THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF ANIMAL CARE AND USE
1140 BIOINFORMATICS BLDG
CAMPUS BOX 7193
CHAPEL HILL, NC 27599-7115
T: 919 966-5569
F: 919 966-8429

August 14, 2020

Gary Borkowski, DVM, MS, DACLAM
Global Director
5205 Chairman's Court
Suite 300
Frederick, Maryland 21703

RE: 000329

Dear Dr. Borkowski,

In anticipation of our upcoming site visit, please find a PDF copy of the Program Description of the Animal Care and Use Program for the University of North Carolina at Chapel Hill (UNC-CH) [000329]. If you have any problems with receipt of this information or opening the PDF, please let me know. We look forward to the site visit and the opportunity to have a peer review of our program.

To facilitate participation of key individuals involved with the UNC-CH program, we are suggesting the following dates for the visit. We hope the site visitors will find one of these weeks suitable to their schedules.

Best Dates
October 6-9
November 10-13

Possible Dates
November 2-5
November 9-12
September 29 - October 2

Due to the pandemic, we respectfully request that site visitors work with us to facilitate social distancing and adhering to University requirements for wearing masks. We will conduct group meetings via virtual sessions or a hybrid (part virtual part face-to-face) whenever possible. Many of our investigators, whose laboratories we would normally visit, have requested virtual meetings or very small groups of 1-2 people to comply with University policy. As details regarding the pandemic evolve, planning may change.

We ask that site visitors do not visit any rodent colonies within 24 hours prior to entering our facilities and provide documentation to confirm a negative tuberculin skin test or negative chest radiograph within the last year. If visitors have received respirator training (N-95 and/or Powered

Air Purifying Respirator) and have a physician's clearance for wearing a respirator, it may be possible for them to enter the ABSL areas. Entry into these areas would be under escort and only during pre-arranged times in which no active research activities are ongoing and all biological agents contained. Individuals visiting these areas may experience strict travel restrictions following entry. Representatives from these areas will be available to meet with the site visit team during the visit.

Our marine facility, located 150 miles from campus, is dedicated to studies of ocean fish and is currently not very active with only a few studies involving grazing with small numbers of fish. Previous site visitors have evaluated the facility via skype. In addition, personnel operating a small zebrafish facility located about 100 miles from campus should be available to answer questions and interact via Skype.

Other than two off-campus facilities located a short distance away, animal facilities are on the UNC-CH campus. We have similar numbers of facilities and investigator laboratories as during the last visit and believe four days with four visitors will be sufficient.

We look forward to the visit and appreciate the time that the site visitors commit to this effort of improving our animal care and use program. If there is anything we can do to facilitate the process, please let us know.

Sincerely,

Program Description
Animal Care and Use Program

<Program Unit Name>
University of North Carolina at Chapel Hill

<Parent Organization>
University of North Carolina System

File # 000329

August 14, 2020

For
AAALAC International

Table of Contents

Appendices

Appendix 17: Principal Investigator Maintained (Satellite) Housing Facilities - not provided

Program Description

Section 1. Introduction

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

The University of North Carolina at Chapel Hill (UNC-CH) includes all schools and centers that are part of the University of North Carolina at Chapel Hill. Three major Schools, the College as well as two offsite locations currently have animal facilities.

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.

The UNC-CH is a major research university and one of 17 campuses of the consolidated UNC system. UNC-CH was chartered in 1789 and has been dedicated to programs of excellence in undergraduate, graduate, and professional education, basic and applied research, and community service. Student enrollment totaled 29,877 in 2019 (undergraduates 19,032, graduates 8,245 and professional students 2,478). In 2019 UNC-CH ranked 10th nationally in NIH extramural funding to institutions of higher education, and grants and contracts constitute approximately one third of the University's annual revenue.

Thus, animal-related research and teaching programs are critical to the mission of UNC-CH. The animal care and use program is centrally managed by the Division of Comparative Medicine (DCM). Faculty in three major Schools, the College of Arts and Sciences, and two offsite locations work with animals.

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.

UNC-CH has a PHS Assurance and uses the standards of the *Guide* and *PHS Policy* for all animals and the Animal Welfare Act regulations for USDA-regulated species. Also, the *Agriculture Guide* is used when appropriate for swine.

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

DCM is responsible for the husbandry and veterinary care of all animals associated with the UNC-CH program. DCM reports to the IO/Office of the Vice Chancellor of Research (OVCR). DCM is structured in five sections: Husbandry Services, Veterinary Services, Research Administration and Care Assurance, Pathology and Diagnostic Services and Administrative Services.

The IACUC also reports to the IO/VCR. The IACUC is chaired by The administrative and compliance functions of the IACUC are conducted by the Office of Animal Care and Use (OACU), directed by

Appendix not provided

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.

Members of the IACUC
Various other school and departmental representatives are expected to participate and will be identified for the site visitors prior to or at the time of the site visit.

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

As of 3/15/2020 there were approximately 734 approved animal care and use protocols under the direction of 361 PIs. **Appendix not provided**

The research programs at UNC-CH are diverse, covering basic and applied research and involving a diverse and sophisticated animal disease models involving transgenic and knockout rodents and both traditional and non-traditional non-rodent animal models. Research areas include: developmental and molecular biology; control of cellular growth; tumor and transplantation immunology; autoimmunity; cystic fibrosis; muscular dystrophy; inflammatory bowel disease and intestinal biology; cancer chemo- and immunotherapy;

chemical carcinogenesis; gene therapy; genetics; neuropharmacology; neuropathology; neurobiology of pain; neurobehavioral and psychological systems, trauma and resuscitation; mechanisms of thrombosis and hemostasis; atherogenesis and other cardiovascular diseases; drug development, drug interactions and dependence; alcoholism; reproductive biology; pathogenesis, treatment and control of infectious diseases; nutrition; oral biology, dental appliances and periodontal disease.

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

UNC-CH total research funding for 2020 was approximately $1.14 billion. Most of the research funding on campus comes from federal sources. In 2020, total NIH funding was ~$701 million dollars. Within the Health Sciences, an estimated 25% of this supports research projects involving animal subjects in some phase of the research activity. The DCM has an expense budget with approximately two-thirds recovered through a campus-wide recharge system. The remaining is provided as an institutional support.

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 UNC-CH Center for Galapagos Studies is a joint effort between UNC-CH and the Universidad San Francisco de Quito (USFQ) in Ecuador. The two universities constructed this facility to advance the shared goal of promoting science and education that will help protect these fragile island ecosystems and enhance the lives of their inhabitants. The site is adjacent to USFQ's Galapagos Academic Institute for the Arts and Sciences on Playa Mann, Isla San Cristobal. UNC-CH PIs working with animals in this location submit their protocols to the UNC-CH IACUC for review and approval. Animals are not housed at this location and UNC-CH does not own the animals. This unit is not part of our program application because the facility is maintained and operated by the Ecuador government and only native wildlife are studied in their natural setting and under the purview of the Ecuador government.

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.

UNC-CH NRI is located offsite in DHMRI vivarium. This program has its own IACUC and AAALAC accreditation. UNC-CH maintains a Memorandum of Understanding with the DHMRI facility.

Work conducted by the UNC-CH Animal Models Core (AMC) is contracted to TV, Inc. The AMC is part of the UNC-CH program and the relationship of UNC-CH with TV is detailed in the Master Service Agreement with TV, Inc. A TV employee has an appointment as UNC-CH adjunct faculty and serves as the PI of the AMC and all associated animal use protocols. All AMC protocols are reviewed by the UNC-CH IACUC. All animal work is conducted in UNC-CH animal facilities. All animals are housed in the UNC-CH facilities and personnel working with animals in the AMC are covered under the UNC-CH occupational health program and adhere to UNC-CH animal care program stipulations.

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

NA

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.

meets as needed with the IACUC Chair and OACU Director to review animal program issues. The OACU Director meets every other week with the Senior Associate VCR/Research Compliance Officer (AVCR/RCO), who reports directly to the IO. The IO meets with the DCM Director/AV every week to discuss animal program concerns. The AV meets weekly with the VCR leadership team and relays animal related issues. The IO and AVCR/RCO attend the IACUC Semiannual Program Review subcommittee meetings and receive the

Semiannual Animal Program Review and Facility Inspection Report along with a summary letter addressing findings and any required action items. In addition, the IO receives all IACUC monthly meeting minutes, all ACRs, and all informational memos that the IACUC sends to PIs and research personnel who work with animals.

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.

DCM currently has twelve veterinarians on staff.

including access to all animals. directs the veterinary care program and devotes 100% of total time to the animal care and use program.

coordinates with the other veterinarians in DCM to provide the veterinary care needed for the laboratory animals. He has delegated program authority and responsibility for the Institution's animal care and use program. assists the DCM Director in the development and monitoring of Veterinary Services throughout the University. schedules veterinary oversight of building rotations and distributes the clinical case load among the veterinarians and veterinary technicians as needed. He integrates new veterinarians and veterinary residents into the Veterinary Services rotations. directly supervises the Veterinary Residents, Veterinary Technician Services Manager and Surgery/Enrichment manager and indirectly supervises all the other veterinary technicians in Veterinary Services (coordinating the areas of Veterinary Services: Clinical Services, Surgical Services, and Pharmacy Services). contributes 100% of his time to the animal care and use program. He serves as a clinical veterinarian and alternate IACUC member.

supports essential research core facilities such as the Diagnostic Testing Lab in the Division of Comparative

Medicine, Animal Histopathology lab, Animal Tumor Models core, and the National Gnotobiotic Rodent Resource. devotes 85% of total time to the animal care and use program and 15% of her time to collaborative research as a veterinary experimental pathologist. She provides pathology service and serves as an alternate IACUC member.

provides collaborative pathology support for experiments using animal models and other types of pre-clinical studies. devotes 25% of total time to the animal care and use program and 75% of her time to collaborative research as a veterinary experimental pathologist. The Animal Studies Core Manager reports to She provides backup diagnostic pathology service and works closely with

She has delegated program authority and responsibility for the Institution animal care and use program. devotes 25% of her total time to the animal care and use program and 75% of her time to primary research studying infectious diseases. Her animal care duties include providing oversight and care for ABSL facilities as the biocontainment veterinarian and direct supervision of the DCM Veterinary Diagnostic Laboratory Service. As the Head of Animal Health Surveillance, she oversees rodent sentinel health surveillance, rodent quarantine, rodent import/export/transfer, and outbreak testing; this includes establishment of quarantine conditions, testing and release, coordination of testing for health status determination of UNC animal colonies, oversight of UNC animal export to off campus PIs, and development of preventative measures for infectious disease. She serves on the Institute Biosafety Committee, ABSL Team, as a clinical veterinarian and alternate IACUC member.

She has delegated program authority and responsibility for the Institution animal care and use program. devotes 80% of her total time to the animal care and use program and 20% of her time to her primary research host-microbial interactions. She serves as a clinical veterinarian and alternate IACUC member. She provides oversight of the exotics species staff primarily located with the College (zebrafish, frogs, etc.).

and has delegated program authority and responsibility for the Institution animal care and use program. devotes 65% of her time to DCM Vet Services and 35% of her time to research in rodent models of pain and circuit-based approaches to dissect pain pathways in the periphery and in the brain. She serves as a clinical veterinarian and alternate IACUC member.

The Training and Care Assurance Manager and CF animal studies manager and their veterinary technicians report to devotes 100% of total time to the animal care and use program. He also serves as an alternate IACUC member.

has delegated program authority and responsibility for the Institution's animal care and use program. devotes 100% of total time to the animal care and use program. She serves as a clinical veterinarian.

has delegated program authority and responsibility for the Institution's animal care and use program. devotes 100% of total time to the animal care and use program. She serves as a clinical veterinarian.

has delegated program authority and responsibility for the Institution's animal care and use program. is a part-time employee at UNC-Chapel Hill and NCSU and devotes 40% of his time to the animal care and use program.

has delegated program authority and responsibility for the Institution's animal care and use program. devotes 100% of total time to the animal care and use program. She serves as a clinical veterinarian.

has delegated program authority and responsibility for the Institution's animal care and use program. participates in the joint UNC/NCSU veterinary anatomic pathology training program. He devotes 40% of his time to the animal care and use program and supports the diagnostic and experimental pathology programs at UNC.

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.

with 11 years of experience in veterinary medicine, 1.5 years' experience in laboratory animal medicine. She provides health care, surgery support, postoperative care, and health monitoring for animals at the CF. She attends national, regional, and local meetings to meet continuing education requirements.

with 7 years' experience in veterinary medicine, 2.5 years' experience in laboratory animal medicine. She provides health care, surgery support, postoperative care, and health monitoring for animals at the CF. She attends national, regional, and local meetings to meet continuing education requirements.

with 40+ years as a veterinary technician at CF and 6 months as Swine specialist on commercial hog farm. She provides health care, surgery support, postoperative care, and health monitoring for animals at the CF. She attends national, regional, and local meetings to meet continuing education requirements.

with 10+ years' experience. She provides health care, surgery support, postoperative care, and health monitoring for animals at the CF. She attends national, regional, and local meetings to meet continuing education requirements.

with 20 years of animal experience. He provides health care, surgery support, postoperative care, and health monitoring for animals at the CF. He attends national, regional, and local meetings to meet continuing education requirements.

with 16 years' experience working in veterinary medicine as a veterinary technician. She has worked at CF for 12 months as a tech monitoring pet health, helping with husbandry and assisting with animal treatments and medications. is enrolled online with Penn Foster College to become a Registered Veterinary technician. She complied with all training and classes required by the university.

c. Interinstitutional Collaborations [*Guide*, p. 15]

Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

In inter-institutional collaborations, the responsibility for animal care and use, IACUC review and oversight, and veterinary oversight belongs to the institution owning the animals. UNC-CH requires verification of IACUC approval and a signed

Memorandum of Understanding (MOU) between UNC-CH and the collaborator for the performance of animal research, testing, or teaching, where both institutions have a current and active PHS Assurance (for NIH-funded projects), and may/or may not have a USDA registration and/or AAALAC accreditation. Both institutions' animal care and use programs enter this MOU which specifies the agreed terms and conditions under which both institutions shall collaborate. Collaborations with foreign institutions (and involving PHS funding) require a Foreign PHS Assurance, IACUC approval, and a finalized MOU [available upon request].

2. Personnel Management

a. Training, Education, and Continuing Educational Opportunities

Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe how training is documented.
Note: Do not include details about the training program, which should be described in the following sections.

The IACUC provides oversight and evaluates the effectiveness of training programs and the assessment of personnel competencies in a variety of ways including conduction of facility and laboratory inspections, Post Approval Monitoring (PAM), review of surgical records and other documentation, procedural observations (i.e., observation of survival and non-survival surgical technique) and assessment of animal handling skills through classroom and one-on-one training/certification in hands-on training classes. The UNC required rodent hands-on researcher training transitioned in August 2019 from an OACU Training and Compliance Coordinators (TCC) service to the DCM Training Team. OACU worked with DCM to ensure adequate coverage and appropriate transition of duties. The DCM Training Team provides assessment of rodent handling skills through classroom and one-on-one training/certification in hands-on training classes. Technique training and certification in species other than mice and rats, is provided by the DCM Veterinary Staff. Individuals are not certified as proficient in handling techniques until trained and observed by a DCM Training Team member, a certified Laboratory Animal Coordinator (LAC), a DCM veterinarian, or a trained and qualified DCM employee. The LAC Certification Program, established at UNC-CH in 2004 as a method of certifying LACs and training research personnel who handle animals, remains in OACU and now has a greater emphasis on LAC and laboratory personnel education with a focus on helping researchers to succeed and learn best practices regarding animal care and use. Training and certification documentation are maintained in the OACU Animal Research Registration database.

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.

Division of Comparative Medicine Professional and Animal Program Personnel:

Training or experience in laboratory animal medicine or in the use of the species at the institution: 25+ years' experience in animal care, veterinary, and laboratory animal medicine. He attends national, regional, and local meetings to meet continuing education requirements.

Training or experience in laboratory animal medicine or in the use of the species at the institution: Manager of Laboratory Animal Resources at Oak Ridge National Laboratory (ORNL) 1988-1996, 20+ years' experience in laboratory animal pathology. She attends national, regional, and local meetings to meet continuing education requirements.

Training or experience in laboratory animal medicine or in the use of the species at the institution: 23 years of experience in veterinary medicine and surgery, 17 years of experience in laboratory animal medicine. He attends national, regional, and local meetings to meet continuing education requirements.

Training or experience in laboratory animal medicine or in the use of the species at the institution: has 10 years of post-doctoral veterinary experience, including 3 years in small animal practice, 8 years in laboratory animal medicine, and two years of postdoctoral research using mouse models. She attends national, regional, and local meetings to meet continuing education requirements.

Training or experience in laboratory animal medicine or in the use of the species at the institution: has over 9 years of experience in laboratory animal medicine and over 13 years of experience working with animals in a research setting. She attends national, regional, and local meetings to meet continuing education requirements.

Training or experience in laboratory animal medicine or in the use of the species at the institution: has 20 years of experience in biomedical research and 10 years' experience in veterinary anatomic pathology She attends national, regional, and local meetings to meet continuing education requirements.

Training or experience in laboratory animal medicine or in the use of the species at the institution: has over 9 years of experience in laboratory animal medicine and over 13 years of experience working with animals in a research setting. She attends national, regional, and local meetings to meet continuing education requirements.

Training/Experience: Dr. Long has over 15 years of experience as a veterinarian with 10 years being in the field of laboratory animal medicine. He regularly attends local and national veterinary meetings to meet continuing education requirements.

July 2017-present. has 3 years' experience in both veterinary medicine and laboratory animal medicine, with 5 years' experience in laboratory animal science prior to veterinary school. She attends residency didactic lectures as well as local and national veterinary meetings to meet continuing education requirements.

Laboratory Animal Medicine (UNC – Chapel Hill) May 2019-present. has 7 years' experience in veterinary clinical medicine and 1-year experience in laboratory animal medicine. She attends residency didactic lectures as well as local and national veterinary meetings to meet continuing education requirements.

has 1 year of experience in veterinary medicine (internship) and 1 year of experience in veterinary and comparative pathology (residency). He attends residency didactic lectures as well as local and national veterinary meetings to meet continuing education requirements.

has <1-year experience in veterinary medicine and laboratory animal medicine, with ~6 months externship experience in laboratory animal medicine during veterinary school. She attends residency didactic lectures as well as local and national veterinary meetings to meet continuing education requirements

with over 20 years of experience in laboratory animal husbandry. He attends national, regional, and local meetings to meet continuing education requirements.

with over 35 years of veterinary technical services and husbandry experience. She attends national, regional, and local meetings to meet continuing education requirements.

with over 21 years of veterinary services and laboratory animal husbandry. She attends national, regional, and local meetings to meet continuing education requirements.

with over 18 years of experience in laboratory animal husbandry. She attends national, regional, and local meetings to meet continuing education requirements.

with over 13 years of experience in laboratory animal husbandry, laboratory rodent colony management, and animal study management, plus eight years IACUC related training and compliance experience. She attends national, regional, and local meetings to meet continuing education requirements.

Gnotobiotic manager in Animal Research for over 9 years. He attends national, regional, and local meetings to meet continuing education requirements.

with 14 years of laboratory animal experience. She attends national, regional, and local meetings to meet continuing education requirements.

with over 16 years of laboratory animal experience. He attends national, regional, and local meetings to meet continuing education requirements.

with 15 years of laboratory animal experience. He attends national, regional, and local meetings to meet continuing education requirements.

with over 19 years of laboratory animal experience. He attends national, regional, and local meetings to meet continuing education requirements.

with over 11 years of laboratory animal experience. She attends national, regional, and local meetings to meet continuing education requirements.

with 7 years of laboratory animal experience. She attends national, regional, and local meetings to meet continuing education requirements.

with 3 years of laboratory animal experience. She attends national, regional, and local meetings to meet continuing education requirements.

with 14 years of laboratory animal experience. She attends national, regional, and local meetings to meet continuing education requirements.

with 22 years of laboratory animal experience. He attends national, regional, and local meetings to meet continuing education requirements.

with 12 years of laboratory animal experience. She attends national, regional, and local meetings to meet continuing education requirements.

with 24 years of laboratory animal experience. She attends national, regional, and local meetings to meet continuing education requirements.

She has an Associate degree in veterinary technology and Masters degree in Public Health, and over 25 years of experience in diagnostic laboratories.

with 13 years laboratory animal experience. He attends national, regional, and local meetings to meet continuing education requirements.

with 20 years of laboratory animal experience. He attends national, regional, and local meetings to meet continuing education requirements.

with over 19 years of laboratory animal care and veterinary technician experience. She attends national, regional, and local meetings to meet continuing education requirements.

with 24 years of animal experience in clinical and surgical care and monitoring. She attends national, regional, and local meetings to meet continuing education requirements.

with over 20yrs experience in laboratory animal care and veterinary technician experience. She attends national, regional, and local meetings to meet her continuing education requirements.

with 6 years of animal care experience, 2 years enrichment experience. She attends national, regional, and local meetings to meet her continuing education requirements.

with 3 years of laboratory animal care experience and 1-year enrichment experience. She attends regional and local meetings to meet continuing education requirements.

with over 8 years of animal care and veterinary technician experience. She attends regional and local meetings to meet continuing education requirements.

with 13 years of animal care and veterinary technician experience. She attends national, regional, and local meetings to meet her continuing education requirements.

with 24 years of animal experience. Clinical care and health monitoring. She attends national, regional, and local meetings to meet continuing education requirements.

with 17 years of animal experience. Clinical care and health monitoring. She attends national, regional, and local meetings to meet continuing education requirements.

with 14+ years of laboratory animal care and veterinary technician. Experience. She attends national, regional, and local meetings to meet continuing education requirements.

with 17 years of animal experience. Clinical care and health monitoring. She attends national, regional, and local meetings to meet continuing education requirements.

with 3+ years of laboratory animal medicine experience. Attended an AVMA accredited program for veterinary technology. Attends national, local, and regional meetings to meet continuing education requirements and to learn all things new in the field of veterinary medicine.

with 20 years of laboratory animal experience. She attends national, regional, and local meetings to meet continuing education requirements.

with 20 years of animal experience. Clinical care and health monitoring, etc. She attends national, regional, and local meetings to meet continuing education requirements.

with 12 years in core performing various procedures on laboratory rodents including xenograft passage and microsurgeries. 2½ years prior experience with Gnotobiotics and 4 years Zootechnics Institute. She attends national, regional, and local meetings to meet continuing education requirements.

with eleven years laboratory animal experience, 3.5 years in IACUC, 7.5 years as a veterinary technician. She attends national, regional, and local meetings to meet continuing education requirements.

with 10 years in core. Techniques performed include specialized techniques such as neo-natal facial vein and stereotactic injections. Two years previous experience in animal husbandry. He attends national, regional, and local meetings to meet continuing education requirements.

19 years in laboratory animal medicine with two years in core. He has five years in a Gnotobiotic core. Clinical care and health monitoring,

dosing protocols, etc. He attends regional and local meetings to meet continuing education requirements.

with 5 years' experience in Animal Study Core; trained in various techniques including mouse tail vein catheters and bioluminescent imaging. She attends regional and local meetings to meet continuing education requirements.

who provides care to and research support for animals housed in the Biosafety Level 3 facilities. She has over 10 years of laboratory animal experience and over 2 years' experience working with animals in an ABSL setting. She attends national, regional, and local meetings to meet continuing education requirements.

who provides care to and research support for animals housed in the Biosafety Level 3 facilities. She has over 2 years of laboratory animal experience and over 1-year experience working with animals in an ABSL setting. She attends national, regional, and local meetings to meet continuing education requirements.

with over 3 years of laboratory animal experience. She attends national, regional, and local meetings to meet continuing education requirements.

with over 15 years of laboratory animal experience, veterinary technician, and animal husbandry experience. She attends national, regional, and local meetings to meet continuing education requirements.

Office of Animal Care and Use (OACU) Professional Staff:

The University provides budget so that OACU staff and IACUC members can attend local North Carolina Association of Biomedical Research (NCABR), IACUC 101, AALAS and other animal welfare related conferences as well as the PRIM&R Conference. For the national conference, preference is given to staff in supervisory or program management roles and/or staff that have identified a special need for a workshop offered (CE for trainers, technical expertise, animal enrichment training, etc.)

Training or experience in veterinary medicine and animal welfare regulation: 5+ years' clinical veterinary experience in small animal practice; 26+ years in animal welfare regulation, compliance, and management. Attends veterinary educational seminars as well as IACUC related conferences and webinars to meet continuing education requirements necessary to maintain veterinary license and CPIA certification. Serves on AAALAC International Council and CPIA Council. Participates in the PRIM&R conference facilitating workshops since 2010 and participates in OLAW focused audits.

Training or experience: Veterinary Assistant/Animal Hospital Administrator, 3 years. IACUC Office, 9+ years. Office/staff management, 17 years. Attends national, regional, and local educational seminars on animal care program regulatory knowledge and IACUC best practices.

Training or experience: 10+ years' laboratory animal experience including primary research, study support, husbandry, clinical care and health monitoring, gnotobiotic and genetically modified models.

Training or experience: Training or experience: 7+ years laboratory animal experience including husbandry and study support.

Training or experience: 7 years' animal husbandry experience at an AZA accredited zoological facility, 1-year DCM experience, 6 years research lab technician experience, 3 years 10 months Grant Congruency Management experience.

Training or experience: 29+ years laboratory animal experience with rodents, 13 years as an IACUC member, 1 year as the IACUC Vice Chair, 1+ year as the IACUC Chair.

Training or experience: 24+ years' experience working with laboratory mice. 6 years IACUC experience at the Genomics Institute of the Novartis Research Foundation (GNF) and manager of GNF animal care program at the time of initial AAALAC accreditation. 8 years as an IACUC member at UNC and 1+ years as IACUC vice chair.

Training or experience: 20+ years in research administration and compliance.

Environment Health and Safety and Occupational Health Professional Staff:

Training or experience: 10 years research chemist, 11 years as safety professional, 11 years as EHS representative for IACUC and DCM.

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

1) Indicate the number of animal care personnel.

~185 DCM personnel:

4 Husbandry – Assistant Operations Directors (AOD)
10 Husbandry – Managers
10 Animal Husbandry Research Support Technicians
63 Animal Husbandry Technicians
25 Cage Wash
2 Cage Wash - Cage Processing Specialists
1 Husbandry - Training & Care Assurance Manager
2 Husbandry - Training Coordinators
3 Husbandry - Training Research Support Technicians
2 Husbandry - Transport/Import/Export
5 Husbandry - Gnotobiotics Animal Husbandry Technicians
1 Husbandry - Gnotobiotics Cage Processing Specialist
1 Husbandry - Gnotobiotics Manager
2 Husbandry – ABSL Technicians
4 Husbandry - Aquatics & Exotics
1 Husbandry - Animal Studies Core Manager
6 Husbandry - Animal Studies Core Technicians
1 Husbandry - Colony Management Supervisor
4 Husbandry - Colony Management Technicians
8 Animal Health Care - Veterinarians
4 Animal Health Care - Veterinary Residents
1 Animal Health Care - Veterinary Services Manager
7 Animal Health Care - Veterinary Technicians
1 Animal Health Care - Surgery/Enrichment Manager
3 Animal Health Care - Surgery/Enrichment Technicians
1 Animal Care - Diagnostic Lab Supervisor

1 Animal Care – Diagnostic Lab Technician
9 General Administration
1 Maintenance Manager
3 Maintenance & Repair

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.

42 Assistant Laboratory Animal Technician (ALAT)
46 Laboratory Animal Technician (LAT)
25 Laboratory Animal Technologist (LATG)
4 Certified Manager Animal Resources (CMAR)
9 Institute for Laboratory Animal Management (ILAM)
8 Registered Veterinary Technician (RVT)
1 Academy of Surgical Research (ASR)
1 Surgical Research Specialist (SRS)
7 American College of Laboratory Animal Medicine (ACLAM)
2 American College of Veterinary Pathologist (ACVP)

Training of DCM Personnel:
The DCM provides formal training for all new animal care employees. The DCM training program for laboratory animal technicians involves a series of training modules (written materials + hands-on training) that cover all basic skills required to conduct standard operating procedures (SOPs) for routine animal husbandry. DCM has approximately 70 SOPs on which the animal care staff can be trained, depending on the area they are assigned to and the species housed there. The Training Team consists of one Training & Care Assurance Manager, two Training Coordinators, and two Research Support Technicians (RSTs). The Training RSTs are assigned solely to the task of training and proficiency of husbandry employees within the Division. The DCM facility managers and RSTs assist in providing one-on-one training with new employees in times of need. To complete the training, an employee must read all SOPs pertinent to their position and indicate that they have mastered each procedure. The Training RST provides hands-on training with the employee for tasks required for the position, and then assigns a final rating to the employee. The supervisor assesses the employee's final proficiency for all SOPs. The DCM Training Coordinators work in conjunction with the DCM facility manager whenever anyone is identified to need additional training or staff responsibilities have changed. Facility managers also hold regular building meetings to review SOPs with their staff. Veterinarians rotate through the buildings and conduct additional training as needed. In addition, monthly DCM staff meetings and seminars are held to update staff on new and improved husbandry practices and to acquaint staff with the research of scientists. The DCM Training & Care Assurance Manager is responsible for

oversight of the training program, while the Training Coordinators manage the day-to-day operations and documentation of personnel training.

DCM facility managers, supervisors, and research support technicians attend hands-on rodent courses and lectures led by the DCM Training Team. Furthermore, the DCM staff is encouraged to participate in the certification training programs sponsored by the American Association for Laboratory Animal Science (AALAS). Certification courses are offered by the DCM Training Coordinators and DCM pays for the study materials, examination fees, and additional resources. The Division also pays for national and local AALAS membership for all certified staff, supervisors, and veterinary staff. DCM staff members attend local AALAS Branch meetings and DCM routinely sends members of its management, veterinary services, training, and husbandry staff to the AALAS National Meeting each year. DCM staff members attend a variety of continuing education meetings both locally and nationally.

DCM Training Coordinators provide weekly certification classes for the ALAT, LAT, and LATG levels when the need and interest arises. In addition, DCM provides a Leadership Training Program to develop leadership skills to improve staff development.

AALAS Continuing Education:
Over the years the University has sent approximately 10% of all DCM staff (15-18 individuals) annually to the AALAS Convention. Preference is given to staff in supervisory positions, training programs and/or staff that have identified a special need for a workshop offered (CE for trainers, specialized equipment training, research technical expertise, animal enrichment training). Individuals may be asked to present what they have learned to others in our weekly staff meetings. Additional criteria for making the decision on who attends the meeting include some of the following considerations: 1) If someone is presenting or volunteering to help with the convention, they are approved if request is made before they submit poster, volunteer, etc. 2) Staff who express interest are assigned points for years of service, certifications, attendance record and seniority in the Division. 3) The date of the last convention faculty/staff attended. 4) Selections are made so all areas of Division are represented, vets, vet techs, husbandry, administration, etc.

