings, etc.)				
Euthanasia chambers	Hand wash	After use	Dimethyl benzyl ammonium chloride, triclosan, isopropanol	
Macro-Environment				
Animal Housing Rooms:				
Floors	Sweep/mop	Daily	Sodium hydroxide, glycolic acid	
Walls	Mop	Weekly	Sodium hydroxide, glycolic acid	
Ceilings	Mop	Between studies	Sodium hydroxide, glycolic acid	
Ducts/Pipes	NA	NA		
Fixtures	Hand wash	As needed	Dimethyl benzyl ammonium chloride, triclosan, isopropanol	
Corridors: Central Vivarium, Experimental Insectary				
Floors	Sweep/mop	Daily	Sodium hydroxide, glycolic acid	(b)(7)(E) & (b)(7)(E) 1X/wk (b)(7)(E) & (b)(7)(E) daily

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)
Walls	Mop	Weekly	Sodium hydroxide, glycolic acid	
Ceilings	Mop	Between studies	Sodium hydroxide, glycolic acid	
Ducts/Pipes	NA	NA		
Fixtures	NA	NA		
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area: NA				
Feed Storage, Bedding Storage, Animal Care Office				
Floors	Sweep/mop	See comments	Sodium hydroxide, glycolic acid	(b)(7)(E) & (b)(7)(E) 1X/wk (b)(7)(E) & (b)(7)(E) daily
Walls	Mop	See comments	Sodium hydroxide, glycolic acid	(b)(7)(E) & (b)(7)(E) 1X/wk (b)(7)(E) & (b)(7)(E) daily
Ceilings	Mop	See comments	Sodium hydroxide, glycolic acid	(b)(7)(E) & (b)(7)(E) 1X/wk (b)(7)(E) & (b)(7)(E) daily
Ducts/Pipes	NA	NA		
Fixtures	Hand wash	As needed	Sodium hydroxide, glycolic acid	
Support Areas: Animal Rooms/Labs (b)(7)(E) and (b)(7)(E)				
Floors	Sweep/mop	After use	Sodium hydroxide, glycolic acid	

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)
Walls	Mop	After use	Sodium hydroxide, glycolic acid	
Ceilings	Mop	After use	Sodium hydroxide, glycolic acid	
Ducts/Pipes	NA	NA		
Fixtures	Wipe down	After use	Sodium hydroxide, glycolic acid	
Support Areas: Main Corridors (b)(4) personnel)				
Floors	Sweep/mop	Dry mopped on a daily basis, wet mopped on a weekly basis using a solution with an antibacterial cleaner, spray buffed weekly	(b)(4) [Alcohols (C9-11, ethoxylated), Sodium Bicarbonate]	
Walls	Wiped down	Bi-weekly	(b)(4) [Ethyl alcohol, butane, propane]	
Ceilings	Dusted	Monthly	(b)(4) shield furniture polish [polydimethylsiloxane, isobutane, carnauba wax]	
Ducts/Pipes	NA			

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)
Fixtures	Cleaned and polished	Weekly	(b)(4) shield furniture polish [polydimethylsiloxane, isobutane, carnauba wax]	
Support Areas: Elevators (b)(4) personnel)				
Floors	Floors are dry mopped or vacuumed daily and wet mopped with an antibacterial cleaning solution twice weekly.	Daily/Weekly The elevator tracks are vacuumed twice weekly	(b)(4) [Alcohols (C9-11, ethoxylated), Sodium Bicarbonate]	
Walls	Hand cleaned with stainless steel cleaner	Daily	Stainless steel cleaner and polish [hydrotreated light distillates (petroleum), white mineral oil, isobutane, propane] (b)(4) [Alcohols (C9-11, ethoxylated), Sodium Bicarbonate]	
Ceilings	Dusted	Weekly	NA	
Ducts/Pipes	NA			
Fixtures	Stainless steel and metal surfaces are cleaned and polished weekly	Weekly	(b)(4) shield furniture polish [polydimethylsiloxane, isobutane, carnauba wax]	

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)
Support Areas: Restrooms (b)(4) personnel)				
Floors	Cleaned and mopped with an antibacterial cleaner	Daily	(b)(4) (Alcohols, C9-11, ethoxylated), Sodium Bicarbonate]	
Walls	Wiped down with antibacterial cleaner weekly, spot cleaned as required daily. Complete floor to ceiling washing quarterly	Weekly	(b)(4) [lauramine oxide, n-alkly (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium chloride]	
Ceilings	Drop ceilings dusted monthly. Hard ceilings washed quarterly	Monthly		
Ducts/Pipes	Air vents dusted	Monthly		
Trash	Emptied	Daily		
Showers	Cleaned with an antibacterial cleaner floor to ceiling	Daily	(b)(4) non-acid disinfectant bathroom cleaner [alcohol ethoxylate, dialkyl dimethyl ammonium chloride, alkyl dimethyl benzyl ammonium chloride]	