Travel approvals in addition to the Annual AALAS Convention include mandatory continuing education requirements to maintain license/certification (e.g. ACLAM, CMAR, state veterinary medical license, veterinary technician and AALAS certification.) The university sends all laboratory animal medicine trainees to two workshops each year (the local Workshop in Laboratory Animal Medicine, and either POLA or AALAS).

Lastly, DCM pays to maintain licenses and certifications current (e.g. ACLAM, state and USDA veterinary licenses and to take AALAS certification tests for all employees).

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

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

The IACUC ensures that research personnel have the necessary knowledge and expertise in the species and the proposed animal procedures by requiring that each individual handling animals receives hands-on training and certification either by a DCM Training Team member (previously OACU Training and Compliance Coordinators) in a wet lab course or one-on-one session, a DCM/OACU certified LAC, or a qualified DCM veterinary/technical staff member. During hands-on courses, students earn a Proficiency rating of I, II, or III, with a Proficiency I indicating that the trainer deems the person proficient to train others. If a person is both a LAC and has a Proficiency of I, they can train and certify other researchers in those techniques (See more specific LAC Certification details in 1.a below).

At the time of application and amendment processing, OACU staff review the applications to ensure that at least one trained and certified individual is assigned to each technique described before the application is approved. The techniques performed and the training status of each individual listed is assessed. If the application includes a USDA-regulated species or a non-traditional species, the application may be approved prior to all personnel receiving training. It is placed on 'Protocol Monitoring' until training is complete. The OACU Education and Oversight (E&O) team reviews these items monthly to ensure that lab personnel have worked with DCM to complete the training in a timely manner.

a) Briefly describe the content of any required training.

<u>IACUC Online Orientation</u>
The "IACUC Orientation," developed in-house and tailored to the UNC-CH animal program, is the preliminary training for IACUC members, OACU staff, researchers, students, and other personnel working with animals. Before protocol/amendment approval, individuals listed on the protocol must complete this training and the accompanying test. The IACUC Orientation includes 13 modules providing an overview of federal regulations and institutional requirements pertaining to humane care and use of animals as well as a detailed explanation about each section of the online protocol. It includes information on the 'Three Rs' and provides examples of how each relates to animal experimentation. It includes details on minimization of pain and distress, including the administration of analgesics and anesthetics. It also has links to the University's Health

Science Library tutorial on performing literature searches for animal alternatives, the Animal Welfare Information Center, and other databases which feature animal alternatives. In addition, the Orientation includes information about zoonotic disease, allergy risk, and other human health risks.

DCM Online Orientation and DCM Facility Tour

PIs, Co-PIs and all individuals working with animals are required to complete the DCM Orientation which reviews expectations and standard operating procedures within the animal housing facility. It includes 6 training modules that provide information on the animal facilities, husbandry care, university policies and procedures, veterinary care, zoonotic disease, allergy risk, other health risks to humans, and cross-contamination prevention. In addition, researchers must participate in a DCM Facility Tour before they are given access to the specific DCM animal facility in which their animals are housed. This tour, provided by the DCM facility managers/supervisors and research support technicians (RSTs), supports the DCM Orientation, while providing more detailed information. It also includes training on facility security and building specific issues and equipment, as well as a tour of the specific DCM facility.

DCM also provides training to new researchers and/or researchers using a new animal model at UNC-CH. This training provides information pertaining to the services provided by DCM, necessary forms that must be completed, and required training for research staff to begin housing and utilizing the animal model.

Laboratory Animal Coordinator (LAC) Certification

Each PI must appoint a LAC for his/her laboratory and for each protocol/application. The LAC may be the PI or may be a qualified laboratory member designated by the PI. Each LAC is required to attend a lecture provided by OACU covering LAC responsibilities and animal welfare rules and regulations. Once the LAC has attended the LAC Lecture, they are responsible for coordinating animal-related activities in the laboratory and serving as the laboratory liaison.

The LAC may also be deemed proficient by the DCM Training Team and be certified to train others in specific techniques. They may provide the hands-on training for other researchers in those techniques. LACs are trained and individually observed. The LAC Certification provides training consistency because each LAC is trained/certified by DCM Training team in the same standard techniques and procedures and acquires sufficient proficiency to train individuals in their laboratory prior to being given access to certify others.

DCM Hands-on Rodent Training

The hands-on training of research personnel is handled in the following manner: every individual handling mice or rats is required to either attend a DCM hands-on training class/session or be certified by an approved LAC. The DCM Training team (with assistance from DCM Veterinary and technical staff) provides research personnel three types of hands-on rodent training and certification workshops – Rat Handling and Techniques, Mouse Handling and Techniques, and Aseptic Surgical Technique. The rat and aseptic classes are offered at least monthly and the mouse class is offered at least twice monthly. If the demand exceeds the set schedule, additional classes are offered. DCM Training team also devotes several hours each week to one-on-one training, assisting research personnel with specialized procedures, retraining techniques not mastered during the hands-on class session, or accommodating researchers with scheduling conflicts. The Mouse and Rat Handling and Technique courses cover basic handling, identification, blood withdrawal, injection, anesthesia, sexing and euthanasia methods. The Aseptic Technique class covers the procedures necessary to maintain aseptic technique for survival surgery and basic suture/closure methods.

Other Required Training of Research Personnel Working with non-Rodent Species

DCM veterinarians and veterinary technicians provide personalized training and certification of research personnel handling USDA-regulated and/or other non-rodent species. Researchers working with USDA-regulated species are required to receive the online training described previously. LACs in laboratories using these species attend the lecture component as previously described. The hands-on training is performed one-on-one and is species, as well as, protocol specific. It covers basic handling and techniques. Laboratory members conducting survival surgery are required to attend the Aseptic Technique course. Procedures such as injections and blood withdrawal are covered as dictated by the protocol. Senior animal husbandry personnel provide training on animal handling and restraint when necessary. Members of the veterinary faculty offer their expertise when requested and whenever anyone is identified as needing guidance. The Veterinary Services staff are identified as LACs on several protocols and are involved in protocol design and conduct surgical/anesthetic procedures as needed. Most survival surgeries involving these animals are conducted in the DCM surgical suite under the supervision of the DCM Veterinary Services. Researchers performing non-survival surgeries receive training in anesthesia administration and monitoring from DCM veterinarians and Veterinary Services or OACU.

Mouse Cage Density Standard Lecture
This lecture provided by OACU covers the specifics of the University Standard on Mouse Cage Density and implementation of breeding and mouse colony management. It is required of individuals listing 'mouse breeding' as a technique on the protocol.

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

Submitted applications include the names of laboratory personnel who will work with animals and the various techniques they will perform. The online ACAP system is linked to the electronic training certification system and OACU Education and Oversight Coordinators (EOC) assess the protocol to determine whether personnel have the necessary training/certification. Online IACUC and DCM Orientation, DCM Facility training, and Occupational Health registration must be completed before the individual independently works with animals or can enter the animal facilities unsupervised (i.e., building card access is not granted until the individual is trained/registered). Species-specific hands-on training and, if necessary, aseptic technique training are completed before the individual independently works with animals. (The uncertified individual may accompany a certified laboratory member into the facility to work with animals in a supervised, training capacity only.)

LAC training and certification occurs before an individual assumes LAC responsibilities.

At least one individual listed on the protocol must have completed the Standard on Mouse Cage Density Lecture prior to approval of a protocol that includes mouse breeding.

The above training is required before an individual receives final approval on an application. Training/certification data is maintained in the OACU Researcher Registration training database which links to the protocol database.

c) Describe continuing education opportunities offered.

Researchers complete the DCM Orientation every three years. The other training is available at any time depending on the class waiting list and one-on-one schedule availability. Continuing education may be required depending on issues found during PAM visits or related to animal welfare concerns or protocol non-compliance. If additional techniques are added to a protocol, researchers are trained and certified in those techniques before

amendment approval. Anyone that requests additional training or hands-on practice is offered a one-on-one training session.

Two informational OACU lectures, formerly offered quarterly, are now offered to researchers upon request. *IACUC Animal Concerns and Deficiencies* examines topics such as animal welfare concerns, protocol and non-compliance issues and inspection deficiencies. Attendees learn about reporting, impacts on the laboratory and strategies for avoiding incidents. In *Animal Care Application Processes*, participants learn the basics of navigating the protocol, the IACUC review process, application approvals, amendments, renewals and continuation applications.

A significant portion of the laboratory semiannual inspection and procedural observation is devoted to continuing education and inspectors review revised standards and procedures as part of the inspection.

On a periodic basis, IACUC provides all research staff with an *IACUC Informational Memo* which includes information on new procedures and standards.

The 'Network for Laboratory Animal Coordinators' (NLAC) is a network for LACs and other animal research personnel at the institution. The NLAC email list serve allows exchange of animal-related information and serves the 'reduction' principle by facilitating sharing of excess animals. The NLAC Steering Committee hosts seminars for LACs, researchers, DCM professional staff and PIs providing continuing education, standard updates and pertinent topics. Examples of past seminar topics include: Security, Training, Emergency Preparedness and Media Webinar Series; OLAW Monitoring for Humane Endpoints webinar; JAX Technical Seminars; Rat Tickling: A Technique for Eliciting Positive Affect; AALAS Mouse Anesthesia: Using Science to Improve the Process; and Mouse Cage Density compliance.

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]

The experience of research personnel performing surgery ranges from novice to highly qualified human and veterinary surgeons. The IACUC requires hands-on training of researchers who will perform survival surgery. Researchers receive the required training/certification either in class or from their certified LAC. This course covers the following: planning for survival

surgery; methods for instrument, patient and surgeon preparation; identification of appropriate rodent anesthesia; aseptic techniques (creating and maintaining an aseptic field during incision and suturing); proper instrument handling; anesthesia administration and monitoring; and proper post-surgical monitoring and recording. For certain rodent procedures and micro-surgeries, the IACUC permits a 'no touch technique' (which permits the use of non-sterile gloves) and attendees are apprised of these principles. In addition to the demonstration and hands-on portion of this course, attendees are shown the NIH Survival Surgery Video.

Also, individuals handling rodents must receive training/certification in proper rodent handling either in our Animal Handling class or from their certified LAC.

Training of personnel performing surgical procedures in USDA-regulated species is handled case-by-case. Most survival surgeries in these animals are conducted in the DCM surgical suite under the supervision of the DCM Veterinary Services. Researchers performing non-survival surgeries receive training in anesthesia administration and monitoring from DCM Veterinary Services.

OACU E&O team assesses personnel training qualifications as part of protocol and amendment pre-review. Surgeons are listed on the protocol with the role 'survival surgeon' and/or 'non-survival surgeon'. The survival surgeon role triggers the requirement of training. Surgical technique and adherence to protocol is also assessed by OACU, IACUC and veterinary representatives as part of the semiannual laboratory inspection and PAM Procedural Observations.

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

The IACUC requires researchers to receive hands-on anesthesia administration training. Researchers receive the training/certification in the Rodent Handling class, from their certified LAC, or from the DCM Veterinary Services. The rodent handling classes cover identification of appropriate rodent anesthesia, injection techniques, documentation, as well as anesthesia administration and monitoring anesthetic depth.

Prior to working with inhalational anesthetics, researchers receive hands-on training in the use of vaporizers from DCM Veterinary Services. Anesthetic technique and adherence to protocol is assessed by OACU, IACUC and veterinary representatives as part of the semiannual laboratory inspection and PAM Procedural Observations.

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

The IACUC requires researchers to receive hands-on training to perform euthanasia. Researchers receive the training/certification in the Rodent Mouse Handling classes, from their certified LAC, or from DCM Veterinary Services. The rodent handling classes cover the following: identification of appropriate rodent euthanasia agents; administration of various euthanasia methods (CO2, isoflurane, and or injectable anesthetics followed by a physical method); monitoring depth of anesthesia prior to applying a physical method; and confirming death with a physical method. The use of a physical method such as cervical dislocation or decapitation in an unanesthetized animal is taught as needed, first using carcasses or anesthetized animals followed by a live animal. Mice and rats are the most heavily utilized animals on campus and 'CO2 followed by a physical method' is the most common euthanasia method. All DCM animal facility procedure rooms and PI laboratories where CO2 euthanasia is performed are required to have the methods section of the University Standard for Mouse and Rat posted. The Standard has been updated to be compliant with the *2020 AVMA Guidelines on Euthanasia*. Some DCM facilities are also equipped with Euthanex Chambers. Due to the prolonged contact time with CO2, a secondary physical method is not required when rodents are euthanized by this method.

The method of euthanasia is stated in the protocol and the OACU assesses personnel training qualifications as part of protocol review. OACU, IACUC and veterinary representatives review as part of the semiannual laboratory inspection and PAM Procedural Observations.

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).

Occupational Health and Safety of Personnel (OHSP) is a collaboration between DCM, IACUC, OACU, Department of Environment, Health and Safety (EHS) and the University Employee Occupational Health Clinic (UEOHC).

UEOHC, under the direction of for UNC-CH provides medical services for personnel working with animals and DCM personnel. along with key members from UNC-CH EHS and DCM are responsible for program design, risk assessment, hazard mitigation, and day-to-day implementation of the DCM medical surveillance program. serves as the designated EHS liaison for DCM hazard mitigation and works closely with the to ensure medical surveillance and training compliance for DCM staff.

North Carolina state regulations require that the UNC-CH have several health and safety committees that review workplace inspections and injury and illness data, make advisory recommendations to the administration, and perform other functions determined by the State Personnel Commission. These committees include the Hazards Management Safety Committee, Occupational Health and Clinical Safety Committee, Laboratory and Chemical Safety Committee, Radiation Safety Committee, Institutional Biosafety Committee, and Campus Security Committee. These workplace safety committees report to the University Safety and Security Committee (USSC) which reports directly to the Chancellor.

The USSC is responsible for reviewing and approving each of the workplace safety committees' recommended safety policy and procedures. After review and approval of safety policies and procedures, USSC forwards recommendations to the Chancellor for final approval before implementation.

is a member of the Institutional Biosafety Committee (IBC) and the USSC. is a member of the IBC. DCM AOD, is a member of the Hazards Management Safety Committee. is a primary IACUC member.

2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc.

[*Guide*, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

The hazard identification process begins with protocol review. The protocol form requires that the PI define the hazardous agents to be used in the research. In addition to the veterinary pre-review and the IACUC member review, each protocol receives an initial review of hazards by an EHS employee. The provisions for safe handling of hazards are then reviewed by EHS in concert with other parties, as necessary. This hazard review ensures that PIs and their staff, as well as DCM staff, are aware of hazards and have the proper engineering controls and PPE during administration, handling and disposal.

In addition, EHS requires all PIs working with hazardous agents to have a Laboratory Safety Plan (LSP) on file. The LSP identifies all laboratory related hazards, required controls and personal protective equipment (PPE) for the specific research conducted by lab. The LSP is updated at least annually by PI and lab staff review plans annually to verify that they understand the laboratory hazards, controls and required PPE of their work environment.

All personnel with animal exposure, including IACUC members and students, complete the evaluation conducted by the UEOHC. Personnel with animal exposure are identified on the animal use protocol or by working in certain jobs in the University (DCM, Facilities Services personnel). People with animal exposure are required to complete a health history questionnaire that is evaluated by a health professional in the Occupational Health and Safety program.

Personal Protective Equipment (PPE) Hazard Assessments are done for most positions in DCM (veterinarians, husbandry technicians, cage-wash technicians, etc.) when the employee starts the position. They are updated at least annually and when a change occurs. These PPE Hazard Assessments clearly outline the hazard, task and required PPE for that position. the supervisor reviews the information with the employee and then both individuals sign the document. DCM Training Coordinators complete a medical surveillance and EHS training checklist prior to the employee starting in DCM to determine EHS requirements for each employee. This checklist is shared with EHS staff so they may flag employees appropriately. In addition to when changes occur, both the checklist and the PPE Hazard Assessment are updated anytime a person transfers to another area.

UNC-CH Facilities Services personnel that perform maintenance in DCM areas are required to take the online training module “Occupational Health Program for Employees with Animal Exposures”. Hazard specific training is

available when necessary. The PPE Hazard Assessment is conducted with employees at least annually.

Service contractors maintaining or servicing equipment in the DCM facilities should present a proof of health risk assessment by their company healthcare provider. In addition, Service Contractors should provide proof of TB testing before entering rooms where Nonhuman Primates (NHP) are housed.

Contractors are required to take the DCM training module "Security and Hazard Awareness in Animal Facilities for Non-Animal Users" and receive a DCM facility orientation. Hazard specific training is available when necessary. All completed training forms are maintained by the DCM Training Coordinators.

IACUC members, including the non-affiliated and non-scientist members are enrolled in the UEOHC as part of their initial IACUC Orientation Process and thereafter.

Visiting Scholars that are added to the IACUC protocol must show evidence of Occupational Health coverage from their home institution before working with animals.

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

EHS staff participate in semiannual inspections of all facilities and check safety aspects of the program during these inspections. Industrial hygienists from EHS also perform workplace hazard surveillance in the animal facilities including heat stress and noise monitoring. All hazard use must be approved by EHS or the appropriate institutional committee (e.g., IBC for recombinant DNA research). The IACUC will not approve an animal use protocol involving the use of an experimental hazard until documentation assuring review and approval for the use of the hazardous substance is received from EHS.

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]

EHS employs a staff of professionals trained in the field of occupational health and safety to provide support for University activities and to ensure a safe and healthy environment. An employee is responsible for notifying their immediate supervisor of a violation or deficiency which does not promote a safe and healthy working environment. Additionally, the employee's immediate supervisor is notified of every injury or accident regardless of how trivial an

accident may appear. An employee accident report form and supervisor accident report form should be turned into EHS and, depending on severity of the incident, EHS might complete an accident investigation and formal incident report.

Employees may request an inspection or evaluation of conditions which they believe may constitute a health or safety hazard. The types of hazardous conditions that should be reported include, but are not limited to, the following: unsafe work practices; suspected health hazards; failure to wear required safety equipment; failure to guard machines; improper storage of chemicals; presence of irritating or noxious odors; fire hazards; interference with safe egress; natural gas odors; chemical spills; petroleum spills; compressed gas release; and radiation exposure.

Accident and incident statistics are discussed and reviewed at regularly scheduled University safety committee meetings and during the IACUC semiannual program review meetings.

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.

All individuals (employees and students) who participate in animal research are identified through the protocol review process and complete a screening questionnaire that identifies the animal(s) they work with and the number of hours spent working with the animals. All animal workers are screened for animal allergies before starting work and every two years thereafter to monitor for possible animal allergies. There are no exemptions from this program. In-person evaluation is required for persons with baseline or worsening animal allergies.

Employees responsible for the direct care of our research animals (DCM) are seen yearly by Occupational Health Services for medical review & examination, animal allergy screening, and clearance for and testing for use of the appropriate respirator. Immunizations may be required for DCM personnel based on their essential job functions and the specific animal populations with which they work. DCM accounting and finance employees are exempt from the medical evaluation.

b) Describe provisions for allowing an individual to decline participation in all or parts of the medical evaluation and preventive medicine programs (if applicable). Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.

There are no provisions that allow an individual to decline participation in either program.

c) Describe provisions for assuring confidentiality of medical information.

Occupational Health Services follows best practice and compliance with OSHA, ADA, EEO, HIPAA and GINA (Genetic Information Non-discrimination Act) regulations. Medical evaluations are kept separate from personnel files.

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

UNC-CH personnel that perform maintenance in DCM areas or have incidental contact with animals take the online training module "Occupational Health Program for Employees with Animal Exposures." They are flagged during their Hazardous Management Program inspection. EHS examines their work requirements and flags them for appropriate trainings.

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.

DCM personnel undergo mandatory initial and annual health evaluations. Evaluations include general health and fitness assessment, identification of potentially disqualifying conditions, administration of work-required immunizations, risk for exposure to human and animal blood borne pathogens, screening for animal allergens and medical clearance for respirator use. Other programs include hearing conservation for DCM employees using the robotic cage wash and additional medical surveillance for DCM employees who work in/enter biosafety level laboratory settings as part of the University's BioSurety program.

The BioSurety Program assesses whether existing medical conditions or treatments might compromise a worker's ability to perform essential job functions safely and reliably. The BioSurety Program encompasses pre-entry, annual and exit evaluations, as well as event-driven assessment, investigation, ongoing health monitoring and pre/post exposure prophylaxis services.

The following applies to personnel who work with species where a zoonotic risk is possible. When handling sheep, N95 or PAPR respiratory protection is required and personnel are enrolled in the Respiratory Protection Program which includes a physical at UEOHC. Personnel who handle macaques are enrolled in the immunization program through UEOHC and are trained in Macaque Bite Scratch Kit and emergency response protocols.

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.

He is board-certified in Occupational & Environmental Medicine as well as Physical Medicine & Rehabilitation. He is a member of the EHS Leadership Group and is one of the leads of the University's BioSurety Program. He is a signatory official on all medical surveillance SOPs for BSL level research on campus as well as special use protocols where there is a potential for exposure to Q-fever, Herpes B, pseudo-typed rabies, etc.

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.

Zoonoses/Lab Animal Allergy training is required for all DCM personnel. An online module is also available for others that might have limited contact with animals such as maintenance personnel. All personnel listed on the who work with animals must take the online IACUC Orientation once and the DCM Orientation every three years. Both Orientations include the 'Animals and Human Health Risks' module which has information regarding allergies and zoonotic diseases.

Personnel exposed to animals receive a UEOHC evaluation. Personnel (including students) with animal exposure are identified through the protocol or by working in certain jobs or functions in the University (DCM, Facilities Services personnel, IACUC members). These people must complete a health history questionnaire that is evaluated by a health professional in the Occupational Health and Safety program. The medical program addresses laboratory animal-associated allergy, vaccination, tuberculosis screening, treatment of bites, scratches and other physical injuries related to work exposures or practices, and the selection and use of PPE. In addition, it includes lifestyle counseling as it relates to worker health, wellbeing, and workplace performance. For most individuals using animals (rodents), the actual medical hands-on component is minimal, such as updating tetanus immunization, periodic tuberculin testing for NHP users, or physical exam and other medical review for patients with significant allergy scores. All on-the-job injuries are handled by the UEOHC.

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.

A daily change of scrub shirts and pants are provided for all DCM personnel. Laundry service is provided by a commercial laundry. Each employee has a shoe allowance to purchase safety footwear for use exclusively in the workplace. DCM also purchases safety glasses, including prescription glasses for those required to wear safety glasses. Boots and protective clothing are provided for personnel working in high moisture areas. Respirators are provided by DCM and fitted by EHS personnel for staff exposed to respiratory hazards (including allergies if indicated) as part of the University's Respiratory Protection Program. Hearing protection is provided for staff enrolled in the University Hearing Conservation Program administered by EHS. Upon entry into most DCM animal rooms gloves and disposable gowns are required. Certain areas require additional PPE, such as BSL areas and large animal spray down areas. PPE signs are posted at the entry to every animal room or area.

b) Describe arrangements for laundering work clothing.

DCM utilizes a contracting service to launder uniforms. The contractor is responsible for supplying 14-21 sets of new uniforms to each employee initially and ensures that clean uniforms are available. All soiled uniforms are placed in a designated container and are picked up by the contractor weekly.

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

DCM provides work clothes for husbandry and vet care staff. Many animal rooms have sinks for hand washing. Shower-locker-changing facilities are provided in all major buildings.

Limited wearing of uniforms is allowed outside the workplace for short excursions, i.e. short errands, etc. However, uniforms should not be taken home, worn outside the facility on extended excursions, worn outside if a staff member has worked in a primate or biohazard area, or worn outside if the uniform is soiled.

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

Eating, drinking, and smoking are not permitted in animal facilities. Eating and drinking are allowed in assigned employee break rooms. Smoking is prohibited in all UNC-CH facilities. Various snack bars and cafeterias are available to DCM personnel.

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).

Most animal housing areas are maintained as barrier facilities for housing of SPF rodents, especially valuable genetically modified animals, or irreplaceable animal models. PPE is determined based on housing type and animal species. Each facility has specialized areas for receiving and storage of food, bedding, and chemical supplies.

There are separate spaces for washing, sterilizing equipment, supplies and, depending on the volume of work, bulk walk-in machines (including robotic processing) for washing cages, bottles, glassware, racks, and waste cans; a utility sink; a bulk sterilizer for equipment, food, and bedding; and separate areas for holding soiled and clean equipment to limit exposure of hazards.

Automation and semi-automated processes (including autowater, bedding dispensers, pneumatic bedding disposal) are used in buildings to improve ergonomic handling of husbandry tasks.

Custom caging designed for housing NHP were purchased to assure complete security and safety for DCM employees, animal handlers, and PIs. Restraint gloves are used for handling animals.

Suitable pig boards and appropriate caging/chutes are used when handling and moving large pigs.

DCM employees that work in areas where noise levels exceed OSHA occupational exposure limits are enrolled in the University Hearing Conservation Program. As part of the program, enrolled employees are provided adequate hearing protection at no cost. Warning signs requiring hearing protection are posted to the entrances to the "noise-hazardous" areas as defined by OSHA. The program is designed to protect University employees from long term hearing loss associated with noise levels in the workplace in compliance with the OSHA Standard 29 CFR Part 1910.95 Occupational Noise Exposure. The program provides annual audiometric testing, annual training, and adequate hearing protection for enrolled employees. In DCM, enrolled employees include animal care staff in the canine facilities and staff that work in specific cage washing facilities. Warning signs stating "Hearing protection required in this area" have been posted on the entrances to these facilities.

EHS manages and determines the space for storing and segregating hazardous wastes before incineration or removal.

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

UNC-CH's rodent cage census is currently ~99% housed in individually ventilated caging (IVC). Rodent allergen concentrations are decreased with sealed IVC under negative pressure or with filtered-top lids on static microisolation caging located in exhausted isolation cubicles. IVC rodent cage changing is every two weeks, thus limiting personnel exposure frequency by increasing the cage-change interval. All cages are opened and changed under a HEPA-filtered cage-change hood or biosafety cabinet. In several buildings, IVC rack air-handler unit air is redirected towards soffit exhausts and/or directly ventilated outside of animal holding rooms.

A daily change of scrub shirts and pants are provided for all DCM personnel. Laundry service is provided by a commercial laundry. Gloves and a yellow gown are worn when working with animals and/or changing cages under a hood. Each employee has a shoe allowance to purchase safety footwear for use exclusively in the workplace.

Respirators are provided by DCM and test fitted by EHS personnel for staff exposed to respiratory hazards (including allergies, if indicated) as part of the University's Respiratory Protection Program. Upon entry into DCM animal rooms personnel are required to don disposable gowns and gloves. People with animal exposure are required to complete a health history questionnaire that is evaluated by a health professional in the Occupational Health and Safety program. The medical program addresses laboratory animal-associated allergy and workplace performance.

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

Hazard (biological, chemical, and radiological) forms are posted in the animal housing area that specify the special practices that pertain to the safe handling of animals exposed to hazardous agents. Generally, studies involving hazards are segregated areas of the animal facility, and one individual assigned to the care of animals in each area reviews aspects of care with the facility manager and veterinary staff. All hazards active in the facility are periodically reviewed with all technical personnel who might be involved in the weekend care of these animals to reinforce their

understanding of proper procedures. The use of proper procedures is monitored by the facility supervisor, veterinary staff, EHS personnel and the laboratory director in charge of the study.

A DCM orientation module covering OSHA regulations and UNC-CH policies is available online along with a specific DCM BSL2 training. UNC-CH animal facilities have several areas designed for containment and most animal studies involving experimental hazards are in these areas (e.g. isolation cubicles).

In all cases the areas used for animal housing are compatible with the designated ABSL level for the agent. BSL2 biohazardous and radiological designated housing (isolation cubicles) and/or segregated from general non-infectious animal housing.

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

The majority of PPE utilized is disposable and is only used once. For reusable items, such as respirators, employees are trained on the proper inspection, care, cleaning, and storage.

The UNC-CH Laboratory Safety Manual requires that each research group be responsible for ensuring that emergency eyewash facilities, both within the laboratory space and in nearby common areas, remain operational and accessible. The eyewash stations are checked once a month, documented by dating the inspection tag or separate log located on or near the unit.

e) Respiratory Protection

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

For DCM staff, respiratory protection is utilized when dumping dirty cages if an engineering control such as a HEPA-filtered cage dumping station or biological safety cabinet is not available. Additionally, certain species (e.g. sheep, NHPs) or certain hazardous agents require respiratory protection for personnel who enter the rooms to perform work.

University research personnel use respirators for protection when there is potential for exposure when working with Biological Hazardous agents (e.g., bacteria such as tuberculosis, viruses, and other infectious agents).

Dependent on the type of work operation and type of hazard, either an N-95 disposable respirator or Powered Air Purifying Respirator (PAPR) is required. Fit testing and the appropriate use of respirators are a function of EHS as part of the University's Respiratory Protection Program. The UNC-CH Respiratory Protection Program provides respirators to protect the health of employees in accordance with OSHA 1910.134. The program includes medical surveillance, training, and fit testing. In addition, training is required which outlines proper inspection, care, cleaning, and storage of respirators.

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

Each employee assigned a respirator for carrying out his/her job responsibilities receives a medical evaluation to determine his/her ability to use a respirator before being fit tested or required to use the respirator in the workplace. Employees complete a medical questionnaire at the time of their medical examination at the UEOHC. The medical staff perform a medical evaluation of the ability of the employee to wear a respirator, conduct fit-testing, and determine the need for additional medical evaluations or restrictions on the use of respiratory protection devices. The medical questionnaire and examinations are administered confidentially during the employee's normal working hours or at a time and place convenient to the employee. Employees are encouraged to discuss the questionnaire and examination results with a member of the UEOHC medical staff.

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

Respirators are selected by the applicable work unit with assistance from EHS based on many factors including the following: the nature of the hazard; the concentration of the contaminant to which an employee is exposed; the extent of the hazard; regulatory requirements; work requirements and conditions; and the characteristics and limitations of available respirators. The DCM PPE Hazard Assessment includes respiratory protection and is reviewed at least annually with staff by supervisors.

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).

DCM Training Coordinators and EHS provide general instructions and Standard Operating Procedures (SOPs), on the safe operation of the DCM autoclaves, cage washers, and other animal care affiliated equipment. Most required and reoccurring training is centered on the different equipment and how each safety consideration (e.g. steam, hot water, chemical agents, etc.) will vary and the types of safety features that equipment may or may not have (e.g. power buttons, lock/unlock key switches, stop/abort cycles, open/close doors, etc.). It is imperative that employees are trained to locate and use the safety features specific to the equipment they will be operating. SOPs and DCM Training Team discuss how the equipment is maintained and all personnel protective equipment necessary to perform tasks. Each facility has informational signage for hazard communication posted near the pertinent equipment.

Use of DCM equipment by an individual prior to familiarization with the relevant SOPs and hands-on training by the Facility Manager and/or the DCM Training Team is prohibited. Completion of these two requirements must be documented within DCM Research Training Database. All DCM employees who utilize autoclaves are required to take the EHS online Autoclave Safety training.

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.

DCM Maintenance staff receive assessment trainings to use the forklift which was conducted by UNC-CH Facilities. In addition, they completed online Course Powered Industrial Truck (#73202) and Practical (#73201). Employees are all up to date as of March 2020.

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.

Even under emergency circumstances, the IACUC encourages PIs to first contact DCM to arrange for transportation prior to using a private vehicle. The University is not responsible for any damages and liabilities caused by the transport of laboratory animals in a private vehicle. The *IACUC Standard for Animal Transport and Biosecurity* describes transport expectations.

Transportation of animals using university vehicles that are not maintained by DCM (i.e., Zipcars, Point to Point, Campus Bus, or Carolina Motor Pool) is not permitted. The use of private vehicles is strongly discouraged to transport laboratory animals as it presents a risk of contamination due to exposure to allergens, zoonoses, and other hazards associated with animal exposure.

The animal transport method (if not DCM) and destination for all animals should be outlined in the IACUC approved animal protocol or accompanying amendment(s). PIs transport animals from DCM housing facilities to research laboratories, whereas DCM transports to the DCM designated Core holding room (e.g., Telemetry / Cardiovascular Core, Animal Imaging Center, Behavioral Phenotyping Core). Once cages are in the designated DCM holding room, PIs can move animals from the core testing back to the DCM core holding room or back to the PI's laboratory. In situations in which the animals are transported to a laboratory located in another building and then returned to the DCM facility, the animals are returned to a DCM High Risk Return Room.

DCM staff move animals between animal facilities in DCM vehicles and within facilities by appropriate transport containers. PIs may move animals to their laboratories and to core testing facilities. When the animals are moved through common halls, they are placed in opaque transport containers and draped to decrease visibility of animals. In rare circumstances where DCM cannot provide transportation, PIs may transport animals in vehicles if all environmental safety and animal welfare standards in the *IACUC Standard for Animal Transport and Biosecurity* are met. In limited circumstances and in coordination with DCM, PIs may move animals between animal facilities.

Animals from dealers are transported by air or climate-controlled vehicle. Most rodents from other institutions are shipped by air and held at the airport and picked up by DCM personnel so that the animals are transported directly from the airport to DCM. Ferrets and rabbits are sometimes transported in their vendor filtered shipping container in vehicles that do not have a separation between cargo and the driver.

Recent NHP moves for imaging studies from surgical suite to the imaging suite occurred in the vehicles; however, the driver and person in back with the NHPs are in full PPE with monkey bite treatment kits. After the animal transfer is complete, the vehicle is decontaminated, and the cleaning recorded on the log kept in the vehicle. Larger transports with multiple animals, are moved with the International truck which has separate sections for driver and a conditioned animal holding area. The vehicles are lined with sanitizable material that allows full decontamination as needed.

Zoonoses/Lab Animal Allergy training is required for all DCM personnel. An online module is available for research and maintenance personnel that may have limited contact with animals. Every three years, all personnel listed on the protocol who work with animals must take the DCM Orientation which includes a module entitled 'Animals and Human Health Risks' with information regarding allergies and zoonotic diseases.

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

In the DCM surgery suite, anesthetic gases are exhausted via active scavenging devices to the building exhaust or vacuum systems. Mobile anesthetic units are also equipped with passive scavenging systems to use as needed (charcoal filter canisters). DCM provides isoflurane vaporizers in the project rooms. Individuals who utilize this equipment must be trained by the DCM Veterinary Services staff. These units are exhausted via the chemical fume and ducted BSC hoods in these areas. Anesthetic gases are occasionally actively scavenged by snorkel ventilation or exhausted induction chamber in DCM project rooms.

In PI laboratories, methods of personnel protection are under the guidance of EHS, and the use of inhalant anesthetic agents in these areas has been registered with EHS through the IACUC/Hazardous agent review processes. Employee and area monitoring for potential exposure to waste anesthetic gases is conducted by EHS, including the use of sevoflurane and isoflurane under conditions of local exhaust ventilation, active and passive scavenging. Isoflurane is one of the most common waste anesthetic gases used and an SOP and fact sheet is available that outlines safe work practices. There are a few cases where the isoflurane 'drop method' is approved for use at the bench (or ducted BSC) after EHS has monitored the area and personnel.

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.

Appendix not provided

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

Appendix not provided

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

Radioactive agents are captured in protocol via Radiological Hazard form. The irradiator protocols are not on the Radiological Hazard form but would be in protocol text. The use of UV light, magnetic fields, and noise would be detailed in the protocol. **Appendix not provided**

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.

EHS requires all PIs working with hazardous agents to have a Laboratory Safety Plan on file to describe all work involving: radioactive materials, x-rays, lasers, hazardous chemicals, biological hazards, recombinant DNA, or laboratory research animals. The UNC-CH Laboratory Safety & Biological Safety Manual has been distributed to PIs and is readily available to employees at http://ehs.unc.edu/manuals/. EHS maintains an extensive web

site that includes forms, data sheets, self-study modules, employee training history, training schedules, the UNC-CH Laboratory Safety Manual, and links to Safety Data Sheets. The LSP lists all laboratory personnel that use hazardous materials and their activities to ensure appropriate training has occurred. All laboratories are inspected annually as part of the Collaborative Laboratory Inspection Program (CLIP). All animal housing areas are inspected semiannually.

SOPs for work with specific hazardous agents are in place. EHS specific SOPs pertaining to animal research include: "DMBA: Use in Animals", "Formaldehyde Solution Use in Small Animals", "MS-222", "Tamoxifen", "Isoflurane", "Urethane" and "Handling Animals Dosed with Chemical Hazards". All BSL facilities also have SOPs related to facility/animal care.

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 IACUC will not approve a protocol involving hazardous agents until EHS documents approval. DCM posts biological, chemical, and radiological hazard forms on room or cubicle doors to alert workers to hazardous agents. PPE requirements which address hazardous agent use are posted on the door of each room.

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.

When animals are to be dosed with a chemical hazard, laboratory workers should provide advance notification to those who will take care of their animals and should label each cage appropriately. For animals housed in DCM-managed areas, at least three business days prior to dosing the animals, the laboratory will notify the DCM Facility Manager/Supervisor of the dosing schedule and route of administration. The cages are then marked with yellow "Chemical Hazard" cards. All bedding present in a rodent cage within 3 days of dosing is considered contaminated until it is disposed of appropriately. A lime green "Chemical Hazard Last Dose" card is placed on cages by the research staff when the last chemical hazard dose is administered. Rodent cages are covered with micro-isolator lids and/or are maintained on a ventilated rack. Employees must wear full personal protective equipment for handling animals, cages, and bedding. Cages are opened only during cage changing and/or animal care or study-related reasons in HEPA-ventilated cage changing station, a biological safety cabinet, or a chemical fume hood. In most areas, bedding is dumped in a HEPA-ventilated dumping station,

such as the "Bedding Disposal Cabinets" used in several DCM facilities. If not available, employees wear an N-95 respirator or Powered Air Purifying Respirator (PAPR) when working with open cages. Bedding that contains chemical hazards is segregated from regular animal bedding for incineration. After all contaminated material is dumped, the waste bag(s) is tied closed, sealed inside an incineration box, placed into a carcass cooler, and is recorded on the "Incinerator Box Tracking Sheet".

All animal carcasses are bagged and boxed as medical waste for incineration via an outside waste contractor. BSL2 & 3 carcasses are autoclaved prior to being added to medical waste boxes. Carcasses that contain Short- or Long-Lived radionuclides are frozen in the PI's laboratory (or in the vivarium) with waste pickup requested by the PI. Animal carcasses that contain Very Short-Lived radionuclides are held for ten half-lives and surveyed by the PI. If the carcass survey cannot be distinguished from background radiation, it can go into the regular waste stream.

Infectious waste (BSL2 or higher) is autoclaved and disposed in regular trash after autoclaving. Sharps are collected in appropriate containers and either autoclaved if a biological waste or disposed to dumpster if non-hazardous. All animal bedding that UNC-CH's Office of Waste Reduction and Recycling collects on the animal bedding route, is collected by Waste Industries in 35-gallon carts filled by DCM employees. The carts containing used animal bedding are dumped into a rear load garbage truck. The driver hooks the carts to a cart tipper at the rear of the truck and uses a mechanical lift to tip the cart contents into the hopper. The exception is the pneumatic system which uses a sealed-enclosed container. All the bedding collected (1-3X/week), either in the rear load truck, enclosed container, or via dumpsters, goes to Waste Industries transfer stations.

Bedding that contains Short- or Long-Lived radionuclides is frozen in the PI's laboratory (or in a PI freezer in the DCM space) with hazardous waste pickup requested by the PI.

Hazardous wastes are handled through EHS with the individual generating the waste properly labeling the waste container and filling out an online waste pickup request form. EHS then transports the waste to their EPA-permitted Treatment, Storage and Disposal facility for final waste disposal by Stericycle.

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

For BSL2+ and higher hazardous agents: Personnel working with infected humanized mice are trained in special precautionary techniques and wear additional PPE such as puncture resistant gloves when anesthetizing, restraining, or infecting animals. These personnel may also be enrolled in additional physical and immunization program requirements through the UEOHC.

Personnel who work with species where a zoonotic risk is possible: When handling sheep, N95 or PAPR respiratory protection is required and personnel are enrolled in Respiratory Protection Program which includes a physical at UEOHC. Personnel who handle macaques and primatized mice (engraftment of nonhuman primate cells) may be enrolled in the immunization program through UEOHC and are trained in Macaque Bite Scratch Kit and emergency response protocols.

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.

DCM specific training required for all staff includes a general safety orientation (covering OSHA regulations and UNC-CH policies), Zoonoses/Lab Animal Allergy, Autoclave Safety and Compressed Gas Safety training. Specific safety training based on job assignment includes: (BSL2 or higher, Blood Borne Pathogen, Respiratory Protection, Occupational Noise, Lock-out/Tag-out of Energized Equipment and others as needed.

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.

Not Provided.

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

Animals exposed to chemical hazards are housed in normal housing rooms in IVC racks and cages/racks labeled as "Chemical Hazard." Animals exposed to biological hazards are housed within isolation cubicles, germ-free isolators, or ABSL2 designated rooms segregated from general animal housing. All

dirty caging is flagged for special handling and disposal according to Chemical or (ABSL2/Biological) Hazard SOP.

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

Tecniplast biocontainment caging is used in some BSL2 and higher rooms. These airtight cages with high negative intra-cage pressure are ideal for biocontainment and bioexclusion. Biosafety cabinets are used for rodent cage changes and animal work (described in DCM SOPs: Rodent Cage Change, and DCM Biosafety Cabinet or Changing Station). Also, we have procedures for handling chemical hazards used in rodents (see DCM SOP: Handling Animals Dosed with Chemical Hazards) and Biological Hazards (see DCM Animal Biosafety Level 2 SOP). Our SOPs are reviewed and updated on a biannual basis and our hoods are recertified on a yearly basis.

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

All required PPE (disposable gown and gloves) is worn in every animal room unless otherwise posted on the room or area entry sign. For ABSL2 areas, additional PPE may be required dependent on the agent being used. This may include Tyvek sleeves, protective glasses, goggles or face shields, shoe covers, bonnets, masks and a second pair of gloves. Additional ABSL2 PPE, including the outer pair of gloves, Tyvek sleeves, and shoe covers, is discarded inside the animal room prior to leaving. Items are placed in an autoclavable biohazard bag that is autoclaved before being discarded. Alternately, if the facility's autoclave load is too small, items are put in a bag and box that is sent out for incineration. Staff must complete a yearly online training for working with ABSL2 agents.

In ABSL areas varying PPE is worn based on biological agent including Tyvek suits and respirators (N95 or PAPR). Dedicated scrubs are worn in the ABSL facilities. Tyvek jumpsuits, shoe covers and/or dedicated shoes, double gloves, and solid front disposable gowns are donned in all ABSL facilities. A PAPR is also worn and a pre-check of the hoses, helmet and battery power is conducted each time PPE is donned. N95 masks may alternatively be worn with arboviruses. Staff attend yearly training for ABSL work and PPE requirements.

For biological agents, animals are housed in individually ventilated Tecniplast caging systems under negative pressure and the cubicle room is negative relative to the hall, where appropriate. All work with infected animals is

performed in the biosafety cabinet under containment. BSL2 agents are housed in cubicles, and any necropsy and aerosolized procedures are performed under containment in biosafety cabinets. Risk assessments to determine need for vaccine, PPE, and appropriate disinfectant are done for all BSL agents.

Chemical agents including highly toxic agents, carcinogens, reproductive hazards, and anti-neoplastic agents follow the DCM SOP "Handling Animals Dosed with Chemical Hazards." Precautions outlined in the SOP include use of a chemical hazard cage card to designate cages, door signage to alert others that chemical hazard studies are housed in room, segregation and incineration of bedding during and after dosing and use of respiratory protection for husbandry staff that dump cages during hazard administration.

Protocols involving administration of radionuclides to animals require information on specific arrangements for housing the animals during the project. Information required includes:

1. The kind and number of animals to be used in the study (# per experiment + total # of experiments).
2. The radionuclide to be administered per animal and how administered.
3. The fate of the animal and suspected excretion rate of the radionuclide.
4. Instructions for handling and monitoring of the animals and proposed method of disposal of the animal and excreta. These instructions shall be posted in the animal housing area.

Dispositions of animals, location(s), time frame(s) after administration, and any decontamination procedure after administration is outlined by the PI in the hazard form that is completed with the animal protocol. Personnel exposure and the appropriate controls are determined by the EHS review of the hazard form of the animal protocol. Cage changing instructions and waste disposal are also reviewed in the animal protocol.

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.

Policies and procedures for animal transportation, facility decontamination, and patient protection have been established and SOPs approved by the UNC-CH EHS. Main guidelines are listed below. Detailed procedures are described in the SOP.

Main Guidelines:
At no time should human subjects (e.g. patients) have any contact with animal subjects. This includes:

- No visual contact
- Should not be able to hear the animal
- Should not be able to identify anything associated with animal experiments

All waste and supplies brought in and used in the animal experiment must leave with the animal.

All surfaces where animals had contact (this will usually be limited to inside the scanner only) should be disinfected by the staff with an EHS recommended disinfectant.

Equipment and devices that will regularly be used for animals such as anesthesia equipment or carts should be dedicated to animal use only, labeled as such, and stored elsewhere. Animals will use a dedicated hose and nosecone for anesthesia, not mixed with any accessories for human subjects. For animal vital sign monitor, disposable probe, or a dedicated probe (to monitor heart rate, respiration rate, or blood pressure), will be used to avoid any mixture with human usage.

Anyone who is involved in animal handling should have appropriate training and be approved by IACUC. All the procedures are included in an approved IACUC protocol.

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.

The *IACUC Standard for Animal Transport and Biosecurity* outlines policies and provides guidance to researchers on how to safely transport animals across UNC-CH facilities and between UNC-CH facilities and off campus sites. Researchers are expected to follow these procedures to ensure the health and well-being of research animals as well as the health of research personnel engaged in the transportation and any individuals that may indirectly come in contact with the animals or vehicles used to transport the animals.

Animal movement through public areas is discouraged, service elevators are recommended. Cages containing animals treated with hazardous

agents need extra protection (e.g. secondary containment) to ensure that the transporter and building occupants are not exposed and animals cannot escape. Containers should comply with the following: able to be sanitized (or disposable); secure; spill proof; escape proof; and solid flooring. Opaque containers are provided for transport or containers should be covered such that animals and containers are not visible to the public during animal movement.

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.

has delegated authority from the Chancellor to appoint the members of the IACUC. **Appendix not provided**

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

Appendix not provided

The UNC-CH IACUC meets formally once per month for the purpose of protocol review and discussion of programmatic issues requiring IACUC attention. Additional meetings and subcommittee meetings are scheduled, as necessary.

IACUC Subcommittees include the following:

1. Program Review (meets every 6 months)
2. Animal Concern (meets as needed)
3. IACUC-DCM Leadership (meets monthly prior to IACUC meeting)

The Program Review subcommittee meets semiannually to review the animal program. All IACUC members are invited to attend this meeting. The IACUC Chair provides a meeting summary at the next convened IACUC meeting.

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

New IACUC members review the UNC-CH IACUC and DCM Orientation training modules, complete a one-on-one orientation with the OACU Director, attend an inspection orientation, and attend several IACUC meetings prior to serving as a protocol reviewer. One-on-one orientation topics include the following: IACUC responsibilities, operation and procedures; review and approval of new or continuing animal proposals; protocol modifications; semiannual reviews and inspections; post-approval monitoring; reporting and subsequent handling of animal welfare concerns and protocol non-compliance; and OACU support of IACUC members and processes.

Members are offered a copy of the IACUC Handbook and web links for the *Guide*, PHS Policy, institutional policies, guidelines, and access to the online protocol system. Prior to conducting semiannual inspections, IACUC members complete a facility inspection training to become familiar with facility operations and identification of facility and laboratory inspection issues. The institution provides funding for IACUC members to attend local meetings relevant to their IACUC role. The North Carolina Association of Biomedical Research (NCABR) is a very active research advocacy group that provides regular local IACUC and IBC training. In May 2019, five IACUC members and two OACU staff attended the NCABR Basic and Advanced IACUC training. Also, NCABR made the States United for Biomedical Research webinars available to UNC-CH. Four webinars including the topics of security, training, emergency preparedness, and media guidance were live streamed for LACs, DCM and OACU staff, IACUC members and PIs. IACUC members are encouraged to view NABR and OLAW webinars. At the monthly IACUC meetings, training topics are presented by the OACU Director, IACUC Chair, or invited guests and cover current issues, best practices, policy/standard updates, and process changes. In addition, several of the IACUC members have attended OACU hands-on training classes to become more familiar with the training researchers receive.

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.

Appendix not provided

The protocol form is required for all activities proposing to use live vertebrate animals. IACUC approval must be obtained before any work is initiated. IACUC reviews are performed at initial submission and again every 3 years. Annual updates are required for all ongoing projects involving USDA-regulated species and DOD/VA funded projects.

PIs submit electronically through the protocol system. Following a protocol submission, OACU staff notifies the following groups to start pre-review.

- DCM Veterinarians – review and consult with PI, as necessary.
- EHS – identify items that require chemical-, biological-, or radiological-hazard forms. Check for the use of recombinant DNA, viral vectors and/or transgenic animals which requires IBC review and approval and verify laboratory safety plans.
- OACU Administrative staff – add applications to the IACUC meeting agenda; review online personnel training items (e.g., Research Registration Profile, Laboratory Worker Registration, IACUC and DCM Orientations); ensure Occupational Health Animal Handler form marked as complete; identify missing forms and attachments; and verify that frequently overlooked items are complete and/or updated.
- OACU Education and Oversight staff – review hands-on training and verify personnel handling animals have received training/certifications for techniques they will perform. Confirm that minor procedural items conform to IACUC standards.
- Chair – reviews/edits and approves suggested assignments provided by OACU Director. OACU office assists IACUC Chair with communicating assignment of primary reviewers after receiving Chair designation/approval.

Pre-review comments and concerns are compiled and entered the online form. PIs are contacted to address administrative clarifications and minor items prior to the review date. All other items remain as unresolved comments until assigned reviewers confirm these have been adequately addressed during the post-meeting process.

<u>Designated Member Review (DMR)</u>
DMR is used for selected protocols. The IACUC Chair and veterinary reviewers determine protocols which may be appropriate for DMR.

- Each IACUC member receives an email with protocols suggested for DMR and with directions to access/ review protocols online. Members are reminded to submit concerns and/or call for Full Committee Review (FCR).

- If any IACUC member calls for FCR, that process is followed.
- If no call for FCR, the protocol is assigned a designated reviewer who reviews and forwards concerns. A veterinarian consults as described below.
- Concerns are collected and entered in the online form.
- Protocols are included in the Closed Agenda for the upcoming IACUC meeting.

Full Committee Review (FCR)

The OACU Director makes suggestions for primary reviewers which the IACUC Chair accepts/approves or modifies.

- Two weeks before the IACUC meeting, the primary reviewers receive notification of their assigned applications.
- The reviewers forward their comments to the OACU staff for entry following the IACUC meeting.
- A summary of each FCR application and the major concerns of the primary and veterinary consultant are presented at the monthly IACUC meeting for discussion.
- FCR occurs during a convened meeting of a quorum of the IACUC. Following the meeting, applications requiring modifications to secure approval undergo DMR.

All members are not typically present at a meeting. So, the IACUC uses the OLAW category of 'DMR Subsequent to FCR'. All IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use 'DMR Subsequent to FCR' when modification is needed to secure approval. Any IACUC member may, at any time, request to see the revised protocol and/or request FCR of the protocol.

Veterinary Consultation

DCM veterinarians receive protocols for pre-review upon online submission.

- Prior to the IACUC meeting, the veterinarian assesses the protocol and sends an email to the PI outlining any concerns.
- The PI is invited to consult with the veterinarian to discuss any aspect of the protocol or the veterinary concerns.
- The veterinarian enters concerns into the protocol file.
- If the protocol is FCR, the major veterinary concerns are presented for discussion at the monthly meeting.

Dissemination of Documents

- One week prior to the IACUC meeting, OACU assembles materials for review including new and continuation applications.
- All IACUC members are sent email directions for accessing.
- One day prior to the IACUC meeting, OACU provides all IACUC members updated meeting materials that include changes made the previous week.

- The updated material includes a revised agenda that notes applications selected for DMR vs. FCR.
- The meeting logs and agendas are coded to highlight applications containing items of note.

Conducting IACUC Meetings and Application Review

The IACUC meets as often as necessary to discuss programmatic issues and review research proposals. Monthly meetings have been sufficient.

The Chair calls the meeting to order. The Open Agenda items include the following:

- call for any comments and approval of the previous month's open minutes
- IACUC member training topic
- review of updated/new IACUC Standards
- DCM updates

The Chair then moves to go into Closed Session during which the closed agenda items are reviewed:

- call for any comments and approval of the previous month's closed minutes
- discussion of unapproved foreign collaborations and subcontracts involving USDA-regulated species
- discussion of new or outstanding Animal Concern Reports (ACRs)
- discussion of semiannual inspections and associated categorization
- review of amendments and exceptions for FCR
- review of new/continuing FCR applications

The assigned primary reviewer presents a summary of the protocol and discusses major concerns. The veterinary consultant presents any major concerns. IACUC members who are named as PIs of a protocol or who have a conflict of interest recuse themselves by leaving the room and do not contribute to protocol discussion. During protocol review, only abstentions or dissentions are recorded. No vote count is recorded for unanimous decisions. Requests to perform procedures not conforming to accepted standards (i.e., requests for exception) are reviewed. The IACUC votes on the outcome of these requests and the outcome is documented in the meeting minutes.

In the event of a University Emergency event (e.g., pandemic, severe weather), the IACUC conducts the meeting by conference call/zoom. The IACUC has successfully used this format during the pandemic and on two occasions following storms which forced University offices to close. Each time, the IACUC conducted the conference call with a quorum of the IACUC participating. All members are given as much advance notice as possible for meetings to be conducted via teleconference. The IACUC adheres to the OLAW FAQ B8 guidance on conducting convened meetings via teleconferencing. Written meeting minutes are documented.

Justification of Species and Animal Numbers and Experimental Group Sizes
Section 3.0 of the protocol requires scientific justification for the animal species, including anatomic, physiologic, and genetic features that make the species desirable for this model. PIs contrast their selection with other available models, if applicable. Section 4.0 of the protocol covers the principles of reduction, refinement, replacement, and animal numbers. Using the specifics of the experimental plan, the PI justifies the animal number requested by indicating statistical methods, assumptions, software (tables, graphs, and/or other references) used in calculations. The protocol form queries which of the following methods are used for reducing the animal numbers. For any of the following items not checked, the PI provides a brief comment about why the option is not appropriate:

- Rational selection of group size (e.g., pilot studies to estimate variability, power analysis)
- Careful experimental design (e.g., appropriate choice of control groups)
- Maximizing the use of animals (e.g., selecting the minimal number of animals per group required for statistical verification, sharing tissues with other PIs)
- Minimizing the loss of animals (e.g., proactive post-operative care, avoidance of unintended breeding)

Weighing Potential Adverse Events against Potential Benefits
The IACUC evaluates the goals, objectives, and potential benefits of the study, described in Section 5.0.1, against the humane endpoints and potential adverse events, described in Sections 6.0.7 and 7.0, to determine if the protocol adequately justifies the use of animals for the study.

Review of Potential to Cause Pain and Distress in Animals and Alternative Methodologies
All protocols are evaluated for the potential to cause pain or distress. Animals are assigned a pain category based on the USDA pain/distress column in the USDA annual report. Section 4.1 *Alternatives to Animals Classified in USDA Pain Categories D or E* is dedicated to the PIs' consideration of alternatives to any procedure likely to produce pain or distress in USDA-regulated species and DOD or VA funded projects. The IACUC reserves the right to require any PI to conduct a search for alternatives. One of the IACUC non-scientific members is a Health Sciences librarian who assists with evaluating the key words/search terms used in literature searches to determine if the search criteria provides adequate information with respect to alternate methods, replacement, or refinement. In addition, the IACUC primary reviewer and veterinary consultants evaluate the search criteria.

Post-Meeting Processing
After the IACUC meeting, OACU consolidates comments to include all pre-review administrative, personnel, EHS, as well as the primary reviewer and veterinary comments and comments generated during the meeting. Once the PI addresses

concerns, the revised protocol is returned to the appropriate designated reviewer(s). As the reviewer(s) indicate(s) resolution of each comment, OACU documents the information. This process continues until each reviewer is satisfied with the changes, at which point the reviewer sends an email confirming approval of the revised protocol. If any reviewer requests modifications, the other reviewers are apprised. If a protocol has more than one reviewer, reviewers receive identical versions of the protocol and should be unanimous in decision. Revised applications deemed not approvable are referred to FCR.

Application Approval
The PI is sent a notification letter indicating the application has been approved and can be viewed and accessed online. The approved protocol the approval date, expiration date and the IACUC Chair's electronic signature.

Grant Congruency Reviews
Prior to the award of funds, congruency reviews are performed for NIH/DOD proposals and awards from sponsors that follow NIH Policy [e.g., National Science Foundation (NSF), American Cancer Society (ACS), American Heart Association (AHA), Department of Veterans' Affairs (VA), Cystic Fibrosis Foundation (CFF), March of Dimes (MOD), and USDA National Institute of Food and Agriculture.]

Protocol Monitoring
Approved protocols that require additional oversight are placed on "Protocol Monitoring" and tracked by OACU. E&O sets a deadline to follow-up with the necessary parties. This method of monitoring is primarily used when a PI works with a USDA-regulated or unconventional species and the animals are received prior to conducting hands-on training. It is also used when the IACUC or veterinarians request to observe a procedure the first time it is performed.

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.

Most significant changes are handled by DMR after all members have received an electronic copy of the amendment to be reviewed and after all members can call for FCR. Any request for FCR of an amendment, results in FCR. If no member requests FCR, the IACUC Chair designates himself or appoints one or more qualified IACUC members to serve as the designated reviewer(s).

Upon submission, the significant change is evaluated and is processed by one of the methods described below.

Application Changes Handled by Email

- Termination of protocol
- Removal of personnel
- Change in animal housing location

Significant Changes to an Approved Application Requiring the Submission of an Amendment

Handled by DMR

- Addition of new procedures
- Change in specific study objectives
- Addition of rodent strains that have significant health phenotypes
- PI transfer from one qualified UNC-CH faculty member to another
- Change(s) in the degree of invasiveness of a procedure or in the degree of pain/distress an animal may experience (Note: changes to painful/distressful procedures involving USDA covered species require an updated literature search)
- Unanticipated or marked increase in clinical signs or animal deaths
- Addition of a non-survival or survival surgery when the original application does not include surgery (assessed case-by-case to determine need for FCR)

Handled by FCR (anything that an IACUC member requests for FCR)

- Most Requests for Exception
- Most USDA-Regulated Species
- Most Pain Category E

Significant changes to an approved application which require Administrative or Veterinary Verification and Consultation

Significant changes handled by the OACU staff or IACUC Chair

- Addition of qualified personnel (other than change in PI)
- Addition of a qualified UNC-CH collaborator
- Addition of personnel technique(s)
- Addition of a specific role for already approved personnel (e.g., LAC, surgeon, etc.)
- Increase in animal numbers not exceeding 25% of originally approved number (does not apply to requests for a change in animal species or for amendments with changes in study objectives or health status of the animals or for which additional procedures are included)

Significant Changes handled administratively according to IACUC-reviewed and -approved policies/standards in consultation with an authorized veterinarian*

- Changes in the use of anesthetics, analgesics, sedatives/tranquilizers (drugs should be listed in the IACUC-approved drug formulary), or experimental compounds

- Changes in euthanasia to any method approved in the 2020 *AVMA Guidelines for the Euthanasia of Animals*
- Changes in the duration, frequency, type, or number of procedures performed on an animal
- Addition or change of a collaborator or an approved core facility and any associated changes in housing location, or location where procedures will be performed

Significant Changes Requiring Submission of a New Protocol

- Change in animal species (exception: when multiple species [e.g., fish, wild birds] are described in the protocol)
- Change in overall purpose of a study
- Greater than 25% increase in the number of animals indicated in the original approved application (handled on a case-by-case basis, DMR may be allowed)

* The *University of North Carolina at Chapel Hill Standard for Amendments and Other Protocol Changes* describes the process for handling protocol changes. The *University of North Carolina at Chapel Hill Standard on Significant Changes to Protocols: Standard on Veterinarians Acting as Reviewers in Administrative Handling of Selected Changes to Protocols (Veterinary Verification)* describes handling of changes by the VVC process.

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.

Section 6.0.7 in the protocol describes the humane endpoints of the study. The PI provides the criteria used to determine when an animal will be euthanized or removed from the study at or prior to the study endpoint. Animals that may experience unrelieved pain or distress prior to the endpoint (as defined by the "*University of North Carolina at Chapel Hill Standard on Humane Endpoints in Rodents*") should be humanely euthanized, unless an exception to an IACUC standard is approved.

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

If humane alternative endpoints are not available or the endpoint will exceed that allowed by IACUC standards, the application should include scientific justification for not using an earlier endpoint and the criteria for euthanasia that will be used for this Exception (Section 8.0 of protocol). The Exception is included in the protocol and approved by the IACUC.

Section 6.0.2 of the protocol describes monitoring frequency and provision for after hours, weekends and holiday care. DCM Veterinary Services offers supportive care as needed and the protocol may indicate whether special monitoring has been arranged with DCM. Animals showing any of the following signs are to be euthanized by approved methods, unless an approved Exception states otherwise: inability to ambulate or maintain an upright position that prevents the animal's easy access to food and/or water; agonal breathing and cyanosis; severe muscular atrophy or other signs of emaciation (Body Condition Score ≤ 2); or severe ulceration of skin or uncontrolled bleeding.

The observation frequency is increased as animals approach the clinical sign endpoints or if the animals are experiencing increased morbidity or mortality.

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.

PIs seeking approval to conduct experiments that include humane endpoints are responsible for assigning personnel trained and experienced in recognizing signs of illness, injury, or abnormal behavior to monitor animals. Daily health monitoring is conducted by DCM husbandry staff; however, laboratory staff are expected to monitor their animals periodically during the week as well. When animals with abnormalities are identified, the case is entered into the medical records and Veterinary Services makes an assessment shortly thereafter. DCM notifies the laboratory personnel. The laboratory should promptly make an assessment. If personnel responsible for the project cannot be contacted, DCM Veterinary Services can administer care and/or euthanize the animal as needed. PIs are encouraged to determine, in advance of an emergency, what procedures should be used to care for abnormal animals.