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)
Fixtures	Including basins, water closets, counter tops cleaned with antibacterial cleaner daily. Stainless steel paper towel dispensers wiped down with SS cleaner. Mirrors are cleaned with window cleaner	Daily	(b)(4) [lauramine oxide, n-alkly (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium chloride] (b)(4) [Limestone, Sodium carbonate, calcium hydroxide (Ca(OH)2), (Troclosene sodium, dihydrate), (benzenesulfonic acid, mono-C10-16-alkyl derivs., sodium salts)] (b)(4) (Alcohols, C9-11, ethoxylated), Sodium Bicarbonate] (b)(4) non-acid disinfectant bathroom cleaner [alcohol ethoxylate, dialkyl dimethyl ammonium chloride, alkyl dimethyl	

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)
			benzyl ammonium chloride]	
Support Areas: B1-116 Office and B1 Break Room (b)(4) personnel)				
Floors	Sweep and mop with an antibacterial cleanser	Weekly	(b)(4) [(Alcohols, C9-11, ethoxylated), Sodium Bicarbonate]	
Walls	Cleaned with antibacterial cleaner monthly, spot cleaning where required daily	Monthly	(b)(4) & (b)(4) cleaner [diethylene glycol butyl ether, 2-butoxyethanol, sodium lauryl sulfate, ammonium hydroxide] (b)(4) Ethyl alcohol, butane, propane]	
Ceilings	Dusted	Annually		
Ducts/Pipes	Dusted	annually		
Fixtures	Dusted	annually		
Trash	Emptied	Daily		
Support Areas: (b)(4) and (b)(4) floor break areas (b)(4) personnel)				

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)
Floors	Vacuumed	Daily		
Walls	Dusted	Weekly		
Ceilings	Dusted	Annually		
Ducts/Pipes	Dusted	Annually		
Fixtures	Including sinks and counter tops, cleaned with antibacterial cleaner	Daily	(b)(4) cleaning agent [propylene glycol n-propyl ether] (b)(4) Ethyl alcohol, butane, propane] Stainless steel cleaner and polish [hydrotreated light distillates (petroleum), white mineral oil, isobutane, propane]	
Trash and recycle bins	Emptied	Daily		
Implements (note whether or not shared): Animal areas				
Mops	Mechanical washer	Weekly	Bleach solution Autoclaved	Not shared - room specific
Mop buckets	Rinsed after each use Rack washer	Daily		Not shared – room specific

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)
		Chemically decontaminated and mechanically washed in rack washer between studies		
Aquaria nets	NA	NA		
Other	NA			
Implements (note whether or not shared): Non-animal support areas				
Mops	Microfiber cleaning pads		Bleach	Separate pads are used for each area. The pad is not re-used, but placed in a bag and washed in a bleach solution after each use.
Mop buckets	A common bucket is used in multiple labs, since the pad is not re-used, no cross contamination of labs can take place. Buckets are cleaned out and rinsed after each use.		(b)(4) [(Alcohols, C9-11, ethoxylated), Sodium Bicarbonate]	

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:				
Vehicle(s) Enclosed heated/cooled cart	Hand washing	As needed	(b)(4) solution of purified water, ethyl alcohol, Polypropylene Glycol N-Butyl Ether, Alkyl Polyglucoside, Didecyl Dimethyl Ammonium Chloride, Chlorhexidine Diacetate, Fragrance, Silicone Emulsion and Polyethyleneimine).	
Other transport equipment (list)	NA			

*Please provide chemical, not trade name.