DCM Veterinarians, veterinary technical, and husbandry management round on weekly basis (or as often as needed) to discuss ongoing health problems throughout campus. DCM husbandry and veterinary technical staff are routinely trained to recognize health abnormalities in various animal species. DCM SOPs outline how staff should assess and identify health cases, perform proper documentation, enter information, and collaborate or communicate regarding these cases.

With appropriate training and ongoing oversight (e.g., veterinary services frequent rounding, monthly staff meetings, Q&A performed by DCM training staff, and IACUC facility inspections), DCM staff are able to evaluate abnormalities and communicate observations to begin the appropriate treatment(s) and/or help determine study-specific endpoints.

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.

Expected conditions or complications should be detailed in the protocol in Section 7.0. This section indicates, "Unexpected deaths and signs of illness, distress or other deviations from normal in animals should be reported promptly and investigated, as necessary, to ensure appropriate and timely delivery of veterinary medical care. Any unexpected outcome as a result of the experimental manipulation of the animals or due to animal phenotype [Genetically Modified Animal (GMA)] should be reported to the IACUC by submission of a protocol amendment detailing the unexpected outcome and the corrective action that will be put in place to prevent the unexpected outcome from re-occurring."

If the rate of occurrence of expected conditions exceeds what is anticipated, the PI should notify the IACUC and amend the application accordingly. If unexpected adverse events have occurred, the application should describe measures to minimize these occurrences and corrective actions should be developed with veterinary consultation. Additionally, E&O, IACUC members, and DCM veterinarians review records and inquire about any adverse events during semiannual inspections.

The protocol annual review form for USDA-regulated species asks the PI to describe any major unexpected events, complications or deaths associated with the experimental treatments or animal phenotype. Unexpected deaths, signs of illness, distress, or other deviations from normal in animals should be reported to DCM veterinary services promptly and investigated, as necessary, to ensure appropriate and timely delivery of veterinary care.

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."

Protocol Section 5.6 is completed for prolonged physical restraint. Details regarding brief restraint for routine clinical or experimental procedures such as injection of drugs, blood withdrawal, or procedures with anesthetized animals are not included. The PI provides the information below in the protocol.

- Location where procedures will be conducted.
- Purpose of the restraint.
- Scientific justification including consideration of alternatives to physical restraint, such as the use of positive reinforcement or systems that do not limit an animal's ability to make normal postural adjustments.
- Describe restraint to ensure proper size, design, and operation to minimize discomfort, pain, distress, and the potential for injury to the animal and the research staff.
- Time length of restraint.
- Acclimation to the restraint method.
- Criteria and clinical signs used to determine that the animals should be released from the restraint device.
- Animal care provided during the period of restraint, including how often animals will be observed and how animals will be monitored.
- Course of action if the animal shows signs of distress or clinical abnormalities.
- Non-human primates - the plan for providing special attention to environmental enrichment during the period of restraint.

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.

Prolonged restraint is avoided unless it is essential for achieving research objectives. Trained staff should closely observe animals to ensure that the animal adapts to the restraint device. When possible, animals are given positive reinforcement and undergo acclimation to adapt to the equipment and research personnel. If the animal fails to adapt to the restraint training or develops lesions or illness, the animal should be removed immediately from the study and veterinary care provided. All animals are included in the animal enrichment program and monitored for severe behavioral changes/abnormalities. Behavioral concerns should be reported to vet services to determine if animals

need temporary or permanent removal from the study or if modification of training and/or restraint device is required to proceed with the study.

Appendix not provided.

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.

Protocol Section 5.3 includes Survival Surgery and asks for details regarding multiple survival surgeries. Multiple survival surgeries on the same animal are discouraged unless the practice is scientifically and/or humanely justified (i.e., related components of a research project, conservation of scarce animal resources, veterinary care reasons). PIs clarify whether animals are subjected to more than one survival surgical procedure for the study. If so, they provide a scientific justification and indicate how many survival surgeries will be conducted on each animal. In addition, the protocol should include any pain, distress or functional deficit that may result from the multiple procedures and a description for how distress will be minimized.

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.

The IACUC procedure for approval of protocols with multiple survival surgery includes veterinary pre-review, review of available alternatives (for USDA-regulated species, DOD, VA) and appropriate analgesia and anesthesia. During protocol review, the IACUC evaluates the scientific justification and other information to determine the impact of the multiple survival surgeries on the animal's well-being. Review criteria are the following: rationale and scientific justification for each procedure; potential stress of each procedure on the animal; recovery time between surgeries; and post-surgical care.

Appendix not provided.

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.

Protocol Section 6.1, Dietary Manipulations, Food or Fluid Restriction/Regulation describes caloric or nutrient restrictions or excesses. If food will be restricted, the protocol requests a description of the duration, a scientific justification, and the monitoring strategies to ensure animals do not experience unnecessary distress. Body weight monitoring and maintenance of body weight log should be kept. These records are reviewed as part of the semiannual inspection.

If animals are provided less than ad lib fluids or drinking water for experimental reasons, the protocol includes details regarding the amount/day, monitoring, criteria used to determine well-being of animals, and scientific justification. Monitoring documentation is reviewed as part of the semiannual inspection.

DCM husbandry staff and research facility personnel observe animals daily. Abnormalities or health concerns are noted and reported to veterinary services. Daily food and fluid consumption and behavioral/clinical changes are noted. When animals are on special diet or water (including restriction), individual cages are identified with a "PI Will Feed and/or Water" cage card and a "Principal Investigator Duties to be Performed Check Sheet" is posted in the animal room and completed by lab personnel. During daily husbandry rounds, technicians review the check sheet to ensure that the lab is providing feed and water.

If there is a concern regarding nutrition or hydration, additional steps should be instituted to ensure animal well-being (e.g., increase monitoring frequency of body weight, food and fluid consumption, hydration status, and behavioral/clinical changes) to determine whether animals should be treated or removed from study. If animals are demonstrating signs of illness or if there are concerns, DCM husbandry technicians contact the researchers and Veterinary Services.

Appendix not provided

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.

If the protocol includes a Non-Pharmaceutical Grade (NPG) agent, the PI should consider the grade, purity, sterility, pH, pyrogenicity, and pharmacokinetics of the agent, as well as animal welfare and scientific issues. The use of NPG compounds in animals is based on scientific necessity, lack of availability of an acceptable veterinary or human pharmaceutical-grade compound, and specific review and approval by the IACUC. Cost savings alone is not typically a justification for the use of NPG agents except, as indicated by OLAW, in cases such as pentobarbital where "exorbitant cost increases of pentobarbital have placed it logistically into the unavailable category. Pentobarbital from a reagent or analytical-grade powder, properly prepared by a pharmacist or other knowledgeable individual (e.g., chemist, veterinarian, researcher), with assurance of appropriate storage and handling, and approval by the IACUC is acceptable."

The protocol Section 11.3 includes NPG compounds used. One or more of the following should be checked as scientific justification:

- Current lack of availability of a comparable pharmaceutical grade compound; switch to the pharmaceutical grade compound when available.
- Required for comparison to previous studies in which the compounds have been shown to be generally safe and efficacious.
- The compound has been shown to be generally safe and efficacious and is used in ongoing studies and is required for comparison purposes.
- Available formulations contain substances that would compromise the scientific validity of the study.
- Specify and justify any other reasons.

If NPG compounds, such as investigational, experimental, or novel test compounds (not including analgesics, anesthetics, or euthanasia agents) will be administered, the PI checks the appropriate scientific justification from the list below.

- The goal of these experiments is to examine the effects produced by these compounds.
- Current lack of availability of a comparable pharmaceutical grade compound.
- Required for comparison to previous studies.
- Currently being used in ongoing studies and are required for comparison purposes.
- Available formulations contain substances that would compromise the scientific validity of the study or available formulations are not suitable for preparation as an injection.
- Other (specify)

For all NPG compounds used, the protocol should include assurance that the steps below are taken. Scientific justification should be provided if these criteria will not be followed.

- The method of drug preparation and storage conditions will ensure sterility of the drug.
- Drugs (including solvents and compounding) will meet established documentable standards of purity and composition of the final product (i.e., sterility, pyrogenicity, stability, pH, osmolality)
- For orally administered drugs, the vehicles or diluent will be food grade, and for drugs administered.

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.

If the proposed research involves field investigations, a progress summary describing work conducted during the past year is required and the protocol requires the following:

- If the work requires state, federal or foreign permits, the PI attaches a copy to the protocol and/or indicates the dates of permit application and addresses of the agencies to which applications were made.
- Indicate the location where animals range naturally.
- If the research may affect the survival or reproduction of the animal, explain the anticipated impact on the population/species studied and the alternatives considered.
- Describe the method of capture and cite the literature reference if the method is standard procedure or complete details if it is a non-standard method.
- Provide an estimate of the expected mortality for each capture method.

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

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

PIs are strongly discouraged from reusing animals as a reduction strategy. Reduction should not be a rationale for reusing an animal that has already undergone experimental procedures, especially if the animal's well-being could be compromised. In addition, the ACAP form and the USDA-regulated species annual renewal form ask whether animals were used on multiple protocols. If the PI answers 'yes', the PI indicates the procedures performed and a scientific justification for using animals under multiple protocols.

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.

In a limited number of cases there is sequential use of a single animal (pig) in serial imaging studies by 2-3 PIs, each of which has their own approved protocol a non-survival surgical procedure being the last procedure. Each procedure occurs immediately after the other, under the same (continuous) anesthetic episode. All 3 PIs have approved non-survival protocols. The animal is anesthetized once and euthanized under general anesthesia at the end of the final procedure. Veterinary Services provides anesthetic support and monitoring for all three procedures.

UNC-CH is home to the state-of-art imaging equipment, including whole body PET/MR and PET/CT imaging systems. In 2016, studies were initiated to utilize this imagining system to examine the ability of C-11 labeled PET imaging agents to identify mood-related neural receptors in terms of their biodistribution and receptor binding specificity using a non-human primate model. At termination of this study the animals were transferred to a large animal imaging core protocol where they are occasionally used for non-invasive CT or MRI imaging studies. These same animals are infrequently transferred to other protocols utilizing non-invasive CT or MRI imaging studies. As there are currently no clinical methods to non-invasively measure adipose tissue mass other than post-mortem histology, this study holds significant promise for a wide range of future studies evaluating intervention strategies for obesity.

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.

The IACUC strongly encourages PIs to pursue companion animal adoption when suitable research animals are no longer appropriate for research/teaching. However, the IACUC recognizes that adoption cannot be accomplished for all companion animals, nor is it deemed appropriate for animals with certain health conditions or those exposed to experimental conditions that could potentially jeopardize human health or the animal's health or ability to thrive in a new environment. If feasible, after veterinarian approval and consultation with the PI, animal adoption is evaluated and approved by a DCM Veterinarian (e.g., adoption may be appropriate for one healthy animal in a litter, but not for the entire litter).

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).

The IACUC meets as often as necessary to review new and continuing research protocols, amendments, and any required annual renewals. Currently, monthly meetings are sufficient to meet needs.

The protocol is reviewed initially and at least once every three years by either FCR or DMR. Most amendments are reviewed by DMR. Any IACUC member may request FCR and certain circumstances (e.g., requests for something outside of accepted standards) automatically warrant FCR.

Only applications for USDA-regulated species and projects funded by the DOD or VA are reviewed annually by the IACUC.

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

Every six months, an IACUC subcommittee (consisting of the IACUC Chair, at least two other IACUC members, the AV or DCM veterinary representative, EHS representative, the IO [and/or designee] and OACU staff members) meets to review the animal care and use program. All IACUC members receive an invitation to attend the program review meeting and the agenda.

The Chair leads the meeting and uses a version of the OLAW Program and Facility Review Checklist consistent with the *Guide* 8th edition. DCM veterinarians present aspects of veterinary care and husbandry and rodent hands-on training information; OACU staff review administrative processes, grant congruency information, IT improvements, personnel training items, compliance issues and investigations of concerns involving animal care and use; EHS representatives review handling of hazardous agents and occupational health issues pertaining to animal handlers; and the IO provides administrative updates. At the next scheduled IACUC meeting attended by a quorum of the IACUC, the Chair presents a summary of essential points discussed at the IACUC program review. Members vote whether to accept the recommendations of the subcommittee. In addition, a portion of each IACUC meeting agenda involves review and discussion of programmatic issues.

Throughout the year, on a staggered schedule, the IACUC performs semiannual inspections of DCM facilities, PI laboratories where animal procedures are conducted, and PI-maintained satellite housing facilities. Each active area receives an inspection every six months. No facilities are exempted from review unless no animals have been used or housed during the previous six months. The E&O team leaders record IACUC

comments during inspections, compile comments, and prepare the inspection reports. At each IACUC meeting, IACUC members receive copies of the DCM facility inspections conducted that month and EOCs present details of any deficiencies cited in PI laboratory inspections. In addition, at the end of each six-month cycle, the OACU compiles the inspection reports conducted into the Semiannual Facility Inspection Report for IACUC review during the Semiannual Animal Care Program Review. The final approved Semiannual Program Review and Facility Inspection report is delivered electronically to the IO with a cover letter which summarizes findings and recommendations.

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**. (Note: due to the size of this document, it is included as a separate attachment rather than an Appendix.)

Appendix not provided

Current Post Approval Monitoring (PAM) at UNC-CH:

- DCM Animal Facility Semiannual Inspections - conducted every six months with a team of IACUC members, DCM veterinarians, OACU members, DCM operation and facility managers and EHS representatives.
- PI Laboratory Semiannual Inspections - conducted in labs approved for Animal Procedural Space Exceptions (i.e., laboratory areas where a limited number of animals are kept short-term) or where survival or non-survival surgery, pain category E, aversive conditioning, or major procedures are performed. At least two IACUC members (one being a veterinarian) accompany the EOC on every lab visit involving a USDA-regulated species to ensure adequate record review and oversight. Following DCM facility inspections, one or two of the IACUC team members accompanies the EOC on PI laboratory inspections in the same or nearby building. During the inspection, EOCs lead the discussion with the laboratory member to review the procedure(s), status of animal handler training/certification, enrollment in occupational health, and anesthetic, analgesic and euthanasia agents (pharmaceutical grade, dose, route, frequency, expiration, and security). EOCs use a laboratory inspection checklist to guide the inspection.
- Satellite Housing Facility Inspections – PI-managed housing areas (i.e., Satellite Facilities) are inspected at least semiannually and generally on a quarterly basis. The focus of the satellite inspection is animal care,

maintenance of husbandry records, and physical plant. There is DCM veterinary representation on each satellite facility inspection at least annually.

- PI Laboratory Bi-annual Informational Visits (for labs performing minor procedures such as injections, blood withdrawal, euthanasia or when work is performed in DCM/Core space and not PI's laboratory) - the focus is on training and updating the laboratory on IACUC standards and procedures. The same inspection checklist used for the semiannual inspections guides the discussion.
- Procedural Observations – conducted in labs performing survival or non-survival surgical procedures. Laboratory personnel are observed every 3 years or more frequently if there is a new surgical procedure or new personnel performing the procedure.

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.

USDA Inspections
June 13-14, 2017 – no non-compliant items
May 14, 2018 – no non-compliant items
August 28, 2019 - no non-compliant items

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

Procedural Observations and Training
OACU conducts PAM and Procedural Observations for survival and non-survival surgery, pain category E and aversive behavioral conditioning. The focus of the Procedural is to view the researcher conduct a mock procedure to ensure qualifications and compliance with the approved protocol and institutional policies. Upon successful completion of a Procedural, future observations will occur approximately every 3 years (or sooner if there has been turnover of laboratory personnel). The Procedural does not take the place of the semiannual inspection; however, it may be conducted at the same time. The frequency of the Procedural may increase due to reports from DCM, IACUC, or questions raised during protocol review.

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

Mechanisms that facilitate individuals to report concerns:

To increase awareness of the reporting mechanism, the IACUC posts *Reporting Animal Mistreatment or Animal Protocol Noncompliance* fliers in prominent locations in the DCM animal facilities, in PI laboratories where animal work is conducted and on the institutional website. The flier includes instructions for how and to whom to report a concern. Multiple points of contact (email, website, office locations, and phone numbers) are provided including the IACUC and OACU, the University Research Compliance Officer, and the Ethics Hotline (an anonymous reporting service). The reporting process allows for anonymity, compliance with applicable whistleblower policies, non-discrimination against the concerned or reporting party, and protection from reprisal.

How the IACUC reviews reported concerns:
Concerns and self-reports are initially triaged by the OACU which requests written feedback from the PI regarding the allegation. OACU sends an initial notification regarding the concern, with all identifying information redacted, to the IO, AV, Office of University Counsel, University Research Compliance Office, IACUC Chair, and OACU Director. OACU provides an investigation summary and the PI's response to the Animal Concern Subcommittee (ACS), a designated IACUC subcommittee responsible for reviewing animal concerns/non-compliance and making recommendations to the IACUC. The ACS, which consists of the IACUC Chair, the AV, OACU Director, two other IACUC members as well as alternate members, provides its recommendations and further questions for investigation.

OACU prepares Part 1 of the IACUC Animal Concern Report (ACR). ACR Part 1 summarizes the following: 1) Complaint/Allegation; 2) Steps Taken During Allegation; 3) Pertinent Information Provided by PI; 4) Detail for Each Allegation; and 5) Conclusions and Subcommittee Recommendations. Part 1 is sent to the ACS, PI, and the same individuals noted above for the initial email notification. In addition, if the ACS has recommended that the issue is reportable, a verbal report is made to OLAW and/or USDA. IACUC members receive Part 1 for review and discussion at the next meeting. The IACUC reviews the report and ACS recommendations, deliberates, makes any modifications it deems necessary, and votes whether to accept the report and close the concern or to delay final action until a later time.

After receiving all necessary input and follow-up from the IACUC, OACU prepares a final document for the IO to review and sign. If reportable, the signed report is sent to the PI, AV, Office of University Counsel, University Research Compliance Office, IACUC Chair, OACU Director and OLAW. The institution contacts AAALAC to inform the executive office when an ACR involves programmatic or sensitive issues.

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.

The University Disaster Plan for the Animal Program is maintained by DCM. The DCM Director, EHS Director, SOM Director of Planning, and UNC-CH Director of Facilities meet routinely to discuss current animal facilities and pending issues. UNC Police or UNC-CH Facilities Services personnel will contact the DCM should an emergency occur that involves research animal buildings and both units have designated staff dedicated to UNC-CH's animal program. DCM leadership is included on all emergency contact lists and listserv to alert of campus issues, planned and unplanned outages, and emergencies.

Designated DCM Staff are listed in an Emergency and Off-Hours contact phone list. For after-hours emergencies on weekends and holidays, Animal Husbandry on-call or Veterinary Care Supervisor on-call is contacted. In instances where a DCM employee discovers a potential emergency, he or she immediately contacts UNC-CH Police and, when out of harm's way, a senior DCM official.

The building supervisor (or Senior Division Official onsite) acting as Evacuation Monitor should round through the building to make sure all personnel have left. He/she should meet at the pre-arranged location to assure that all staff are accounted for and should report to the Incident Command Post. The Evacuation Monitor should also notify the Director and/or AOD of the situation. Almost all animal facilities are equipped with sprinkler systems. The building supervisor, acting as Evacuation Monitor should round through the building to make sure all personnel have left. He or she should meet at the pre-arranged location to assure that all staff are accounted for and should report to the Emergency Command Center. The Evacuation Monitor should also notify the Director and/or AOD of the situation. On-campus animal facilities are equipped with sprinkler systems.

Winter storms, though infrequent, can cause significant disruption to animal care routines, limiting staff ability to travel to the work site. Although not likely, a winter storm could damage utility services. Usually there is advance warning with a winter storm. So, staff has time to prepare, making sure all water bottles and feeders are filled, sufficient supplies are present.

The University's electrical infrastructure is such that the chance of complete electrical power loss for an extended time is minimized. Three electrical substations provide redundancy with the ability to transfer the power load to the other stations should one substation go down. In addition, supply lines from Carolina Power and Light are underground, limiting possible disruption. The Co-generation Facility, used primarily for steam, also can generate 50% of the electrical needs of the campus. These systems worked well in past emergency situations when UNC-CH lost power for less than an hour while the surrounding community was without for days. Chances are any electrical outages would be of short duration. Animal facilities have emergency generators providing power

for building exhaust and supply fans as well as some building lighting. The University has a 10,000-gallon storage tank of generator fuel to maintain operation. Redundancy is built into most steam and chilled water distribution lines with more than one route available to each building.

The University's water tower provides a ready supply of water and proved invaluable during Hurricane Fran when flooding and inadequate back-up systems caused Orange Water and Sewer Authority (OWASA) to lose its processing and pumping capabilities. The community lost water services for several days, while the University maintained a steady supply. OWASA, with the help of the University has worked to make its systems more redundant. If notified of an impending emergency, all available water bottles will be filled prior to the event and DCM has a 600-gallon storage tank specifically for emergency water purposes to service campus facilities. Bottled water may be purchased, and water conservation measures will be instituted. Offsite facilities are on well water or have a 275-gallon water tote that will be filled and driven on a trailer. The animal facilities are second only to UNC hospitals for emergency supplies.

Each animal facility has sufficient supplies of feed and bedding for one to two weeks. Spot changing of rodent caging would replace routine cage changing schedules and feed and water would be topped off rather than discarding partially full bins and bottles. The University's Central and Scientific Storerooms stock bedding and most husbandry supplies for DCM with enough inventory for at least a month. DCM's feed vendor ensures feed will be accessible from a different warehouse sources throughout the U.S. should additional feed be needed.

In case of any type of emergency where animals need to be relocated, they will be transported to other facilities via one of the ten climate-controlled vehicles available for transportation of animals. The vehicle is appropriately warmed or cooled before introducing animals, and climate control (65 to 75 degrees) maintained throughout transportation and off-loading. DCM has several climate-controlled vehicles with 4 wheel or all-wheel drive capability. The large International trucks can fit up to eight 34" by 37" transport cages in the rear. Entire racks of mice can be moved by this truck, with straps available to secure cages on shelves. DCM has planned in the past with other academic programs to house animals if needed during a disaster.

Animals will be moved to a facility that is comparable in health status. The Director, Associate Director of Veterinary Services or (ranking veterinarian in case of emergency) will be consulted regarding current viral status of buildings before animals are moved. The animal rooms should be evacuated in room order and animals with biological hazards are to be moved last and transported separately.

Animal rights activism can manifest itself in many ways: picketing outside an animal facility or research lab, infiltration of animal facility or research staff, sabotage of research activities, etc. DCM staff and researchers are encouraged to report suspicious persons or activity immediately to UNC Police. The Senior Division Official should also contact the

IACUC, IO/VCR, and UNC Police to report the incident. These senior administrative officials shall decide whether the emergency should be reported to NIH's OLAW, the USDA Animal Care Regional Office or AAALAC.

The USSC is responsible for reviewing and approving DCM's Disaster Plan and the DCM Director is often included in Campus Safety & Risk Management Emergency Preparedness Table-Top exercises.

is a member of the USSC.
is a primary member of the IACUC. A copy of DCM's Disaster Plan and SOP will be available for review during the site visit.

II. Animal Environment, Housing and Management

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

Each room has a temperature and humidity sensor that is tied to a Building Automation System (BAS). There is a central group called Energy Management Control System (EMCS) within UNC Facilities Services that monitors data sent by building BAS systems. If temperature or humidity readings drop or increase above a set point EMCS is alerted. In addition, DCM has an annual contract with Johnson Controls Incorporated that provides annual commissioning of sensors and monitoring 24/7/365 of DCM buildings. DCM vivaria have designated senior husbandry personnel that receive notifications when temperatures or humidity are out of range. When a problem is found after hours personnel can call emergency staff that is on-call.

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]

Appendix not provided
Campus facilities services monitor temperature of the supply air and the operation/function of the air handlers for all animal facilities. The animal housing set-points are monitored to not exceed the *Guide* recommended ranges for that species. DCM has monitoring software that is maintained by Johnson Controls Inc. (JCI) automated environmental monitoring system. This system continuously monitors the temperature and humidity of the animal rooms and reports any deficiencies via email to the DCM building supervisors and is monitored by UNC-CH facilities services. One facility has the Edstrom Watchdog system for each of the animal holding rooms. In addition, there is a manual monitoring program for all animal rooms whereby husbandry staff check digital high/low thermometers each day and record values in the husbandry log. DCM has an SOP which describes the appropriate action if high/ low temperature has exceeded the acceptable range. Some satellite facilities that are currently monitored only by the manual in room monitoring system.

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]

Most animal room environmental conditions are remotely monitored, and personnel alerted if rooms are outside the thermoneutral zone of the housed species. Animal rooms not on remote monitoring systems are manually checked as needed (e.g., at least daily) to ensure that animals are not stressed or in danger. Nesting material is provided for all rodent and small mammal species. If animal rooms were unable to maintain appropriate temperatures, DCM would work with facilities to provide supplemental heating or cooling. In addition, bedding (e.g. pine shavings for dogs) and evaporative coolers (e.g. swine) are provided for animals to aide in behavioral thermoregulation as needed. If necessary, animals would be relocated per DCM's disaster plan.

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.

Ventilation rates for animal rooms should be at least 10-12 air changes per hour. More than 99% of rodents are housed in Tecniplast ventilated cages. Facility services measures the air exchange rates for animal rooms at least every three years in

preparation for the AAALAC site visit and anytime if there are renovations or questions/concerns regarding room ventilation or if the DCM facility has been modified. Some facilities are equipped to monitor air changes per hour remotely.

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

DCM has Tecniplast ventilated racks for mice and rats that provide 70-75 air changes per hour in each animal cage. HEPA filtered exhaust air from the Tecniplast units are vented into the animal room in most facilities where the IVC racks are directed into soffits and/or ducted out of the rooms. In one facility there are colonies of gnotobiotic mice housed in flexible film isolators.

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.

The air supply for all animal housing areas is 100% fresh – none-recycled.

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).

Zebrafish species
Fish are housed in aquaria of various sizes and manufactured by Tecniplast or Aquatic Enterprises. These racks are recirculating rack systems that constantly monitor the water quality including the water temperature, pH, and conductivity. The water quality readings will display on the touch screen of each system control. The Main zebrafish facility uses four sizes of plastic housing tanks (0.7 Liter- 8 Liter). The two-rack linked Aquarius System in the Quarantine room uses two sizes of plastic housing tanks (2L-4L). The facility is undergoing another expansion this fall to increase the facility to include an 800-tank multilink recirculating rack system.

Technicians document each task completed on the Zebrafish Feeding Log, the Daily Check List, and Weekly Checklist in each room, after the work has been completed. The logs are reviewed, initialed, and dated by the DCM Zebrafish Core Supervisor at least once each week.

Other fish species
Ocean fish are housed in a research facility on the coast of NC. The facility has both holding rooms and several outdoor tanks and ponds. Water is provided to aquaria and tanks/ponds via a flow through pump system that circulates ocean water from the nearby sound to the enclosures (including aquaria) and then returns effluent water to the ocean. Animals are housed there infrequently; however, regardless a Facility

Manager manages the flow system and coordinates with DCM on repairs. Holding tanks vary but are typically 4.3m (length) x 1.2m (width) x 0.5m (depth). Researchers check their animal daily and scrub the holding tanks between experiments as needed.

Turtles
Turtles are housed one per 48-gallon holding tank until they are released at about 11 months of age. Each culture tank is 18" long x 18" high x 36" wide with either an acrylic or tempered glass window that is 17.5" x 17.5" on the 18" x 18" side. The tanks are constructed of fiberglass with an epoxy gel-coated interior. Artificial sea water for the system is made by dissolving a marine salt mix in distilled water to the appropriate concentration. The distilled water is produced and stored onsite and is accessed in the facility by a dedicated supply line. Water circulates continuously between the sump tank and the holding tanks at a rate of between 36.6 and 48.8 gpm. Aquarium water is filtered by mechanical, biological, and photochemical (UV sterilizer) means. A five percent water change is performed weekly.

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).

Zebrafish
The maximum density depends on the size of the tank and the age of the fish: 25-50 embryos per plate, 25-50 larvae per tank (which get dispersed to new tanks as they grow), and 5 adult fish per liter.

Regardless of location, water source is municipal water that is Carbon and RO-filtered and UV-sterilized before being supplied to the system. Automatic sensors track pH and salinity and the addition of bicarbonate and Ocean Sea Salt to maintain pH and salinity within parameters is automated within the system. Mechanical filters are changed as needed (usually monthly), and UV bulbs are changed every 12 months. Water is monitored weekly for pH, conductivity, ammonia, nitrates, nitrites and daily for temperature. Because of the design that adds some water continually to each tank, most waste and debris is continually removed to help the aquaria clean. A 10% water change is performed daily. Aquaria are sanitized as often as necessary to maintain aquaria free of debris and are sanitized by scrubbing algae/debris and washing in a dishwasher with dilute bleach.

Temperature: All systems have in-tank heaters and temperature probes located in the sump. The Main system has a backup heater as well. pH: Each system monitors and automatically doses a solution of 30 g/L sodium bicarbonate in RO water as needed. Conductivity: Each system monitors and automatically doses a solution of 30 g/L sea salt in RO water as needed. Ammonia is monitored weekly using a liquid test kit (API or LaMotte) and measured against a colorimetric grid. Ammonia levels are monitored

every day in newly established systems. Alkalinity, hardness, nitrate, free/total residual chlorine, dissolved oxygen is monitored weekly using a liquid test kit (API or LaMotte) and measured against a colorimetric grid.

Sump tanks are checked quarterly and siphoned as necessary to remove accumulated waste in the system.

- Mechanical filters are checked monthly and changed as needed (generally need to be changed quarterly) according to manufacturer recommendations.
- Carbon filters are checked monthly and changed as needed (generally need to be changed quarterly) according to manufacturer recommendations.
- UV sterilization bulbs are changed as needed according to manufacturer recommendations (generally every 12 months)
- Probes are recalibrated according to the manufacturer recommendations (pH probes quarterly and every six months for the conductivity probes).
- Aquarius Racks: require extra maintenance as follows:
    - Sump screens are replaced daily, flushed with RO water and air dried.
    - The 50 and 80 µm filters are replaced weekly, scrubbed with RO water, disinfected with bleach for 20 min, soaked in RO water for 20 min, rinsed with RO water, and allowed to air dry.

Other fish species

The unique environment, the Croatan-Albemarle-Pamlico Estuarine System, is the second largest estuarine system in the U.S. and an ideal site to study the ecology, conservation, and restoration of coastal marine resources and to develop and apply new technologies in research. For the waterfront property on the North Carolina coast, water is provided to aquaria and tanks/ponds via a flow through pump system that circulates ocean water from the nearby Bogue sound to the enclosures (including aquaria) and then returns effluent water to the ocean. The water quality reflects what is occurring in the ocean water on a constant flow-through system. Mechanical filtration excludes debris from the flow through system and tanks. Housing density can vary from 1-50 fish/ 2000 liters. Feed varies depending on study type and species housed but most studies are involved in foraging/ grazing behavior and natural diets are preferred. Enclosures are cleaned when studies are completed. Security is maintained by locked doors.

Aquatic Turtles

Temperature and humidity are monitored and recorded daily. Lighting is controlled by automated timers. Continuous filtration of aquarium water is provided by four different methods. Mechanical filtration is provided by three 25-micron needled felt filter bags and a protein skimmer. Biological filtration is provided by the nitrifying bacteria that populate the biological filter. Photochemical filtration is provided by a UV sterilizer. When aquarium water pH drops to 8.0 or lower, Seachem Marine Buffer is added to increase buffering capacity. The frequency of buffer addition varies widely and depends on system bioload. As the turtles grow and eat larger quantities of food, buffer addition is done more frequently. A five percent water change is

performed weekly to remove nitrates. Salinity is monitored daily using a hydrometer. Salinity is measured daily by hand, and ammonia, nitrite, nitrate, alkalinity, and pH levels are measured weekly using Lifegard brand test strips. Each week, any visible detritus is removed from the holding tanks using gravel vacuums and nets, and all interior surfaces are cleaned using sponges and brushes.

Water containing detritus that is removed by the gravel vacuum is filtered through a 25-micron needled felt filter bag, and the filtered water is returned to the system. Any floating detritus is removed with a fine-meshed net. The walls, bottoms, and windows of the tank interiors, as well as the water inlet pipes, are subsequently wiped down using scrubber sponges and soft-bristled toothbrushes dedicated for interior tank cleaning. The standpipes are removed and cleaned in the sink under running tap water using a scrubber sponge, bottle brush, and soft-bristled toothbrush dedicated for interior tank-cleaning. The tank exteriors are cleaned using hot tap water and sponges dedicated for exterior tank cleaning. The filter bags are rinsed with a spray nozzle in the sink and then soaked in hot tap water and a cup of chlorine bleach inside a dedicated 2.5-cubic-foot capacity washing machine for at least 48 hours overnight and subsequently put through a wash cycle and air-dried. Any animal waste removed with a net is disposed of by washing it down the sink drain and into the sewage system. The turtles are released into the ocean before they have reached 30 months of age. A thorough cleaning of the system is performed at the end of the study using dilute bleach.

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.

Separation of noisy husbandry practices (e.g. cage wash, breakrooms) and animal holding areas minimizes disturbances to both human and animal occupants of the facility. When possible, noisy animals, such as dogs, swine, and nonhuman primates, are housed away from quieter animals, such as rodents and rabbits. Most animal room walls are made of masonry brick that allow containment of sound and vibration. Radios, alarms, and other sound generators are not used in animal rooms unless they are part of an approved protocol or enrichment program.

Ventilated rodent housing systems are without moving components, such as ventilated caging systems with blowers located on the racks. The Zebrafish Centralized Life Support (CLS) systems are housed either outside of general housing and/or are located on palletized isolation pad to prevent transmission of vibration and noise. The CLS noise levels have been studied and found to be below the normal water flow sounds generated by the 22+ racks of tanks. Regardless, a sound barrier curtain was constructed to surround the CLS to further reduce the noise level in the holding room.

Attempts are made to minimize the generation of vibration, including from construction projects and renovations, and if excessive, animals are relocated to other facilities. If

relocation is not possible, the renovation schedule is frequently communicated to researchers to prevent disruption of studies.

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 conforms to the *Guide* and the *Ag Guide* to determine adequacy of space. The institution complies with these standards in most cases. The *ETS 123* does have a species-specific section for ferrets which helped inform our current SOPs and housing guidelines. Species-specific details are included in individual housing SOPs.

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 reviews each exception to the *Guide* as well as exceptions to institutional policy/standards as part of the IACUC protocol review. For mouse cage space, since 2004 the institution has had a performance-based standard outside of *Guide* recommendations for the cage density of breeding mice. The IACUC assesses this performance-based item at semiannual program review and continues to endorse density as described in the *UNC-CH Mouse Cage Density Standard* based on more than 15 years of data including litter health, morbidity and mortality reports, breeding performance, activity and use of cage space, ammonia levels, and other objective criteria.

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).

Each animal enclosure should be provided with at least one enrichment item except those for which an exception has been submitted to and approved by the IACUC. All mouse and rat cages are provided with some type of environmental enrichment (including red huts, tubes, lofts, nesting material, etc.)

The *University Standard on Environmental Enrichment for Research Animals* requires that all mouse/rat breeding cages be provided with some form of nesting material and all nude mice be provided with nesting material or a red hut, platform, or shelter. Non-human primates have perches or other enclosed elevated resting areas in their enclosures. Chew chains may be provided to swine enclosures to provide manipulanda for chewing and nosing about. Rabbit cages are equipped with multi-level housing/perch areas. Dogs are provided with raised benches or beds within their enclosures*.

Species	Resting Boards/ Beds	Shelves/ Perches	Toys/ Manipulanda	Foraging Opportunities	Nesting Material	Swings	Other(Specify)
NHPs		X	X	X		X	X-(Privacy areas) Nest boxes (New Worlds)
Dogs	X*		X		X– Whelping rooms		
Rabbits		X	X	X	X- Pregnant/nursing does		
Ferrets	X- fleece cozy or hammock		X	X	X- pregnant/nursing jills		
Swine			X	X			
Rats			X**		X		X- rat tubes
Mice			X**		X		X-Huts/PVC pipe

Guinea Pigs			X		X		X***-Huts
Hamster/ Gerbil			X**		X		X-rat tubes/PVC pipe
Turtles				X			X-standpipe
Fish				X	X-spawning tanks		X-hiding places

* Type differs between facilities, not every run is provided with one. Beds may be withheld if dogs or cats are destructive to them (or urinating and defecating on them). Additionally, they may be withheld if a facility has pens large enough that allow dogs to escape soiled areas.
**May have additional enrichment (i.e., nylabone, manzanita wood) upon request or under special circumstances.
***Guinea pigs may be provided with hide boxes or huts when housed in tub style caging.
****Low density or single housed xenopus may have plastic plant material.

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).

Specifics for each species are included in the IACUC-endorsed species-specific Enhancement Plans, drafted, and maintained by the Environmental Enrichment Committee (which includes DCM Management, environmental enrichment staff, DCM Veterinarian and DCM Training staff).

The more general *University Standard on Environmental Enrichment for Research Animals* includes the following broadly described standards for each species.

- NHPs will be group housed, when possible, and provided a variety of toys, puzzles, food treats and television on a rotational basis.
- Ferrets, guinea pigs, gerbils and hamsters will be provided with at least one of the following: food treats/hay, bells, balls, hide boxes or chew toys.
- Rabbits will be provided with food treats (fresh fruit/vegetables, hay) and other environmental enrichment. If food treats are unacceptable, an Exception is required.
- Dogs and pigs will be provided with balls, mirrors, chains, food treats, and/or chew items.
- All aquatic and other species will be provided with enrichment according to their specific needs, which may include group housing.

Every attempt is made to choose items that enrich the animal's environment and are durable, cage dedicated, sanitizable, and safe. If necessary, pilot studies are conducted before broadly introducing new enrichment items.

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

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

Social housing of all social research animal species is the default housing environment at UNC-CH. Social animals should be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility.

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.

Single housing of non-USDA regulated social species (other than short term recovery from experimental manipulation) is justified and described in the protocol Section 6.0.5b. Possible reasons for single housing include breeding, weaning, medical or compatibility issues and scientific justification for experimental reasons.

DCM veterinary staff may require individual housing of animals due to medical (and/or isolation/quarantine) concerns. This will be indicated in the animals' medical record and may not be described in the protocol. DCM Veterinary Services and IACUC consider demonstrated incompatibility within social groups to be grounds for immediate separation for protection of animals.

For single housing of USDA-regulated species the protocol form requests the specific reason(s) and justification for single housing as well as an estimate of how long the animal will remain singly housed. The IACUC evaluates the requested period case-by-case. Single housing of a regulated species on a permanent or extended basis for experimental reasons requires an exception withing the protocol and IACUC approval.

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

When necessary, single housing of social animals is limited to the minimum period necessary. Where possible, visual, auditory, olfactory and, depending on the species, protected tactile contact with compatible conspecifics is provided. In the absence of other animals, additional enrichment is offered, such as safe and positive interaction with the animal care staff, as appropriate to the species;

periodic release into larger enclosures; supplemental enrichment items; and/or the addition of a companion animal in the housing area.

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.

In addition to IACUC review of the *University Standard on Environmental Enrichment* and the *University Standard* on *Social Housing of Research Animals*, a committee, composed of members of IACUC, veterinarians, DCM staff, and PIs, prepares and reviews species-specific plans for each of the animal species housed at UNC-CH. The plans list accepted enrichment materials, means of introducing them and measuring their effectiveness, and methods of monitoring their use. Toy rotation, food enrichment, playtime, and/or radio, or TV time are all documented on the monthly enrichment logs. These are located on the door of the animal holding rooms.

Members of the committee discuss the enrichment program with individual PIs to ensure that items of enrichment do not interfere with study objectives and, if problems are noted, explore alternative means of enrichment for animals on the project.

Pair or group housing in social species and provision of environmental enrichment is considered the norm and if either/both cannot be employed, the PI describes and gives scientific justification for lack of its use in the IACUC protocol. Review of social housing is also done at time of semiannual facility inspections.

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.

Staff receive species-specific training on using positive interaction and reinforcement in handling and moving animals between pens and cages to minimize stress during routine husbandry procedures. Newly acquired animals are placed in clean, sanitized pens and cages and are allowed an acclimation period prior to manipulation. Newly received animals are generally held for a minimum period of 48-72 hours (depending on the species and procedural use) without undergoing any experimental or other manipulation. Traffic through animal housing areas and changes in assigned husbandry personnel are minimized. Any experimental procedures performed on awake animals and means of acclimation of animals to the procedures should be described, justified, and approved during the IACUC protocol review process. If the IACUC deems it necessary, an EOC and/or the veterinary staff will monitor the procedure.

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

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

The facility on the coast has outdoor tanks with a flow through pump system that circulates ocean water from the nearby sound to the enclosures (including aquaria) and then returns effluent water to the ocean.

Some sites are indoor/outdoor facilities. Animals are acclimated to this environment and are supplemented with heaters and air conditioners, as appropriate, under thermostat set-point control.

There are also three roofed buildings/barns whose sides are partial block walls and partially open. Two are modular buildings. The newest facility is a large block building. Openings are covered with hardware cloth. Concrete slats are supported by cinder blocks over a concrete floor. The galvanized metal penning provides at least 60 square feet of space each. Pen dividers are rods, so animals in adjacent pens can see each other and touch noses for social interaction. There are heavy-duty curtains can be closed during cold weather. Heating is forced air, with a mist system for evaporative cooler. Exhaust fans are opposite the evaporative cooling units.

The farrowing building has aluminum siding on the outside and seamless fiberglass on the interior (walls, floors, and ceilings). Three European-style farrowing pens are contained in this building. Each pen is 8’ x 8’ with swing sides for the sow to allow for more sow space as piglets get larger.

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.).

Some facilities have natural shading or installed shade cover for the play areas.

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.

Songbirds are no longer maintained.

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).

UNC-CH does not use any naturalistic environments.

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

NA

iii. Describe how animals are captured.

NA

C. Animal Facility Management

1. Husbandry

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

i. List type and source of food stuffs.

All diets are procured from commercial laboratory animal diet vendors on University contracts. The primary vendor is Lab Diet. We receive irradiated or autoclavable rodent chows. We also get chows for most of our non-rodent species from Lab Diet as well. Special research diets are purchased occasionally by various PIs from Bioserv, PMI Feeds, etc.

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

Lab Diet is our primary animal feed vendor. Feed storage rooms are fully climate controlled. Temperatures are controlled and do not exceed 70 degrees and humidity does not exceed 55%. If needed, the current vermin control program includes live (or snap) traps for rodents and insect sticky huts located every 10-15 feet throughout the facility. The facility is inspected daily, and staff take immediate action if vermin activity is noted.

Lab Supply delivers feed once a week (or as needed) to each facility housing animals, including our offsite facilities. Feed and bedding are stored on dunnage racks or pallets off the floor in dedicated rooms in each facility. This allows for ease of cleaning and accessibility. The storage rooms are maintained at 68 F +/- 2.

The facility is monitored regularly by staff for signs of vermin and the facility is inspected once a month by the pest control contractor. If DCM staff note any signs of insects or vermin, they place a work order and the issue is addressed immediately by a Pest Control Contractor.

Once feed bags are opened, they are dumped in large and small sealable bins with lids and kept in the clean cage wash or animal rooms.

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).

All diets, including those needing special formulation are purchased from commercial laboratory animal diet vendors or provided by the PI. DCM has limited need to prepare any special foods for its animals. However, DCM does prepare supplemental enrichment feed items and has refrigerators or coolers in designated buildings for storing supplemental fruits and vegetables. Fruit and vegetables are sanitized with dilute bleach before giving to animals.

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

Rodent feed is given ad libitum unless otherwise approved on a protocol. Feed for larger animal species is given in the measured amount indicated on the room door, individual cage and in the applicable SOP when appropriate. Feed is provided in a species appropriate hopper, bowl or feeder and is not in contact with soiled bedding. NHPs, pigs, and dogs are fed 1-2X/day. Puppies are fed twice daily, while piglets are fed ad lib. Rabbits are fed a calculated amount (150 grams) each day.

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

All diets, except canned dog food are specifically produced for laboratory animals in mills free of antibiotics and other additives. All feed is purchased from a commercial vendor that stipulates required nutritional quality in keeping with laboratory animal standards. In all facilities stock is rotated by the feed vendor upon delivery. Milling dates are checked by the building supervisor after vendor delivery. Feed bags have the milling date stamped clearly on the bag and all feed is determined to be usable 180 days after milling. Feed without milling dates is marked with a date of arrival. The milling date of feed stored in animal rooms is written on a card attached to the container and DCM personnel monitor the dates.

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).

Edstrom carbon filtered, reverse osmosis water treatment units provide purified water to all laboratory animals in these buildings. Most animals receive hyperchlorinated water ad lib from polycarbonate bottles with stainless steel sipper tubes or an automatic watering system of PVC or stainless-steel pipe with stainless steel drinking valves.

Some dogs are provided water in stainless steel bowls.

Some limited number of rodents may receive acidified water in polycarbonate bottles with stainless steel sipper tubes.

Animals at some locations are provided carbon-filtered well water working in conjunction with the softening treatment system. This water is treated to remove particulates and contaminants.

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

The DCM Diagnostic Laboratory does microbial testing annually for each animal facility site. The reverse osmosis systems are both remotely and visually monitored Monday through Friday via a Daily Log Sheet to assure proper function. Twice per year, each leg of automatic watering room distribution piping is sampled from a representative room piping quick-disconnect or flush valve and tested for coliforms, pseudomonads and total plate count. In addition, OWASA also provides monitoring of water for contaminants is the primary microbial and chemical examination.

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

Water purification and delivery equipment is maintained in proper operating condition by providing routine Operational Maintenance (OM) and scheduled Edstrom Preventative Maintenance (PM) annual contract. The maintenance program is designed to detect incipient failures before they occur, as well as extend the life of the equipment. DCM Husbandry Services provides daily data recording, periodic filter changes, and solution replacement during routine OM, ensuring readiness of the equipment. Through a PM agreement with Edstrom, the equipment is inspected, tested, measured, and adjusted every six months by a manufacturer

trained and certified technician. In the PM process, multiple components are replaced to preserve and restore equipment reliability and efficiency. All tasks and readings conducted during the PM are documented.

To prevent contamination of the AWS, the distribution lines are flushed 1-2 times per day with pressurized water (10-15psi) for 60-120 seconds. In the event of biological contamination within the AWS, remediation will take place immediately through chlorine sanitation and high-pressure flush of the AWS.

Routine water samples are submitted for testing. If it were determined the water distribution lines needed additional cleaning, a portable sanitizer would be utilized to clean the system.

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

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

Most bedding used in DCM is direct contact and DCM utilizes three types. Bed-o-Cobs, a corncob product with excellent ammonia control, is used in all ventilated caging and most of our rodent species cages. Alpha Dri, a paper particle product, is used in sentinel cages and some nude mice cages as needed and Tek-Fresh, a paper particle product, is used for post-surgical animals. Bed-o-Cobs is the primary bedding used. Nestlets are added to all rodent cages (with or without litters) for nesting or to exhibit burrowing behavior.

- Guinea Pigs: Direct corncob bedding (Bed-o-Cob)
- Hamsters/Gerbils: Direct corncob bedding (Bed-o-Cob).
- Mice: Direct paper particles (Alpha Dri) or direct corncob bedding (Bed-o-Cobs)
- Rats: Direct paper particles (Alpha Dri) or direct corncob pellets (Bed-o-Cobs)
- Rabbits: Indirect paper refuse pan liners
- Dogs: Supplied with kiln-dried pine wood shavings
- Ferrets: Indirect paper refuse pan liners or kiln-dried pine wood shavings on the floor or within nesting boxes

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

Bed-o-Cobs and shavings are stored in an off-site storage warehouse for limited times. The warehouse utilizes vermin control through a contract company. DCM works with this company to ensure safe practices on campus.

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

Our bedding contractor has UNC-CH dedicated trucks that only contain animal bedding (e.g., no animals allowed during transport) during deliveries. Assurance certificates are received from vendors for beddings materials. All bedding material are purchased from a commercial vendor in keeping with laboratory animal standards. Analyses for heavy metals, mycotoxin, organophosphates, chlorinated pesticides and mold tests and Material Safety Data Sheets are requested from the manufacturers.

Bedding in all facilities is examined as it is removed from the bag by technicians. The manufacturer will provide some monitoring for microbial contaminants. All rodent bedding is supplied in sealed irradiated bags and/or autoclaved prior to contact with animals.

All rodent cages receive either irradiated or autoclaved bedding. Sterilized rodent cages are autoclaved with bedding inside the cage and monitored by a SteriGage card or biological indicator in a representative cage. Any damaged or soiled items 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.

Vans with heating and cooling and a large, open sanitizable rear are the main methods of transporting vendor rodent deliveries from DCM's central receiving point (GM animal facility) to each animal facility as well as transporting animals to and from the Raleigh-Durham Airport some 15 miles from campus.

For transporting larger animals or greater number of animals, DCM has a one and one-half ton International truck with an enclosed, insulated body and Thermo-King heating/cooling device that maintains 72°+/- 3° F. The body is equipped with a lift gate, lights and tie down equipment for cage racks. The truck was purchased in 2019. As a backup truck, DCM has kept its original International truck. It is a one and one-half ton truck with an enclosed, insulated body and Thermo-King heating/cooling device that maintains 72°+/- 3° F. The body is equipped with a lift gate, lights and tie down equipment for cage racks. The truck was purchased in 1995.

Minivans are used to transport animals to and from some facilities for diagnostic and research purposes.

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.).

HEPA filtered vacuums
Portable high-pressure sprayers
Sterilizers of various sizes
Microisolator cage change hoods
Nuaire HEPA Filtered cage dump stations
Tecniplast Automated HEPA Filtered and downdraft cage dump stations
Tecniplast Bedding dispensing systems (BDS)

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

i. Bedding/Substrate Change

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

Species	Cage Type	Change Frequency
Dogs	Runs	Daily
Pigs	Pens	Daily
Non-human primates	Suspended	Daily
Guinea Pigs (IVC)	Solid Bottom	1X/wk.
Rodent (Static)	Solid Bottom	1X/wk.
Small Rodents-(IVC)	Solid Bottom	1X/2wk.
Rabbits	Suspended	3X/wk.
Rats (Static)	Solid Bottom	1X/wk.
Rats-(IVC)	Solid Bottom	1X/1-2wk.
Ferrets	Suspended	3X/wk.
Note: Please see individual satellite section for nontraditional species husbandry practices.		

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

During the semiannual program reviews, the IACUC reviews the existing performance-based IACUC-approved change interval for IVC solid bottom mouse cages. DCM changes these cages every two weeks with spot changes conducted as needed.

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

cages/enclosures.

Soiled liners are removed from litter pans within the animal housing room or in the cage wash area (dirty side); clean bedding/liner is placed into litter pans within the cage wash area (clean side).

Soiled bedding is removed from animal cages in the cage wash area (dirty side). Clean bedding is placed in cages in the cage wash area (clean side).

In facilities where there is only one side to the washroom clean cages are filled in the clean cage storage room.

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.

The IACUC reviews each exception to the *Guide* as well as exceptions to institutional standards as part of the IACUC protocol review. With reference to mice (and other small rodents housed), the IACUC has approved cage change every two weeks for IVC caging (with spot changes as necessary). The IACUC reviews the need for this exception at every semiannual program review. UNC-CH and Tecniplast (IVC vendor) have jointly performed verification of the microenvironmental conditions (e.g. ammonia and CO2, microbiologic load, observation of the animals' behavior and appearance, and the condition of bedding and cage surfaces). In addition, DCM continues to monitor performance standards (morbidity and mortality data, breeding performance, and other objective data) within its various colonies and report back to the IACUC as needed.

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).

Each day that a cage washer is used, a heat sensitive indicator is applied to a cage and run through the washer to assure that the machine is reaching 180º F. These indicators are then placed in the building supervisor's record

book. DCM's Diagnostic Laboratory supervisor performs microbiological monitoring on various items such as cages, pens, sipper tubes, etc. twice per year. Once a week, Steam-24 biological indicators are placed at different levels of a sterilizer load and incubated afterwards to test sterilization effectiveness. Each sterilizer load is monitored by a SteriGage card. The cage washer chemical contractor monitors all cage washers monthly for chemical dispensation, operation, and rinse temperature. Outside contractors maintain and service all cage washers and autoclaves and are notified any time indicators fail to color convert.

b) Describe preventive maintenance programs for mechanical washers.

All mechanical equipment including, rack washers, tunnel washers, sterilizers are serviced under preventive maintenance contracts by the manufacturing vendor (e.g. Tecniplast, Steris, Getinge, etc.). The contracts include regular preventative maintenance and service within 24 hours in the event of equipment malfunction.

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.

Soiled bedding is emptied into portable waste receptacles. UNC-CH Waste Reduction and Recycling has contracted an outside vendor to pick up the non-contaminated bedding. Bedding contaminated with chemical agents including toxics, carcinogens, reproductive hazards, and anti-neoplastic agents follow the DCM SOP, "Handling Cages Dosed with Chemical Hazards." Hazardous bedding is segregated for incineration and personnel use respiratory protection during the dumping of cages.

ii. Animal carcasses.

Carcasses are bagged/boxed and placed inside in a freezer and/or refrigerator specifically for this purpose. Contents are removed once per week for incineration by Stericycle. Exception: Uncontaminated pig carcasses are processed by a rendering plant. If contaminated via experimental procedures, pig carcasses are cut into pieces and sent for 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).

Clegg's Pest Control currently maintains the University pest control contract. A service tech does a monthly walk through to check for vermin. If problems are noted or reported to Clegg's, treatment options appropriate for the vermin and for the research environment are discussed/determined. Research staff are notified on the rare occasion that Max Force Bait Gel or boric acid is used in an animal room. In rare cases, if something stronger was necessary then synthetic pyrethrins would be used and the area would be cleared of animals. The licensed exterminator consults with the DCM before using any treatment.

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.

If the use of a pesticide is needed DCM will send out a broadcast email alert to individuals in the specific areas. If there anyone had concerns, discussions would take place and appropriate actions taken.

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.

Laboratory Animal Technicians and one husbandry manager (on a rotational basis) perform husbandry duties on weekends and holidays. Environmental monitoring, checking/reporting sick and dead animals, feeding and watering are standard procedures. Rodent cages are spot changed as required and USDA non-rodent cages and/or runs are cleaned as throughout the week. Veterinary technicians and staff veterinarians also serve on-call rotation, perform campus rounds and are available on 24-hour call. There are veterinarians or veterinary technical staff on campus to provide needed medical care and ongoing evaluation. An AOD or Manager always carries a radio pager during the weekday, weekends, and holidays. UNC-CH Campus Police and Facility Services has the pager number and emergency telephone numbers and will notify the appropriate person in case of an emergency.

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

Fulltime staff rotate weekends and holidays. We may employ weekend staff to fill in business needs at remote facilities. They are fully trained, work during the week as well, and are signed off on all appropriate SOPs and EHS requirements.

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

Each animal facility has signage posted (usually near a telephone) which provides contact pager numbers for husbandry and veterinary staff. A member of the husbandry staff and veterinary staff always carries the on-call pager and can be contacted 24/7. UNC-CH Campus Police have a call list of DCM personnel to contact in case of an emergency. All DCM animal care supervisors and veterinary staff have a telephone list of key DCM personnel.

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).

Rats, mice, guinea pigs, gerbils, hamsters, ferrets, rabbits, dogs, and nonhuman primates are identified by bar coded cage cards containing the following information:

- Cage Card #
- PI
- IACUC Protocol Number
- Tattoo # or identification # (if any)

(Optional additional information includes:

- Animal Order Requisition #
- Source of the Animal
- Arrival Date
- Weight or Age on Arrival)

In addition, rabbits are identified via a plastic or metal ear tag. NHPs are tattooed in the chest/thigh area. Dogs have tattoos and/or implanted chips. Pigs may have ear tags. Pigs coming from other sources could have either ear tags, tattoo, or ear notches. Some PIs assign each rodent a pedigree number and, if collecting tissue for genetic testing, they may use toe collection to number the animal before 10 days of age. Other researchers use ear tags or ear notching to identify post-weaning aged rats and mice.

b. Breeding, Genetics, and Nomenclature

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

Most of our PIs are fully cognizant of the need for using animals with genetic characteristics necessary for the type of scientific investigation planned. On rare occasions, if it has been noted during the IACUC protocol review process that further discussion regarding the animal model of choice is warranted, a member of the veterinary staff or IACUC provides additional advice. DCM also refers individuals needing laboratory animal genomic information to appropriate on-line resources such as Mouse Genome Informatics (MGI).

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.

We do not have a formal program for advising PIs on the use of standard nomenclature in their scientific communications. However, on the occasions when an PI or needs laboratory animal genomic information, DCM refers them to appropriate on-line resources such as MGI for internationally recognized standards for rodent 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).

UNC-CH's Systems Genetics Core Facility (SGCF) provides management of genotyping using the Mouse Universal Genotyping Array (MUGA) and Mouse Diversity Array (MDA). This new low-cost high-density genotyping platform called MegaMUGA. MegaMUGA is built on the Illumina Infinium platform and was designed to expand the number of markers and versatility of the successful Mouse Universal Genotyping Array (MUGA).

There are three types of probes in MegaMUGA. In addition to traditional SNP probes, a second probe type for tracking known structural variants (insertions, deletions, and duplications). A third probe type was designed to detect the presence of sequences present only in genetically engineered mice (Cre, Luciferase, etc.) There are three genotyping platforms for assessing the genetic architecture of various mouse resources, including the developing Collaborative Cross. Using a 550K marker genotyping platform called the Mouse Diversity Array (MDA), the SGCF genotyped nearly every available classical laboratory mouse strain, wild-derived inbred strain, numerous F1 crosses, and wild mice. Genotypes along with various QC and visualization tools for over 350 common mouse strains help

monitor and accelerate the inbreeding process of the developing Collaborative Cross strains.

In addition, a large collection of common laboratory strains, murine-derived cell lines, and outbred mouse resources have been genotyped using MUGA. These genotypes as well as a collection of comparative genomics analysis tools are available from this website. Lastly, DCM can collect tissue and send samples to individual laboratories or Transnetyx for gene expression data, genotyping, and oligonucleotide services. DCM will either use the individual laboratory colony management software, Jackson Labs, or Transnetyx.

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."

Husbandry staff monitors all animals daily and reports to Veterinary Services any unusual/unexpected behaviors or phenotypes. Veterinary Services follows up on anything that is an unexpected outcome, consults with the PI, and notifies the IACUC.

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.).

Except for a few programs that utilize field caught or non-traditional species (e.g., turtles, frogs, wildlife used for teaching), PIs order animals from vendors by using the DCM online ordering system. They cannot place orders directly through to the vendors. The DCM Animal Procurement Specialist sends an Animal Receiving Report to the UNC-CH Animal Transport Coordinator (ATC) each week. This report lists all the animals that will be delivered the following week. The DCM Animal Procurement Specialist also sends this report, with bar coded cage cards to each DCM Facility Manager that will be receiving animals that week. When a vendor delivers animals, the ATC counts the number of boxes and ensures that it matches the number on the invoice. Any discrepancy is noted on the invoice. The ATC then signs the invoice. The shipping labels of each box are checked for accuracy using the Animal Receiving Report. The Requisition number, species, strain,

weight, age, sex, stock number, and PI's name on each box should exactly match the information that is on the Animal Receiving Report.

DCM veterinarians periodically review commercial vendors for suitability and may make site visits for animals supplied from local farms or suppliers. Herd/colony health surveillance as well as preventative medicine programs are reviewed.

2. Transportation of Animals

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

For internal transfers, an online internal transfer form, is completed by the PI/LAC. The PI/LAC identifies the animals that should be transferred by writing the building and room number that the animals are to be transferred to on the DCM Transfer Card and properly attaching it to the cage card holder of the cage. The ATC reviews the Internal Transfer and works closely with the veterinarian for approval. The ATC contacts the PI/LAC and informs him/her that the transfer was approved, the cards are in the mailbox and that they can transfer the cages at their convenience. The method of transport is to be accomplished in a relatively short period to ensure the health and safety of the animals. If any cages are taken out of a facility, they should be properly covered in accordance with the *Standard on Animal Transport and Biosecurity*. Each building has a designated cart, clearly labeled, for the ATC to place the transferred cages. The ATC informs the Facility Manager and Research Support Tech (RST) that the animals transferred have arrived. The Facility Manager or RST is responsible for making sure the correct animals were delivered before the animals are placed into the room.

Dedicated climate-controlled vehicles are used to transport animals, both intra- and inter-institutionally. These vehicles are checked and sanitized regularly to assure a high level of biosecurity and animals are moved by trained personnel. The *Standard on Animal Transport and Biosecurity* addresses the potential use of non-dedicated vehicles.

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.

Dogs are bred in-house colony or rarely obtained as purpose-bred animals from commercial vendors. If dogs leave campus (e.g., examination at veterinary school), then all dogs that come back from off-campus sites are quarantined to observe for any

sign of Bordetella or other infectious agents. All dogs that develop clinical signs of diarrhea or blood in feces have fecal samples tested and puppies 6-8 weeks of age have fecal tests to survey for parasites and follow-up as needed (e.g., positive samples).

Rabbits are purchased from a North Carolina vendor and are free of *Pasteurella multocida, hepatic coccidiosis, Encephalitozooan cuniculi*, and ear mites. Periodically, or approximately once every 3 years, nasal swabs are cultured on representative animals in the colony to check for *pasteurella* and *bordetella. Encephalitozoon cuniculi, Carbacillus, Rotavirus, Clostridium piliforme,* and *Treponema* is done once every 3 years unless already collected during that time in association with other routine blood collection. Fecal samples are collected at time of arrival and 2 weeks after arrival and tested for parasites.