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)(E)	Rack washer	Emergency "off" button; labeled exit door, de-energizing cord on both sides, instructional signage	Guarantee 180-degree hot water rinse; temperature-sensitive tape used on every load; RODAC plates of caging tested quarterly; randomly ATP test items that are processed through the rack washer
(b)(7)(E)	(b)(7)(E)	Tunnel washer	Emergency "off" button; instructional signage	Guarantee 180-degree hot water rinse; temperature-sensitive tape used in every load; RODAC plates of caging tested quarterly; randomly ATP test items that are processed through the tunnel washer
(b)(7)(E)	(b)(7)(E) floor	Bulk autoclave	Emergency "off" button; lock-out key; instructional signage	Class V Chemical Integrator (tests time/temp/steam saturation) for each load Quarterly spore test conducted After any repair – spore test conducted prior to use Annual re-build spore test conducted prior to use
(b)(7)(E)	(b)(7)(E) floor	Bulk autoclave	Emergency "off" button; lock-out key; instructional signage	Class V Chemical Integrator (tests time/temp/steam saturation) for each load Quarterly spore test conducted After any repair – spore test conducted prior to use Annual re-build spore test conducted prior to use
(b)(7)(E)	(b)(7)(E) floor	Bedding dispensing unit	Emergency "off" button	N/A
(b)(7)(E)	All animal suites	None – hand-washing areas	Limited to PPE Eyewash fountains	Visual assessment; cleaned daily with antibacterial cleanser; no monitoring done Checked one a month for proper function and flushed

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

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).

AAALAC Lighting System Summary

Room Number	Room Name	Room Type	Intensity Ft-C	Lighting Fixture Type	Photoperiod	Lighting Controls	Override Mechanism
(b)(7)(E)	Chemical Holding	SUPPORT	50	Pendant office type	NA	Wall mounted sensor	NA
	Waste Holding	SUPPORT	50	Pendant office type	NA	Wall mounted sensor	NA
	ARB Office	SUPPORT	50	Recessed for wet locations	NA	Wall mounted sensor	NA
	Glassware	SUPPORT	50	Recessed for wet locations	NA	Wall mounted sensor	NA
	Women's Restroom	SUPPORT	50	Recessed office type	NA	Wall mounted sensor	NA
	Men's Restroom	SUPPORT	50	Recessed office type	NA	Wall mounted sensor	NA
	Break Room	SUPPORT	50	Recessed office type	NA	Wall mounted sensor	NA
	Animal Bedding	SUPPORT	50	Pendant office type	NA	Wall mounted sensor	NA
	Food Storage	SUPPORT	50	Pendant office type	NA	Wall mounted sensor	NA
	Elevator Lobby	SUPPORT	50	Recessed office type	12:12	Automatic via BAS	NA
	Loading Dock	SUPPORT	50	Pendant office type	12:12	Automatic via BAS	NA
	Airlock	SUPPORT	50	Recessed for wet locations	14:10	Automatic via BAS	NA

Appendix 17: Satellite Housing Facilities

Room Number	Room Name	Room Type	Intensity Ft-C	Lighting Fixture Type	Photoperiod	Lighting Controls	Override Mechanism
(b)(7)(E)	Clean Flea	ANIMAL HOLDING	30 - 37	Recessed office type	14:10	Automatic via BAS	Manual via BAS
	Clean Flea Cubicle	ANIMAL HOLDING	30 - 37	Recessed office type	14:10	Manual via BAS	Manual via BAS
	Clean Flea Cubicle	ANIMAL HOLDING	30 - 37	Recessed office type	14:10	Manual via BAS	Manual via BAS
	Clean Tick	ANIMAL HOLDING	30 - 37	Recessed office type	14:10	Automatic via BAS	Manual via BAS
	Clean Tick Cubicle	ANIMAL HOLDING	30 - 37	Recessed office type	14:10	Automatic via BAS	NA
	Clean Tick Cubicle	ANIMAL HOLDING	30 - 37	Recessed office type	14:10	Automatic via BAS	NA
	Work Lab	ANIMAL HOLDING	30 - 37	Recessed office type	12:12	Automatic via BAS	NA
	Women's Restroom	SUPPORT	50	Recessed office type	NA	Wall mounted sensor	NA
	Men's Restroom	SUPPORT	50	Recessed office type	NA	Wall mounted sensor	NA
	Work Corridor	SUPPORT	50	Recessed office type	12:12	Automatic via BAS	NA
	Work Lab	ANIMAL HOLDING	30 - 37	Recessed office type	16:08	Automatic via BAS	NA
	Isolation Lab	ANIMAL HOLDING	30 - 37	Recessed for wet locations	16:08	Automatic via BAS	NA
	Elevator Lobby	SUPPORT	50	Recessed for wet locations	12:12	Automatic via BAS	NA