Ferrets are obtained as purpose-bred animals from commercial vendors or bred within the colony. Fecal samples are collected upon arrival into the facility, while ferrets are in quarantine and repeated 1-2 weeks post treatment after any positive fecals.

There are routine health maintenance programs for all NHPs. NHPs are tested every six months for TB by intradermal injection (eyelid) of Old Tuberculin. They receive annual physical examinations by a veterinarian and blood samples are tested for CBC and comprehensive chemistry, and intestinal flora screened annually.

For long-term housed swine, fecal samples are tested for endo-parasites (by direct and flotation) from 10% herd with representatives of all housing areas on an annual to biannual basis and 10% of herd including representative animals from all buildings are tested annually for six leptospiral serovars including *bratislava, porcine parvovirus* and *Actinobacillus pleuropneumoniae* prior to re-vaccination. Pigs are tested for brucellosis, pseudorabies, swine influenza, and transmissible gastroenteritis yearly or every two years, depending upon overall herd health status.

Most rodents are obtained from approved vendors. Rodents obtained from other than approved sources are housed in quarantine until their health status is assessed (see quarantine section).

A program is in place for monitoring the health status of rats and mice every four months using sentinel animals and, in some cases, those provided by PIs. The racks of IVC are routinely tested for pinworms and ectoparasites by PCR of Exhaust Air Duct (EAD) dust, or pooled fecal samples. The mouse pinworm and fur mite panel tests for A*spiculuris tetraptera, Myocoptes, Radfordia/Myobia* and *Syphacia obvelata*. The rat pinworm and furmite panel tests for *Aspiculuris tetraptera, Myocoptes, Radfordia/Myobia,* and *Syphacia muris*. Various other agents (see below) are tested by serology, and/or PCR.

There are four IDEXX/RADIL serological testing levels for mice: UNC Mouse Serology Profile I (EDIM, MHV, MPV, MVM, TMEV), Profile I Plus (EDIM, MHV,

MPV, MVM, TEMV, MNV), Profile II (Mycoplasma pulmonis, CAR bacillus, Ectromelia, EDIM, LCMV, MAV1, MAV2, MCMV, MHV, MPV, MVM, Polyoma, PVM, Reo3, Sendai, TMEV), and II Plus (Mycoplasma pulmonis, CAR bacillus, Ectromelia, EDIM, LCMV, MAV1, MAV2, MCMV, MHV, MPV, MVM, Polyoma, PVM, Reo3, Sendai, TMEV, MNV) or IMPACT II PCR Profile (Mycoplasma spp., Sendai, MHV, PVM, MVM, MPV, TEMV, MNV, Reo, Mouse rotavirus, Ectromelia, LCMV, Polyoma, LDEV, MAD1, MAD2, MCV.

Frequency and types of tests are as follows:

1. Sterile rooms: twice a year (three times for select rooms), the sentinels are tested for UNC Mouse Serology I Plus, Pasteurella, pinworms, fur mites and Helicobacter by PCR (pooled feces and/or EAD swabs), and once a year UNC Mouse Serology II Plus, Pasteurella, pinworms, fur mites and Helicobacter by PCR (pooled feces and/or EAD swabs). Immunocompromised animals from the Gnotobiotic Core are tested by the IMPACT II PCR once a year with pooled lungs, spleens, kidneys, and small intestines.
2. Sterile rooms elsewhere: twice a year (three times in select rooms), UNC Mouse Profile I, and once a year Profile II Plus, Pasteurella, pinworms, fur mites and Helicobacter by PCR (pooled feces and/or EAD swabs).
3. Hot-wash rooms: twice a year, UNC Mouse Profile I, and once a year Profile II. Pinworms and fur mites are tested by PCR as described above at the same frequency as serologic testing.

There are two serological testing level for rats: UNC Rat Profile I that consists of H1, KRV, RCV/SDAV, RMV, RPV, RTV that are tested twice yearly, and UNC Rat Profile II consisting of H1, KRV, RCV/SDAV, RMV, RPV, RTV, Sendai, PVM, Mycoplasma pulmonis that are tested one time yearly. Pinworms and fur mites are tested by PCR as described above at the same frequency as serologic testing.

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

Dogs are vaccinated for Distemper, Adenovirus, L. canicola, L. icterohaemorrhagiae, L. pomona, L grippotyphosa, parinfluenza, and parvovirus at 8, 12, and 16 weeks and one year with a booster every 3 years thereafter. Rabies vaccination occurs at 16 weeks, and 1 year with a booster every 3 years with 3-year duration vaccine. Internal parasites such as Coccidia are treated to eliminate the agent and fecal samples are re-tested at appropriate intervals. Puppies are given Pyrantal pamoate at 8, 12 and 16 weeks or ponazuril at 4 weeks of age. All dogs to be held greater than one year receive monthly heartworm preventative given year-round. The preventative starts at approximately 16 weeks of age.

Adult ferrets will receive Rabies and Canine Distemper vaccines once yearly. Ferret kits to be held greater than one year will receive a Canine Distemper vaccine at 6, 10, 14 weeks of age and then annually thereafter. They will receive their first rabies vaccine at 10 or 12 weeks of age and then annually thereafter.

Swine to be held greater than one year are vaccinated for *Leptospira bratislava, L. canicola, L. grippotyphosa, L. hardjo, L. icterohaemorrhagiae and L. pomona*, porcine parvovirus, and erysipelas at 6-month intervals. At least 10% of swine herd including representative animals from all buildings are tested **annually** for six leptospiral serovars, including *bratislava*, porcine parvovirus and Actinobacillus pleuropneumoniae prior to vaccination. Additional agents to be tested on a **2-3 year basis** include: Mycoplasma hyopneumoniae, Brucella abortus, Pseudorabies virus, Porcine Reproductive & Respiratory Syndrome Virus, Swine Influenza Virus, TGE and porcine corona viruses PEDV, PdCV.

Veterinary Services has developed a written Outbreak Management Guideline to assist in the decision-making process in the case of outbreaks of excluded infectious agents in rodents. The process of control, containment, and/or elimination depends on many factors including the agent, research, location of affected rodents, availability of replacement strains and genotypes, number of rodents affected, etc. The exact details of the outbreak management are handled on a case-by-case basis and so the written process is in the form of guidelines, rather than a SOP.

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

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

All rodents are delivered receiving area where DCM Animal Transport Specialists check the orders and then deliver the animals to their appropriate housing units. Most rats are vendor-quality animals from Harlan or Charles River-Raleigh. Most mice are vendor-quality animals from the Jackson Laboratory, Envigo, Charles River, and Taconic. These animals are evaluated as they are unboxed and placed in cages by the laboratory animal technicians in the respective buildings. Rodents introduced from other institutions are quarantined in special quarantine facilities for a minimum of approximately 5 weeks. All quarantined rats and mice are tested for internal and external parasites upon arrival using fur pluck, anal tape test and fecal flotation. In addition, they are all treated with spot-on selamectin upon arrival and at release from quarantine and placed on fenbendozole-medicated feed for duration of quarantine. After a minimum of 4 weeks in quarantine, a minimum of 10% of each shipment of rodents or 10 animals, including representatives of each strain, are live bled and serologically tested using the UNC Mouse Profile II Plus or the UNC Rat Profile II. Only after all tests are determined to be negative, are animals released from quarantine to the designated housing facilities.

Some pigs are obtained from an in-house breeding colony and therefore bred for research. Swine that are obtained from other sources have vendor herd health surveillance/vaccination history evaluated prior to introduction. All introduced swine have a minimum of fecal testing for parasites upon arrival and any disease signs are noted and reported to the clinical veterinarian.

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.

Isolation cubicles are used for rodent quarantine for imported purpose bred rodents with clean health status from other institutions. A separate isolation cubicle is used for mice with questionable sentinel surveillance data from the sending institution, as well as for other rodent species.

Swine obtained for short-term acute studies or for long-term chronic studies are quarantined in place and separated by vendor source.

Swine are usually obtained from one source and are group housed. No quarantine period is required. Several shipments of animals have been tested by the vendor and received negative test results.

Dogs are quarantined for 2-3 weeks to ensure no respiratory or GI disease is introduced to the colony and tested for internal and external parasites. Each animal receives an intake and quarantine exit exam from a veterinarian and may also receive routine (CBC/Chemistry) bloodwork.

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

We strongly discourage PIs from using animals until the animals have had a chance to stabilize. A minimum period of 48-72 hours (depending on the species and procedural use) is generally recommended for acclimation before undergoing any experimental procedure or other manipulation. Traffic through animal housing areas and changes in assigned husbandry personnel are minimized. If possible, animals used for survival surgery in the DCM surgery area are delivered at least the week prior to the scheduled surgery. For non-survival procedures, this is not required and larger animals like pigs may sometimes be delivered 1-2 days prior to procedure.

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

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

Animals are separated by species and are further segregated according to their SPF status or source. In addition, each animal facility is ranked according to the overall health status of animals from clean (least health risks) to dirty (greater health risks). Rooms within facilities are also ranked from clean to dirty. Most facilities are equipped with card readers and are controlled at the individual door level with an anti-passback

feature to prevent inappropriate room/building order. All research personnel with animal facility access adhere to the posted building and room rankings by entering clean rooms or facilities first, wearing appropriate PPE. For most rodent facilities, once animals leave the animal facility they can only be returned to designated "high risk" return rooms or cubicles and cannot re-enter to the original colony. If routine health surveillance of sentinel animals indicates potential health status concerns, further restrictions of animal movement/housing may be imposed, both within a facility as well as between facilities. Ninety-nice percent or more of the rodents are housed in individually ventilated microisolator cages, so the cage serves as additional separation/biosecurity between cages of animals. Animal cages are opened under a HEPA-supplied cage change hood or biosafety cabinet.

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

In general, animals are separated by species. However, there are occasional situations where species are mixed. The IACUC has reviewed and approved the following situations.

There is one room where gerbils and rats are housed in the same room in IVC caging.

There is a room in the ABSL facility where guinea pigs and mice are housed in IVC and/or biocontainment caging on separate racks in the same room from time to time.

Lastly, one room contains multiple reptile and amphibian species within the same room in different holding tanks. These animals are not laboratory animals and are used for community outreach to local K-12 schools by a student organization and are under veterinary care by DCM.

c. Describe isolation procedures and related facilities for animals.

In the event a potential outbreak or a sick animal is thought to have an infectious disease and treatment is indicated, it would be isolated in an isolation cubicle or other location for isolation. This may or may not result in a re-ranking of room order, change in PPE and/or husbandry practices with the facility. Animals that are sick but do not represent a threat to other animals are generally treated in their home cages. These decisions are made on a case by case basis with active input from DCM veterinary faculty.

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.

Observation of animals for illness or abnormal behavior is a responsibility of any DCM staff member who has animal care duties. Laboratory Animal Technicians are responsible for daily observations of all species as part of their husbandry routines. They are trained to look for species specific behavioral changes as well as the more obvious signs of distress or disease. Personnel in the animal husbandry group are expected to be watchful of more subtle signs on their daily rounds through the facilities to which they are assigned. When signs of illness are observed that require immediate attention, the veterinary technicians or veterinarians are called or paged. Signs of disease or distress, which do not require immediate attention, are identified by a Laboratory Animal Technician by placing a DCM animal health concern card and recording the clinical case into a computerized health record program. This program is checked periodically throughout the day by veterinary technicians or veterinarians and animals are examined accordingly. Labs can contact veterinary services directly via phone, pager, or email for animal care.

DCM veterinarians and/or veterinary technicians make regular rounds through all facilities to check animals and monitor the Health Surveillance program. Frequency of rounds could be several times a day in larger facilities and is at least once weekly in smaller, on-campus units during the five-day workweek. Veterinary technicians and veterinarians go to facilities during weekend and holiday rotations as well.

Clinical cases from all facilities are reviewed at a weekly meeting (Friday) of the veterinarians, veterinary technicians and at least one Operations Manager. This meeting is the summation of weekly veterinary care activities, a preparation for weekend treatments and a means to communicate health care situations to all appropriate staff. Another staff meeting (monthly) of senior husbandry personnel, training coordinators and the director concentrate on husbandry issues, but health-care issues and their reporting and feedback are also addressed. Such meetings also provide an opportunity for the DCM Director to communicate information on pending proposals under review by the IACUC. In the event unusual veterinary or husbandry needs are generated by new studies they are reviewed at these staff meetings. Veterinary technicians, veterinarians and senior husbandry personnel carry smart phones and access to veterinarians is available round-the-clock. Lastly, husbandry facility managers attend a monthly meeting with Veterinarians and other senior DCM leadership where operational SOPs are reviewed, and species-specific health-care concerns are reported and addressed.

Training Coordinators and DCM senior personnel observe various technicians performing tasks to ensure proficiency of training and quality assurance of critical policies pertaining to animal welfare. Policies are discussed during monthly DCM staff

meetings based on training frequency (2-4X/yr.), relevance (e.g., new species) and perceived need (staff turnover).

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

Multiple methods are used for communication. In general, the animal care staff identify the animal by placing a DCM animal health concern card and utilize the computer system for reporting sick animals. They will call or page the veterinary technicians (or veterinarian) if an animal needs immediate attention. The veterinary technicians will generally email the veterinarians if they would like the veterinarian to examine the animal. If more immediate care is needed, they will call or page the veterinarian. PIs and their technicians are generally notified either by email or a phone call within 24 hours of a case being evaluated by a veterinarian or veterinary technician.

When signs of illness are observed that require immediate attention, the veterinary technicians are called or paged. Signs of disease or distress which do not require immediate attention are recorded by Laboratory Animal Technicians in a computerized health record program. This program is checked periodically throughout the day (including weekends and holidays) by veterinary technicians or veterinarians and animals are examined accordingly. Once the Veterinary technician or veterinarian has examined an animal, notes are entered into the veterinary record and the researcher(s) are notified of findings and treatments/recommendations. A cage card is placed on the animal cage to indicate that the animal is under observation, whether there is a health concern, and/or veterinary care is being provided.

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.

Each non-rodent species has an individualized wellness plan – rodents are covered by the sentinel program. Veterinarians provide overall guidance and set health wellness policies for routine preventative care and vaccinations of dogs, pigs, ferrets, rabbits, NHP and frequency of colony health status surveillance. This plan covers frequency of examination, any vaccinations given, and details of blood testing for the species. Necropsies are done on these species following euthanasia if they have shown any signs of illness or unexplained death. Necropsies are done on selected rats and mice that have shown signs of disease. This enables us to monitor for potential problems within these colonies.

There are routine health maintenance programs for all primates. NHP are tested every six months by intradermal injection (eyelid) of Old Tuberculin and receive a physical examination and blood work annually.

Dogs are maintained under standard procedures for vaccination, parasite control and dental care. For animals with bleeding tendencies, bleeding episodes are treated primarily by the veterinary technicians, and some of the hematomas, as well as other problems, are brought to the attention of the veterinarians. Veterinarians typically perform clinical rounds at least once weekly more often as needed (e.g., examine a sick animal). All dogs receive a complete physical exam and bloodwork (CBC/Chemistry) yearly per the canine wellness plan.

Pigs are tested for endo-parasites (by direct and flotation) from 10% herd with representatives of all housing areas on an annual to biannual basis and 10% of herd including representative animals from all buildings are tested annually for six leptospiral serovars including bratislava, porcine parvovirus and Actinobacillus pleuropneumoniae. A subset of long-term housed pigs is also tested for brucellosis, pseudorabies, swine influenza, PRRS and coronaviruses and transmissible gastroenteritis yearly or every two years, depending upon overall herd health status.

Adult ferrets will receive Rabies and Canine Distemper vaccines once yearly. Ferret kits intended to be housed long term (>1year) will receive a Canine Distemper vaccine at 6, 10, 14 weeks of age and then annually thereafter.

The veterinary staff provides advice on monitoring any rodent breeding colonies. A program is in place for monitoring the health status of rats and mice every four months using sentinel animals and those provided by PIs. As additional viral antibody free areas have been established this program has increased. The sentinels are routinely tested for pinworms (direct examination of intestinal contents or anal tape and fecal flotation), ectoparasites (plucked hair) and serology (mice – EDIM, TMEV GDVII, MHV, Mycoplasma pulmonis, MPV, MVM, Parvo NS-1, PVM, Sendai, CAR bacillus, Ectromelia, LCMV, MAD1, MAD2, MCMV, Polyoma, and Reo3. Level II Plus includes: EDIM, TMEV GDVII, MHV, Mycoplasma pulmonis, MPV, MVM, Parvo NS-1, PVM, Sendai, CAR bacillus, Ectromelia, LCMV, MAD1, MAD2, MCMV, Polyoma, Reo3, and MNV; rats- RPV, RMV, KRV, H-1, RTV(Rat theilovirus), Sendai, PVM, and Mycoplasma pulmonis).

All foster dams in the Mutant Mouse Regional Resource Center are sent to IDEXX BioResearch for complete health testing when their litters are weaned (virtually a continuously ongoing surveillance program).

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.

Animals are checked at least once daily (365 days/year) by DCM husbandry staff and/or PI staff (for Satellite housing) during regular work hours and on weekends and holidays to identify health cases, including emergency cases, and Veterinary Services monitors all these cases. When signs of illness are observed that require immediate attention, the veterinary technicians are called or paged. A veterinarian or a veterinary technician in Veterinary Services monitors the Veterinary Services pager 24 hours a day, every day of the year. Researchers or husbandry staff can page the Veterinary Services pager about emergency cases during regular work hours, on weekends, and holidays or outside regular work hours and a veterinarian or a veterinary technician will answer the emergency page. Also, veterinary technicians, veterinarians and senior husbandry personnel carry smart phones as an additional contact option. All veterinarians and veterinary technicians have key and badge entry to all clinical areas to ensure ready access to all drugs, therapeutics, and diagnostic/therapeutic equipment needed to provide emergency care.

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

When possible, Veterinary Services attempts to call the regular work hours or after-hours number for the PI in emergency cases to discuss the treatment of the animal. However, if the PI or their designee cannot be reached, or if the health of the animal does not allow the time to call before initiating emergency treatment, full authority is given to the AV or his/her designee to initiate emergency treatment based on professional judgement and clinical evaluation of the patient(s) in question.

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.

Signs of disease which do not require immediate attention are recorded by Laboratory Animal Technicians or veterinary technicians in a computerized health record program. This program is checked periodically throughout the day by veterinary technicians or veterinarians and animals are examined accordingly. (For animals requiring immediate attention, husbandry staff calls or pages and these animals are examined and treated first, and the record created or updated subsequently.) The computer program is accessible in all the buildings and a new case can be created by any of the animal technicians. After creation of a case, updates to the computerized records are made by the husbandry building managers, research support technicians (husbandry technicians with specialized training and demonstrated ability to manage a number of common, minor rodent clinical cases) or primarily the veterinary technicians and veterinarians. The veterinary technicians are responsible for seeing that any treatments and /or communications with PIs are recorded in the computerized health record system. The

medical record is considered resolved when the animal has recovered or been euthanized. Computerized health records are also generated for USDA species. Some animals also have a written record maintained at their facility that contains both experimental and clinical data. The clinical data in the written record is also contained within the computerized health record maintained by DCM. Veterinarians and veterinary technicians have access to these written records, as well as some of the research staff working with the animals. The written records are kept in designated areas or cabinets in the buildings where the animals are housed. Records are maintained for the life of the animal (or until the animal leaves UNC-CH and at least three years after). A card system has been developed for cage side record keeping of rodent cases. The AV and Associate Director of Vet Services oversee the program and decides on what changes to make, if any, to the recordkeeping process. The AV has access to all medical records.

Green Health Check cards identify animals to be examined. Animal cards indicate animals that are being treated or otherwise monitored for health reasons. For guinea pigs, hamsters, gerbils, and rodents, primarily, treatment and clinical observation notes are made on the red cards. White treatment labels are placed on red cards to follow and assure treatment compliance. When a case is resolved, the animal card is removed from the cage and the computerized record becomes the archived record, and these are kept for three years. Copies of diagnostic test results and clinical lab results are maintained in the diagnostic lab as well as in animal records and attached to the computerized. This card system as well as computerized medical records is used for some animals. Veterinary technicians make regular (generally daily- weekly) rounds through their assigned buildings to examine health cases within the building and they update the cage-side cards and the computerized medical records with medical progress notes.

In addition, the clinical veterinarians make at least monthly rotations with the veterinary technicians in their assigned buildings and view together a subset of cases in the building. Veterinarians may also update the cage-side cards and the computerized medical records with medical progress notes. Veterinary technicians also request veterinarian checks on certain cases and veterinarians update the cage-side cards and the computerized medical records with medical progress notes after their vet checks, or may email their findings to the veterinary technicians and request the veterinary technicians to paste their notes into the computerized medical record. Communications with the research staff about cases are generally noted in the medical progress notes of the computerized medical records. Designated cards may also be placed on cages that are deemed as “resolved but appear abnormal”. For instance, if an animal has a healed wound, but alopecia is still present, a stable card will be placed on the cage. Additionally, if a strain of mice has a specific phenotype that appears abnormal, but is clinically stable, a stable card may also be placed on the cage. The veterinary technician will write a clear description of the stable condition and date it. Husbandry staff is trained to alert Vet Services, should the condition change.

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 mission of the Office of Research Information Systems (ORIS) is to provide quality information technology/information systems support to research offices involved in all aspects of the research enterprise at UNC-CH. ORIS also designs and maintains cutting-edge information systems for use by faculty and staff within the research community. DCM's management of animal ordering, inventory, billing, animal transfers, cage management, and veterinary care medical care and medical records utilize an online enterprise software system.

Medical records are often initiated by DCM husbandry technicians, but could be initiated by anyone identifying an abnormality requiring attention (PI staff, veterinary technicians, etc.) Medical record entries are performed by and medical records are maintained by DCM veterinary technicians and veterinarians. DCM husbandry and clinical staff, and in some cases PI staff have access to the records.

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

The AV has access to and responsibility for all medical records.

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

a. In-house diagnostic laboratory capabilities.

Programs are supported by the DCM Diagnostic Laboratory. The laboratory has the personnel and equipment to perform most diagnostic procedures in microbiology, hematology, cytology, and serum chemistry. Special serum chemistries and blood gas analyses are also done in the clinical laboratories of the UNC-CH Hospital or they are sent to commercial laboratories. CBCs and progesterone levels are typically run at the facility of need. Cage-side testing of blood gases, electrolytes and limited blood chemistries using a hand-held I-Stat is also available. Annual activity last year was approximately 12,000 cases/tests.

b. Commercially provided diagnostic laboratory services.

UNC-CH contracts with IDEXX Bioresearch for rodent testing and may also utilize CRL for confirmatory testing. Other commercial labs utilized are ANTECH or IDEXX for non-rodent species, North Carolina Veterinary Diagnostic Laboratory for agricultural species and other State or Federal Veterinary Diagnostic Laboratories for specialized tests.

c. Necropsy facilities and histopathology capabilities.

Necropsy facilities - The DCM Diagnostic Laboratory performs nearly 400 complete diagnostic necropsies annually. is responsible for the necropsy service and are assisted by and as well as veterinary residents in training. Necropsy facilities have an adjustable height downdraft necropsy table suitable for animals weighing up to 150 lbs. Rodent necropsy facilities with backdraft dissection stations are available in the diagnostic lab along with an ancillary diagnostic laboratory equipped with hematology and clinical chemistry analyzers. An additional rodent necropsy space with backdraft dissection stations are available. A small building is used at remote facilities for necropsies from those closed colonies. This building contains an adjustable height necropsy table for adult swine and a commercial grade band saw. In collaboration with the LCCC, histopathology slides are prepared through the Animal Histology Core. Immunohistochemistry and special stains can be obtained through this LCCC core lab or through the Histopathology laboratory at the North Carolina State University College of Veterinary Medicine in Raleigh. Electron microscopy services are available through a core laboratory in the UNC-CH Department of Pathology and Laboratory Medicine.

d. Radiology and other imaging capabilities.

The radiology facility supports DCM's diagnostic programs. DCM has a Digital radiography (DR) system that allows images to be viewed digitally without the need for film processing. Radiograph images are stored on a hard drive and attached to computerized records and/or can be distributed electronically to researchers and veterinarians as needed. In addition to the fixed unit there is a portable digital x-ray machine that can be used at sites if necessary. The main facility also has a portable dental x-ray unit (eXTend) with images processed and saved on a Progeny digital imaging program.

There is also a computed x-ray (CR) system for use. This facility is also used for research projects. A Faxitron Cabinet X-ray system is available for small rodents. A portable ultrasound machine is also available. This Mindray portable ultrasound machine is equipped with three probes (two linear, one convex) and can easily be taken to other locations to perform imaging.

In addition, imaging facilities support biomedical research through the imaging of animal models. Through this service, DCM veterinarians have access to the current imaging services including MRI/MRS, PET/CT/SPECT, Optical/Bioluminescence, and Ultrasound.

5. **Drug Storage and Control**

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

Within DCM veterinary drugs are stored in lockable cabinets within the surgery laboratory. Controlled substances are stored in a locked safe in the surgery laboratory. Some veterinary drugs are maintained where controlled substances are stored in a locked safe. There is an institutional license covering controlled drugs lockboxes. These lock boxes are currently empty, but should controlled drugs be needed in this facility, the mechanism is in place already for their addition.

PIs performing surgeries on rodent animal models in their labs maintain their own drugs. If a PI needs to use controlled drugs the PI is responsible for maintaining a controlled drug license. Controlled drugs are reviewed during the semiannual inspections.

b. Describe record keeping procedures for controlled substances.

A log is kept for all controlled substances used by DCM. This log is maintained in the surgery laboratory. There are logs in place in the lockboxes. Currently, these logs are blank since there are no drugs in the lockbox. Semiannual inventory of controlled drugs is performed by DCM vet services. Records of PIs performing surgeries in their own laboratories are reviewed as part of the IACUC semiannual review process. The OACU provides templates for documenting use of controlled substances. The EHS website also has instructions for maintaining controlled substances. All controlled substance use is recorded in compliance with DEA regulations including semiannual inventory.

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.

Several mechanisms are available for adequate pre-surgical planning. The DCM veterinary staff pre-review each IACUC application describing survival and non-survival surgery, make recommendations, and are available for consultation. OACU staff (which includes a veterinarian) are available for consultation and help with planning of protocols. Qualified OACU personnel review submitted protocols before they go to the IACUC for review. During the pre-review, OACU personnel make additional surgical planning recommendations. Major survival surgical procedures for non-rodent species are generally conducted in the DCM surgical facility and the veterinary staff coordinates pre-surgical planning including the responsibilities of personnel (pre-anesthesia, monitoring, surgeons,

and postoperative care), adequate equipment availability, and anesthetic and analgesic agents. The PI meets with the DCM surgery staff to plan details of the surgery. There are a few specific survival and non-survival surgeries in non-rodent species that take place in the PI's laboratory. These spaces have been reviewed by the veterinarians, OACU, EHS and are approved by the IACUC.

All surgical areas used for any species are evaluated by IACUC representatives during semiannual inspections. Special attention is paid to physical separation of preparation areas from surgical field functional areas, drug storage, decontamination procedures, availability of hand washing and surgeon preparation space, and limited access during procedures. Approval and subsequent inspections of these spaces is based on provisions in the *Guide* and the OLAW checklist.

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.

The DCM surgical space is used by multiple PIs for surgeries and maintained by DCM Veterinary Services. Researchers that perform surgical procedures outside of this DCM space is expected to obtain and operate all surgical support equipment as described in their approved protocol. The presence and use of this equipment are monitored during semiannual inspections, Procedural Observations, and Post Approval Monitoring. The IACUC has approved a limited number of PI laboratories as suitable for surgical procedures in USDA-regulated species.

The four operating rooms (three for major, one for minor procedures) all have ceiling mounted surgical lights, and ceiling mounted connectors for air, vacuum, and oxygen. The anesthetic machines are equipped with scavenging devices and are exhausted through the vacuum system. All four rooms are occasionally used for non-survival (therefore non-sterile) surgical procedures to support teaching functions. This area receives heavy use.

Surgical support equipment includes 6 gas anesthetic machines, four ventilators, isoflurane vaporizers, a sevoflurane vaporizer, Surgivet multichannel recorders, a portable Lifepack 9 ECG monitor/defibrillator, suction apparatus, and sufficient surgical equipment for abdominal and thoracic procedures. A Biovision laparoscopic imaging system is available in the surgery laboratory for laparoscopic surgical procedures. There is a dedicated recovery room in this surgical facility.

There are a limited number of areas where surgery of USDA-regulated species is performed outside of the DCM surgery lab.

Rodent surgical (survival and non-survival) procedures are either conducted in DCM procedure rooms within animal housing facilities or in PI lab spaces that are approved for surgery as described in the protocol. When active, these spaces are inspected semiannually.

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).

The UNC-CH IACUC categorizes surgical procedures as major or minor as well as survival and non-survival. A major survival surgery is one from which the animal is allowed to recover from anesthesia and which penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions (such as laparotomy, thoracotomy, craniotomy, joint replacement, and limb amputation). Minor survival surgery does not expose a body cavity and causes little or no physical impairment (e.g., wound suturing, peripheral vessel cannulation, or procedures routinely handled as outpatient type procedures at a veterinary clinic.) Minor procedures still require aseptic technique and appropriate anesthesia and analgesia.

   b. How is non-survival surgery defined?

A non-survival surgery is one in which an animal, anesthetized for a surgical procedure, is euthanized prior to recovering (waking) from a surgical plane of anesthesia.

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

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

Training credentials of research personnel performing surgery are included as part of protocol review. The EOCs review the credentials of persons performing surgery as part of the semiannual inspection.

Most USDA-regulated species survival surgeries are done in the DCM surgical facility where patient preparation is monitored by the veterinary staff. This facility has the appropriate equipment to support most surgical procedures and includes scrub sink, sterile equipment, prep room dedicated operating rooms, etc. Spaces within facilities have been approved by the IACUC as suitable for minor surgeries performed by the PI or emergency survival surgical procedures for USDA-regulated species. Aseptic technique is reviewed as part of the semiannual inspection for all laboratories used for surgery.

The requirements for aseptic technique are described in full detail in the Standard on *Rodent Survival Surgery which will be available for review*:

Patient Preparation

- Apply a bland ophthalmic lubricant to the eyes since the blink reflex is lost during anesthesia. For extended procedures, reapplication of the ophthalmic lubricant should occur as needed to keep the eyes from drying out.
- The area around the surgical site should be devoid of hair with removal achieved using a clipper, plucking under anesthesia or a depilatory.
- Prepare the surgical site by using ethyl alcohol or isopropyl alcohol, followed by an Iodophor solution or Chlorhexidine scrub.
- Using cotton tipped applicators or gauze, start with the first alcohol application. Follow the alcohol application with the first Iodophor or Chlorhexidine application.
- Starting in the center of the incision site, spiral outward in concentric circles toward the margins of the prepared area (never go back and forth over a cleansed area with the same gauze).
- Repeat the alcohol and Iodophor or Chlorhexidine step for a total of three times each.

Surgeon Preparation:

- Surgical personnel should wear a clean lab coat, mask, bouffant cap, and sterile gloves.
- If performing multiple surgeries, new gloves should be donned between animals.
- Most aseptic surgery requires hand scrubbing and sterile gloves to be worn. Some (micro)surgery may not require the use of sterile gloves (e.g., surgeries where only instrument tips contact exposed tissue, blastocyst transfer, some stereotaxic procedures, and many mouse surgeries.)

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.

From the *Standard on Rodent Survival Surgery:* All instruments should be properly sterilized. Ensure the instruments are cleaned and free of all organic material before sterilizing. A sterility indicator is placed inside or on the surgical pack to confirm proper sterilization. Acceptable methods include autoclave, gas sterilization with ethylene oxide, and cold sterilization. (A copy of the Standard, which includes a table with all approved Sterilants and contact times will be available during site visit.)

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

If instruments are to be used in subsequent surgeries, instrument tips should be re-sterilized between surgeries, so that the tips (the part touching the animal) are always sterile. Gross debris is removed prior to placement of instruments in the sterilizer. (If using a bead sterilizer, instruments should be cool before touching tissue.) Instrument tips should not be allowed to touch non-sterile surfaces.

d. Indicate how effectiveness of sterilization is monitored.

Monitoring sterilization includes assessing the cycle time, temperature, and pressure of sterilization equipment by observing the gauges or displays on the sterilizer. Some tabletop sterilizers have recording devices that print out these parameters. Correct readings do not ensure sterilization, but incorrect readings could be the first indication that a problem has occurred with the sterilization cycle. An internal chemical indicator is placed in every sterilization package to ensure the sterilization agent has penetrated the packaging material and reached the instruments inside. Also, an external indicator is used when the internal indicator cannot be seen from outside the package. Instruments, gowns, and other materials are generally steam autoclaved. Autoclave tape and sterilization indicators within the packs monitor sterilization of individual packs. Autoclave operation is monitored using Getinge Biosign Steam-24 biological indicators and incubated afterwards to test sterilization effectiveness weekly.

Although PI laboratories are visited by members of the IACUC and surgical procedures are reviewed by the OACU EOCs as part of post approval monitoring, in general, monitoring of effectiveness of sterilization is the responsibility of the PI. If the veterinary staff observes infected surgical incisions in animals, aseptic technique will be reviewed with the PI to determine if improper technique is a possible source of the infection.

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

Some Cores provide fee for service project and surgical support. They provide a variety of established and experiment-specific animal surgical/microsurgical models for a broad range of research applications, with the primary function of meeting PI needs. The Core Director and staff have extensive experience with mouse, rat, and other animal surgical and microsurgical models across many disciplines. The Core

focuses on murine models which have become a predominant tool for many research labs; models in other species are also done and offered through arrangement, with applications from invertebrates to primates.

DCM Surgical Services are available for project anesthesia and surgical support. The facility includes a scrub sink in the instrument prep room adjacent to two of the ORs, two animal preparation (scrub) rooms, an instrument preparation-storage room, and three separate major operating rooms along with a minor procedures/dental room. There are two rooms used for storage of drugs and supplies and a dedicated post-operative recovery room as well as a large animal necropsy room.

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.

Anesthetics and monitoring for surgical procedures are determined in consultation with a DCM veterinarian and described in the approved protocol. The veterinarians, as part of the pre-review of IACUC protocols, specifically assess the anesthetic monitoring and potential for pain and distress. Records of surgeries are maintained in accord with USDA requirements and the *Guide*. These records include the administration of anesthetics, fluids, and any drugs; details of the procedure, including pre-surgical prep, intra-operative monitoring; the method of euthanasia, including all drugs administered to cause death; and the individual performing these tasks. Anesthetics and analgesics, including the name, dose, route, and time of administration are also recorded. Additionally, adverse outcomes requiring euthanasia of the animal prior to completion of the procedure is noted. All records relating to surgical procedures are subject to review during inspection or audit.

Intraoperative anesthesia is monitored by trained staff when procedures are conducted in a PI's laboratory.

Most USDA-regulated species surgeries are conducted in the DCM surgical suite and monitored by DCM Veterinary Services. During the anesthetic period, monitoring is required. Monitoring equipment routinely records indices such as heart rate, respiratory rate, end tidal CO_2, core body temperature, arterial oxygen saturation, blood pressure, blood gases via iStat and/or ECG. Other clinical parameters are routinely used to assess the animal's cardiovascular and respiratory status include character of respirations and heart sounds, mucous membrane color, capillary refill time, and hydration state. Animals are provided external heat supplementation (recirculating water, induction, or forced warm air) for all anesthetic procedures. Observations and monitoring parameters for anesthetic depth and physiologic status should be recorded in the anesthetic record. Any changes in anesthesia (e.g. increasing isoflurane delivery) or administration of additional medications should be noted, including route and dosage. Administration of intra-operative fluids should be noted in the anesthetic record, including type of fluid, rate of administration, and total volume given. At the end of the procedure, the anesthetic/surgical record should

document the time of completion, e.g. finishing skin closure for surgical incision. If the animal is still intubated, it must be continuously monitored until swallowing reflexes return and the animal is extubated.

Rodents should be kept warm with an external heat source both during surgery and until ambulatory. They are not to be left unattended and anesthetic depth is monitored during the procedure (e.g. mucous membranes, toe pinch, and heart rate, respiration rate and/or character, if applicable) until fully recovered from anesthesia (i.e., until moving around and able to right themselves when placed on their back). Animals may be placed in an empty rodent cage while recovering from surgery. Contact bedding is removed to prevent bedding aspiration during recovery and the animal is laid on paper toweling or an absorbent pad. Laboratories are required to keep records of all surgeries performed, anesthesia and analgesia. Procedure cards are provided by DCM to document postoperative care and analgesia at the cage level.

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.

Any animal subjected to survival surgery should have appropriate support and monitoring in the immediate and subsequent post-operative period. Surveillance is required until the animal is sufficiently recovered from anesthesia to maintain sternal recumbency. Vital signs are to be recorded on an established schedule during that period. The records are then maintained in the surgery laboratory for surgical procedures performed there (most major non-rodent survival surgeries). At least daily observation should follow recovery from surgery and appropriate evaluations and treatments should be recorded. These records remain with the animal until daily observation is no longer necessary and are then maintained in the surgery laboratory. Non absorbable skin sutures or staples should be removed after an appropriate healing period (usually 7-10 days). These duties are the responsibility of the PI and their staff. The veterinary staff will also observe these animals daily to assure that appropriate care is provided. If pre-arranged, DCM personnel will perform these functions. Veterinarians are constantly on-call to give advice or undertake treatment if necessary.

The above is required for minor surgical procedures for non-rodent surgery that may be performed in an PI laboratory. No formal reporting system exists for such procedures; however, the surveillance program by the IACUC and DCM personnel is effective in identifying the potential for and minimizing any postoperative problems that are considered likely to arise.

Post-operative care for rodent species is described in the PI protocols and generally requires daily observation and post-operative pain medication. These are reviewed semiannually. Surgical records for rodent procedures are to be maintained by the PI laboratory and reviewed during semiannual inspections.

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

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

The protocol form requires PIs to indicate whether the animal may experience pain or distress. The IACUC evaluates the pain level the animal is likely to experience based upon information provided in the protocol, and this serves as the basis for discussions that may occur during the protocol review-approval process. These discussions may result in modifications of the anesthetic methods proposed or the provisions for post-operative analgesia. The veterinarians, as part of their pre-review of protocols, specifically assess the potential for pain and distress.

The IACUC reviews all studies from the standpoint of their potential to produce pain and distress. Protocols that do not adequately address this are sent to the PI with issues that must be resolved to the IACUC's satisfaction. Formal guidelines have been developed in a few areas, such as humane endpoints, morbidity, and maximal tumor burden.

Analgesia is required for painful procedures unless scientifically justified within the protocol. Protocols which describe animals experiencing unrelieved pain or distress (without the benefit of analgesia or anesthesia) must include a scientific justification which the IACUC reviews and considers. The application must include specific criteria for removal of the animal from the study. The IACUC may require a pilot study, with limited animals, to develop endpoint criteria if the outcomes of an experiment are not known.

The selection of analgesic agents depends on many factors such as the species and age of the animal, the type and degree of pain, the likely effects of particular agents on organ systems, the length of the operative procedure and the safety of the agent for the animal. Each protocol also includes criteria for removal of the animal from the study and/or euthanasia.

UNC-CH IACUC has several guidelines and standards pertaining to pain and distress that are available for review on the IACUC website.

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

Proper training is fundamental in ensuring animal welfare. Species-specific SOP and hands-on training in animal care and recognition of pain and distress is routinely provided to current DCM staff, and as part of the onboarding training process facilitated by the dedicated DCM Training Team. Species-specific Enhancement Plans (for enrichment) and species-specific DCM SOPs are revised and reviewed with staff on a routine basis. DCM training staff and managers perform retraining of animal care staff as indicated or when staff are working with a new species.

In addition, Animal Care staff are encouraged to participate in AALAS Learning Library modules and certification training classes sponsored by the Research Triangle Branch AALAS and at UNC-CH. Regular AALAS certification courses are taught on site and coordinated by the DCM Training Coordinators. Also, the Division pays National AALAS membership for interested staff, has sent at least ~10% of DCM staff attend the AALAS National Meeting in previous years and hopes to continue the practice. Some staff return and present relevant information at the DCM staff meetings.

Training of research personnel in addressing pain and distress is often procedure-specific and provided one-on-one or during PI laboratory meetings with DCM veterinarians, research staff, or senior veterinary services staff qualified to teach.

More general training in such subjects as regulations, aseptic technique, anesthesiology, euthanasia techniques, and animal handling is provided by veterinary, veterinary technical services or other DCM staff qualified to teach. The extent of training depends on the duties and responsibilities of the individuals involved.

Evaluation of outcomes and results (e.g. during rounding) is critical in assessing technical experience and the need for training. If the procedures cause pain or distress, then veterinary services is involved to ensure that the researchers are informed. Training is provided so that the procedures are performed competently. Open communication and cooperation between the veterinary staff, technical core staff, and the researchers regarding innovations in technique are essential in ensuring the most up-to-date and refined use of animals.

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.

The use of anesthetic, tranquilizer and analgesic agents is reviewed during the protocol review process and both the OACU staff and DCM veterinarians serve as a reference for PIs that need additional information in these areas. The IACUC has endorsed species-specific anesthetic and analgesic formularies for the commonly used species on campus available on the IACUC web site. Occasionally, PIs propose to use anesthetics or dosages that are not available in the published literature or that deviate from published ranges and this prompts additional interaction with the IACUC or DCM, or the submission of additional information. **Appendix not provided**

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

The use of anesthetic, tranquilizer and analgesic agents is reviewed during the protocol Veterinary Pre-Review process and both the OACU and DCM veterinarians serve as a reference for PIs that need additional information in these areas. The IACUC has endorsed species-specific anesthetic and analgesic formularies.

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.

Monitoring of the effectiveness of analgesics is the responsibility of those providing those providing the post-operative care and those providing daily health checks. The methods used to monitor anesthesia/analgesia are reviewed as part of the protocol review, during laboratory semiannual inspections, and during daily husbandry.]

Purple PI Monitoring cards and pink post-operative monitoring cards are utilized for enhanced communication between the research staff typically administering the analgesics, and the DCM staff performing daily health checks. If DCM husbandry staff identifies animals that may require further relief, they input a health check for veterinary technician involvement. Any personnel trained to work in DCM (DCM staff & research staff) are trained to utilize Green Health Check cards for identification of potential cases.

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.

Animals anesthetized and paralyzed by neuromuscular blocking agents (NMB) should be monitored by assessing response to external stimulus, heart rate and blood pressure to detect changes that might indicate the need for additional anesthesia. Depth of anesthesia is assessed before paralysis and continuously during and after the paralytic period. Parameters such as heart rate and blood pressure should be recorded every 15 minutes with closer monitoring during times of noxious stimuli. Monitoring data should be available for IACUC review. In general, elevation in any vital parameter of 10%-20% above baseline indicates the need for supplemental anesthesia. Plans for the administration of supplemental anesthesia based on blood pressure and heart rate changes should be described in the protocol and supplemental anesthesia should be administered until the baseline parameters are attained. Monitoring data should also document the dose, time, and route that all anesthetics, paralytics, and analgesics are administered with records kept on file and readily available.

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

Within the Surgical suite, all anesthesia machines are checked for leaks prior to surgical episodes. Yearly preventative maintenance and calibration are done on all DCM owned inhalant vaporizers on campus. The preventative service is also advertised to the research community which may have their vaporizers serviced at that time. According to the

Standard on Anesthetic Vaporizers, service and maintenance should be performed on an established schedule, consistent with the manufacturer's recommendations. If no such recommendation exists, vaporizers should be evaluated every two years.

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.

Rodents – Fetuses and Neonates:
Fetuses up to 14 days in gestation: Euthanasia of the mother or removal of the fetus should ensure rapid death of the fetus at this stage of development.

Fetuses 15 days in gestation to birth: Anesthesia may be induced by injection of the fetus with a chemical anesthetic, or by deep anesthesia of the mother with a chemical agent that crosses the placenta, e.g., pentobarbital. Decapitation with sharp scissors and cervical dislocation are acceptable physical methods of euthanasia when used by a trained person. When chemical fixation of the whole fetus is required, fetuses should be anesthetized prior to immersion in or perfusion with fixative solutions. When fetuses are not required for study, the method chosen for euthanasia of a pregnant mother should ensure rapid death of the fetus.

Adult Rodents:
Gaseous Carbon Dioxide (CO2): must be supplied using a compressed gas tank with flowmeter according to specifics in the most current AVMA Guidelines for the Euthanasia of Animals. The use of dry ice as a source of CO2 for euthanasia is not permitted.

Inhalant Anesthesia: anesthetic agent(s) delivered as a volatile gas to the respiratory tract to induce anesthesia.

Injectable Anesthesia: chemical agent(s) administered by injection with a needle and syringe to induce anesthesia. Common routes of injection include, but are not limited to, intraperitoneal (IP), intramuscular (IM) or intravenous (IV).

Automatic Carbon Dioxide (CO2) Systems: The automated three-stage euthanasia cycle includes charge, dwell, and exhaust. Automation also eliminates the need for physical verification of death and its emotional impact on personnel.

Unanesthetized Physical Euthanasia — Individuals who perform physical euthanasia on unanesthetized animals are first trained and certified by IACUC approved designees.

Physical euthanasia on unanesthetized animals, irrespective of age, can only be done if the procedure is described in the approved protocol.

Cervical Dislocation — cervical dislocation in unanesthetized neonatal and adult rodents is permitted only if it is performed correctly by a trained person, and it is described in an approved protocol. Manual cervical dislocation is a humane method of euthanasia when limited to rodents weighing less than 200 grams. Personnel using cervical dislocation must be adequately trained, demonstrate their technical proficiency, and should consistently apply this method humanely and effectively.

Decapitation — decapitation in unanesthetized neonatal and adult rodents is permitted only if it is performed correctly by a trained person, and it is scientifically justified in an approved protocol. Guillotines that are designed to accomplish decapitation in adult rodents in a uniformly instantaneous manner are commercially available. Sharp scissors can be used to decapitate neonatal rodents.

Euthanasia of sick or injured animals:
Sick or injured animals that cannot be successfully treated or relieved of pain and distress should be euthanized promptly. Research personnel are responsible for euthanizing sick, injured or moribund animals as soon as these conditions are noted. These animals should not be held for later euthanasia by DCM personnel. To investigate unexpected illnesses, research personnel may contact Veterinary Services to arrange for euthanasia and necropsy of the animals. DCM veterinarians have the authority to euthanize moribund animals, as well as animals experiencing more than momentary or slight pain and/or distress. If the DCM veterinarian is unable to contact research personnel regarding the care or treatment of a moribund animal, veterinarians or designated representatives are authorized to euthanize the animal.

Euthanasia of animals in animal housing areas:
Euthanasia of rodents may take place in rodent housing rooms containing IVC and/or a fume hood that exhausts to the outside. The euthanasia method used should be described in the approved protocol. Note: In extenuating circumstances and with permission from DCM Veterinary or IACUC staff members, an acceptable euthanasia method not described in the approved protocol may be performed in the animal housing rooms.

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

PIs are advised to check guillotine and scissor blades to ensure sharpness. The equipment used to perform decapitation should be maintained in good working order and serviced on a regular basis to ensure sharpness of blades. The use of plastic cones to restrain animals appears to minimize stress from handling, minimize the chance of injury to personnel, and improves positioning of the animal in the guillotine. During semiannual inspections, IACUC representatives discuss with and advise researchers about maintaining sharp blades.

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

For large animal species, death is confirmed before necropsy and disposal of any animal remains. A combination of criteria including lack of pulse, breathing, corneal reflex and response to firm toe pinch, inability to hear respiratory sounds and heartbeat by use of a stethoscope, graying of the mucous membranes, and rigor mortis. In small animals, verification of death may be supplemented by percutaneous cardiac puncture after the animal is unconscious. Failure of the needle and attached syringe to move after insertion into the heart (aspiration of blood provides evidence of correct location) indicates lack of cardiac muscle movement and death.

With the exception of the automated CO2 system and a few approved protocol exceptions, in order to confirm that animals are dead, one of the following secondary physical methods should be performed on animals that have been anesthetized with approved agents: cervical dislocation, decapitation, thoracotomy [open the chest cavity using sharp scissors or scalpel], or collection of vital organs. Note: In addition to DCM personnel, only research personnel who have been properly trained and are listed on the approved protocol can perform these physical methods.

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.

For all animal facilities the husbandry manager or supervisor reports to an AOD who provides husbandry management, support and oversight and reports to the DCM Director who directs the animal husbandry and veterinary care program and has delegated program authority and responsibility for the Institution's animal care and use program. Each animal room has a temperature and humidity sensor that is tied to a Building Automation System (BAS). There is a central group called Energy Management Control System (EMCS) within UNC Facility Services that monitors data sent by building BAS systems. If temperature or humidity readings drop or increase above a set point EMCS is alerted. EMCS monitors building HVAC parameters from 6:30 AM to 10:30 PM during week and 6:30 AM to 4:30 PM on weekends. In addition, DCM has an annual contract with Johnson Controls Incorporated that provides annual commissioning of sensors and monitoring 24/7/365 of DCM buildings. DCM has senior husbandry personnel that receive notifications when temperatures or humidity are out of range.

When a problem is found after hours personnel can call emergency staff that is on-call. Below is a general listing of facilities:

1) This off-campus facility is located 13 miles away from main campus consists of 56 acres and 28,015 nsf. The site has three buildings: One story building is 7314 nsf, a second building is 4908 nsf, and lastly a third 9,300 nsf one story building. In addition, this site houses two storage buildings for general DCM storage totaling 6,493 nsf.

2) This 695 nsf facility includes two suites for ABSL rodents. A single corridor provides access to animal rooms and support areas.

3) This 2,807 nsf facility is in the basement of a research building and includes nine (8) separate housing rooms for rodents. One of these rooms is located on the first floor and is serviced via elevator from the basement. A single corridor provides access to animal rooms and support areas.

4) This 7,313 nsf facility is in the basement of the building which includes (4) separate rooms for rodents and adjacent procedural rooms. A single corridor provides access to animal rooms and support areas.

5) Off-campus facility ~14,434 nsf includes six buildings (3 not currently used). Three are roofed buildings whose sides are partial block walls and partially open. Two are modular buildings. The newest facility is a large block building. A further description of the buildings is as follows:

Main building: This 5428 nsf facility provides treatment/isolation space and a four pen whelping room and a two pen isolation room for maintaining animals, as well as PI laboratories, two detached indoor-outdoor kennels each containing runs are connected to the main building by a covered breezeway.

Necropsy room: This 358 nsf facility contains an adjustable height necropsy table and a commercial grade band saw.

This 603 nsf curtain-sided building is cinder block halfway up, then open sides with sloped roof. Openings are covered with hardware cloth. Concrete slats are supported by cinder blocks over a concrete floor. The galvanized metal penning provides 60 square feet of space each. Pen dividers are rods, so animals in adjacent pens can see each other and touch noses for social interaction. There is a trough drain along back side to floor drain at one end, an exhaust fan, waterproof light fixtures, receptacles, and switch. Heavy-duty curtains can be closed during cold weather. Heat is natural gas forced air heat. There is one watering nipple per pen, stainless steel feeders and a drip hose above pens to provide extra cooling. This building is currently used for storage only and does not house animals.

This 1082 nsf curtain-sided building has a cinder block base with open sides covered with hog wire and concrete slat floors over concrete pit. Galvanized rod penning provides social

interaction between pens. Ten pens are 5 x 10 feet. 2 pens are 6 x 10 feet. Three breeding pens are 12 x 10 feet. There is a mist system for cooling in addition to natural ventilation and forced air heating. Heavy-duty curtains can be closed in the winter. The pit has automatic flushing. This building currently does not house animals.

This 450 nsf building has tri-bar flooring, galvanized steel penning, stainless steel feeders. Heating is forced air, cooling is an evaporative cooler. The building has aluminum siding on the outside and seamless fiberglass on the interior (walls, floors, and ceilings). Three European-style farrowing pens are contained in this building. Each pen is 8' x 8' with swing sides for the sow to allow for more sow space as piglets get larger. All pens (nursery and farrowing) are over a small pit that is drained and flushed weekly when in use.

This 5,150 nsf building is of concrete block half-wall construction with painted aluminum siding above. Most floors are concrete slats with tri-bar flooring in one room. The pens are galvanized steel with stainless steel feeders, and automatic waterers. Cooling is done with evaporative coolers. Heat is forced air natural gas. Exhaust fans are opposite the evaporative cooling units. Slats are over a pit that is drained and flushed weekly.

6) This facility has an Upper Basement (UB) and Lower Basement (LB). There are two on-site managers overseeing the daily facility operations of the UB and of LB. This 59,673 nsf facility is arranged on two floors and houses SPF viral- antibody free rodents in 37 animal rooms. The National Gnotobiotic Rodent Resource Center is in LB and has one on-site manager to oversee daily operations. There are currently 100 flexible film isolators and three racks of ISOcages that contain rodents. Lastly, one of four national Mutant Mouse Research Resource Centers maintains housing and procedural rooms in LB.

7) This 4016 nsf facility includes 4 animal rooms. It also has an additional room with 3 biohazard cubicles.

8) This facility contains 12,310 nsf including 10 animal rooms, and 1 procedure room, 3 isolation cubicles, the experimental surgery and radiology suites and a necropsy room. There is also one holding room on the second floor that supports the Mutant Mouse Research Resource Center and is considered a part of the main vivarium.

9) This 12,247 nsf of newly renovated vivarium space was completed in 2019. It has 8 animal rooms, 13 cubicles split between 2 separate rooms and 7 procedure rooms and there are 3 APSE rooms outside the vivarium for spaces needing to keep animals longer than 12 hours.

10) This 9653 nsf facility was newly renovated in 2019. It consists of 6 animal rooms off a single corridor and has a BSL2 suite with 7 isolation cubicles and a NuAire ducted Class 2 biosafety cabinet. There is a large bulk autoclave for the BSL2 area with dirty to clean pass of equipment out of the suite.

11) This ABSL space includes 458 nsf with autoclave, animal housing, two BSC's and -80 freezer within the space.

12) This 8,377 nsf facility includes 11 animal rooms for multiple species including rodents, rabbits, pigs, dogs, and primates. It also has an additional room with 6 BSL2 cubicles. There is also 1 holding room located outside of the vivarium on the 7th floor that supports the inhalational research programs but is considered a part of the main vivarium.

13) This 18,595 nsf building has animal facilities arranged on two floors and houses viral free animals in 15 rooms. The mouse behavioral facility is located on the first floor. The behavioral core includes a state-of-the-art laboratory for the measurement of mouse phenotypes and offers training and consultation regarding the utilization of animal models. Available testing regimens include a standardized battery for measures of general health and neurological reflexes, procedures for sensory and motor abilities, and evaluations of social interaction, sensorimotor gating, cognitive function, and abnormal repetitive behavior.

14) This 11,102 nsf facility includes 9 animal rooms, a set of six biohazard (ABSL2) containment cubicles and a set of five positive pressure isolation cubicles and 3 PI maintained procedure rooms. Four offices and a break room are just outside the animal space.

15) This 7,222 nsf facility is in the basement of the building; zebrafish housing rooms (30 racks), a nursery room and a zebrafish quarantine room, 2 procedure rooms (for microinjection and fluorescence). Two corridors provide access to animal rooms and third floor support areas.

16) This 2,743 nsf facility contain two suites of sand toads, one suite for the educational animals, and one suite containing multiple amphibians, snakes and reptiles and a large holding room for the turtles.

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)

1. Located off campus, this site has three buildings with a single corridor to access the animal rooms in each building.
2. Research labs are not located on the premises. However, some rooms serve as wet laboratory space for the on-site research staff. Animals are transported to campus for use, or researchers will drive to the facility. One procedure room is available in each of building.
3. One building includes 20 indoor kennels, 11 indoor-outdoor kennels. Another building includes 32 indoor kennels. The last building includes 5 animal holding rooms. There is a cage washroom that serves the facilities on this site.
4. The walls are epoxy painted cinder block. The ceilings are painted concrete or painted waterproof drywall. The floors are sealed epoxy. The doors are sealed wood, steel, or steel-sealed composite.
5. One pass air system that consist of an air handler unit and roof exhaust fans, except when exhaust fans are on the sides of the building. Humidifiers are in ductwork servicing the rooms where animals are located. Supply box terminals are constant volume with pneumatic controls.
6. All entrances have scan card readers which require a badge to gain access. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera.
7. One building has skylights along the roof edge (25' off ground). This facility is on a light cycle as well. There is an outer perimeter security fence, building security and security cameras. In the event of anyone entering the buildings unauthorized, security and DCM would be notified.
8. Chemicals are stored in the general storage room.

2)

1. The BSL facility contains a suite for ABSL housing with a clean/dirty corridor.

2. Research support labs are maintained within the ABSL suite.
3. The facility includes two sides: Southern and Northern side. The southern ABSL facility where an aerosolization chamber and rodents are housed in IVC and/or biocontainment caging. The northern side houses ABSL rodents in biocontainment caging.
4. The floors throughout the facility are epoxy quartz and the walls and ceilings are of wallboard construction with epoxy finish that is impermeable and airtight. The doors are steel and glass construction.
5. The HVAC is one pass air system that consists of one air handler unit and roof exhaust fans. Humidifier located on air handler unit at location. Supply box terminals are constant volume and have digital controls. EMCS monitors data sent by building BAS systems. EHS, DCM senior husbandry personnel, and Public Safety receive alarm emails to their smart phones when HVAC parameters are out of range.
6. All entrances into the building have scan card readers which require a badge to gain access. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera. There is also a separate security code required to enter the animal facility.
7. Automated light timer with a manual override stays on for 30 minutes when triggered after dark, and then turns off automatically. The photoperiod control is 12:12.
8. Chemicals are not stored within facility.

3)

1. The basement is a conventional animal facility design serviced by a single corridor. A single corridor provides access to animal rooms and support areas.
2. An elevator connects the animal housing area directly to the area where most of the animal-related research is conducted, minimizing the mixing of personnel with animals that occurs in shared elevator systems. Researchers also move animals to other laboratories in this building.
3. There are 9 animal rooms located within the facility, all housing rodents. One of these rooms is located on the first floor and is serviced via elevator from the basement. All rodents are housed on Tecniplast IVC racks with auto-watering.
4. The walls are epoxy painted concrete. The ceilings are painted waterproof drywall. The floors are sealed epoxy. The doors are steel.
5. One pass air system that consist of one air handler and heat recovery units and exhaust fans. Humidified air is supplied via duct work. Supply box terminals are constant volume and have digital controls. EMCS monitors data sent by building BAS systems. EMCS is facilities manned by pager from 6:30 AM to 10:30 PM during week and 6:30 AM to 4:30 PM on weekends. DCM vivarium have designated senior husbandry personnel to receive alarm emails to their smart phones when temperatures or humidity are out of range. When a problem is found after hours personnel can call emergency staff that is on-call.
6. All entrances, support areas and animal rooms have scan card readers. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera.

7. No exterior windows. Facility is controlled automatically by Johnson Control lighting system. Photoperiod is 12/12 unless requested differently by researcher. Species housed in this facility is rodents and the light intensity is 28-35 ft. candles. Light fixtures are water-resistance and each room has an override control. Once activated the lights turn on for 30 minutes then cycle off.
8. Chemicals are stored in room 10.

4)

1. This conventional animal facility design serviced by a general corridor. There are 4 animal rooms, 4 procedure rooms and a rodent surgical procedure room. An AWS with stainless steel room distribution piping supplies reverse osmosis filtered hyperchlorinated treated water to rodents housed in Tecniplast IVC racks. The AWS uses an automatic flushing system to control free-floating bacteria.
2. Procedure rooms are located within the facility where most animal experimental manipulations are performed. There is also an elevator connecting the animal facility to the research labs upstairs if animals need to be transported to the lab. No live animals can be returned to the animal facility.
3. Has 4 SPF-animal rooms with library style racks to maximize space. There are four rodent rooms that house mice and rats, respectively. There are four procedure rooms that are unassigned and can be used for experiments.
4. The walls are epoxy covered cinder block. The ceilings are painted water-resistant plaster. The floors are sealed epoxy. The doors are steel.
5. The HVAC system is a one pass air system that consist of one air handler unit and heat recovery units and exhaust fans. Humidifier in duct work. Supply box terminals are constant volume and have digital controls. Valves associated with the reheat coils are normally open.
6. Security is controlled by badge-activated UNC One Card system. All entrances to the facility have a slide card reader that requires a badge card to enter. Additionally, each animal room and the two behavioral procedure rooms have an Edstrom Watchdog system 4-digit key pin access panel to enter the rooms. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera.
7. There are no exterior windows.
8. Chemicals are stored in rooms B505, B509, and B516E.

5)

1. Located 15 minutes off main campus, the research laboratory space is in the main building and adjacent modular buildings.
2. The main building includes a treatment room and laboratory space for studies. Two wings adjacent to the main building enclose indoor-outdoor runs with access corridors both in the inside and outside areas. The outside facilities are located behind the main building and kennel areas and are accessible by a variety of walkways.
3. The walls are painted concrete and cinder block. The ceilings are painted concrete. The floors are sealed epoxy in the dog runs.

4. There are several buildings at this location. Main building and dog areas have one pass supply air and roof exhaust fans. Other buildings at location have various HVAC equipment. Valves associated with the reheat coils are normally closed at the main building. Emergency generator backup power is provided for all buildings and sanitary pumps.
5. There is a scan card reader and keypad gate at the driveway entrance kept locked during non-work hours. There are 3 buildings, each equipped with either a scan card access or keypad entry system utilized at all times. The animal housing area is surrounded by an additional fence. All outside gates are secured. Security cameras are in use at this facility.
6. Entrance and animal rooms have scan card readers that requires a badge card to enter.
7. Chemicals are stored in the Large Barn and on carts in the hallway of the pig barn.