Appendix 17: Satellite Housing Facilities

Room Number	Room Name	Room Type	Intensity Ft-C	Lighting Fixture Type	Photoperiod	Lighting Controls	Override Mechanism
(b)(7)(E)	Post Autoclave	SUPPORT	50	Surface mounted for wet locations	NA	Wall mounted sensor	NA
	Decon	SUPPORT	50	Surface mounted for wet locations	NA	Wall mounted sensor	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	ACL3 Manipulation	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	16:08	Automatic via BAS	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	16:08	Automatic via BAS	Manual via BAS
	ACL3 Manipulation	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	16:08	Automatic via BAS	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	16:08	Automatic via BAS	Manual via BAS
	Work Lab	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	12:12	Automatic via BAS	Manual via BAS
	ACL3 Manipulation	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	12:12	Automatic via BAS	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	12:12	Automatic via BAS	Manual via BAS
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS

Appendix 17: Satellite Housing Facilities

Room Number	Room Name	Room Type	Intensity Ft-C	Lighting Fixture Type	Photoperiod	Lighting Controls	Override Mechanism
(b)(7)(E)	ACL3 Manipulation	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	Storage	SUPPORT	50	Surface mounted for wet locations	NA	Wall mounted sensor	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	12:12	Automatic via BAS	Manual via BAS
	ACL3 Manipulation	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	12:12	Automatic via BAS	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	Isolation Lab	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	12:12	Automatic via BAS	Manual via BAS
	ACL3 Manipulation	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	12:12	Automatic via BAS	NA
	ACL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	12:12	Automatic via BAS	Manual via BAS
	Air Lock	SUPPORT	50	Surface mounted for wet locations	NA	Wall mounted sensor	NA
	Change	SUPPORT	50	Surface mounted for wet locations	NA	Wall mounted sensor	NA
	Change	SUPPORT	50	Surface mounted for wet locations	NA	Wall mounted sensor	NA

Appendix 17: Satellite Housing Facilities

Room Number	Room Name	Room Type	Intensity Ft-C	Lighting Fixture Type	Photoperiod	Lighting Controls	Override Mechanism
(b)(7)(E)	Work Area	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	SPF Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	SPF Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	Change	SUPPORT	50	Recessed for wet locations	NA	Wall mounted sensor	NA
	Soiled Cage	SUPPORT	50	Recessed for wet locations	12:12	Automatic via BAS	NA
	Clean Cage	SUPPORT	50	Recessed for wet locations	12:12	Automatic via BAS	NA
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ABSL3 Procedure Lab	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ABSL3 Holding	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	Toilet	SUPPORT	50	Recessed office type	NA	Wall mounted sensor	NA
	Toilet	SUPPORT	50	Recessed office type	NA	Wall mounted sensor	NA
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA

Appendix 17: Satellite Housing Facilities

Room Number	Room Name	Room Type	Intensity Ft-C	Lighting Fixture Type	Photoperiod	Lighting Controls	Override Mechanism
(b)(7)(E)	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	12:12	Automatic via BAS	NA
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	12:12	Automatic via BAS	NA
	Soiled Corridor	SUPPORT	50	Recessed for wet locations	12:12	Automatic via BAS	NA
	Elevator Lobby	SUPPORT	50	Recessed for wet locations	12:12	Automatic via BAS	NA
	Post Autoclave	SUPPORT	50	Recessed for wet locations	NA	Wall mounted sensor	NA
	Decon	SUPPORT	50	Recessed for wet locations	NA	Wall mounted sensor	NA
	Change	SUPPORT	50	Recessed for wet locations	NA	Wall mounted sensor	NA
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA

Appendix 17: Satellite Housing Facilities

Room Number	Room Name	Room Type	Intensity Ft-C	Lighting Fixture Type	Photoperiod	Lighting Controls	Override Mechanism
(b)(7)(E)	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	ABSL3 Isolation/Quarantine	ANIMAL HOLDING	30 - 37	Surface mounted for wet locations	14:10	Automatic via BAS	Manual via BAS
	ABSL3 Ante	SUPPORT	50	Surface mounted for wet locations	14:10	Automatic via BAS	NA
	Incinerator	SUPPORT	50	Pendant office type	NA	Wall mounted sensor	NA

[a] A list of each room is not needed; group or cluster rooms by species or function
[b] Include such features as water resistance, red lighting, *etc.*
[c] Note if light cycle inverted/reversed.

Appendix 17: Satellite Housing Facilities

Note: In the Program Description Section 2. IV. (Physical Plant), item C., describe the criteria used to determine a "Satellite Animal Holding Area." In the Table below, summarize these animal housing areas. Note that the total square footage for all each of these must also be included in the Summary of Animal Housing and Support Sites **(Appendix 2)**, and applicable information regarding these areas included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (**Appendix 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
NA	NA	NA	NA	NA			

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

DVBD does not have any satellite facilities.