6)

1. The upper and lower basements of this building are treated as separate vivaria. An automatic watering system (AWS) with stainless steel room distribution piping supplying reverse osmosis treated water for all animals housed in Tecniplast IVC cages. The AWS uses an automatic flushing system to control free-floating bacteria. The animal rooms and procedure rooms are served by a single corridor. The first floor is arranged in a clean-dirty corridor arrangement with a soiled to clean arrangement in the cage wash area. The CC System Genetics Mouse Colony is a large panel of new inbred mouse strains currently being developed through a community effort (Churchill et al. 2004). The CC addresses many short comings in available mouse strain resources, including small numbers of strains, limited genetic diversity, and a non-ideal population structure. The CC strains are derived from an eight way cross using a set of founder strains that include three wild-derived strains. The lower floor is served by a clean-dirty corridor system providing access to animal rooms and support areas, and the cage wash area is arranged in a dirty-clean pattern. Animals are not allowed to return to the facility once they leave the vivarium. LB contains the SPF-barrier facility, NGRR Core, the MMRRC, the AMC, and several humanized mouse cores.
2. The upper floor (UB) includes seventeen project/procedure rooms within the facility, many of which serve as core facilities for PIs whose animals are housed in this facility. Most of the animal users have labs in the floors above the facility. The lower floor (LB) facility includes significant animal research space for the researchers housing animals and ten procedure rooms, many of which serve as core facilities for PIs across campus. PIs are housed either in upper floors of this building, or in other buildings on campus.
3. Gnotobiotic animals are housed in conventional caging inside a flexible film isolator. All other rodents are housed in Tecniplast IVC racks. Set of biohazard cubicles containing 8 and 18 Illinois-type cubicles located on each floor, respectively.
4. Ducted and recirculating filtered exhausted biosafety cabinets are in procedure room and in most housing rooms throughout each area. This area is used for containment of animals exposed to biohazards.
5. UB consists of ten sterile housing areas and three non-sterile housing areas. There is one remote return room on the fourth floor.

6. The walls are epoxy painted cinder block. The ceilings are painted waterproof drywall. The floors are SeamTek® N2 sealed monolithic flooring. The doors are sealed fiberglass composition.
7. One pass air system that consist of one air handler and heat recovery units and exhaust fans. Humidified air is supplied via duct work. Supply box terminals are constant volume and have digital controls.
8. All entrances, support areas and animal rooms have scan card readers. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera.
9. No exterior windows. Facility is controlled automatically by Johnson Control lighting system. Photoperiod is 12/12 unless requested differently by researcher. Species housed in this facility is rodents and the light intensity is 28-35 ft. candles. Light fixtures are water-resistance and each room has an override control.
10. Chemicals are stored in an upper basement room.

7)

1. A conventional animal facility design. A single corridor provides access to the animal rooms and support areas. An AWS with stainless steel room distribution piping supplies reverse osmosis treated water to rodents housed in Tecniplast IVC racks. The AWS uses an automatic flushing system to control free-floating bacteria.
2. Research laboratories exist throughout the three upper floors of the building and the research staff normally accesses the facility by a shared elevator or stairwell at the back of the building. The animal facility contains three rooms of extended lab space for researchers housing animals in the facility.
3. Has two rodent housing rooms, one Animal Metabolism Phenotyping Core room, one experimental housing room and BSL2 rodent housing room. There is also BSL2 suite with 3 isolation cubicles. All caging is on IVC racks.
4. The walls are epoxy painted cinderblock. The ceilings are painted waterproof drywall. The floors are sealed epoxy and the doors are steel.
5. All entrances and animal rooms and procedure rooms to the facility have scan card readers that requires a badge card to enter. The facility is equipped with several security cameras that capture video when there is movement on the camera.
6. There are no exterior windows.
7. Chemicals are stored in rooms B243.

8)

1. A conventional animal facility design. A single corridor provides access to the animal rooms and support areas. An AWS with stainless steel room distribution piping supplies reverse osmosis treated water to primarily rodents housed in Tecniplast IVC racks. The AWS uses an automatic flushing system to control free-floating bacteria.
2. Most animal users are School of Medicine researchers with laboratories on upper floors within the building. Animals are only allowed to return to a designated “high risk” return room in the facility once removed.

3. The newly renovated facility has two large bays with library style high-density IVC racks, a reverse light cycle room, sterile and non-sterile housing and BSL2 suites one with seven cubicles and the other with six cubicles. All caging in MEJ are IVC.
4. The walls are epoxy covered cinder block. The ceilings in animal rooms are painted waterproof drywall. The floors are sealed epoxy. The doors are steel and FRP plastic in the renovated area.
5. The HVAC is one pass air systems that consist of two air handler units and heat recovery units and exhaust fans. Humidifier located in one of air handler units. Supply box terminals are constant volume and have digital controls. Valves associated with the reheat coils are last position.
6. All entrances, the BSL2 suites and the autoclave area connected to the suite have scan card readers. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera.
7. There are no exterior windows.
8. Chemicals are stored in rooms 1402.

9)

1. The animal rooms and procedure rooms are served by a single corridor. an automatic watering system (AWS) with stainless steel room distribution piping supplying reverse osmosis treated water for all animals housed in Tecniplast IVC cages. The AWS uses an automatic flushing system to control free-floating bacteria. All rodents are housed in Tecniplast IVC cages.
2. Research laboratories exist throughout the building and research staff access the facility by an elevator located in the interior of the building, by an external door that connects adjacent conjoined building, or an exterior door directly into the building.
3. This building has five mouse rooms and two procedure rooms. Animals are only allowed to return to a designated "high risk" return room or cubicles after being removed. There is a set of biohazard cubicles and one biosafety hood. The animal surgery suite is located within the facility and includes 3 operating rooms and rooms for surgical prep, dentals, non-sterile surgery, radiology, recovery, induction, necropsy, and the pharmacy. There is a procedure room and study room built for Faraday cage studies. There is also one holding room on the second floor that supports the Mutant Mouse Research Resource Center and is considered a part of the main vivarium.
4. The walls are epoxy painted cinder block. The ceilings are painted waterproof drywall. The floors are sealed epoxy. The doors are steel.
5. The HVAC is a one pass air system that consist of one air handler unit and roof exhaust fans. Humidifier located on air handler unit at location. Supply box terminals are constant volume and have digital controls. EMCS monitors data sent by building BAS systems. DCM vivaria have designated senior husbandry personnel to receive alarm emails to their smart phones when temperatures or humidity are out of range. When a problem is found after hours personnel can call emergency staff that is on-call. All entrances to the facility have a swipe card reader that requires a badge ID card to enter. All animal and procedure rooms are also badge ID entry. Additionally, the facility is equipped with several security cameras that capture video when there is movement on the camera.

6. No exterior windows. Facility is controlled automatically by Johnson Control lighting system. Photoperiod is 12/12 unless requested differently by researcher. Light fixtures are water-resistance and each room has an override control.
7. Chemicals are stored in corridor rooms and in chemical carts in various corridors.

10)

1. This facility is a conventional animal facility design. A single corridor provides access to the animal rooms and support areas. An AWS with stainless steel room distribution piping supplies reverse osmosis treated water to primarily rodents housed in Tecniplast IVC racks. The AWS uses an automatic flushing system to control free-floating bacteria.
2. Animals are only allowed to return to a designated "high risk" return room in the facility once removed.
3. Two rodent housing rooms, four rooms with trench drains and housing equipment for flexible large animal holding. The BSL2 suite contains seven isolation cubicles. All mouse caging is IVC.
4. The walls are epoxy covered cinder block. The ceilings in animal rooms are painted waterproof drywall. The floors are sealed epoxy. The doors are steel and FRP plastic in the renovated area.
5. The HVAC is a one pass air system that consist of two air handler units and heat recovery units and exhaust fans. Humidifier located in one of air handler units. Supply box terminals are constant volume and have digital controls. Valves associated with the reheat coils are last position.
6. All entrances, the BSL2 suite and the autoclave area connected to the suite have scan card readers. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera.
7. There are no exterior windows.
8. Chemicals are stored in rooms 1208.

11)

1. This facility contains a suite for ABSL housing.
2. The facility contains IVC and biocontainment caging and a small autoclave unit. Decontaminated caging is washed in the adjoined vivarium.
3. The floors throughout the facility are epoxy quartz, and the walls and ceilings are of wallboard construction with an epoxy finish that is impermeable and airtight.
4. The HVAC is one pass air system that consists of one air handler unit and roof exhaust fans. Humidifier located on the air handler unit at location. Supply box terminals are constant volume and have digital controls. EMCS monitors data sent by building BAS systems. DCM senior husbandry personnel and Public Safety receive alarm emails to their smartphones when HVAC parameters are out of range.
5. All entrances into the building have scan card readers which require a badge to gain access. The facility is also equipped with several security cameras that capture video when there is movement on the camera. There is also a separate security code required to enter the facility.

6. There are no exterior windows. Automated light timer with a manual override stays on for 30 minutes when triggered after dark, and then turns off automatically. The photoperiod control is 12:12.
7. Chemicals are stored in a general storage room within the facility.

12)

1. A conventional animal facility design. A single corridor provides access to the animal rooms and support areas. An AWS with stainless steel room distribution piping supplies reverse osmosis supplies treated water to animals. The AWS uses an automatic flushing system to control free-floating bacteria.
2. The Animal Imaging Facility is located adjacent to the animal holding rooms and supports biomedical research through the imaging of animal models. When scheduling for PET/MRI scanner, PET/CT scanner will be blocked for no human study, and vice versa for PET/CT study. Human studies are not scheduled after large animal studies. At no time should human patients have any contact with animal subjects (e.g. visual contact, should not be able to hear the animal, should not be able to identify anything associated with animal experiments). Prior to the transportation, animals are placed in clean cages or transport kennels.
3. Animals are transported to the imaging suite on the first floor via the dedicated "Animal Elevator" and double door to the imaging rooms. Cages are covered by non-transparent sheet or cloth. Animals are not allowed to enter through patient areas.
4. The facility has multiple housing rooms on the main floor and one animal housing room outside the facility is on the 7th floor. There is also a BSL2 room with six isolation cubicles and two ducted biosafety cabinets. Animals are only allowed to return to a designated "high risk" return room in the facility once removed (e.g. imaging). There are multiple procedure rooms.
5. The walls are epoxy painted cinder block. The ceilings are painted waterproof drywall. The floors are sealed epoxy and the doors are FRP plastic.
6. The HVAC is a one pass air system that gets supply off building air handler units. Dedicated exhaust fans for area. Humidifier in duct work. Supply box terminals are constant volume and have digital controls. Valves associated with the reheat coils are last position.
7. All entrances, support areas and animal rooms have scan card readers. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera.
8. There are no exterior windows.
9. Chemicals are stored in rooms B103.

13)

1. The first floor is arranged in a clean-dirty corridor arrangement with a soiled to clean arrangement in the cage wash area. The second floor is served by a single corridor providing access to animal rooms and support areas, and the cage wash area is arranged in a dirty-clean pattern. A set of biohazard cubicles are located on each floor. All rodents are housed in Tecniplast IVC racks except for some animals housed in the cubicles. These are housed in static shoe box cages and delivered water via bottles. All

other rodents are housed in Tecniplast IVC caging. Water is delivered via an automatic watering system (AWS) with stainless steel room distribution piping supplying reverse osmosis treated water for all animals housed in IVC cages. The AWS uses an automatic flushing system to control free-floating bacteria.

a. Floors 1 and 2 are treated as separate vivaria. The Mouse Behavioral Core facility is located within the first floor. The Core includes a state-of-the-art laboratory for the measurement of mouse phenotypes and offers training and consultation regarding the utilization of rodent models. Available testing regimens include a standardized battery for measures of general health and neurological reflexes, procedures for sensory and motor abilities, and evaluations of social interaction, sensorimotor gating, cognitive function, and abnormal repetitive behavior. The Core utilizes most of the facility housing for behavioral testing.

2. The second-floor facility includes significant research space for the researchers housing animals.
3. #1 has three rodent rooms, eight behavioral project rooms, one high risk-return room and a biohazard cubicle suite. #2 has eight rodent rooms and a biohazard cubicle suite.
4. The walls are epoxy painted cinder block. The ceilings are painted waterproof drywall. The floors are sealed epoxy. The doors are steel.
5. The HVAC is a one pass air system that consist of one air handler unit and roof exhaust fans. Humidifier located on air handler unit at location. Supply box terminals are constant volume and have digital controls. EMCS monitors data sent by building BAS systems. DCM vivaria have designated senior husbandry personnel to receive alarm emails to their smart phones when temperatures or humidity are out of range. When a problem is found after hours personnel can call emergency staff that is on-call.
6. All entrances to the facility have a swipe card reader that requires a badge ID card to enter. As an ongoing project, additional scan card readers will be added to the second-floor rooms and support areas. #1 recently had badge readers added in March of 2019. Additionally, the facility is equipped with several security cameras that capture video when there is movement on the camera.
7. No exterior windows. Facility is controlled automatically by Johnson Control lighting system. Photoperiod is 12/12 unless requested differently by researcher. #1 has one 24-hour dark housing room and one reverse light cycle housing room. The species housed in both facilities are rodents. Light fixtures are water-resistance and each room has an override control.
8. Chemicals are stored in multiple rooms, and in chemical carts in various corridors. In second floor chemicals are stored in multiple rooms and in chemical carts in various corridors.

14)

1. Design of this building allows five animal rooms, set of six biohazard containment cubicles and a set of five positive pressure isolation cubicles to be serviced via a clean/dirty corridor system, including three PI maintained study rooms while four animal rooms one PI assigned study room, and two common project rooms are serviced via a single corridor. The offices and break area are outside the facility.

2. Many of the researchers have labs in the floors above the facility. Primary users of the animal facility are researchers with laboratory and office space in the building, including those from the Centers for Alcohol Studies, Gene Therapy, and Musculoskeletal Diseases. There are several rooms dedicated solely for behavioral studies for rodents. Two rooms with biosafety cabinets serve as common project space available for all. One room with a biosafety cabinet serve as a PI assigned procedure room.
3. The facility has six non-sterile mouse rooms, three non-sterile rat rooms, a biohazard containment area, and a positive pressure isolation area.
4. EMCS HVAC parameters are manned by pager. DCM vivaria have designated senior husbandry personnel to receive alarm emails to their smart phones when temperatures or humidity are out of range.
5. The walls are epoxy painted cinder block. The ceilings are painted waterproof drywall. The floors are sealed epoxy. The doors are steel.
6. One pass air system that consist of one air handler unit and roof exhaust fans. Humidifiers located in duct work. Supply box terminals are constant volume and have digital controls. When a problem is found after hours personnel can call emergency staff that is on-call.
7. All entrances, support areas and animal rooms have scan card readers. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera.
8. No exterior windows. Facility is controlled automatically by Johnson Control lighting system. Photoperiod is 12/12 unless requested differently by researcher. Species housed in this facility is rodents and the light intensity is 28-35 ft. candles. Light fixtures are water-resistance and each room has an override control.
9. Chemicals are stored in 1144 and 1160.

15)

1. A conventional animal facility design serviced by two general corridors. There are 9 tank rooms, 3 procedure rooms. An AWS with stainless steel room distribution piping supplies reverse osmosis filtered hyperchlorinated treated water to rodents housed in Tecniplast IVC racks. The AWS uses an automatic flushing system to control free-floating bacteria. Water dedicated to aquatic species undergoes reverse osmosis filtering and hyperchlorination and then flows through two large activated carbon tanks to remove the chlorine before entering the fish rooms. Water quality is frequently monitored via the life support system and/or manually for nitrates, nitrites, ammonia, chlorine, hardness, and other parameters.
2. Procedure rooms are located within the facility where most animal experimental manipulations are performed. There is also an elevator connecting the animal facility to the research labs upstairs if animals need to be transported to the lab. Fish may be returned to the quarantine room only. No other live animals can be returned to the animal facility.
3. Two rabbit rooms, five zebrafish rooms and two aquatic procedural rooms.
4. The walls are epoxy covered cinder block. The ceilings are painted water-resistant plaster. The floors are sealed epoxy. The doors are steel.

5. One pass air system that consist of one air handler and heat recovery units and exhaust fans. Humidified air is supplied via duct work. Supply box terminals are constant volume and have digital controls. EMCS monitors data sent by building BAS systems. DCM vivaria have designated senior husbandry personnel to receive alarm emails to their smart phones when temperatures or humidity are out of range. When a problem is found after hours personnel can call emergency staff that is on-call. The Main system (20 racks) and quarantine system (2 racks) send email alerts when water quality parameters are out of specification.
6. All entrances, support areas and animal rooms have scan card readers. Also, the facility is equipped with several security cameras that capture video when there is movement on the camera.
7. No exterior windows. Facility is controlled automatically by Johnson Control lighting system. Photoperiod is 14:10 unless requested differently by researcher. Species housed in this facility are rabbits and zebrafish. Light fixtures are water-resistant, and each room has an override control. The light intensity is 28-35ft. candles. Mean light intensity across all fish rooms is 10 ft candles.
8. Chemicals are in B09.

16)

1. A conventional animal facility design.
2. Procedure rooms are located within the facility where most animal experimental manipulations are performed. There is also an elevator connecting the animal facility to the research labs upstairs if animals need to be transported to the lab.
3. There are in a large room for turtles and four suites which houses a variety of amphibians, snakes and toads for the Department of Biology and the Carolina WISE program.
4. The walls are epoxy covered cinder block. The ceilings are painted water-resistant plaster. The floors are sealed epoxy.
5. One pass air system that consist of one air handler and heat recovery units and exhaust fans. Humidified air is supplied via duct work. Supply box terminals are constant volume and have digital controls. EMCS monitors data sent by building BAS systems. DCM vivaria have designated senior husbandry personnel to receive alarm emails to their smart phones when temperatures or humidity are out of range. When a problem is found after hours personnel can call emergency staff that is on-call.
6. All entrances have scan card readers. All support areas and animal rooms are locked with keys.
7. There are no exterior windows.
8. Chemicals are stored in secure storage spaces.

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.

Appendices not provided

At UNC-CH a Satellite Facility is defined as a vivarium facility not under the direct management of DCM. Regardless, PI-managed facility staff coordinate husbandry care with DCM leadership. At UNC-CH, all animals, whether satellite or centralized facility, are under the direct veterinary care of the AV. There are 4 Satellite Facilities, not managed by DCM, which house small numbers of rodent species or animals maintained and utilized a significant distance from the University. One is located approximately 150 miles from Chapel Hill. The other NRI zebrafish facility is located about 100 miles from campus.

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.

The authority and oversight of these facilities lies with the institution through the IACUC. Satellite Facilities are approved in rare instances where there is appropriate justification for housing animals long-term outside of DCM facilities. In addition, IACUC approval of a proposed Satellite Facility will be granted only if the environment, housing, care, and oversight meet the standards of the *Guide*, federal law, and current institutional (e.g., EHS, DCM) policies are met. The approval process requires that the PI initially submit a request with justification to the IACUC through the protocol submission process. Justification for a proposed Satellite cannot be based on convenience. Rather, it must be based on factors such as the inability to house animals in a DCM facility, the inability of DCM to provide the desired space, care, or scientific reasons. If the IACUC approves the Satellite justification, then the PI can begin coordinating an initial inspection of the proposed site. IACUC, DCM, and EHS representatives are included in the initial inspection. These representatives will help identify any potential problematic issues such as cluttered space, improper storage of equipment, re-circulating or inadequate air exchange, and the inability to control temperature, humidity, and light cycles. The PI's written documentation indicating correction of previously identified issues will prompt IACUC, DCM and EHS representatives to re-inspect the proposed site. The Satellite Facility inspections are conducted on at least a semiannual (and often quarterly) basis. Failure of the PI to meet all required expectations will result in the loss of privilege and decommissioning of the Satellite Facility. The PI is responsible for enrolling all personnel exposed to the animals in the UEOHC Program. The PI is responsible for ensuring that all personnel involved in animal handling are properly trained in animal care and use. Veterinary and IACUC Compliance oversight will continue as if the animals were in a DCM facility. DCM will have access to animal facilities and assist in animal care.

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.

The University's electrical infrastructure is designed to minimize complete electrical power loss for an extended period. Three electrical substations provide redundancy, with the ability to transfer the power load to the other stations should one substation go down. In addition, supply lines are underground, limiting possible disruption. Duke Energy can also transfer power to UNC when needed.

All DCM facilities have emergency generators providing power for building exhaust and supply fans as well as some building lighting

#16 animal facility contains the of amphibians, snakes, birds, and turtles and does not have a dedicated backup generator. DCM has purchased a mobile unit and is provided as needed. The facility has not lost power in more than 30+ years.

If animal rooms are unable to maintain appropriate temperatures, DCM would work with facilities to provide supplemental heating or cooling unit. UNC-CH has multiple mobile diesel fueled generators with a wide range of power output choices for a variety of applications. The University has a 10,000-gallon storage tank of generator fuel to maintain generator operation.

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).

DCM staff does not recall a situation when a system malfunction resulted in significant losses.

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.

UNC-CH has an extensive range of capabilities and a unique collection of resources regarding animal genetics, genomics, and modeling of human disease. It is renowned for its high caliber animal models research, which is critical for the preclinical work required to make drug and biological discovery a reality. UNC-CH's program consists of multiple NIH-supported resources such as the humanized mouse cores, CC mouse breeding program, one of the four national MMRRC and the NGRRC.

The MMRRC at UNC distributes and cryopreserves scientifically valuable, genetically engineered mouse strains and mouse ES cell lines with potential value for the genetics and biomedical research community. The MMRRC Production Facility is in the barrier maintained lower basement. To be housed in the lower basement, mice must be re-derived via embryo transfer or originate from an approved vendor. The lower basement is a highly restricted area with access via card key readers only and currently houses MMRRC, Animal Models/Transgenic Core and Gnotobiotic Core. All husbandry personnel, cage wash and all supplies are dedicated to the facility. Entrances to the MMRRC Production Facility are locked via card key readers and restricted to dedicated husbandry and MMRRC staff. Mice are imported into the MMRRC facility by embryo transfer only. Importing Germ-free gnotobiotic Swiss Webster mice from Taconic and inoculating them with Altered Schaedler flora created the original colony of pseudo-pregnant recipient females and vasectomized males. The MMRRC has a separate importation colony at an off-site facility where all donated strains are housed prior to re-derivation. All animal manipulations are done at the satellite facility and embryos are transported for transfer into a pseudo-pregnant recipient female. All personnel don protective clothing to enter the facility. All cages are completely covered in transport to a bulk autoclave.

Any materials, equipment and animal orders are decontaminated through a misting tunnel or manually sprayed down with approved disinfectant before entering DCM vivaria. Our animal care procedures are the same for all our rooms/colonies. All mice are housed in micro-isolator Tecniplast ventilated caging (Green Line Sealsafe Plus) in positive pressure rooms. All bedding (irradiated-corn cob), water bottles, cardholders, nestlets, enrichment tunnels and food are autoclaved. NuAire Class II Type A2 Biological Safety Cabinets or animal cage changing stations are used for all changing and opening of cages to handle rodents. All Biological safety cabinets and cage stations are wiped down before and after every use with approved disinfectant. All staff don protective sleeves and double glove in order enter our mouse rooms. All staff spray down their sleeves before working in the biological safety cabinet and change gloves between racks and/or individual labs.

The NGRRC maintains several inbred and transgenic strains of germ-free mice that can be purchased and shipped to PIs or used in experiments carried out within the 100 gnotobiotic isolators and bioexclusion racks in LB facility. Animals are derived into germ-free conditions via Caesarian section or embryo transfer.

The UNC-CH Animal Models Core (AMC) Facility provides mouse and rat genetic modification services, reagents, and related technologies. The Core's services are available to both UNC-CH and Non-UNC clients. The AMC offers a full range of services for production of knockout, knockin or conditional knockout/knockin animals. The AMC offers a range of services to help PIs save costs by cryopreservation of valuable strains. The AMC also assists with importation of cryopreserved strains from collaborators or consortia. The AMC is in LB and produces animals with vendor-quality specific pathogen exclusion in our highest barrier facility.

The Animal Metabolism Phenotyping (AMP) core provides contemporary phenotyping techniques for metabolism and energy balance in mouse models of nutrition and disease. The AMP core offers technical support and expertise for measuring traits related to metabolism in mouse models of obesity and nutritionally relevant disease. The AMP core at UNC-CH houses 30 Lafayette Instruments voluntary wheel running cages in a dedicated room in the #6 vivarium and an additional 30 wheel running cages in #7.

MBPL is run by a Core Director. The MBPL provides PIs within the Neurodevelopmental Disorders Research Center and throughout the UNC-CH research community with a wide variety of automated mouse behavioral tasks to analyze targeted gene mutations relevant to basic research and models of human diseases, inbred strains, pharmacological treatments, gene therapies, etc. This laboratory was designed to evaluate mouse behavior across a wide range of domains, including sensory, mood, social, and cognitive function. MBPL Core.

The SGCF has 5 dedicated mouse rooms for the CC in the #6 that, in total, can house up to 5040 cages. The CC is a large panel of new inbred mouse strains currently being developed through a community effort (Churchill et al. 2004). The CC addresses many short coming in available mouse strain resources, including small numbers of strains, limited genetic diversity, and a non-ideal population structure. The CC strains are derived from an eight way cross using a set of founder strains that include three wild-derived strains. The SGCF has dedicated technicians and provides over 7200 Collaborative Cross and CC RIX mice per year for projects as well as expertise on breeding, care, and handling of this special mouse resource. The SGCF also provides management of genotyping using the MUGA family of arrays. Stock animals are located within the barrier and then enter production for distribution.

The Animal Imaging Facility is located adjacent to the animal holding rooms and supports biomedical research through the imaging of animal models. Through this service, researchers will have access to the current imaging services including MRI/MRS, PET/CT/SPECT, Optical/Bioluminescence, and Ultrasound. Most of the animals housed in this facility will utilize the SAF. PIs are housed either in upper floors of this building, the

LCCC or in other buildings on campus. There are four human research imaging scanners, which can be used for imaging research study on large animals as well. The four human research scanners are Siemens TimTrio 3T MRI scanner, Siemens Biograph PET/MRI , Siemens biograph PET/CT , and Siemens Magnetom 7T . Animal imaging studies are scheduled by the BRIC staff on a corresponding scanner calendar.

UNC-CH has several irradiators:

1. Cesium-irradiator
2. X-ray irradiator
3. Cesium Irradiator
4. X-ray irradiator
5. Cesium-irradiator
6. Cesium-irradiator
7. X-ray irradiator

DCM High Risk Return Rooms are located within several facilities for animals returning from laboratories, cores, and irradiators. For example, if animals enter an irradiator that is not within a DCM facility, then they are assigned animal space in our high-risk return room in another facility and not returned to the breeding colony. All cages are autoclaved out of the high-risk return rooms.

2. Other Animal Program Support Facilities

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

IDEXX, Charles River Laboratories, and Antech provide diagnostic support for DCM animal colonies. The Animal Clinical Chemistry Core Facility can assist research PIs who would greatly benefit from availability of service (on a cost-per-test basis) that replicates for animals the laboratory tests that are routine for humans. Examples include blood chemistry, urinalysis, and hematology. This core facility has been providing services for the UNC-CH campus since 1997. For studies that require gene expression data, genotyping, and oligonucleotide services, DCM can collect tissue and send samples to laboratories or Transnetyx.

Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.
Appendix Not Provided

Abbreviation/Acronym	Definition
appendix not provided	

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, etc.), the total square footage/meters (or acreage) for animal care and use, and the total square footage/meters (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, cage washing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). 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.

Appendix not provided

Animal Housing and Support Sites						
Location (building, site, farm name, etc.[a])	**Distance from main facility[b]**	**Approx. ft^2, m^2, or acreage for animal housing**	**Approx. ft^2, m^2, or acreage for support or procedures**	**Species housed**	**Approx. Daily Animal Census by species**	**Person in charge of site**

Appendix 2: Summary of Animal Housing and Support Sites

Animal Housing and Support Sites						
Location (building, site, farm name, etc.[a])	**Distance from main facility[b]**	**Approx. ft^2, m^2, or acreage for animal housing**	**Approx. ft^2, m^2, or acreage for support or procedures**	**Species housed**	**Approx. Daily Animal Census by species**	**Person in charge of site**

Sub Totals:			
Total animal housing and support space:		**(please specify ft^2 or m^2)**	

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

Appendix 3: Line Drawings

Provide floor plans of each centralized animal housing facility. Plans should be provided on 8.5” x 11” or A4 paper. Ensure that the drawings are legible, including room numbers if used, and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.) either directly on the drawing or in a Key/Table.

Appendix not provided

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 not provided

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.

Appendix Not 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)
Appendix not provided											

(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)

Appendix 5: Animal Usage

(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:

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

Animal Type or Species	Approximate Annual Use	Animal Type or Species	Approximate Annual Use

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

Appendix not provided

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 not provided

Appendix 7: IACUC/OB Membership Roster

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

Appendix Not Provided

Appendix 8: IACUC/OB Minutes

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

Appendix not provided

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.

Appendix not provided

Appendix 10: IACUC/OB Periodic Report

Due to the size of the document, we have included the semiannual program review and inspection report as a separate attached so as not to unnecessarily increase the size of the Program Description.

Appendix not provided

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.

Appendix not provided

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.]**

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

Room No.	**Specific Use**	**Temperature Set-Point** (define units)	**Electronic / Emergency Monitoring of Temperatures** (Y/N)	**Alert/Alarm Temperature Ranges** (if applicable; define units)	**Humidity Control** (Y/N)	**Relative Pressure**	**Air Exchange Rate** (per hour)	**Date Verified / Measured**
		(settings to be verified)					**(values to be measured)**	

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

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

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

Appendix not provided

Location (1)	Species (2)	System Design					
		Group / Individual (3)	Water Type (4)	Pre-treatment (5)	Circulation (6)	Filtration (7)	Disinfection (e.g., UV, ozone)

Appendix 12: Aquatic Systems Summary – Part I

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

Appendix Not Provided

Monitoring ***Indicate in the boxes below the frequency of monitoring and method of control for the following parameters. (1)***									
Location (from Part I)	**Temperature**	**Salinity**	**pH**	**NH_4**	**NO_2**	**NO_3**	**Dissolved O_2**	**Total Dissolved Gases**	**Other. Please List (2):**

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

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

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.

Appendix not provided

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**

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**

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**

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:

Appendix Not Provided

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				

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)

*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.]

Appendix Not Provided

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness

Appendix 16: Lighting Summary

Using the Table below, summarize the lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity (range), construction features (e.g., water resistance), photoperiod (light:dark) and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms (including alarms, if applicable).

Location:	**All Facilities**

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

Appendix Not Provided

Room Type[a]	**Light Intensity Range**	**Lighting Fixture Construction Features**[b]	**Photo-period** (hrs)[c]	**Photoperiod and Lighting Control**	**Override Mechanisms** (if applicable)

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

[a] A list of each room is not needed; group or cluster rooms by species or function
[b] Include such features as water resistance, red lighting, *etc*.
[c] Note if light cycle inverted/reversed.

Repeat Location and Table as necessary for each location, including satellite housing locations.

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 each of these must also be included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Systems Summary (**Appendix 16**).

Appendix Not Provided

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

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